Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☐ Change Request 3449
☐ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: Never heard of change request, but received Benefit Policy Manual.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: OIG report that came out several years ago suggested that we request previous records to see if they were for maintenance therapy

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: We've published chiropractic services manual to all chiropractors, including information about the AT modifier.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits ☒ Post-payment edits ☐ Other

Explain—probe for basis of edits: We would love for CMS to come forward with more frequency restrictions. Post-payment probes based on aberrant data – claims, dollars – reviewed for medical necessity of frequency, subluxation, etc.

If yes, how effective has this process been?

☒ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: Targeted review after probe for error rate – error rates remain high, often greater than 8%. It's better for us to have a reason to pull these claims rather than base edits on frequency, given the political nature of the issue with chiropractors. When it stops being acute treatment, we stop paying for it. A lot of chiropractors are "wise" to this and might be manipulating records to show a new injury. Each office has different records; we usually ask for an initial visit and the 6 months surrounding aberrant billing. The episodes often run into one another.

If yes, how do you determine the effectiveness of these processes? Very high error rates

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☒ Yes ☐ No

Explain: Very limited. Only if it's an edit they've asked us to put in place for them. Our PSC deals strictly with fraud.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? Frequency limit suggested at 24/yr, (b)(4) implemented 24, but after commenting period was over we were not comfortable automatically denying them. We had a lot of push-back from the chiropractors, they were threatening to sue us. We just left what we had and took the number out – it's mostly a statement of national coverage. It's hard to limit

frequencies through an LCD process. It might be better approached with caps such as physical therapy. We go back a rolling 12 month period when looking at frequency.

When? Tried to develop frequency limits a couple of years ago

Why?_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain: Not affected by that. (b)(4) has not been awarded yet (b)(4). Should hear soon.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe: We will consolidate the LCDs among the jurisdiction and choose the most clinically appropriate policies and incorporate the best edits. It will likely be a reiteration of national coverage policy. Don't anticipate any problems. We have common LCDs for all three states, but separate contractor numbers for each.

8. Is there anything we haven't discussed that you would like to share?

If we could, we would definitely limit the number of services per episode, and ideally just a limit per year per beneficiary. From a medical review manager standpoint, when you turn on a frequency limit for chiropractors, it overwhelms the staff because the volume is extremely high, even with a limit as high as 24. Medical necessity-wise, a limit of 12 is probably appropriate.
It's amazing how many services the beneficiaries receive, but the chiropractors have been documenting new injuries. Any limits need to be nation-wide.
Sometimes the statistician will look for beneficiaries receiving services from multiple providers, but we don't normally do that.

Generally, we don't use chiropractors for review because we don't look at medical necessity or whether a subluxation occured; we look only for documentation of acute injury/support of the AT modifier.

If Physical Therapy is a limited benefit as described, chiropractic services should be limited as well.

Carrier #_____

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☐ Medicare Benefit Policy Manual ☐ Other
☐ Change Request 3449
☐ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance:_____
_____
_____
_____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☐ No

If Yes, describe education:_____
_____
_____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☐ No

If Yes, describe instruction: _____
_____
_____

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☐ Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits _____
_____
_____
_____

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain:_____
_____
_____

If yes, how do you determine the effectiveness of these processes? _____
_____
_____
_____

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☐ No

Explain:_____
_____
_____

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☐ Yes ☐ No

If yes,
Describe the LCD?_____
_____
_____
_____

When? _____

Why?_____
_____
_____
_____
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_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____
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7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☐ No

If Yes, please explain:_____
_____
_____

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☐ No

If Yes, please describe:_____
_____
_____

8. Is there anything we haven't discussed that you would like to share?

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Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: _____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: We discuss it on the all CMD calls, but I wouldn't say they've provided specific education on it. It appears to be a national problem based on the calls.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: Successful webinar series, nurse provides education to "problem providers", a couple of seminars specific to chiropractors. Published article when AT mod came out, revised policy and re-published that as well (posted on listserv & website). We've recently established aggressive post-payment reviews based on trends and provided education related to that, which seems to improve documentation. 96% (b)(4) 97% (b)(4) 92% (b)(4) claims have AT modifier – the error rates are in the 90% range, probably 40% are maintenance; the rest are documentation

issues or using things that aren't manual manipulation. Part of the problem is that chiropractors have their own "language" and use "travel cards," which aren't sufficient for documentation purposes. They're starting to get the message that they won't get paid unless they have a treatment plan and specific goals, etc. The CMS manual has pretty clear language about what is expected, and our LCD primarily mirrors those requirements. When reviewing a specific service, we often don't get a treatment plan, etc. if it was created at the first visit for the episode – this is no more than what we ask from allopathic physicians. We then request documentation for the beginning of the episode. The general trend is that they'll be treated for several months, 3-4 times/month, but there's no documentation of a treatment plan or any goals. Many commercial insurers will limit services at 24-30 per year. The standard treatment seems to be 2-3 tx/wk for 3-4wks; some chiros will do intensive therapy including 2 tx/day for 4-5 days and then once/wk for a few weeks thereafter. These seem to be "valid" treatment timeframes, but there's no clinical evidence.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits ☒ Post-payment edits ☐ Other

Explain—probe for basis of edits Don't have staff to deal with pre-payment edits – only a couple of providers that are flagged after review (we re-evaluate their billing practices after 3 mos + education). In the past, chiropractors attached the GA modifier to everything, and we just turned around and paid them like a slot machine. Now they have a new modifier, AT, which says that if you attach it, we'll pay you. I think there's a basic lack of understanding; we're making some inroads, but we're not 100% yet. They still submit the AT & GA modifier together quite frequently. The PSC for (b)(4) is seeing that as well. We recently published a news article to indicate that if you're using AT, you shouldn't also use GA.
We've identified basic trends post-pay, looking for those with 2+ Standard Deviation from their peers. We ask them for a number of claims, which we review, and then advise them of their error rates, recoup the funds, and educate them on what they need to do for the future. They then go on pre-pay review and are re-evaluated at 3 mos. I think they're amenable to change, but nobody's made them. We don't have a lot of staff to review providers on a pre-pay basis. For some of the chiropractors with high error rates that seem to be due to one simple thing, like not identifying the level of subluxation, might just get education and not go on pre-pay review like others with more widespread problems.

If yes, how effective has this process been?

☐ Very Effective ☒ Somewhat Effective ☐ Not Effective

Explain: The education for chiros on pre-pay review seems to be somewhat effective – a better definition of an exacerbation would be helpful.

If yes, how do you determine the effectiveness of these processes? _____

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☒ Yes ☐ No

Explain: Our contract calls for us to meet regularly with other contractors; we meet every month with the PSC to identify trends, be sure we're not compromising their investigations, etc. They look primarily for fraud & abuse, while we look primarily to improve quality & reduce error rates. We do make referrals for egregious providers. They make referrals to us if it looks like the provider just needs education or have questions about whether something looks like fraud or may just involve a disgruntled employee or competitor. They don't have medical directors.
If they refer someone to us for education, and we educate and educate and educate, and 6 months later they're doctoring records or still billing at the high rate inappropriately, we'll refer them back to the PSC for fraud/abuse. Right now, we have a provider who "overwrote" a date of service instead of providing the proper correction, and another who submitted additional documentation that was very different from original notes upon request for clarification.
CERT?

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? LCDs consistent with the national coverage policy.
Used to have an edit in place based on frequency that would kick claims out for medical review. They knew in a very short time which number we would change the limit to—we got so many claims kicked out that way we couldn't review them all. Because of staffing issues, we don't have those kind of limits now.

When? _____

Why?_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain:_____

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe: won't be awarded for a few months

8. Is there anything we haven't discussed that you would like to share?

My personal opinion is that CMS should limit the number of visits per year, but I don't know if that's politically feasible. The webinars seem to have been helpful, and gave an opportunity for Q & A with chiropractors.
I think education is the only way to make a difference, and it seems the chiropractic community is more receptive in recent years. We could do more education if we had more in the budget. The definition of the exacerbation is the same problem we have with vignettes for E&M codes – there are too many. Trying to define where acute care stops and chronic care starts is a highly individual thing. Putting some limit on services is perhaps a better way to go. We all saw what happened with PT limits, they got gutted, so is that what would happen with chiropractic limits? You don't want to punish the innocent with the guilty, because there may be people out there who need 30 acute care visits in a year because of two injuries. If we're going to say that chiropractic care is somehow valid, then it would be difficult to limit those. Nobody is making a decision of "do we want to buy this product or not"—it is up to the beneficiary – what economists would call a "moral hazard." I'm not sure there's a good way to do it that would ensure fairness & justice.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☐ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: Previous CR3063. Q&A re: CRs; standard national meetings (MR manager meetings held every 4-6 wks, Contractor Medical Director meetings)—a lot of back and forth discussions go on when policies change. CERT workgroup.
The AT modifier existed previously, but was not required. The requirement was helpful because it required the provider to take ownership of determining whether it is for active treatment. Most all of the chiropractors in the community think all of their care is active, but this makes them attest to it.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: nothing specifically identifying misuse, but the PIM gives guidance on data analysis to identify providers at the greatest risk.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: began late 2003; chiro services have been on medical review strategy since 2004. We initiated state-wide educational group sessions due to high paid claims error rate ((b)(4) had 11 in 2004, 13 in 2005, and 4 in 2006; (b)(4) had 8 during the same period.) We partnered with the state chiropractic associations and they were very effective at getting the chiropractors to attend the sessions. These included demonstration of claim review for the chiropractors to show how documentation is required for the claims. The goal was to be able to remove the pre-payment edit and do more post-payment review for providers with high payment errors, because other programs represented larger vulnerabilities in dollars – balance resources.
Web-based training module.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☒ Post-payment edits ☐ Other

Explain—probe for basis of edits Had a pre-payment edit in place because of high chiro CERT error rates ((b)(4)~36.0 paid claims error rate; (b)(4) 21.9%)—we were denying 1/3 of claims under review. Although chiro had a high paid claims error rate, it did not have as significant impact as far as $ amount.
Pre-payment edits have been removed at this point, and now we're concentrating on post-payment reviews. Profile providers according to risk factors for payment errors (ratio 2 = session/bene during period of time).
red flags—concurrent use of GA/GY with AT

If yes, how effective has this process been?

☒ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: Post-payment review has been effective in identifying risky providers

If yes, how do you determine the effectiveness of these processes? (b)(4) error rate down to 10.8%, (b)(4) not high enough to get its own category.
We use CERT data, and have developed a database where we download CERT files to do qualitative & quantitative analysis. We have a data warehouse with claims data from the last several years. We look at national comparison data for utilization rates. We also look at appeals data, especially when calculating error rates—in (b)(4) we process a huge volume of appeals, but chiro is not proportionally higher; the relative success of those appeals are relatively similar to any other service.

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☒ Yes ☐ No

Explain: We work closely, particularly in (b)(4), providing documentation for PSC report function and coordinating MR activities so that we're not taking action on any providers that might affect their open cases. We also make referrals to PSCs if chiropractors are suspected of fraud. The only time we receive information back from the PSC is if we are asking to take an MR action, and they determine it is okay because it will not interfere.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? Indications/limitations for coverage, defines acute treatment, outlines requirements for documentations – mostly mirrors national coverage
Specifies diagnosis codes & ICD 9 codes we can automate in the system

When? Since 1994 in (b)(4) and 1998 in (b)(4)

Why? Had frequency parameters, but eliminated them through the education initiative. Most of our coverage determinations are based on Standards of Care. Chiro is unique because there is very little literature stating that for a given condition, [this number] of treatments are necessary. It's the same issue we have with therapy services – Medicare did the right thing by putting a limit on therapy. With the AT modifier, chiropractors are on the honor system. It becomes a bit of a paper chase when you do medical review – it's really their call. A lot that are abusing the AT modifier just have poor documentation, which lead to denial based on medical necessity. We've had good participation with state chiro associations regarding education on documentation (~70% attended at least one session).

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain: Haven't begun transition yet.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☒ Yes ☐ No

If Yes, please describe: MACs are required to consolidate diagnosis & procedure code pre-payment edits and LCDs

8. Is there anything we haven't discussed that you would like to share?

CERT data, though it's not the only source we use, has us re-sort our priorities. Especially considering (b)(4) with so many vulnerabilities, we must consider those services that come out most "loudly."
There's only so much we can do with outlier chiropractors that don't change billing after education. They go on pre-payment review, which often changes behavior. Some just don't agree with documentation requirements – they remain on our strategy, but are not the highest priority. We have a lot of high-dollar oriented pre-payment reviews we're required to do in (b)(4) High amount of funding for program integrity in (b)(4) lower in (b)(4).
(b)(4) chiropractic association has always been supportive & eager for education. We had a little more difficulty in (b)(4) and worked with the national association to bring the (b)(4) president around. It's easier to address education for chiros than other specialties because they only have four codes.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

X	Medicare Benefit Policy Manual	☐	Other
X	Change Request 3449		
X	MedLearn Matters Article 3449	☐	None *(confirm nothing received)*

If Other, describe guidance: CRs become "manualized" and end up in IOM.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☐ No

If Yes, describe education: Maybe. Recall getting instruction to not place hard caps as pre-pay edits, but to do post-pay reviews. Do not recall anything specific. This is the type of activity that is rolled out to contractors to implement.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

X☐ Yes ☐ No

If Yes, describe instruction: List serve article. Information on website. Haven't done much review/education at the provider level. We publish what we are instructed to. We have a small number of chiropractors in our jurisdiction ([(b)(4)]). Chiorpractorwise, we have a low error rate with CERT (4.7%). Chiro services didn't show up in top chart. Tried to reconcile payment rate with chiro error rate looked at CERT did basic data analysis on distribution of billing. Not a cost effective place to put our small, limited resources.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

X☐ Yes ☐ No

If yes, describe process(es)

X☐ Pre-payment edits X☐ Post-payment edits ☐ Other

Explain—probe for basis of edits Pre-pay edits match provider codes with claims. Frequency edits based on diagnosis code (739 series) used. 739.1 limits to 22 services per year, lower back pain is limited to 30 per year. Thoracic is limited to 15 treatments per rolling year. Process in place for post-pay edits, but they currently don't have anyone conducting reviews.

If yes, how effective has this process been?

X☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: Very effective when we implemented them because it lowered claims submission from chiropractors. Now, providers know "caps" and don't submit claims for services they don't think will be paid. Before and after AT modifier we saw that the number of outliers decreased since implementation of AT modifier. Handful of providers who press the envelope.

If yes, how do you determine the effectiveness of these processes? _____

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☐ No

Explain: No referrals to from PSC for chiropractic services. We coordinate LCDs with other contractors. Carrier advisory committees. Globally speaking, we do lot of coordination with [(b)(4)] and [(b)(4)] carriers. Nothing specific to chiropractors, however.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

X Yes No

If yes,
Describe the LCD? 22 per rolling year for 739.1, 30 for lower back. Thoracic region (739.2-739.8) lower frequency levels at 15. When applicable, thoracic region requires less intensity and frequency of treatment. GA or GZ modifier in conjunction with AT? GA and GZ got really popular when they first came out, but waned since then. No discernable patterns.

When? _____

Why?Small contractor with limited resources. Try to automate everything.

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): CMS instructed (b)(4) to not use hard caps. (b)(4) is active on carrier advisory committee. To that extent, they are involved. Policy revision in 2005, we had high rate of appeals being paid. Not aware of current appeal rate. Don't see many of these (appeals) so think providers have gotten gist of how to submit claims. General advisory of providers that we are noticing higher number of denials. Once they figured out, I can get 12 for this and 18 for that, there isn't value in them sending claims that we are going to reject. As in every service, there are some providers who are going to take policy and schedule around to manipulate.

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes X☐ No

If Yes, please explain: A little too early for that at this point.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☐ No

If Yes, please describe: No idea. Regulate policy. Fair

8. Is there anything we haven't discussed that you would like to share?

(b)(4) chiropractors in their jurisdiction. We have similar findings to what OIG found in 2005 report. AT required providers to go on record with attestation that service is acute.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: October 8, 2004 Change Request-added requirement of AT modifier (active/corrective vs. maintenance). Two MedLearn Matters articles were issued Septemeber 04 and December 04. Carrier development parameters were deleted with issuance of Change Requests. Carriers were denying claims without review so CMS took a survey of various contractors to see how they were handling situations. Contractors cannot deny claims without review. Communication from Trailblazer said standard parameters were standard. Set per contractors LCD. Utilization guidelines in LCD are public, while carrier development parameters are internal for contractor. 240.1.5 of manual.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: MedLearn Matters Articles and transmittals, but nothing beyond that. Still working on trying to educate chiropractors. Been there 12 years and still doing same thing. "AT modifiers says 'I want to be paid and they attach it to everything.'".

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: Periodically do bulletin or website articles. Posted education article on October 23. Sent out listserve articles on AT modifier to chiropractors, which is in the modifier reference guide used to educate staff. Process: education referrals where chiros were automatically plugging in AT Modifier. We did education to demonstrate AT modifier should be on case-by-case basis related to condition. Set up teleconference for billers having problems (including AT modifier). Invited 34, but only 4 signed into teleconference. Error rate 50.2%; 54.2% downcode error rate. Prepayment flag after trying to educate billers on correct use.

(b)(4) (Caller information staff)-TA on how to bill correctly

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☒ Post-payment edits ☐ Other

Explain—probe for basis of edits

So many chiro claims can't look at all of them. We look at localities within jurisdiction for pre-payment edits. Started with one locality; in Nov. started w/ second locality. Can't look at every claim. Documentation doesn't meet guidelines for policy. More often AT is billed inappropriately. A little improvement but not significant after provider education.

Post-payment edits flag provider-specific reviews. For all providers we are looking at, if they don't comply consistently, we put them on provider specific review.

Not much "chiro jumping' going on. When looking at claims can see that benes are pretty faithful to one chiro. I have pretty much entire history. One or two will jump, but nothing that would draw your attention to hopping. We would have to do a pretty extensive review to be able to see that. A bit more difficult to narrow by bene.

Workload-try to do as much as we can. Lots of chiro claims-no way to look at 100%. We sent a mailer out w/implemention of AT mod. We identified through CERT that chiros weren't doing well. Tried to do education. PT and chiros worst billers/documenters. Bc we are supposed to use budget dollars and staff most efficiently, we are trying to concentrate in those areas because it is needed.

Told by chiro provider (head of org) he wasn't going to adhere to documentation requirements. We have thought about different avenues to reach this provider group. Thought we needed more contact with group. We formed a provider advisory group, including specialists in different areas, with concentrations in (b)(4) to hold meetings with chiropractors including what info we need to concentrate on as far as education. We ask them to pass on information to other providers. At the beginning of last year, XXXXX from (b)(4) became a member of advisory the group. XXXXX-big org. XXXXX-(b)(4) requested program on chiro services to chiropractic students. We feel if we approach it in this direction, before they go out into practice it might be helpful. Once they get into practice they fall into bad habits. If we catch them in school, we can educate them before they get out in community.

If yes, how effective has this process been?

☒ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: Quarterly pre-payment edit for Jul-Sep 2007 led to downcoding/denial of 93%.

If yes, how do you determine the effectiveness of these processes?

Audit effectiveness to rank audits on scale of 1-5. Looked at 457 claims from July-Sept 2007, and downcoded 93%. Several providers blatantly tell us that they don't have time to document the way we want. By putting AT modifier on there, they are getting paid, and they know they will get paid. One provider doesn't want to adhere to regulations, and now the bene will still go there and pay out of pocket. Benes go month after month for years and years. Chiros keep them "hanging on". We look at post and pre-pay. They continue to bill erroneously through AT modifier.

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☒ Yes ☐ No

Explain:
Occassionally work with PSCs on an individual basis. One provider that is opting out was referred to the PSC.

CR 3449-chiros have highest compliance error rate. Won't change unless increase budget. Not using at mod appropriately. AT modifier says, "get paid".

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD?

Look at indications or requirements. Look at edits, not just for AT modifier. Those that exceed parameters for AT modifier. Section w/I policiy re: ultilzation guidelines in the LCD (on website). (b)(4)
Patients with acute uncomplicated condition may receive 3x wk for 2 wks, 1-3x wk for 2 wks—If there is improvement then treatment may continue for an additional four weeks. After six weeks treatment should usually be only 1-2 treatments per week. For chronic pain and acute complicated pain, patients may receive treatment 3x wk for 4-6 wks, and then 2x wk for another 4-6 weeks. Treatment should usually be less than 12-16 weeks. Carrier development parameters are set higher because of workload – if benes receive more than 45 services within a given timeframe with the AT modifier, the edit comes in. Limitations section of guidelines specifically talk about maintenance therapy.

When? _____

Why?_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation):

They have to be appropriate because they are based on the CMS national coverage policy. Get info on website so chiros can look at info and refer to & be responsible for what is in there. Info re: how to bill how system will handle claim, etc. All manuals, transmittals, etc are listed in policy on 1st and 2nd page under CMS policy. Hopefully providers look at policy to begin with and then use references. In Medicare benefit policy manual 100-02 30.5 and 240.

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain:
Region is in the waiting mode to transition. They have not awarded a MAC yet.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe:
We are just going to keep working. Hard to know at this point.

8. Is there anything we haven't discussed that you would like to share?

Get em all in a big room. Testy group. Problem with these providers. AT modifier is not used. It was a good try to put some parameters in place, buty they aren't adhering to them. From nurses, not adhereing to documentation requirements. I don't know if more education, as you can see we are doing a lot and it isn't helping. Larger staff and more budget money, we could do more outreach in specialty areas. I have 2 staff going on the road to do presentations. It can be difficult—we try to be efficient with budget dollars. Providers choose to not participate or even call on the telephone for a teleconference. We aren't going to berate them on the phone with peers during teleconferences. An educational power point is on the intranet so providers can go through same presentation as the teleconference. I don't know how many times that has been utilized. Good guys and bad guys. Chiros more likely to have bad guys than other providers in Medicare. Another issue is chiro is not just manipulation-more holistic and other areas. Some examples-one chiro was trying to give advice on woman's menstrual cycle and another is selling vitamins. They can do anything they want as long as they don't bill us. We decide what we pay for and not. What we consider typical chiro practice, they aren't doing. Many do only whole spine adjustment (4-5 regions), even if not medically necessary, and then they bill the highest level. It's a different type of specialty that doesn't fit well into the medial profession in general or in Medicare program. Traditional insurances limit chiro services. You get so many services and that is it. Maybe that is more of the answer but we don't know. Legislatures. We are a little frustrated if you cant tell. If we could find an answer to this we would be happy as well. You can see how much time we are putting in for someone who is not adhering when we could be helping in other ways. Spinning our wheels. More budget for outreach, same for medical review aspect. With more staff, we could look at more claims and stop them from going through. Only have 2 looking at pre-pay and they are working on other things. Looked at multiple line items in a day, not across the board, nothing that really says they are doing that. If time element on code that they had to spend, it would give us a better idea. Some whip through some spend a lot of time. Statistician is reviewing data to make recommendations something jumps out and they do more in depth analysis. Our chiro consultant is a decent guy who follows the rules. Problem is finding good guys. Consultant is one out of how many-good guys. He gets upset with his colleagues/peers.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☒ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: Chiropractic services have come up on informal CMS conference calls from time to time – usually items are brought up by carriers to see what other directors are doing

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: _____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: Had several discussions with CMS on something similar to the AT modifier (GA mod) before the CR – we would see an increasing number of chiro claims with the GA modifier so they could bill the bene if the contractor would deny their service. We've been doing complex medical review for years. I worked with CMS on the need for some sort of

modifier to give the chiro community to bill for a service that would be systematically denied (e.g. maintenance that should be paid by the bene). After the CR came out, we found practices that use the AT modifier 100% of the time. It was a good idea on the system-level, but now there is inappropriate billing (with the AT modifier) in the chiropractic community.
We've had numerous educational efforts. (See LCD information).
Numerous chiropractic mailings (starting Aug 04) and programs with the chiropractic associations. We've educated about documentation requirements. We have computer-based learning modules and FAQs online.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☒ Post-payment edits ☐ Other

Explain—probe for basis of edits Our LCD stops short on having a hard cap on the number of services per year because CMS had such an onslaught of opposition from the community. We put in a "soft cap" for the number of services per benes per year, which we change and don't announce – we suspend the claims and do a complex medical review – pre-pay MR edit after 16 services, for example, regardless of AT modifier use or provider. We set the cap based on what workload we can handle.
Our data showed a spike after 3-4 (?) services/yr per bene before the soft cap, and after the cap there was a spike at about 16 services. We changed our strategy so the message wouldn't get out.
We also saw a significant number of patients that were receiving one chiropractic service per month, which were flying under the radar of the soft cap. Those patients are truly getting the maintenance therapy. In professional guidelines for acute therapy, there should be more than one service per month. The only way you can catch this is post-pay. We isolated those records that had a "clean" period with no services (10 days, 21 days, up to 35 days and beyond), and we found tens of thousands that were billed that way – perhaps 12,000 services that were billed as one service per month. In the last 6 mos, we've started targeted post-pay reviews of providers that seem to use this pattern. Our spike in the utilization of chiropractic services with clean periods in between occurs at 7 days—21 days—28 days—previously scheduled visits.
More than 35% of the time when we sent out ADRs requesting records on the service, we would not get records returned to us. In the medical review world, when you don't get a record returned, the denial is a medical necessary denial and then the chiropractor bills the bene directly. This is troubling because nobody got the chance to actually review the record for medical necessity. We don't see that high a percentage in any other specialty, and they never appeal the denial with records—they just put the burden of payment on the bene.

If yes, how effective has this process been?

☒ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: Our efforts have done well to recover money, but the education doesn't seem to be changing the culture of the chiropractic community. As we continue to do complex MR, we continue to deny about 90%

If yes, how do you determine the effectiveness of these processes? 90+% error rates upon medical review when we do get the records because the documentation is horrible and/or reveals maintenance therapy. A higher percentage of appeals occur when we actually get the documentation.

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☒ Yes ☐ No

Explain: Usual routine is to refer records that appear fraudulent upon medical review. If we're working with a specific chiropractor on pre-pay edits and individual educational activities don't appear to decrease error rates, we refer them to the PSCs.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? (Z6) See soft caps above. We also had a chiropractic billing guide that did not work well with the community in (b)(4) because the chiropractors would try to ?

When? Extensive revision in 2000 for billing & documentation requirements, updated with AT modifier guidance

Why?_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☐ No

If Yes, please explain: Just announced a month ago (awarded to us), but it's under protest.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☐ No

If Yes, please describe: We've done some work in preparation in looking at the "best data," national data, and error rates. We'll have to abide by the CMS manual, but I'm interested in input from the other states. We've done some safeguarding of the program in recovering monies, but haven't actually changed the culture. I'm interested in what interventions we can have with the chiropractic community.

8. Is there anything we haven't discussed that you would like to share?

I don't know the answer because chiropractors have not been able to comply with documentation requirements. A lot of the maintenance therapy characterized by one visit per month (which is more than those at more than 24 per year) can only be caught post-pay.
I've asked local OIG and Assistant US attorney if there's anything we can do regarding the third of records we don't even receive from the chiropractors, but it seems the only thing we can do is deny payment.
Comparison to Physical Therapy: guidelines for acute treatment indicate it should be received multiple times per week. The thing I've not seen in the PT world is once-a-month maintenance therapy. There are higher rates in the PT world, but the reasons are different—many come from the absence of a plan of care; physical therapists don't have do document reasonableness & necessity on an encounter basis – they just update every ten days or so. There's really no documented rationale for changes in number of modalities per visit per bene, but that's not a requirement. In chiropractic services the overall documentation is horrible, and there's quite a lot of maintenance that gets billed with the AT modifier in error. Patients view chiropractors as doctors, while they don't necessarily view PTs as doctors, so there's a difference in how patients enter the healthcare arena.
We've looked at pattern of claims history on a calendar, as well as episodes of care for MR. The CERT contractor, (b)(4), historically would suspend a claim but look only at that date of service instead of the whole episode of care, resulting in low error rates (e.g. 15% as opposed to our 90%). The chiropractic community accused us of being overly critical/abusive. Now in the last 6 mos, thankfully, the CERT contractor has started looking at the whole episode.
We found that between 16-24 services/yr, many benes were actually getting the services they need because of new episodes – acute exacerbation of a chronic condition. Our denial rate was more in the 20% region for these patients.
I think CMS needs to change the denial message when we don't receive records so that the bene is not held responsible for that. I like the concept of a hard cap, but in my experience, a cap at 12 would lead to a spike at 11. I wish there was a more effective, efficient way we could do post-payment reviews – they become very costly under CMS requirements.
HighmarkMedicareServices.com lists Z6 LCD and company billing coding article. Search for FAQs and computer-based training module.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: _____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: It would be helpful if we had a bit more guidance across the board. It is currently left open to interpretation. Within (b)(4), there are seven medical directors and we discuss things like this on weekly phone calls. Once a month, we have a call with all carriers across the country and CMS is usually in on that call (a certain group is there all the time, but it's hard to attend all of them – I've attended about 75%).

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: June 04, published (b)(4) article on website; Oct 04 published more information clarifying AT mod; Dec 04 manual/billing guide given at chiro seminars; Jan 05 website posting req of AT mod; Nov 05 Power Point for chiro specialty seminars revised; Dec 05 CERT article including AT mod info; Feb 06, letter sent to all chiropractors including copy of

LCD, reprint of news article from website, FAQs, info on chiro specialty seminars; Nov 07, Power Point revised again for seminars (27 seminars 385 attendees since Oct 2004)

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☒ Post-payment edits ☐ Other

Explain—probe for basis of edits Before AT modifier came out, (b)(4) allowed only 12 procedures per yr per pt, which came about based on post-pay data analysis (a review of claims reviewed all were for maintenance therapy). (b)(4) consolidated with (b)(4) was more liberal and the LCD compromise was to allow 30 sessions in a rolling 90-day period. Perhaps maybe 50% are hitting that edit. 75-80% of those are getting denied based on lack of response. For 2008, we're looking at a probe for those submitting 90-100% w/AT modifier.
I think we do also have a diagnosis edit.
We found a number of other codes going through for chiropractic (e.g. physical therapy, massage, electro therapy).

If yes, how effective has this process been?

☒ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: high denial rate—we're stopping a lot of inappropriate money from going out the door

If yes, how do you determine the effectiveness of these processes? High denial rate

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☒ No

Explain: If they're submitting the AT modifier without documentation to support it, to me that's fraud and not a medical necessity issue. Depending on what we find with these probes, we may make some referrals. Dr. XXXXX and I may differ on this.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? 30 sessions in 90-day rolling period; specific diagnosis codes

When? Combined with (b)(4) in October 2004

Why? _____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): CMS has not been involved with the LCDs. It would be nice to have more clarity, but in the formation of coverage determinations, the system seems to work the way it is.

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain: Has not been awarded yet. We've consolidated among ourselves and this LCD will be coordinated with the next batch of policies.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe: This is sort of a provider problem, not related to a specific place of service. I don't anticipate it will be any different.

8. Is there anything we haven't discussed that you would like to share?

For providers consistently exceeding the 30 service cap, since the edit doesn't seem to deter the use, we could flag them so they must submit documentation with each claim within 30 or 60 days. In the past, that has changed behavior. It's not something we'd like to do because of the administrative burden. This may be so many providers that it would be cost-prohibitive to flag all of them.
If we do the probe and get the documentation from providers that indicates maintenance, we'd like to refer them for fraud investigation. I think that's the way we're going to go because we've made an effort to make sure everyone knows what should be done.
Education has been more effective when we approach the docs individually. For our E&M, we've had anonymous online conferences for heavy-hitters and it did make a difference. This is also labor intensive. The personal touch seems to be the most effective.

The thing you need to keep in mind with chiropractic services is that there's very little research. The 30 services in 90 day determination was very generous. It's not evidence-based. It's not black-and-white.

Carrier #_____

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

(b)(5)

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

X Medicare Benefit Policy Manual
X Change Request 3449
X MedLearn Matters Article 3449
☐ Other
☐ None *(confirm nothing received)*

If Other, describe guidance: Passive form of guidance. CMS notified us of change request and provided the documents. To their credit, they sent it in a draft format and solicited questions/comments from the carriers. (b)(4) had some back & forth questions they responded to at that time. No other specific guidance.
Doesn't believe they used the AT modifier prior to CMS requirement for chiro. KX modifier is another self-certifying modifier for physical therapy benefits – allows provider to exceed dollar cap per annum when services are medically necessary.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes X No

If Yes, describe education: has been confined to the explanation for the use of AT modifier as described above

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

X Yes ☐ No

If Yes, describe instruction: in LCD, also published article in newsletter & website (b)(4) (b)(6) will email to (b)(6) Provider Outreach and Education Dept has open educational Seminars for providers in each specialty. These are scheduled periodically and open to providers and their staffs.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

X Yes ☐ No

If yes, describe process(es)

X Pre-payment edits X Post-payment edits ☐ Other

Explain—probe for basis of edits Claims should be denied w/o AT modifier and paid with it if it meets other guidelines (e.g. frequency parameters and diagnosis – utilization guide (a) for acute uncomplicated case up to 24 tx [3xwk for 2wks, 1-3xwk for 2 wks, 1-2xwk for 6wks] (b) for chronic or acute complicated case tx up to total of 12-16 wks [3xwk 4-6wks, 2xwk 4-6wks]).
post-payment reviews: (1) 2 yrs ago Looked at providers using AT modifiers exclusively or near-exclusively (2) 3-4 yrs ago Looked at distribution among three codes, looking at those using 98942 frequently (upcoding) They found significant error rates for 98942.

If yes, how effective has this process been?

☐ Very Effective X(?) ☐ Somewhat Effective ☐ Not Effective

Explain: Edits work well, but are liberal. A number have been dis-allowed upon post-payment review. Post-payment reviews caught several providers most egregious in frequency/distribution.

If yes, how do you determine the effectiveness of these processes? _____
_____
_____
_____

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes X No

Explain: PSC (b)(4) and we would refer any particularly egregious integrity issues to them. They have the choice to decide whether or not to take the case. They will not take individual providers associated with low dollar amounts.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

X Yes ☐ No

If yes,
Describe the LCD? (besides frequency edits) -- _____osis codes, which medical conditions are not allowed. XXXXX will email to (b)(6)

When? Have had chiropractic local policies for many years;

Why? the biggest problem is getting a consensus on where to limit services (frequency)

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): Contractor discretion

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes X No

If Yes, please explain: while we're in the bidding process, we haven't transitioned yet

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☐ No

If Yes, please describe: don't anticipate any changes in how we deal with chiro because they're Part B services – the FIs have never really dealt with chiro. Doesn't think jurisdiction (b)(4) will be awarded until January and expects 8 mo transition after award ___ _____

8. Is there anything we haven't discussed that you would like to share?

Rendering provider vs. paid provider may identify groups providing services for the same bene instead of UPINs. One provider may be billing und veral provider numbers. Each provider location has a different provider number. (b)(4) tries to include all provider numbers for an individual provider in certain analyses. For provider number, first 5 characters are unique to the individual physician and the last 5 are unique to each group.

(b)(4) consensus conference – guidelines for frequency on chiro services – late 1990s. One of the problems is that guidelines in frequency are defined by the specialty (may be self-serving). We bring in a consultant for record review to identify maintenance therapy. It is difficult to determine even based on diagnosis. The frequency parameters we put in are triggers for review. One thing we frequently find is that three areas of the spine are treated but the notes only mention Lower Back Pain – we try to get records not for a single service, but a complete medical record. Some exceptions do have to be made for necessity (e.g. LBP in Jan and cervical injury due to auto accident in July).

Difference between NY and NJ – we now use rolling dates of service rather than CY.

The perception of allopathic physicians is difficult. They're dealing with vague symptoms and most patients are self-referred. Difficulties defining the standards. Chiropractic care has been very poorly documented in terms of evidence based medicine. The scientific literature is far behind other fields.

The concept of the AT modifier was good, but it was not accepted. It's created a mechanism for chiropractors to circumvent the issue and assure they're paid. It's been very difficult and very adversarial.

Anecdotally, when we review chiropractic services, we don't see a high rate of appeal from the providers.

In this region, the chiro community has not been particularly vocal.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☒ Other
☐ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: session in workgroup—rationale for just having one modifier (MT mod?)
MR managers monthly call in fall 2004
MR conference hosted by CMS included AT modifer info that year

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☒ Yes ☐ No

If Yes, describe education: nothing to contractors

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: we've tried. Revised LCDs – national ?. A lot of probes, would publish articles online about findings (error rates). Listserve. Webinars—100s of attendees, often office staff rather than chiropractors. ? took that function over and has had appeared at national & state association annual meetings.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits Must have AT modifier to get paid.
Most aberrant billers (based on frequency & duration) are probed for review. Typically start w/40-claim probe and then move to provider-specific pre-pay.

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☒ Not Effective

Explain: The chiros probed don't change behavior. They claim they don't see the notices, etc. It takes several months, maybe a year for their error rates to fall. We've not been able to move a number of them from the probe process despite education efforts. They think we're wrong, they go to appeals – it's always very begrudgingly; nobody ever says "gee, I see what you're saying. It's maintenance therapy and I'll stop billing for it." They think that what they do is such a good thing, it ought to be covered.
Lots of the chiropractors abuse the GA modifier.

If yes, how do you determine the effectiveness of these processes? Error rates

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☒ No

Explain: Only if we have a chiropractor that we've repeatedly reviewed/educated and he's refusing to comply, we make a referral to the PSC.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? National policy. One thing not in national policy is that pain alone does not determine medical necessity. This is only identified through a post-payment medical record review, which happens infrequently.

When? Aug 2000

Why? The chiro society disagrees with the CMS definition of acute. They think if the patient is in pain, treatment meets the medical necessity requirement.

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): never spoke with CMS about pain/sufficiency issue

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain: not transitioned yet.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe: the only thing I can think of is consolidating policies within (b)(4). Edits will be the same on the Part B side.

8. Is there anything we haven't discussed that you would like to share?

The specialty disagrees with CMS' definition of acute; they think that everything they do is acute. It's been a very difficult concept to work with chiropractors on.
It would be helpful if CMS would give a more specific definition of chronic subluxation in the context of the AT modifier—define when does it become exacerbated and interfere with function that would require treatment.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: 100-2/Chapter Section 30.5 of the Internet-only Manual. Information incorporated into their internal manuals.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: This can only be identified by audit. They are on phone calls, but we are unaware of anything CMS has provided.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: Use of the modifier only detailed in a medical review.

2005, convoy tour: breakout sessions (proper chiropractic session, 2 sessions a day at 3 sites, chiropractic webinar) – in sessions have 5-30 chiros; association 30-40 chiros; webinar was national with 49 attendees

2006 (Seminar for (b)(4) chiro association seminars). Chiropractic billing guide originally developed in 04 and updated was posted.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☒ Post-payment edits ☐ Other

Explain—probe for basis of edits We only allows claims with the AT for payment (+ dx). LCD limit is 30 services within 365 days. We don't really look at AT modifier for us, just the procedure codes. No analysis in conjunction with GA or GZ modifier. Just do post-payment reviews on problematic providers. High abusers stay the high abusers, education has no effect. Sometimes chiros will choose to opt out of the program.

If yes, how effective has this process been?

☒ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain:see above

If yes, how do you determine the effectiveness of these processes? See above. Documentation is poor, universally. When you request it, you usually find it is for maintenance. We look back 6 months as part of our review.

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☒ No

Explain:PSC will not look at this from a fraud perspective. We noticed that one bene was shared between chiropractors and physical therapists.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD?subluxations that match claim, check for acute vs. maintenance, check for x-ray, did the symptoms and subluxation match? Restates the (b)(4). Chiros feel documentation is onerous. We work with (b)(4) chiro association, but a lot of chiros don't belong.

When? Post-payment reviews

Why?To endure they are medically necessary.

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain:We anticipate transition in mid-2008.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe:_____

8. Is there anything we haven't discussed that you would like to share?

Recommend to Congress a yearly limit. Similar issue with physical therapists. Chiropractic community moves a lot from office to office, mostly paper billers. There are 4000 providers in (b)(4) Rural population goes to chiro more. Limit of 18 services/year flooded us with work. Claims of 1 per month are most likely maintenance but the amount of dollars at risk is low. A limit of 18/yr is a good limit with no resource limitations. Podiatry is a bigger problem than chiro.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
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Data Collection Instrument for Carriers

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1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

X Medicare Benefit Policy Manual	☐ Other
X Change Request 3449	
X MedLearn Matters Article 3449	☐ None *(confirm nothing received)*

If Other, describe guidance:_____
_____
_____
_____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes	X No

If Yes, describe education: _Medlearn matters article 3449 as described above._____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

X Yes No

If Yes, describe instruction: Med review and chiropractic consultant spoke at (b)(4) chiropractic association meeting. Numerous web ex educational sessions (b)(4) Individual letters to chiropractors identified by data.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

X Yes No

If yes, describe process(es)

Pre-payment edits X Post-payment edits Other

Explain—probe for basis of edits _Medical review is data driven. Vulnerabilities are prioritized and worked as budget allows. If Chiropractors are significantly different than their peers a sample of records are requested to determine if there are errors. If we have any questions, we do have a chiropractor as a consultant. If so education is given and we follow Progressive corrective action as instructed by CMS.

If yes, how effective has this process been?

Very Effective X Somewhat Effective Not Effective

Explain: Some providers are receptive to education, and reduce error rates. Many chiropractors feel that the care that they are providing is not maintenance despite our educational efforts. We've had cases where one chiropractor is seeing a bene only once every month and says it's not maintenance therapy; sometimes the spouse even comes in on the same date. Our hearings upheld the denial, but he went to an ALJ (Iowa administrative law judge division) and got them overturned. We did a referral on him to the PSC, but since the ALJ overturned the denials, they couldn't pursue him. We nor the PSC even know when the ALJ hearings are scheduled. They can also make decisions without hearings.

If yes, how do you determine the effectiveness of these processes? Effectiveness is determined by the providers' error rate reducing after education.

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

X Yes ☐ No

Explain: Referrals are made to the PSC if the provider error rate does not reduce despite numerous educational attempts. Often, they do not pursue the cases on chiropractors.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

X Yes ☐ No

If yes,
Describe the LCD? It emphasizes the requirements that are in the benefit policy manual Chapter 15 section 30.5. No frequency edits – just mirrors national coverage. We never had frequency edits.

When? _____

Why? If congress were to change the benefit to put a limit on services, that would be great.

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation):
Contractors do not need CMS approval for LCDs.

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes X No

If Yes, please explain: (b)(4)
(b)(4) (Trailblazers) right now.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes X No

If Yes, please describe:_____
_____
_____

8. Is there anything we haven't discussed that you would like to share?

Cases of maintenance chiropractic care (and other services) are being overturned at the ALJ level after we've worked hard. This is very detrimental. When the word gets out to everyone in the state, it's tough.

The maintenance will continue until CMS puts a frequency limitation in place. Maybe there could be a waiver built in for benes who need medically necessary chiro treatment. If they have an AT, the claim will get paid unless we've got the provider under review.
We have had some problems with chiropractors using G modifiers with the AT, and CMS in 2004 has advised us that it is alright for them to bill that way. We're not sure if we can share that email correspondence because things have changed a lot with MAC contracting – the channels of communication have changed. In that instance we can't have our system auto deny the claim with that combination.

Carrier # (b)(4)

(b)(4)

tic Services: Payments for Maintenance Therapy
Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has (b)(4) received regarding use of the AT modifier for chiropractic services?

X☐ Medicare Benefit Policy Manual ☐ Other
X☐ Change Request 3449
X☐ *MLN Matters* Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance:_____
_____
_____
_____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes X☐ No

If Yes, describe education:_____
_____
_____

(b)(4)

3. Has (b)(4) instructed chiropractors regarding the use of the AT modifier?

X Yes ☐ No

If Yes, describe instruction: (b)(4) *has provided guidance for chiropractors regarding HCPCS modifier AT in the form of articles on our Web site, workshop handouts and in-person education, and a computer based training course. Because information on our Web site is updated regularly, we are listing only currently available resources regarding this modifier:*

- Web site article: "Chiropractic Services: Acute Treatment" (published 1/9/2007)
- Computer based training course: "Chiropractic Specialty Training" (also mailed on CD-ROM to chiropractors in (b)(4) in June 2006)
- Modifier Lookup tool: provides guidance on all HCPCS and CPT modifiers, including HCPCS modifier AT
- Workshop handouts (provided to attendees at in-person events)
- In-person events for chiropractic offices were conducted on the following dates. All events were open to all chiropractic offices:
  - 11/28/06 (clinical and non-clinical instruction)
  - 1/18/07(clinical and non-clinical instruction)
  - 10/6/07 (non-clinical instruction): requested by the (b)(4) Chiropractic Association
  - 10/25/07 (clinical and non-clinical instruction): co-sponsored by the (b)(4) Chiropractic Association

Eight additional Web site articles are available on the (b)(4) Web site specific to chiropractic services.

(b)(4) has a yearly program of utilization review and education efforts. They do some specialized reviews.

4. Does (b)(4) have processes to ensure appropriate use of the AT modifier?

X☐ Yes ☐ No

If yes, describe process(es) Carrier # (b)(4)

(b)(4)
(b)(4) t edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits *Provider specific probes (edits) are performed based on data analysis received from AdvanceMed, the Program Safeguard Contractor (PSC), as well as New Provider probe reviews. Currently, we have 8 providers on probe review for chiropractic services.*

If yes, how effective has this process been?

☐ Very Effective X ☐ Somewhat Effective ☐ Not Effective

Explain: See below

If yes, how do you determine the effectiveness of these processes? *Error rate results from our pre-payment probes are one data element we use to measure our effectiveness. Three provider specific probes for chiropractic services were completed during the first three quarters of FY07, resulting in an average error rate of 39%. Another measure used to determine the effectiveness of our education is the Over-Utilized Codes (OUC) list published on the CMS Web site. According to the November 2007 OUC report, the paid claims error rate for (b)(4) for chiropractic services is 2.6%, which is well below the carrier national average paid claims error rate of 10.6%. (Source: November 2007 Long Report, p. 36-37)*
There were 41,589 claims denied b/c of no AT modifier The % of abuse with 98942 is 80% or greater.

5. Does (b)(4) coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

X☐ Yes ☐ No

Explain: *The PSC does data analysis to determine provider outliers. Aberrant providers are identified for possible probe reviews. In (b)(4) they do their own data analysis. They try to follow-up woth the PSCs but get no response.*

6. Has (b)(4) implemented local coverage determinations (LCD) rega tic services?

☐ Yes X☐ No

If yes,
Describe the LCD?_____
_____
_____
_____

When? _____

Why?_____no statistics to support its use_____
_____
_____
_____
_____
_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____
_____
_____
_____
_____
_____
_____
_____
_____
_____

7. a. Has (b)(4) experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes X☐ No

If Yes, please explain:_____*Sept 08*_____

_____

b. Does (b)(4) anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes X☐ No

If Yes, please describe:_____

_____

_____

8. Is there anything we haven't discussed that you would like to share?

No

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☐ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: CR 3449 2005/2006
Sat in on call with (b)(6) of CMS when MedLearn Matters came out.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: _____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: Education letters on website. LCD – more than 12 considered maintenance therapy, or if bene is seen no more than once per month (note: there appeared to be confusion over the LCD frequency limits were more than 12 per year or less than 12 per year).

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits probes; identifies services only once per month
Pre-pay edits: (1) procedure & diagnosis 304 edit (2) automatically deny claim w/o AT modifier
In the past, (2005-2006) had done post-pay probes. CMS suggested them to do pre-payment probes. (One contract may look at high utilizers compared to peers as post-payment edit.)

If yes, how effective has this process been?

☐ Very Effective ☒ Somewhat Effective ☐ Not Effective

Explain: automatic AT modifier denial not confirming acute therapy; One-on-one education through probe process has been very effective in the demonstration project.

If yes, how do you determine the effectiveness of these processes? Evaluate if billing practices improved after probe & education

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☒ No

Explain: we refer fraud (26 in 2006), but nothing is coordinated regarding chiropractic services

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? no frequency limitation; available on web (b)(4)

When? _____

Why?_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain: (b)(4) transitions March 1 (b)(4) June 1 (b)(4) transition date moved to Sept

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe: we wouldn't be in charge of it unless we received a MAC contract

8. Is there anything we haven't discussed that you would like to share?

Provider outreach: have worked with associations/societies. They've been accommodating to have us but they don't reach all chiropractors.
Policy dated 2001 – consolidation of all 6 states. Several months of intense education with no edits and made 14-16 contacts at that time with all providers. It's a huge effort but seems to work. We've not heard a lot from the chiropractors since. One-on-one education through probe process has been very effective. We were strongly urged by CMS not to review non-participating providers. Many providers have opted out. The issue of non-participating providers has been difficult for medical review staff?
Prior to 2006, we educated providers only to use an AT modifier when a patient has an exacerbation and consequently changes the treatment plan. When CR 3449 came out, they began putting the modifier on all claims for active treatment.
XXXXX will send copy of newsletter article reflecting instruction on use of the AT modifier prior to 2006 and a copy of the letter sent with instruction after 2006.
(b)(4) participated in Chiro Demonstration Project 2005-2007. Found that the chiro community responded well to the intense education provided. Went from 80% denial rate to about 28% over 12 months. Attendance of outliers at invitation-only educational events was high.

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
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1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: It's possible that this was discussed at one of the CMD meetings, but I didn't attend all of them.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☒ No

If Yes, describe education: Probe for progressive medical action as part of review.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction: Chiro services manual on website that is explicit about all services, not just the AT. Also published MedLearn Matters article on listserv & newsletter. Chiropractic seminars, online web-based training.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☒ Yes ☐ No

If yes, describe process(es)

☒ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits Complex pre-pay edits—fail signals medical review of claim if more than 12/mo or 30/yr—high denial rate. They see maintenance, no plan of care, no evidence of manual manipulation (they're using machines).
Automated edit based on dx code per LCD.

If yes, how effective has this process been?

☒ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: Quarterly edit effectiveness shows return rate on appeal.

If yes, how do you determine the effectiveness of these processes? We're not caught in the pay and chase game because the edit catches maintenance therapy before it's paid.

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☒ Yes ☐ No

Explain: If there was a need, we would coordinate that. The PSC hasn't seen fraud – more misuse of a medical benefit, so MR hasn't referred any for fraud. Quarterly meeting coordinated by FBI fraud taskforce—the PSCs are there, the local commercial carriers are there; it's a huge problem with worker's comp claims. We participate in those meetings, but we're a minor player. I know our PSC has dealt with some specific providers.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? In addition to national policy requirements, chiro diagnoses are split into different categories and different numbers of services are permitted. For a tension headache, we would permit up to 12 manipulations, whereas if somebody had a C-diagnosis (nerve root damage), we would permit up to 24 manipulations. We have 4 such categories and a small group of codes in each.

When? Since the early 80's.

Why? We have several Medical Directors, and split the turf by topic instead of geographically. I'm certain the Director for chiropractic services has spoken to Directors from other contractors regarding this issue. This LCD originated many years ago with a group of Directors from different carriers that became available as a "model policy" to all carriers. Some might not have been able to adopt it because their advisory committee wouldn't approve it; some might not have thought it necessary because they didn't identify abuse of chiropractic services.

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain: In the process of transition. (b)(4), and we got that contract. We will acquire Part B in (b)(4) in March. We will lose (b)(4) We will use the Trailblazer policy for chiropractic services.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe: We intend to use the current (b)(4) LCD in (b)(4) for chiropractic, which will be effective for dates of service on or after the date of transition.

8. Is there anything we haven't discussed that you would like to share?

IG in mid-80's suggested capping all chiropractic manipulations at 12/yr, and I liked it. The way we're doing this is obviously very labor-intensive. We would love an arbitrary cap if it were politically feasible. Also going back into the 80s, there were parameters set by CMS where you could automatically deny, and now they've removed those parameters. Now we can't automatically deny – we have to set at simple or complex medical review. It would be great if we could go back to automating it with the MACs. You know it's a problem nation-wide.

Carrier #_____

(b)(5)

(b)(5)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
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1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☒ Medicare Benefit Policy Manual ☐ Other
☒ Change Request 3449
☒ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: ____ Nothing that isn't already on list

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☒ Yes ☐ No

describe education:
(b)(6) Not specific w/AT modifier but with chiro policy. When converting from local medical review policy to LCD, Region (b)(4) CMS rep sat with carrier and went line by line

through policy. Went through medical records from chiropractors to make sure claims were properly formatted and met regulation. Never had this type of assistance from CMS on any other policy. CMS brought in people from Chiropractic organizations. Emphasis was "is practice following regulations?" CMS helped us write the policy including AT modifier. Guidance was that providers were to use AT modifier and carriers were not supposed to establish medical review at that time.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction:

Outreach and publications going back to late 2004 specific to AT modifier. Some associated with Chiropractic Demonstration project (escalated educational activity related to Chiropractic services with 26 county area in northern (b)(4)~2600 eligible providers).
Educational programs April 05: 12 seminars w/ detailed information regarding AT modifier
Teleconference September 2005-December 2006: 6 teleconferences quarterly
Special group representing organization-key members of chiro community held 6 meetings related to AT modifier.
Small provider education to address issues specific to small chiropractic practices met 4 times before may07
5 total conferences with chiropractors w/AT modifier as a topic
Web Presentation specifically on AT modifier and it's appropriate use
Publications: September 04 Listserve notification reminder of AT modifier and active vs. maintenance therapy.
October 04 monthly newsletter CR 3063 Revised requirements for active/corrective treatment.
March 2007 Monthly newsletter-revisiting the AT modifier. Reiteration of all education and how to apply modifier
FAQ on website
Dear Dr. and Letter Fact Sheet on Medicare Participation: pulled educational material into CD-ROM. Articles address AT modifier.

Has all the education helped?
A review of national data indicates that prior to implementation of the AT modifier, chiro procedure codes were increasing for allowed services, but in the last 6 months we had a minor dip in claims. CMS in their wisdom asked contractors to develop annual review plan for 08, Part B extract data and CERT information (error rate report)—our medical review area selected is chiropractic claims with AT modifier. Strategy: Chiro Med Review is part of FY 08 policy. Sent out letters to chiros (probes) using AT more than peers by two standard deviations. If they don't correct with letter or meet standard deviations, carrier will do more specific probe of the chiropractor.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☐ Yes ☒ No

Not at this time. This could be reevaluated depending on probes done in FY 08.

If yes, describe process(es)

☐ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits No frequency edits. Could be evaluated based on probes.

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain:_____

If yes, how do you determine the effectiveness of these processes? _____

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☒ No

Explain: At this time, nothing to warrant referral to PSC.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☒ Yes ☐ No

If yes,
Describe the LCD? We used to have frequency limit of 36 prior to September 2004 (at the 37th service, we would request documentation for the entire CY). Now the policy created with CMS has nothing specific to frequency. One complaint of chiropractors was that they couldn't bill for maintenance therapy and through the AT modifier they can now do that. AT modifier gave them an avenue in which to have claims paid.

When? Have always had LCD

Why?_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): _____

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

☐ Yes ☒ No

If Yes, please explain:
Jurisdiction (b)(4) Only recently covered (b)(4) Part A. Haven't taken on any more work at this time; don't see much difference with MACs. As part of MAC process, carrier reviewed all (b)(4) states' medical review policies. Guidance was to develop least restrictive policy, but that was changed to developing the most medically appropriate policy—it's sill in draft with CMS. It's based on regulations and national guidelines so it isn't really that much different but based on policies in the other (b)(4) states.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

☐ Yes ☒ No

If Yes, please describe:_____

8. Is there anything we haven't discussed that you would like to share?

Feeling on use of AT modifier: providers have not adopted it. When our edit was turned off after 2004, utilization of the AT modifier has gone up. That is why we included it in 08 workplan. Political interest in chiropractic services is strong. CMS RO has had a few contacts in (b)(4) very political issue. Chiropractic Demonstration project allowed certain treatments (PT) to be billed by chiropractors. Carrier mentioned to CMS re: Demo project, there were regularly scheduled calls where carrier would provide data to CMS. (b)(6) at CMS. During these calls, we would discuss AT modifier. At that time, (b)(4) providers generated ~80% of all chiro services nation-wide.

Potential recommendation: National Coverage Determination frequency limitation—policy consistency across country. As CMS has reduced the number of contractors, it's easier for us to deal with things on a national scale.

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for CMS

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

A. Implementation of the AT modifier

1. Prior to 2004, it appears that some chiropractic services were billed with the AT modifier. When did the AT modifier originally apply to chiropractic services? _____

2. When did CMS begin requiring the use of the AT modifier to indicate acute vs. maintenance on claims for chiropractic services?_____

   a. For what reasons did CMS establish the AT modifier?

   _____
   _____
   _____
   _____
   _____
   _____
   _____

   b. Why did CMS require the use of the AT modifier?

   _____
   _____
   _____
   _____
   _____
   _____

c. What prompted CMS to issue provider education on the use of the AT modifier for chiropractic services in 2004?

_____
_____
_____
_____
_____
_____

3. Did CMS anticipate changes in chiropractic billing following provider education regarding the requirement of the AT modifier in 2004?

☐ Yes ☐ No

If yes,
What Changes? _____
_____
_____
_____
_____

If no,
What was the purpose of the provider education? _____
_____
_____
_____
_____

4. Does CMS measure the effect of the AT modifier use on chiropractic billing? *(PSC reports, CERT system, etc)*

☐ Yes ☐ No

If yes,
How? _____
_____
_____
_____
_____
_____

5. Did the requirement of the AT modifier and provider education affect chiropractic billing?

AT modifier	☐ Yes	☐ No	☐ Don't Know
Provider education	☐ Yes	☐ No	☐ Don't Know

Please explain:_____
_____
_____
_____
_____

B. Understanding of chiropractor use of AT modifier

6. Beyond the Medicare Benefit Policy Manual, MedLearn Matters Article 3449, and Change Request 3449, has CMS issued other guidance or education to **contractors** (PSCs and Carriers/MACs) regarding the appropriate use of the AT modifier for chiropractic services?

☐ Yes ☐ No

If yes,
What guidance/education? *(Provide copies)* _____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

7. Beyond the Medicare Benefit Policy Manual, MedLearn Matters Article 3449, and Change Request 3449, has CMS issued other guidance or education to **providers** regarding the appropriate use of the AT modifier for chiropractic services?

☐ Yes ☐ No

If yes,
What guidance/education? *(Provide copies)* _____
_____
_____
_____
_____
_____
_____
_____
_____
_____

C. Ensuring the AT modifier is not used for maintenance therapy

8. Does CMS oversee **contractors** regarding providers' appropriate use of the AT modifier?

☐ Yes ☐ No

If yes,
How?_____
_____
_____
_____
_____
_____

9. Has CMS directed contractors to review chiropractic services?

☐ Yes ☐ No

10. If yes,
Which contractors conducted reviews? _____
_____

What was the nature of the review (frequency, appropriate use, etc)? *(Probe: Were any reviews specific to AT modifier use or maintenance therapy?)* _____
_____
_____
_____

What were the results of the review? _____
_____
_____
_____
_____
_____
_____
_____

If no,
Why has CMS not directed contractors to review chiropractic services? _____
_____
_____

10. Does CMS address **providers** appropriate use the AT modifier through its work with contractors?

☐ Yes ☐ No

If yes,
How?_____
_____
_____
_____
_____
_____

11. Beyond oversight described above, does CMS do anything to review the use of the AT modifier?

☐ Yes ☐ No

Please explain:_____
_____
_____
_____
_____
_____
_____

D. CMS reviews of chiropractic services

12. Has CMS conducted oversight of chiropractic services?

☐ Yes ☐ No

If yes *(Provide copies)*,
What was the nature of the review (frequency, appropriate use, etc)? *(Probe: Were any reviews specific to AT modifier use or maintenance therapy?)* _____
_____
_____
_____

What were the results of the review(s)? _____
_____
_____
_____
_____
_____
_____
_____

E. Oversight and local coverage determinations

13. What role will Medicare Administrative Contractors (MACs) have in oversight of chiropractic services?

14. Does CMS anticipate any changes in oversight specific to chiropractic services, with the transition to MACs?

15. Have carriers and/or MACs implemented local coverage determinations (LCD) regarding chiropractic services?

☐ Yes ☐ No

If yes,
When? _____

Why?_____
_____
_____
_____
_____
_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? _____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

16. Do variations in LCDs for chiropractic services exist among carriers and/or MACs?

☐ Yes ☐ No

If yes,
What are the variations? _____
_____
_____
_____
_____
_____

17. Are LCDs consistent with CMS instructions for the use of the AT modifier?

☐ Yes ☐ No

If yes,
How does CMS ensure consistency? _____
_____
_____
_____
_____
_____
_____

If no,
How are they inconsistent? _____
_____
_____
_____
_____
_____
_____

Why are they inconsistent? _____
_____
_____
_____
_____
_____
_____

18. Have any carriers and/or MACs ***implemented*** coverage determinations with frequency thresholds for chiropractic services?

☐ Yes ☐ No

If yes,
What were the results?_____
_____
_____
_____
_____
_____

19. Are any carriers and/or MACs ***in the process of*** developing frequency thresholds for chiropractic services?

☐ Yes ☐ No

If yes,
Please explain: _____
_____
_____
_____

20. How do carriers and/or MACs ensure that claims are only paid for acute treatment?

_____
_____
_____
_____
_____

21. What is the PSC role in ensuring claims are only paid for chiropractic acute treatment?

_____
_____
_____
_____
_____

22. Do carriers/MACs and PSCs coordinate to ensure the appropriate payment of chiropractic claims?

_____
_____
_____
_____
_____

23. (Prompt: *We understand that CMS encountered resistance in previous attempts to implement frequency controls on chiropractic services.)* Are there any changes CMS would like to make regarding chiropractic services?

☐ Yes ☐ No

Please explain:_____
_____
_____
_____

What barriers, if any, exist to implementing changes? *(e.g., frequency controls)* _____
_____
_____
_____
_____
_____

If barriers exist, what would enable CMS to overcome these barriers? _____
_____
_____
_____
_____

24. Is there anything we haven't discussed that you would like to share?

_____
_____
_____
_____
_____
_____
_____

(b)(6)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for CMS

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

A. Implementation of the AT modifier

1. Prior to 2004, it appears that some chiropractic services were billed with the AT modifier. When did the AT modifier originally apply to chiropractic services? 2004 became mandatory; may have been available before then, and they could use any modifier they felt necessary; perhaps on a local level

2. When did CMS begin requiring the use of the AT modifier to indicate acute vs. maintenance on claims for chiropractic services? Oct 2004

   a. For what reasons did CMS establish the AT modifier?

We received comments from the industry indicating our definition of maintenance therapy in the old manual was confusing, so we tried to tighten up that definition and added the AT modifier so the chiropractors can indicate acute treatment.

   b. Why did CMS require the use of the AT modifier?

We wanted to encourage providers to think about whether treatment is maintenance. We wanted a way to look at the claims to determine whether treatment was active or maintenance. The AT modifier seemed like a good fit because it was already in existence.

c. What prompted CMS to issue provider education on the use of the AT modifier for chiropractic services in 2004?

Any time we issue a CR, we provide education through MedLearn Matters. The actual CR is geared to the contractors and may be more technical, so there is an ongoing effort to issue education. I'm sure we would have anyway, given the attention OIG gave chiropractic services in the past.

3. Did CMS anticipate changes in chiropractic billing following provider education regarding the requirement of the AT modifier in 2004?

X Yes ☐ No

If yes,
What Changes? We're not sure if it helped, but our hope was at the time that it would help. We were expecting a little bit of a drop in claims.

If no,
What was the purpose of the provider education? _____
_____
_____
_____
_____

4. Does CMS measure the effect of the AT modifier use on chiropractic billing? *(PSC reports, CERT system, etc)*

☐ Yes X No

If yes,
How? Measure error rate of chiropractic services through CERT, but nothing specifically related to the AT modifier.

5. Did the requirement of the AT modifier and provider education affect chiropractic billing?

AT modifier	□ Yes	X No	X Don't Know
Provider education	□ Yes	X No	X Don't Know

Please explain: Error rate for chiro increased in 2005, which could have been a result of the change in documentation requirements (6 mo prior to date of service as compared to 1 mo previously) during medical review requests. It's difficult to determine if AT mod/education had an effect.

B. Understanding of chiropractor use of AT modifier

6. Beyond the Medicare Benefit Policy Manual, MedLearn Matters Article 3449, and Change Request 3449, has CMS issued other guidance or education to **contractors** (PSCs and Carriers/MACs) regarding the appropriate use of the AT modifier for chiropractic services?

□ Yes X No

If yes,
What guidance/education? *(Provide copies)* no other manual instructions specific to the AT modifier. Gave contractors flexibility.

7. Beyond the Medicare Benefit Policy Manual, MedLearn Matters Article 3449, and Change Request 3449, has CMS issued other guidance or education to **providers** regarding the appropriate use of the AT modifier for chiropractic services?

t

□ Yes X No

If yes,
What guidance/education? *(Provide copies)* Benefit Policy Manual & Claims Processing Manual only
Has met with chiropractic associations (ACA, ACC, state licensing boards, Congress of Chiropractic something) – 1/4/07 ACA meeting – they indicate all of their problems stem from documentation problems in the chiropractic community. They argue that the error rate isn't that bad in reality; it would be improved if documentation were better. (b)(4) also had a chiropractic consultant come in and give some examples.

C. Ensuring the AT modifier is not used for maintenance therapy

8. Does CMS oversee **contractors** regarding providers' appropriate use of the AT modifier?

☐ Yes X No

If yes,
How? The contractors use their own data to show vulnerabilities—they have to prioritize according to their discretion.

9. Has CMS directed contractors to review chiropractic services?

☐ Yes X No

10. If yes,
Which contractors conducted reviews? _____
_____

What was the nature of the review (frequency, appropriate use, etc)? *(Probe: Were any reviews specific to AT modifier use or maintenance therapy?)* _____
_____
_____
_____

What were the results of the review? _____
_____
_____
_____
_____
_____
_____
_____

If no,
Why has CMS not directed contractors to review chiropractic services? We allow them the discretion to address their largest vulnerabilities. Years ago, some contractors had auto-deny limits and one by one got rid of them because of political pressure and the lack of clinical evidence for where that limit should be set. We do not encourage them to go "out on a limb" to set auto-deny frequency limits.

10. Does CMS address **providers** appropriate use the AT modifier through its work with contractors?

☐ Yes X No

If yes,
How? If there's a provider under review, the contractor would be responsible for providing education. We do have a data team that looks at trends, but without a solution, there's not much to say.

11. Beyond oversight described above, does CMS do anything to review the use of the AT modifier?

☐ Yes X No

Please explain: Providers do their data analysis and put the money where the problems are. This process will remain with MACs.

D. CMS reviews of chiropractic services

12. Has CMS conducted oversight of chiropractic services?

☐ Yes X No

If yes *(Provide copies)*,
What was the nature of the review (frequency, appropriate use, etc)? *(Probe: Were any reviews specific to AT modifier use or maintenance therapy?)* _____
_____
_____
_____

What were the results of the review(s)? _____
_____
_____
_____
_____
_____
_____
_____
_____

E. Oversight and local coverage determinations

13. What role will Medicare Administrative Contractors (MACs) have in oversight of chiropractic services?

They will have full responsibility for Parts A & B as the contractors do now; there will still be fraud contractors as well.

14. Does CMS anticipate any changes in oversight specific to chiropractic services, with the transition to MACs?

No.

15. Have carriers and/or MACs implemented local coverage determinations (LCD) regarding chiropractic services?

X Yes ☐ No

If yes,
When? (b)(4) is the only jurisdiction that would have LCDs available, but all MACs will have them.

Why?_____
_____
_____
_____
_____
_____

How does CMS determine whether the LCDs for chiropractic services are appropriate? We don't look at every policy to approve it – that happens at the contractor level, and they have local advisory committees. The LCDs just can't conflict with the national policies, which CMS regional offices can advise when necessary. We limit involvement so that they can reflect local concerns.

16. Do variations in LCDs for chiropractic services exist among carriers and/or MACs?

X Yes No

If yes,
What are the variations? As long as they don't conflict with national policy, they can address their unique vulnerabilities. OCSQ may know more. Will email (b)(4) contact info.

17. Are LCDs consistent with CMS instructions for the use of the AT modifier?

X Yes No

If yes,
How does CMS ensure consistency? As far as we know. If any providers have concerns, they generally make them known, and we haven't heard anything.

If no,
How are they inconsistent? _____
_____
_____
_____
_____
_____
_____

Why are they inconsistent? _____
_____
_____
_____
_____
_____
_____

18. Have any carriers and/or MACs ***implemented*** coverage determinations with frequency thresholds for chiropractic services?

X Yes No

If yes,
What were the results? As far as I know, there are no auto-denial frequency edits. There may be some frequency edits that suspend claims for review; this will depend on workload of the carriers (b)(4) has these). Resources may be better spent on lowering the error rate another way.

19. Are any carriers and/or MACs ***in the process of*** developing frequency thresholds for chiropractic services?

 Yes X No

If yes,
Please explain: Don't know. I doubt any are doing auto-denials based on frequency.

20. How do carriers and/or MACs ensure that claims are only paid for acute treatment?

Everything is looked at from the perspective of identifying the biggest vulnerabilities. Chiropractic doesn't have that many codes, so it's probably not that hard to deal with. It comes down to resource allocation at the carrier level.

21. What is the PSC role in ensuring claims are only paid for chiropractic acute treatment?

It's all data-driven; if they find something, they may look into it. It's individual for specific locations. The only way chiropractic services would come into question is if someone points out a specific vulnerability. Since most chiropractic providers are relatively small, it may not be a good use of resources to pursue them. (b)(4) is the only PSC that looks into this currently – they didn't come up with a lot of money associated with it, but put together some informational materials on fraud prevention.

22. Do carriers/MACs and PSCs coordinate to ensure the appropriate payment of chiropractic claims?

There's not an official coordination effort. If they feel they need to touch base with one another, they will.

23. (Prompt: *We understand that CMS encountered resistance in previous attempts to implement frequency controls on chiropractic services.)* Are there any changes CMS would like to make regarding chiropractic services?

☐ Yes X No

Please explain: No recommendations

What barriers, if any, exist to implementing changes? *(e.g., frequency controls)* OCSQ requires medical data for national policy – since there's none available, we'd be hard-pressed to come up with a limit.

If barriers exist, what would enable CMS to overcome these barriers? _____
_____
_____
_____
_____

24. Is there anything we haven't discussed that you would like to share?

No.

MEDICAL RECORD DATA COLLECTION INSTRUMENT

OFFICE OF INSPECTOR GENERAL
OFFICE OF EVALUATION AND INSPECTIONS

Medicare Chiropractic Visits: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier: OEI-07-07-00390

Cover Sheet (Project Coordinator's Information – Not to be changed by Reviewers)

HCPCS of Sampled Service: «HCPCS»

Date of Sampled Service: «DOS»

Beginning Date of Treatment Episode: _____
(**H**: Date found on the HCFA 1500 form; **M**: Date found in the medical records;
P: Date given by the provider's office directly to FMAS's Project Coordinator)

Ending Date of Treatment Episode: _____
(**H**: Date found on the HCFA 1500 form; **M**: Date found in the medical records;
P: Date given by the provider's office directly to FMAS's Project Coordinator

Sampled Chiropractor Name: «CHIROPRACTOR_FNAME» «CHIROPRACTOR_LNAME»

Is the Medical Record Included for the Sampled Service? ☐Y ☐N

Common Terms and their Definitions:

Acute treatment: manipulative services rendered to have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function.
AT modifier: A descriptor used on a claim to indicate a sampled service was for active/corrective treatment to treat an injury rather than maintenance therapy.
Exacerbation: A temporary, marked deterioration of the patient's condition due to an acute flare-up of the condition being treated.
Initial visit: The first visit related to the treatment episode for the sampled service; may differ from the date of the first service in the medical record.
Interim visit: Visits after the initial visit and before the sampled service. In certain instances, the sampled service may be the same as or may immediately follow the initial visit, so there may not be interim visits.
Maintenance therapy: Services that seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. "Supportive rather than corrective in nature" is a term that originates from the Medicare Benefit Policy Manual section 240.1.3.] Corrective refers to functional correction of symptoms. The Medicare Policy Manual does provide that "once the clinical status has remained stable for a given condition, without

expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered."
Recurrence: A return of symptoms of a previously treated condition that has been quiescent for 30 or more days.
Sampled service: The service of interest that OIG randomly selected. A service may only be one part of a visit and not the visit itself.
Service: Each procedure a chiropractor performs for a beneficiary.
Treatment episode: The course of treatment characterized by visits related to the sampled service. There may be multiple treatment episodes in a medical record.
Visit: A beneficiary's encounter with a chiropractor. One or more services may be provided during the course of a single visit.

A. Identification of the Treatment Episode:

1. After reviewing the entire medical record, determine the beginning and ending of the treatment episode which included the sampled service of «DOS» and answer below. *Note:* A significant re-injury requiring a revised treatment plan should be classified as a new episode. Episodes may overlap. Only change the initial visit date if you have evidence to support that it is incorrect.

o 1A. Initial visit (First visit related to the treatment episode for the sampled service of «DOS»):
Enter date: _____

This initial visit is a: Recurrence ☐ Exacerbation ☐ Neither ☐

o 1B. Final visit (Last visit related to the treatment episode for the sampled service of «DOS»):
Enter date: _____

If 1A and/or 1B are different than the dates chosen by the practicing chiropractor, please list the evidence to support that it is correct ____

B. Initial visit:

2. For what chief complaint did the patient initially visit the chiropractor (date identified in question 1A above)? ***(Record verbatim in patient's words where available.)***

____

☐ None documented

3. Which of the following diagnostic procedures did the chiropractor use to evaluate the patient's condition? ***(CHECK ALL THAT APPLY)***

☐ X-ray / Imaging *(Answer 3A and 3B)*

o 3A. When was the x-ray or other imaging test performed (please indicate only x-rays relevant to the subluxation)?

☐ More than 12 months prior to the initial visit *(List date)* _____

- Is there a reasonable basis for concluding the condition is permanent?
  ☐ *Yes* ☐ *No* *(Explain)* _____

☐ Less than 12 months prior to the initial visit *(List date)* _____

☐ At the initial visit *(List date)* _____

☐ Less than 3 months after initial visit *(List date)* _____

☐ More than 3 months after initial visit *(List date)* _____

☐ No date provided.

Unless more specific x-ray evidence is warranted, an x-ray is considered reasonably proximate to the initiation of a course of treatment if it was taken no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment. Medicare Benefit Policy Manual §240.1.2.1

o 3B. Who interpreted the x-ray or other imaging test?

☐ This chiropractor

☐ Another chiropractor

☐ Another medical professional (e.g., radiologist, tech)

(List profession) _____

☐ Can't determine

☐ Physical Examination

☐ Pain/tenderness evaluated in terms of location, quality, and intensity

☐ Asymmetry/misalignment identified on a sectional or segmental level

☐ Range of motion abnormality

☐ Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament

To demonstrate a subluxation based on physical examination, two of the four criteria mentioned under "physical examination" are required, one of which must be asymmetry/misalignment or range of motion abnormality. Medicare Benefit Policy Manual § 240.1.2.2. -The term "physical exam" may not be explicitly listed in the record. If the documentation for the initial visit includes any elements of a physical exam, please check the "physical examination" box to answer the lead question.

☐ Other *(Explain)* _____

☐ None documented

4. Does the initial visit include a patient history or any elements of a patient history? *Note:* This is a different requirement from question 5 based on the Medicare Benefit Policy Manual (240.1.2.2.A). The term "patient history" may not be explicitly listed in the record. If the documentation for the initial visit includes any elements of a patient history, please select "yes" for the answer to the lead question.

☐ Yes *(Answer 4A – 4H)*

If yes, does the patient history include. . .	Yes	No	Not relevant
4A. Symptoms causing patient to seek treatment	☐	☐	
4B. Family history, if relevant	☐	☐	☐
4C. Past health history	☐	☐	
4D. Mechanism of trauma (etiology or cause)	☐	☐	
4E. Quality and character of symptoms/problem	☐	☐	
4F. Onset, duration, intensity, frequency, location, and radiation of symptoms	☐	☐	
4G. Aggravating or relieving factors	☐	☐	
4H. Prior interventions, treatments, medications, secondary complaints	☐	☐	

☐ No

5. Does the patient record for this initial visit include a description of the present illness (i.e., chief complaint)? *Note:* Question 4 asks about patient history whereas Question 5 asks about the description of the present illness. This is distinguished in the Medicare Benefit Policy Manual Section 240.1.2.2.A vs. Section 240.1.2.2].

☐ Yes *(Answer 5A – 5F)*

Does the description include. . .	Yes	No
5A. Mechanism of trauma (etiology or cause)	☐	☐
5B. Quality and character of symptoms/problem	☐	☐
5C. Onset, duration, intensity, frequency, location, and radiation of symptoms	☐	☐
5D. Aggravating or relieving factors	☐	☐
5E. Prior interventions, treatments, medications, secondary complaints	☐	☐
5F. Symptoms causing patient to seek treatment	☐	☐

☐ No

6. Did the chiropractor make a diagnosis of subluxation(s) of the spine at the initial visit? *Note:* The term "subluxation" need not be explicitly stated, but the diagnosis should indicate one. The Medicare Benefit Integrity Section 240.1.4 provides additional terms (e.g., off-centered, misalignment; malpositioning; spacing - abnormal, altered, decreased, increased; incomplete dislocation; rotation; listhesis - antero, postero, retro, lateral, spondylo; and motion – limited. Other terms may be used if they are understood clearly to refer to bone or joint space or position (or motion) changes of vertebral elements, they are acceptable). Terms such as "CTL" are NOT sufficient to indicate subluxation by themselves.

☐ Yes *(Answer 6A – 6D)*
☐ No *(Answer 6C and then skip to 7)*

- 6A. How was the diagnosis of subluxation documented? Be descriptive and indicate if the only diagnostic documentation is the vertebral level, such as C2, without any additional diagnostic term(s). _____

- 6B. Did the chiropractor specify the level of each subluxation for which the patient was being treated?

  ☐ Yes *(Specify)* _____
  ☐ No

- 6C. Did the chiropractor specify the location of pain?

  ☐ Yes *(Specify)* _____
  ☐ No

- 6D. In your professional judgment, is the particular vertebra listed in 6B capable of producing the pain in the area determined in 6C?

  ☐ Yes *(Specify if secondary to primary subluxation)* _____
  ☐ No
  ☐ N/A *(Check if you answered 'no' to either 6B or 6C)*

7. In your professional judgment, does the record support a diagnosis of subluxation at the initial visit?

☐ Yes *(Answer 7A)*

☐ No *(Answer 7A)*

- 7A. On what basis did you make this determination? *(CHECK ALL THAT APPLY)*
  - ☐ Question 2
  - ☐ Question 3
  - ☐ Question 4
  - ☐ Question 5
  - ☐ Question 6
  - ☐ Determination based on other information: *(Specify)* _____

8. Did the chiropractor include a treatment plan for this patient? *Note:* If the record indicates a "treatment plan" of "PRN," please answer "yes" and specify "PRN" in item 8D. If the treatment plan indicates "return in x days" please indicate "yes" and describe.

☐ Yes *(Answer 8A – 8E)*

Does the treatment plan include. . .

- 8A. the recommended level of care (duration and frequency of visits)?
  - ☐ Yes *(List duration and frequency (PRN is not acceptable))* _____
  - ☐ No
- 8B. specific treatment goals? Specific treatment goals may include decreased pain, increased function, able to work longer, or specified improvements in Range of Motion (ROM) or Visual Analog (VAS).
  - ☐ Yes *(List goals)* _____
  - ☐ No
- 8C. objective measures to evaluate effectiveness? (used at the initial visit and throughout)
  - ☐ Yes *(List measures)* _____
  - ☐ No
- 8D. Other (e.g. "return PRN"; *please specify*) _____
- 8E. was the treatment plan issued at the initial visit?
  - ☐ Yes
  - ☐ No *(List date)* _____

☐ No

9. In your professional judgment, is the treatment plan consistent with the diagnosis?

☐ Yes *(Answer 9A)*

☐ No *(Answer 9A)*

- 9A. On what basis did you make this determination? *(CHECK ALL THAT APPLY)*
  - ☐ Question 2
  - ☐ Question 3
  - ☐ Question 4
  - ☐ Question 5
  - ☐ Question 6
  - ☐ Question 7
  - ☐ Question 8
  - ☐ Determination based on other information: *(Specify)* _____

☐ No treatment plan and/or diagnosis was provided.

10. Did the sampled service of «DOS» occur on the same date as the initial visit?

☐ Yes (*Skip to 16)*

☐ No. The sampled service of «DOS» is the next visit in the episode. *(Skip to 13)*

☐ No. The sampled service of «DOS» is not the next visit in the episode. *(Continue to 11)*

C. Interim Visits

In answering the following questions, consider the patient's chiropractic treatment after the initial visit through the date of the sampled service of «DOS» but not including the sampled service of «DOS».

11. Does every interim visit indicate a course of services consistent with the treatment plan?

☐ Yes
☐ No *(Answer 11A)*
o 11A. If no, explain: _____

☐ No treatment plan was provided.

12. Does the treatment provided in every interim visit provide a reasonable expectation of recovery or functional improvement?

Deleted: s

☐ Yes
☐ No *(Answer 12A)*
o 12A. If no, explain: _____

D. Sampled Service

Answer the following questions regarding only the sampled service of «DOS». Rely on both your professional judgment and the Medicare Benefit Policy Manual, section 240 in answering.

13. For what complaint did the patient visit the chiropractor during the sampled service of «DOS»? ***(Record verbatim in patient's words where available).***

Deleted: *word*

____

☐ None documented

14. Is there a history in the patient record for the sampled service of «DOS»?

Note: Medicare Benefit Policy Manual Section 2401.1.2.2.B. If patient has one complaint, a statement of "Getting better" would be sufficient to answer Yes to Q14B ONLY. If patient has multiple complaints, the reviewers should select Yes ONLY to 14B for a statement of only "Getting better." If the practicing chiropractor indicates which area of the body is "much better", Q14A can be checked Yes.

☐ Yes *(Answer 14A-C)*

Does the history include…	Yes	No	Not relevant
14A. Review of chief complaint	☐	☐	
14B. Changes since last visit	☐	☐	
14C. System review, if relevant	☐	☐	☐

☐ No

15. Is there a physical exam in the patient record for the sampled service of «DOS»?

☐ Yes *(Answer 15A-C)*

Does the physical exam include…	Yes	No
15A. Exam of area of spine involved in diagnosis	☐	☐
15B. Assessment of change in patient condition since last	☐	☐
15C. Evaluation of treatment effectiveness	☐	☐

☐ No

16. Does the record include documentation of treatment given on the day of the sampled service of «DOS»? Terms such as "CTL" are NOT sufficient to indicate manipulation by themselves.

☐ Yes

☐ No *(Answer 16A and skip to 19)* (indicates service is undocumented)

o 16A. If no, explain: _____

17. Is the sampled service of «DOS» consistent with the treatment plan [i.e., recommended level of care (duration and frequency of visits), specific treatment goals, objective measures to evaluate effectiveness]? If the practicing chiropractor used a "PRN" treatment plan (as noted in B.8), please answer "yes" and "duration and frequency indicated as PRN".

☐ No treatment plan was provided.

☐ Yes, answer the following two subquestions, if appropriate:

- ☐ Duration and frequency indicated as PRN.
- ☐ Inadequate treatment plan was provided (i.e., the sampled service was consistent with the inadequate treatment plan)

☐ No *(Answer 17A)*

o 17A. Please explain: _____

18. Does the treatment provided on the date of the sampled service of «DOS» provide a reasonable expectation of recovery or functional improvement?

☐ Yes

☐ No *(Answer 18A)*

o 18A. Please explain: _____

19. Did the service provided on the date of the sampled service («DOS») support the HCPCS code billed (i.e., did the documentation adequately support the number of regions manipulated)?

☐ Yes *(Answer 19A)*

☐ No *(Answer 19A)*

☐ Insufficient information (check rarely and only in cases of vague, inconsistent, or illegible documentation)

o 19A. Please specify the number of regions manipulated: _____

20. Did the medical record indicate that the Acute Treatment (AT) Modifier on the claim accurately reflected the treatment provided only on the date of the sampled service - «DOS» (i.e., did the medical record show that the service provided was active/corrective treatment and not maintenance therapy). Q20A is based on the reviewer's professional judgment of whether the service was active/corrective or maintenance, while Q20B is based on the documentation in the medical record providing sufficient evidence to make the determination that the service was active/corrective.

☐ Yes *(Answer 20A and 20B)*

o 20A. If you answered "No" to any questions/subquestions 14-18, how did you arrive at this determination? _____

o 20B. Did the medical record meet the documentation requirements set forth in the Medicare Benefit Policy Manual for the date of the sampled service?

☐ Yes

☐ No

☐ No *(Answer 20C)*

o 20C. Comments: _____

☐ Insufficient documentation (check rarely and only in cases of vague, inconsistent, or illegible documentation).

E. Overall Impressions

21. From your general impression of the treatment episode, was any visit maintenance (supportive) rather than active (corrective) in nature?

- ☐ Yes *(List date the visit became maintenance _____)*
- ☐ No
- ☐ Lack of documentation

22. Enter any additional comments in the space below or references to documentation, or lack of documentation, that can provide better understanding of the responses contained herein.

____

23. Date Medical Review Completed: _____

MEDICAL RECORD DATA COLLECTION INSTRUMENT

OFFICE OF INSPECTOR GENERAL
OFFICE OF EVALUATION AND INSPECTIONS

Medicare Chiropractic Visits: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier: OEI-07-07-00390

Cover Sheet (Project Coordinator's Information – Not to be changed by Reviewers)

HCPCS of Sampled Service: «HCPCS»

Date of Sampled Service: «DOS»

Beginning Date of Treatment Episode: _____
(**H**: Date found on the HCFA 1500 form; **M**: Date found in the medical records;
P: Date given by the provider's office directly to FMAS's Project Coordinator)

Ending Date of Treatment Episode: _____
(**H**: Date found on the HCFA 1500 form; **M**: Date found in the medical records;
P: Date given by the provider's office directly to FMAS's Project Coordinator

Sampled Chiropractor Name: «CHIROPRACTOR_FNAME»
«CHIROPRACTOR_LNAME»

Is the Medical Record Included for the Sampled Service? ☐Y ☐N

Common Terms and their Definitions:

Acute treatment: manipulative services rendered to have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function.

AT modifier: A descriptor used on a claim to indicate a sampled service was for active/corrective treatment to treat an injury rather than maintenance therapy.

Exacerbation: A temporary, marked deterioration of the patient's condition due to an acute flare-up of the condition being treated.

Initial visit: The first visit related to the treatment episode for the sampled service; may differ from the date of the first service in the medical record.

Interim visit: Visits after the initial visit and before the sampled service. In certain instances, the sampled service may be the same as or may immediately follow the initial visit, so there may not be interim visits.

Maintenance therapy: Services that seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. "Supportive rather than corrective in nature" is a term that originates from the Medicare Benefit Policy Manual section 240.1.3.] Corrective refers to functional correction of symptoms. The Medicare Policy Manual does provide that "once the clinical status has remained stable for a given condition, without

expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered."
Recurrence: A return of symptoms of a previously treated condition that has been quiescent for 30 or more days.
Sampled service: The service of interest that OIG randomly selected. A service may only be one part of a visit and not the visit itself.
Service: Each procedure a chiropractor performs for a beneficiary.
Treatment episode: The course of treatment characterized by visits related to the sampled service. There may be multiple treatment episodes in a medical record.
Visit: A beneficiary's encounter with a chiropractor. One or more services may be provided during the course of a single visit.

A. Identification of the Treatment Episode:

1. After reviewing the entire medical record, determine the beginning and ending of the treatment episode which included the sampled service of «DOS» and answer below. *Note:* A significant re-injury requiring a revised treatment plan should be classified as a new episode. Episodes may overlap. Only change the initial visit date if you have evidence to support that it is incorrect.

o 1A. Initial visit (First visit related to the treatment episode for the sampled service of «DOS»):
Enter date: 4/12/06

This initial visit is a: Recurrence ☐ Exacerbation ☐ Neither ☐

o 1B. Final visit (Last visit related to the treatment episode for the sampled service of «DOS»):
Enter date: _____

If 1A and/or 1B are different than the dates chosen by the practicing chiropractor, please list the evidence to support that it is correct ____

B. Initial visit:

2. For what chief complaint did the patient initially visit the chiropractor (date identified in question 1A above)? ***(Record verbatim in patient's words where available. If not available in the patient's words, use the chiropractor's description of the presenting problem.)***

____

☐ None documented

3. Which of the following diagnostic procedures did the chiropractor use to evaluate the patient's condition? ***(CHECK ALL THAT APPLY)***

☐ X-ray / Imaging *(Answer 3A and 3B)*

- o 3A. When was the x-ray or other imaging test performed (Please indicate only the x-ray that shows the subluxation closest to the start of the course of treatment)?
  - ☐ More than 12 months prior to the initial visit *(List date)* _____
    - Is there a reasonable basis for concluding the condition is permanent?
      - ☐ *Yes* ☐ *No* *(Explain)* _____
  - ☐ Less than 12 months prior to the initial visit *(List date)* _____
  - ☐ At the initial visit *(List date)* _____
  - ☐ Less than 3 months after initial visit *(List date)* _____
  - ☐ More than 3 months after initial visit *(List date)* _____
  - ☐ No date provided.

Unless more specific x-ray evidence is warranted, an x-ray is considered reasonably proximate to the initiation of a course of treatment if it was taken no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment. Medicare Benefit Policy Manual §240.1.2.1

- o 3B. Who interpreted the x-ray or other imaging test?
  - ☐ This chiropractor
  - ☐ Another chiropractor
  - ☐ Another medical professional (e.g., radiologist, tech)
  - *(List profession)* _____
  - ☐ Can't determine

☐ Physical Examination

- ☐ Pain/tenderness evaluated in terms of location, quality, and intensity
- ☐ Asymmetry/misalignment identified on a sectional or segmental level
- ☐ Range of motion abnormality
- ☐ Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament

To demonstrate a subluxation based on physical examination, two of the four criteria mentioned under "physical examination" are required, one of which must be asymmetry/misalignment or range of motion abnormality. Medicare Benefit Policy Manual § 240.1.2.2. -The term "physical exam" may not be explicitly listed in the record. If the documentation for the initial visit includes any elements of a physical exam, please check the "physical examination" box to answer the lead question.

☐ Other *(Explain)* _____

☐ None documented

4. Does the initial visit include a patient history or any elements of a patient history? *Note:* This is a different requirement from question 5 based on the Medicare Benefit Policy Manual (240.1.2.2.A). The term "patient history" may not be explicitly listed in the record. If the documentation for the initial visit includes any elements of a patient history, please select "yes" for the answer to the lead question. Family history or past health history may be taken from an earlier history.

☐ Yes *(Answer 4A – 4H)*

If yes, does the patient history include. . .	Yes	No	Not relevant
4A. Symptoms causing patient to seek treatment	☐	☐	
4B. Family history, if relevant	☐	☐	☐
4C. Past health history	☐	☐	
4D. Mechanism of trauma (etiology or cause)	☐	☐	
4E. Quality and character of symptoms/problem	☐	☐	
4F. Onset, duration, intensity, frequency, location, and radiation of symptoms	☐	☐	
4G. Aggravating or relieving factors	☐	☐	
4H. Prior interventions, treatments, medications, secondary complaints	☐	☐	

☐ No

5. Does the patient record for this initial visit include a description of the present illness (i.e., chief complaint)? *Note:* Question 4 asks about patient history whereas Question 5 asks about the description of the present illness. This is distinguished in the Medicare Benefit Policy Manual Section 240.1.2.2.A vs. Section 240.1.2.2].

☐ Yes *(Answer 5A – 5F)*

Does the description include. . .	Yes	No
5A. Mechanism of trauma (etiology or cause)	☐	☐
5B. Quality and character of symptoms/problem	☐	☐
5C. Onset, duration, intensity, frequency, location, and radiation of symptoms	☐	☐
5D. Aggravating or relieving factors	☐	☐
5E. Prior interventions, treatments, medications, secondary complaints	☐	☐
5F. Symptoms causing patient to seek treatment	☐	☐

☐ No

6. Did the chiropractor make a diagnosis of subluxation(s) of the spine at the initial visit? *Note:* The term "subluxation" need not be explicitly stated, but the diagnosis should indicate one. The Medicare Benefit Integrity Section 240.1.4 provides additional terms (e.g., off-centered, misalignment; malpositioning; spacing - abnormal, altered, decreased, increased; incomplete dislocation; rotation; listhesis - antero, postero, retro, lateral, spondylo; and motion – limited. Other terms may be used if they are understood clearly to refer to bone or joint space or position (or motion) changes of vertebral elements, they are acceptable). Terms such as "CTL" are NOT sufficient to indicate subluxation by themselves.

☐ Yes *(Answer 6A – 6D)*
☐ No *(Answer 6C and then skip to 7)*

- 6A. How was the diagnosis of subluxation documented? Be descriptive and indicate if the only diagnostic documentation is the vertebral level, such as C2, without any additional diagnostic term(s). _____

- 6B. Did the chiropractor specify the level of each subluxation for which the patient was being treated?

  ☐ Yes *(Specify)* _____
  ☐ No

- 6C. Did the chiropractor specify the location of pain?

  ☐ Yes *(Specify)* _____
  ☐ No

- 6D. In your professional judgment, is the particular vertebra listed in 6B capable of producing the pain in the area determined in 6C?

  ☐ Yes *(Specify if secondary to primary subluxation)* _____
  ☐ No
  ☐ N/A *(Check if you answered 'no' to either 6B or 6C)*

7. In your professional judgment, does the record support a diagnosis of subluxation at the initial visit?

☐ Yes *(Answer 7A)*

☐ No *(Answer 7A)*

- 7A. On what basis did you make this determination? *(CHECK ALL THAT APPLY)*
  - ☐ Question 2
  - ☐ Question 3
  - ☐ Question 4
  - ☐ Question 5
  - ☐ Question 6
  - ☐ Determination based on other information: *(Specify)* _____

8. Did the chiropractor include a treatment plan for this patient? *Note:* If the record indicates a "treatment plan" of "PRN," please answer "yes" and specify "PRN" in item 8D. If the treatment plan indicates "return in x days" please indicate "yes" and describe.

☐ Yes *(Answer 8A – 8E)*

Does the treatment plan include. . .

- 8A. the recommended level of care (duration and frequency of visits)?
  - ☐ Yes *(List duration and frequency (PRN is not acceptable))* _____
  - ☐ No
- 8B. specific treatment goals? Specific treatment goals may include decreased pain, increased function, able to work longer, or specified improvements in Range of Motion (ROM) or Visual Analog (VAS).
  - ☐ Yes *(List goals)* _____
  - ☐ No
- 8C. objective measures to evaluate effectiveness? (used at the initial visit and throughout)
  - ☐ Yes *(List measures)* _____
  - ☐ No
- 8D. Other (e.g. "return PRN"; ***please specify***) _____
- 8E. was the treatment plan issued at the initial visit?
  - ☐ Yes
  - ☐ No *(List date)* _____

☐ No

9. In your professional judgment, is the treatment plan consistent with the diagnosis?

☐ Yes *(Answer 9A)*

☐ No *(Answer 9A)*

- 9A. On what basis did you make this determination? *(CHECK ALL THAT APPLY)*
  - ☐ Question 2
  - ☐ Question 3
  - ☐ Question 4
  - ☐ Question 5
  - ☐ Question 6
  - ☐ Question 7
  - ☐ Question 8
  - ☐ Determination based on other information: *(Specify)* _____

☐ No treatment plan and/or diagnosis was provided.

10. Did the sampled service of «DOS» occur on the same date as the initial visit?

☐ Yes (*Skip to 16)*

☐ No. The sampled service of «DOS» is the next visit in the episode. *(Skip to 13)*

☐ No. The sampled service of «DOS» is not the next visit in the episode. *(Continue to 11)*

C. Interim Visits

In answering the following questions, consider the patient's chiropractic treatment after the initial visit through the date of the sampled service of «DOS» but not including the sampled service of «DOS».

11. Does every interim visit indicate a course of services consistent with the treatment plan?

☐ Yes
☐ No *(Answer 11A)*
o 11A. If no, explain: _____

☐ No treatment plan was provided.

12. Does the treatment provided in every interim visit provide a reasonable expectation of recovery or functional improvement?

☐ Yes
☐ No *(Answer 12A)*
o 12A. If no, explain: _____

D. Sampled Service

Answer the following questions regarding only the sampled service of «DOS». Rely on both your professional judgment and the Medicare Benefit Policy Manual, section 240 in answering.

13. For what complaint did the patient visit the chiropractor during the sampled service of «DOS»? ***(Record verbatim in patient's words where available).***

____

☐ None documented

14. Is there a history in the patient record for the sampled service of «DOS»?

Note: Medicare Benefit Policy Manual Section 2401.1.2.2.B. If patient has one complaint, a statement of "Getting better" would be sufficient to answer Yes to Q14B ONLY. If patient has multiple complaints, the reviewers should select Yes ONLY to 14B for a statement of only "Getting better." If the practicing chiropractor indicates which area of the body is "much better", Q14A can be checked Yes.

☐ Yes *(Answer 14A-C)*

Does the history include…	Yes	No	Not relevant
14A. Review of chief complaint	☐	☐	
14B. Changes since last visit	☐	☐	
14C. System review, if relevant	☐	☐	☐

☐ No

15. Is there a physical exam in the patient record for the sampled service of «DOS»?

☐ Yes *(Answer 15A-C)*

Does the physical exam include…	Yes	No
15A. Exam of area of spine involved in diagnosis	☐	☐
15B. Assessment of change in patient condition since last	☐	☐
15C. Evaluation of treatment effectiveness	☐	☐

☐ No

16. Does the record include documentation of treatment given on the day of the sampled service of «DOS»? Terms such as "CTL" are NOT sufficient to indicate manipulation by themselves.

☐ Yes

☐ No *(Answer 16A and skip to 19)* (indicates service is undocumented)

o 16A. If no, explain: _____

17. Is the sampled service of «DOS» consistent with the treatment plan [i.e., recommended level of care (duration and frequency of visits), specific treatment goals, objective measures to evaluate effectiveness]? If the practicing chiropractor used a "PRN" treatment plan (as noted in B.8), please answer "yes" and "duration and frequency indicated as PRN".

☐ No treatment plan was provided.

☐ Yes, answer the following two subquestions, if appropriate:

☐ Duration and frequency indicated as PRN.

☐ Inadequate treatment plan was provided (i.e., the sampled service was consistent with the inadequate treatment plan)

☐ No *(Answer 17A)*

o 17A. Please explain: _____

18. Does the treatment provided on the date of the sampled service of «DOS» provide a reasonable expectation of recovery or functional improvement?

☐ Yes

☐ No *(Answer 18A)*

o 18A. Please explain: _____

19. Did the service provided on the date of the sampled service («DOS») support the HCPCS code billed (i.e., did the documentation adequately support the number of regions manipulated)?

☐ Yes

☐ No *(Answer 19A)*

o 19A. Please specify the number of regions manipulated (number of regions with substantiated diagnoses): _____

☐ Insufficient information to determine number of regions manipulated
(check only when absolutely necessary and only in cases of vague, inconsistent, or illegible documentation)

20. Did the medical record indicate that the Acute Treatment (AT) Modifier on the claim accurately reflected the treatment provided only on the date of the sampled service - «DOS» (i.e., did the medical record show that the service provided was active/corrective treatment and not maintenance therapy). Q20A is based on the reviewer's professional judgment of whether the service was active/corrective or maintenance, while Q20B is based on the documentation in the medical record providing sufficient evidence to make the determination that the service was active/corrective.

☐ Yes *(Answer 20A and 20B)*

o 20A. If you answered "No" to any questions/subquestions 14-18, how did you arrive at this determination? _____

o 20B. Did the medical record meet the documentation requirements set forth in the Medicare Benefit Policy Manual for the date of the sampled service?

☐ Yes

☐ No

☐ No *(Answer 20C)*

o 20C. Comments: _____

☐ Insufficient documentation (check only when absolutely necessary and only in cases of vague, inconsistent, or illegible documentation)

E. Overall Impressions

21. From your general impression of the treatment episode, was any visit maintenance (supportive) rather than active (corrective) in nature?

☐ Yes *(List date the visit became maintenance _____)*

☐ No

☐ Lack of documentation (check only when absolutely necessary and only in cases of vague, inconsistent, or illegible documentation)

22. Enter any additional comments in the space below or references to documentation, or lack of documentation, that can provide better understanding of the responses contained herein.

____

23. Date Medical Review Completed: _____

Chiropractic Instructions Regarding the Cover Sheet

The 1st page of the instrument is the Cover Sheet which is filled out by FMAS's Project Coordinator. Please do not change any of the information on this sheet.

Of particular note are the dates listed for the Beginning Date of the Treatment Episode and the Ending Date of the Treatment Episode. The date will be followed by parentheses containing the source for the date provided. The legend is as follows:

H: Date found on the HCFA 1500 form
M: Date found in the medical records
P: Date given by the provider's office directly to FMAS's Project Coordinator

EXAMPLE

MEDICAL RECORD DATA COLLECTION INSTRUMENT

OFFICE OF INSPECTOR GENERAL
OFFICE OF EVALUATION AND INSPECTIONS

Medicare Chiropractic Visits: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier: OEI-07-07-00390

Cover Sheet (Project Coordinator's Information – Not to be changed by Reviewers)

HCPCS of Sampled Service:	98940
Date of Sampled Service:	11/9/2006
Beginning Date of Treatment Episode:	**5/5/2006 (H, M, P)**
Ending Date of Treatment Episode:	**2/2/2007 (P)**
Sampled Chiropractor Name: «CHIROPRACTOR LNAME»	«CHIROPRACTOR_FNAME»

Is the Medical Record Included for the Sampled Service? ☐ Y ☐ N

Original is filed in workpaper files **Copy is sent to Special Assistant to the Director, Regional Operations**

ATTACHMENT A

Data Collection Instrument

CERTIFICATION

Name of Inspection: Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier

Number of Inspection: OEI-07-07-00390

No Data is being collected from the public: ❑

Data is being collected from 9 or fewer respondents ❑

Give a brief description of the data used in the study and the source

Data is being collected from 10 or more respondents: ✗

If this block is checked, the data collection instrument certification form must also be completed

Signature of Regional Inspector General

Original is filed in work paper files **Copy is sent to Special Assistant to the Director, Regional Operations**

ATTACHMENT B
Data Collection Instrument

CERTIFICATION

Name of Instrument: Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier

Number and Type of Respondents from whom Response Will be Solicited:
Federal ☐ **Non-Federal** ✗ **200**

Estimated Responses
Percent: **Number:** **100**

Overall Sampling Approach (Select One)
Universe: 600,625 **Purposive Sample:** **Representative Sample: 200**

Description of Universe: Provider-Beneficiary pairs with greater than 12 services in calendar year 2006

For Purposive Samples, Describe Selection Method:

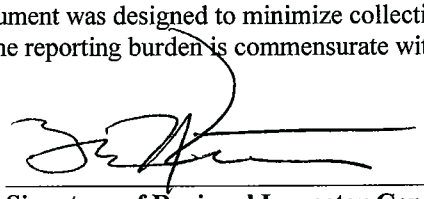
For Representative Samples,
Description of Sampling Method: Provider-Beneficiary pairs with greater than 12 services in calendar year 2006

Confidence Level: **95%**
Precision at Typical Expected Values (give examples): **+/-7%**

Estimated Burden Hours Per Response: 30 minutes each beneficiary
Estimated Total Burden Hours: 100 hours

If the sample size is 499 or less the certification is complete. Otherwise complete attachment C and send all forms along with the design to Headquarters for further action.

REGIONAL INSPECTOR GENERAL: I certify that this survey and data collection instrument is appropriate for the purpose of this study. The survey and data collection instrument was designed to minimize collection of unnecessary data, and the reporting burden on respondents. The reporting burden is commensurate with the value of the information to be received.



Signature of Regional Inspector General

Name and number of inspection for which this instrument is used:

PSC #_____
Date_____
Interviewers_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

X☐ Medicare Benefit Policy Manual ☐ Other
X☐ Change Request 3449
☐ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance: Also use AC websites to see information on LCD. National Government Services put on Webinar on AT modifier and we attended that to make sure we had a handle on new requirements. Jurisdiction: (b)(4)

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

X☐ Yes ☐ No

If Yes, describe education: (b)(6) participates on Manager call. One in May addressed CHrio services and AT modifier. CRD conference held once a year and there was mention of chiro services.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

X☐ Yes ☐ No

If Yes, describe instruction: If there is a chiro that is not referred to law enforcement, we will send an education letter to them. WE have post-pay medical review responsibilities for OH and WV for rPart B. We also do the data analysis for them and identify vulnerabilities. AT that point, we will refer these providers to the carrier. If the provider needs a continued provider flag, we will send them to carrier. We identify overpayments and carrier collects money.

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☐ Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits X☐ Post-payment edits ☐ Other

Explain—probe for basis of edits: Post pay reviews are based on data. Most of the reviews for chiropractors are done through the pre-pay probe. If they find someone with a high error rate, they put them on a flag. In the meantime, they refer provider to us for a statistical sampling and identification of overpayment.

If yes, how effective has this process been?

☐ Very Effective X☐ Somewhat Effective ☐ Not Effective

Explain: We find aberrant providers and will either educate them or do further statistical sampling. We work closely with the AC with regular meetings. We do individual error rates versus entire population rates. I don't believe we have had a chiropractor on flag.

If yes, how do you determine the effectiveness of these processes?_____
_____

5. Does [organization name] coordinate with MACs/carriers to ensure appropriate use of the AT modifier for chiropractic services?

X☐ Yes ☐ No

Explain: Do coordinate with Carriers. Haven't yet gone through transition with MACs yet. We will have an announcement in July of this year and anticipate changes by November 2008. We no longer anticipate having post-pay reviews or data analysis responsibility after MAC transition.

6. Does [organization name] coordinate post-payment reviews with MAC-issued and carrier-issued LCDs regarding chiropractic services?

☐ Yes ☐ No

Explain:_____

7. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding the use of the AT modifier for chiropractic services?

X☐ Yes ☐ No

If Yes, how many reviews/investigations/analyses were conducted?

What was the nature of these? We try to establish peer groups for data analysis. We do the same for chiropractors. About 9 months ago, we did a chiropractic review. Not specific to AT modifier, but we do general data analysis to see what would be normal and who would be aberrant from that norm. Then the analysis drills down to the individual provider level. What is normal? We have established baselines. I couldn't tell you right now what is "normal". Three of the providers we have educated with overpayment. Two have been referred to law enforcement and three others are getting ready to be referred to law enforcement.

What were the results? From medical review standpoint, we see lots of providers billing with AT modifier when not appropriate. They are not doing manual manipulation but putting people on the machine. There is a series of 20 services for this machine, which exceeds the number of services for chiropractor. The LCD was retired by the carrier. Additionally, they are performing a service that isn't even covered by Medicare. We have looked at (b)(6) (it came to our attention). We have been able to form connections. It is a trainin teach people on how to bill for payment. WE have had some outliers who we have been able to trace back to him, but it hasn't been anything overly egregious. We have had a couple of referrals for chiropractors teaming up with physicians for billing E&M services, chiropractic and therapy services. Many times the E&M is the same day as chiropractic service and therapy service. It is difficult to see who is doing what service at what time. We call it "doc in a box". WE have had a couple of these cases with prosecutions.

How much was recovered?

_____

8. Is there anything we haven't discussed that you would like to share?

The use of the AT modifier has given chiropractors "carte blanche" to bill. There is a lot of abuse in the chiropractic area. Stopping at 12 services might be the answer. I would say at least 95% of AT modifier use is wrong. It is a big issue. We are in a similar situation with PT services. When/If we get directives to be more involved in chiropractic review, we discuss changes in workflow. We routinely do chiropractic studies anyway looking for aberrancies. We are always looking for data. We think the question of who should look at chiropractic services (carriers or PSCs) really is "is it a medical necessity issue or is it fraud?". If we can prove someone is billing inappropriately over and over, we could potentially prove fraud. If not, it isn't our area. I put chiropractors in same category as podiatrist with their Medicare involvement and am suspicious. I feel like if they are abusing the AT modifier, they will stand out in data analysis. From a data standpoint, even if the AT modifier, they will be an anomaly in themselves with more services being billed. Because you can, you do. Providers will always bill with the AT modifier. Why not go ahead and put it on? They know it will go through the system, so they just go ahead and put it on. Some providers bill it 100% of the time. This isn't possible, but they still do it because no one says they can't. For medical reviews we have done, claims are denied for multiple reasons, not jut for the AT modifier. A lot of times they don't have the treatment plan with identified goals or other thing that they need to have.

PSC #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. Has CMS provided education on identifying misuse of chiropractic services, *with the AT modifier specifically*?

☐ Yes ☒ No

If Yes, describe education: Medlearn Matters is the only thing they have received.

2. Has [organization name] received referrals from CMS and/or Carriers regarding chiropractors' *use of the AT modifier*?

☐ Yes ☒ No

If Yes, describe referrals and action taken by [organization name]:

If No, has [organization name] requested referrals?: None than they are aware of regarding chiropractic. Do get complaints from carriers and CMS abut specific providers. Do have an intake process with initial screening to ensure it is a fraud/abuse issue before taking a look at it. Also depends on dollar amount-if only $30,000, won't pursue it. Have not opened a case on a chiropractor in years.
Analyze proactive data, select providers, topics where seeing problems within jurisdiction and nationally. Take information from conferences, policy changes (caps for PT), unique in that from data analysis perspective, they do post-pay edits that other PSCs don't do for North Carolina Part A. Work with investigations group to do further look-see. Investigations group, collects data, goes out to provider, looks at records, etc. AL GA MS
Do Part A administration for 15 states for Home Health/Hospice.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☒ No

If Yes, describe instruction/training: _____

If No, what is your obligation regarding providers?: Typically function of the carrier. If we had a case and elected to not do an investigation, we could notify carrier medical review department of the provider/problem. If we get a law enforcement request and think it is a problem across our states, we can make a referral to carrier. Example: Georgia chiropractors were billing non-covered service as covered. VAX-D (vertebral axial decompression) We looked at that ("the rack"). Convicted chiropractor for working with MD and using this machine.

Does [organization name] refer the chiropractor to the carrier for training?

☐ Yes ☒ No

If No, why not?: None specific to chiropractic.

4. Does [organization name] have processes to ensure appropriateness of chiropractic services, *particularly with the use of the AT modifier?*

☐ Yes ☒ No

If yes, describe process(es)

☐ Post-payment edits ☐ Other

Explain—probe for basis of edits: _____

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: _____

If yes, how do you determine the effectiveness of these processes? _____

5. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding chiropractic services, *particularly the AT modifier*?

☐ Yes ☒ No

If Yes, how many reviews/investigations/analyses were conducted? _____

What was the nature of these? _____

What were the results? _____

How much was recovered? _____

6. Does [organization name] coordinate post-payment reviews with carrier-issued LCDs regarding chiropractic services?

☐ Yes ☒ No

Explain:

7. Is there anything we haven't discussed that you would like to share?

As we become aware of things (fraud alerts, etc), DART(Data Analysis Report and Trending) and MERV (Medical Review Vulnerablities) calls with all PSCs, we will look at issues and open internal requests to see if anything is going on. We have not had this particular issue (chiro) on any of those calls. It is something that we will look at. Seems to be a change of thought that MDs are combining practice with chiropractors. We don't know if it is good or questionable. Why would a MD be involved in that practice? My suspicion would be that chiropractors are performing services not covered by Medicare and billing it under the MD. Chiropractors already in practice bringing a MD to augment service or use provider ID to bill. From a data perspective, we can tell if there is a drastic difference in billing practice. We don't have data access to sales records for VAX-D machine. If they had access, they could see who purchased machines and then compare billing patterns to see if there is a change.

PSC #_____
Date_____
Interviewers_____

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☐ Medicare Benefit Policy Manual ☐ Other
☐ Change Request 3449
☐ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance:_____
_____
_____
_____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☐ No

If Yes, describe education:_____
_____
_____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☐ No

If Yes, describe instruction:_____
_____
_____

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☐ Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits:_____
_____
_____
_____

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain:_____
_____
_____

If yes, how do you determine the effectiveness of these processes?_____
_____
_____
_____

5. Does [organization name] coordinate with MACs/carriers to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☐ No

Explain: _____
_____
_____
_____

6. Does [organization name] coordinate post-payment reviews with MAC-issued and carrier-issued LCDs regarding chiropractic services?

☐ Yes ☐ No

Explain:_____
_____
_____
_____

7. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding the use of the AT modifier for chiropractic services?

☐ Yes ☐ No

If Yes, how many reviews/investigations/analyses were conducted?

_____

What was the nature of these?

_____
_____
_____
_____

What were the results?

_____
_____
_____
_____

How much was recovered?

_____

8. Is there anything we haven't discussed that you would like to share?

PSC #_____
Date_____
Interviewers_____

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

(b)(5)

1. What guidance has (b)(4) received regarding use of the AT modifier for chiropractic services?

x Medicare Benefit Policy Manual
x Change Request 3449
x MedLearn Matters Article 3449
x Other
☐ None *(confirm nothing received)*

If Other, describe guidance*: 1._Chiropractic Training via Webinar, presented by National Government Services. 2. AC websites*.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

x Yes ☐ No

If Yes, describe education: 1. Discussed during MR Manager's call on 5/22/07. 2. "Chiro Issues" was an agenda item during the 2005 CMD & MR Manager Conference.

3. Has (b)(4) instructed chiropractors regarding the use of the AT modifier?

x Yes ☐ No

If Yes, describe instruction: Education letters were sent to 3 providers advising the correct use of the AT modifier.

4. Does AdvanceMed have processes to ensure appropriate use of the AT modifier?

x Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits ☐ Post-payment edits x Other

Explain—probe for basis of edits: Routine data studies are run that identify aberrancies.

If yes, how effective has this process been?

x Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: 13 providers were referred from DA.
4 providers were currently under investigation in (b)(4)
1 provider was under investigation in (b)(4)
7 providers were referred to (b)(4) rt of our vulnerability identification process – error her steps have not been reported
1 provider continues under investigation in (b)(4)

If yes, how do you determine the effectiveness of these processes? Data has identified outliers, a portion of whom had been identified by other means as possibly fraudulent providers.

5. Does (b)(4) coordinate with MACs/carriers to ensure appropriate use of the AT modifier for chiropractic services?

x Yes ☐ No

Explain: *AC LCDs and websites are utilized for review guidelines. AC CMD expertise is utilized as necessary.*

6. Does (b)(4) coordinate post-payment reviews with MAC-issued and carrier-issued LCDs regarding chiropractic services?

x Yes ☐ No

Explain: AC LCD guidelines are used during medical record review.

7. Has (b)(4) conducted any reviews, investigations, and/or data analysis regarding the use of the AT modifier for chiropractic services?

x Yes ☐ No

If Yes, how many reviews/investigations/analyses were conducted?
8 reviews were completed from June 2006-December 12, 2007 that addressed AT modifier. None involved claims with dates of service in 2006.

What was the nature of these?
8 Benefit Integrity reviews

What were the results?
3 providers were educated with identified overpayments
2 providers have been referred to Law Enforcement
3 providers are in the process of being referred to Law Enforcement

How much was recovered?
$1,733,183.77

8. Is there anything we haven't discussed that you would like to share?

For the majority of reviews completed, claims were denied for multiple reasons, not just for inappropriate use of the AT modifier.

PSC #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. Has CMS provided education on identifying misuse of chiropractic services, *with the AT modifier specifically*?

☐ Yes ☒ No

If Yes, describe education: MedLearn Matters article

2. Has [organization name] received referrals from CMS and/or Carriers regarding chiropractors' *use of the AT modifier*?

☒ Yes ☐ No

If Yes, describe referrals and action taken by [organization name]: We don't receive referrals from CMS. Our principal (b)(4), seldom refers chiropractic claims. Most of our referrals come from internal data analysis (data processing & statistical/medical review subcontractors).

If No, has [organization name] requested referrals?: _____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☒ Yes ☐ No

If Yes, describe instruction/training: When we identify an issue with overpayment, we send a detailed letter to the provider instructing them on appropriate billing. We also provide them with access to our online learning module.

We sometimes educate entire communities of providers via our webinars, and then track data to see if billing patters improve. We have seen changes in practice. In general, providers think that Medicare is very confusing (billing rules & regulations).

If No, what is your obligation regarding providers?: _____

Does [organization name] refer the chiropractor to the carrier for training?
☒ Yes ☐ No

If No, why not?: _____

4. Does [organization name] have processes to ensure appropriateness of chiropractic services, *particularly with the use of the AT modifier?*

☒ Yes ☐ No

If yes, describe process(es)

☐ Post-payment edits ☒ Other

Explain—probe for basis of edits: We use data runs to identify aberrancies in general, and specific to chiro services (as described below). We provide the carrier a list of providers we're looking at on a monthly basis so as not to duplicate review efforts.

If yes, how effective has this process been?

☐ Very Effective ☒ Somewhat Effective ☐ Not Effective

Explain: We look 6+ mos back to see if the provider has changed billing practices after education.

If yes, how do you determine the effectiveness of these processes? _____

5. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding chiropractic services, *particularly the AT modifier*?

☒ Yes ☐ No

If Yes, how many reviews/investigations/analyses were conducted? We looked at chiropractor trends (excess of 12 services) recently. It was a proactive data analysis proposal regarding use of the AT modifier for chiropractic services. We identified two chiropractors that are currently in the overpayment process (100% error rate upon medical review – (b)(4) is in the process of collecting those dollars.)

What was the nature of these? Data trend analysis looking at 10/1/03-10/1/07 dates of service, hopefully showing a significant drop in claims after 2004 for the 16 states included.

What were the results? We haven't seen the data yet; we hope to retrieve archived data in the next month.

How much was recovered? _____

6. Does [organization name] coordinate post-payment reviews with carrier-issued LCDs regarding chiropractic services?

☒ Yes ☐ No

Explain: Our subcontractor coordinates overpayment collection and provides education to providers in conjunction with (b)(4) We send a letter to (b)(4) detailing the overpayment and our recommendations for education. The demand le s from (b)(4)

7. Is there anything we haven't discussed that you would like to share?

No new trends in chiro services. Anectdotally, we've found some chiropractors teaming up with physicians to bill for services that do not involve manual manipulation, which have led to criminal prosecution.

It seems that CMS is doing their best to educate these providers, and they can always call the carrier to ask questions.

Perhaps carriers need edits on particular providers or across the board. Not necessarily to limit services, but to take a look at problem areas.

PSC #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. Has CMS provided education on identifying misuse of chiropractic services, *with the AT modifier specifically*?

☐ Yes ☒ No

If Yes, describe education: MedLearn Matters, newsflash effective March 1, 2008 SE0749

2. Has [organization name] received referrals from CMS and/or Carriers regarding chiropractors' *use of the AT modifier*?

☐ Yes ☒ No

If Yes, describe referrals and action taken by [organization name]: _____

If No, has [organization name] requested referrals?: _____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☒ No

If Yes, describe instruction/training: _____

If No, what is your obligation regarding providers?: _____

Does [organization name] refer the chiropractor to the carrier for training?

☐ Yes ☐ No

If No, why not?: _____

4. Does [organization name] have processes to ensure appropriateness of chiropractic services, *particularly with the use of the AT modifier?*

☐ Yes ☒ No

If yes, describe process(es)

☐ Post-payment edits ☐ Other

Explain—probe for basis of edits: _____

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: _____

If yes, how do you determine the effectiveness of these processes? _____

5. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding chiropractic services, *particularly the AT modifier*?

☒ Yes ☐ No

If Yes, how many reviews/investigations/analyses were conducted? Have done reviews on chiropractors, but nothing lately.

What was the nature of these? March 14, 2005 was last study on chiropractors – we looked at 25 claims, codes utilized (98942, 98940)

What were the results? _____

How much was recovered? _____

6. Does [organization name] coordinate post-payment reviews with carrier-issued LCDs regarding chiropractic services?

☐ Yes ☒ No

Explain: _____

7. Is there anything we haven't discussed that you would like to share?

Nothing specific to chiropractic. We haven't looked at them.

PSC #_____
Date_____
Interviewers_____

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

- ☐ Medicare Benefit Policy Manual
- ☐ Change Request 3449
- ☐ MedLearn Matters Article 3449
- ☐ Other
- ☐ None *(confirm nothing received)*

If Other, describe guidance: (b)(4) *has access to all the information listed and any other local med, nat med orCMS instruction regarding this benefit. This may be done through AC/MAC, CMS or Commercial systems*_____
_____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

- ☐ Yes
- ☐ No

If Yes, describe education:__*We are not educated by CMS on what to investigate. It is our responsibility to identify potential fraud in our service areas.*
_____*Not applicable to PSC*

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☐ No

If Yes, describe instruction:__*PSC does not educate provider on billing* _*This is a question for AC?MAC*_____
_____*Not applicable*

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☐ Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits:_____ *PSC does not process claims. This is a question for AC/MAC Not applicable*_____

_____

_____

_____

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain:_____

_____

_____

If yes, how do you determine the effectiveness of these processes?_____

_____

5. Does [organization name] coordinate with MACs/carriers to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☐ No

Explain: *We will review this benefit with the AC/MAC if we feel there is an systemic problem that could be prevented through more effective edit or prepare either a AC?MAC or CMS program vulnerability but if we are finding potential fraud and abuse, it will be investigated as a potential for referral to the OIG*

6. Does [organization name] coordinate post-payment reviews with MAC-issued and carrier-issued LCDs regarding chiropractic services?

☐ Yes ☐ No

Explain:__*No our postpayment reviews are part of fraud investigations or case referrals. See #5*_____
_____
_____

7. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding the use of the AT modifier for chiropractic services?

☐ Yes ☐ No

6. If Yes, how many reviews/investigations/analyses were conducted? ____
(b)(6) I would have to run reports but I am sure we have some investigations relating to this. That is a guess.

_____

What was the nature of these?
_____
_____
_____
_____

What were the results?
_____
_____
_____
_____

8. Is there anything we haven't discussed that you would like to share?

_____
_____No_____
_____
__
_____
_____
_____
_____
_____
_____
_____
_____
_____

PSC # (b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. Has CMS provided education on identifying misuse of chiropractic services, *with the AT modifier specifically*?

☐ Yes X No If Yes, describe education: Outside through an ACA or other cases that we work. Policies are available to us via CRs etc. We use LCD medical policies in the jurisdictions we were in. The info is available if we have any questions, we call other contractors etc.

2. Has [organization name] received referrals from CMS and/or Carriers regarding chiropractors' *use of the AT modifier*?

☐ Yes X No

If Yes, describe referrals and action taken by [organization name:
We may have – probably have in (b)(4) Through the complaint process.

If No, has [organization name] requested referrals?:

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes X No

If Yes, describe instruction/training:
If we have resolved a case that was not a referral it would include an educational component.

If No, what is your obligation regarding providers?:

Does [organization name] refer the chiropractor to the carrier for training?
☐ Yes X No

If No, why not?: _ Would refer a chiropractor to the carrier in certain situations.

4. Does [organization name] have processes to ensure appropriateness of chiropractic services, *particularly with the use of the AT modifier?*

☐ Yes X No

If yes, describe process(es) *Does happen in general not specifically with regard to chiropractor services.*

☐ Post-payment edits ☐ Other

Explain—probe for basis of edits:

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain:_____
_____
_____

If yes, how do you determine the effectiveness of these processes?_____
_____
_____
_____

5. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding chiropractic services, *particularly the AT modifier*?

☐ Yes X No

If Yes, how many reviews/investigations/analyses were conducted?

_____

What was the nature of these?

_____
_____
_____
_____

What were the results?

_____
_____
_____
_____

How much was recovered?

_____

6. Does [organization name] coordinate post-payment reviews with carrier-issued LCDs regarding chiropractic services?

☐ Yes X No

Explain: We only coordinate on specific investigations. Trend analysis, spikes and aberrancies.

7. Is there anything we haven't discussed that you would like to share?

(b)(6)

P-4-B summary of interview

PSC #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. Has CMS provided education on identifying misuse of chiropractic services, *with the AT modifier specifically*?

☐ Yes ☒ No

If Yes, describe education: Some of investigative staff had OIG 2005 report.

2. Has [organization name] received referrals from CMS and/or Carriers regarding chiropractors' *use of the AT modifier*?

☒ Yes ☐ No

If Yes, describe referrals and action taken by [organization name]: We had one complaint. We reviewed five medical records and documentation was not supportive of manual manipulation. The chiropractor was utilizing a machine. After the medical review, we resolved the issue with an overpayment/recovery $2200.

If No, has [organization name] requested referrals?: _____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☒ No

If Yes, describe instruction/training: We have to prioritize our work based on federal jurisdictions by the most egregious "crimes" against the US government. We don't look at chiro services and specifically the AT modifier because the money is not there. We look at the highest dollar issues. WE have (b)(4)

If No, what is your obligation regarding providers?: Education requirement falls on the AC.

Does [organization name] refer the chiropractor to the carrier for training?

☐ Yes ☒ No

If No, why not?: The case that we had came from the AC so we did not refer them for training. if we work something, once we resolve the issue, we can refer for education if it is warrented. We have looked at some chiropractic claims data. In looking at individual providers, it is small money in the scope of Medicare fraud. If you add it all up globally, it amounts to something more.

4. Does [organization name] have processes to ensure appropriateness of chiropractic services, *particularly with the use of the AT modifier?*

☐ Yes ☒ No

If yes, describe process(es)

☐ Post-payment edits ☐ Other

Explain—probe for basis of edits: _____

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: _____

If yes, how do you determine the effectiveness of these processes? _____

5. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding chiropractic services, *particularly the AT modifier*?

☒ Yes ☐ No

If Yes, how many reviews/investigations/analyses were conducted? When the 2005 OIG report came out, we did some data analysis. I pulled data for this discussion.

What was the nature of these? _____

What were the results? There is some money there for AT modifier misuse globally, but if you look at individual chiropractors the target doesn't warrant for the money.

How much was recovered? _____

6. Does [organization name] coordinate post-payment reviews with carrier-issued LCDs regarding chiropractic services?

☐ Yes ☒ No

Explain: _____

7. Is there anything we haven't discussed that you would like to share?

I went to a really good fraud training on chiropractic services. It discussed how a chiropractor would open an office with a physician and bill for therapy services. On the pecking chain of fraud, chiropractic services are non-existent. If they opened up chiropractic care (more services), it would be a major problem. It is a grey area that would be very easy to abuse. Define back pain and what is worse back pain. Similar to "homebound" definition. I can see nationally how chiropractic services could be a big problem. It just isn't on our radar because of prioritization of workload and bigger issues. It means there is a problem with how the program is written. CMS oversight now is tremendous versus 10 years ago. BAck in 1992, you didn't even know who HCFA was. Now I am on the phone with CMS almost every day. Medicare is just a beast. The tax code has got nothing on Medicare.

PSC #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:

To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

Answers: As a Program Safeguard Contractor (PSC) we review the billing of the chiropractors after we have been notified by a complainant or the affiliated contractor (AC) of a problem or we had done proactive work which indicated there might be an issue with the provider's billing. The processing of the claims, and therefore the guidance for the processing of the claims, would have been received by the affiliated contractor. As well, any instruction to the provider or coordination of such would also be performed by the affiliated contractor. As a PSC we would use all information available to us be it from CMS or the AC that pertains to the specialty of the provider we are investigating.

1. Has CMS provided education on identifying misuse of chiropractic services, *with the AT modifier specifically*?

☐ Yes ☒ No

If Yes, describe education: CR only

2. Has [organization name] received referrals from CMS and/or Carriers regarding chiropractors' *use of the AT modifier*?

☐ Yes ☒ No

If Yes, describe referrals and action taken by [organization name]: We receive referrals both from CMS as well as the AC, but have not received any on chiropractors specifically. If it's an appropriate referral for our jurisdiction, we enter preliminary information into our database, determine what data is available (reimbursement hx and prior complaints), and check with the AC to see if they've received any complaints that they didn't refer to us or provided any education. We look at billing patterns for aberrancies, and may do a sampling of medical record review, at which time it would be referred to an investigator. Depending on the results, we could take administrative action or report to OIG. Generally, we'll provide feedback to the entity who referred the case – with the AC, we may do an educational/warning letter for the provider, or ask the AC to do education.

If No, has [organization name] requested referrals?:

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☒ No

If Yes, describe instruction/training: _____

If No, what is your obligation regarding providers?: Not our function as a PCS to do that general education. We meet with our AC on a monthly basis. If we see something in our investigation work that might require the AC to perform training, we will communicate that to them. If we do education as a PSC, it is primarily through written means (findings of our review) and specific to a particular investigation.

Does [organization name] refer the chiropractor to the carrier for training?

☐ Yes ☐ No

If No, why not?: Depending on the outcome of investigations, AC may be asked to train providers.

4. Does [organization name] have processes to ensure appropriateness of chiropractic services, *particularly with the use of the AT modifier?*

☐ Yes ☒ No

If yes, describe process(es)

☐ Post-payment edits ☐ Other

Explain—probe for basis of edits: Screening of data – proactive data analysis, but nothing specific to AT. We do look at chiropractic, and have found them hooking up with physicians to bill for therapy, which is unusual. We're finding that the chiropractors have the same addresses as the doctors, and suspect that the chiropractors are performing services instead of physicians.
Therapy services in general are becoming a widespread area of concern; Michigan is a particular problem in our jurisdiction. I know (b)(4) are also problems.

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain: _____

If yes, how do you determine the effectiveness of these processes? _____

5. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding chiropractic services, *particularly the AT modifier*?

☐ Yes ☒ No

If Yes, how many reviews/investigations/analyses were conducted? _____

What was the nature of these? _____

What were the results? _____

How much was recovered? _____

6. Does [organization name] coordinate post-payment reviews with carrier-issued LCDs regarding chiropractic services?

☐ Yes ☐ No

Explain: We're working with the carrier to address multiple issues in (b)(4) to be sure we're not overlapping efforts, but are in-synch with doing our work together within the scope of our contracts. We're creating a plan that will be submitted to CMS for that high-risk designation.

7. Is there anything we haven't discussed that you would like to share?

_____

PSC #_____
Date_____
Interviewers_____

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for PSCs

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

Answers: As a Program Safeguard Contractor (PSC) we review the billing of the chiropractors after we have been notified by a complainant or the affiliated contractor (AC) of a problem or we had done proactive work which indicated there might be an issue with the provider's billing. The processing of the claims, and therefore the guidance for the processing of the claims, would have been received by the affiliated contractor. As well, any instruction to the provider or coordination of such would also be performed by the affiliated contractor. As a PSC we would use all information available to us be it from CMS or the AC that pertains to the specialty of the provider we are investigating.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

☐ Medicare Benefit Policy Manual ☐ Other
☐ Change Request 3449
☐ MedLearn Matters Article 3449 ☐ None *(confirm nothing received)*

If Other, describe guidance:_____
_____
_____
_____

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

☐ Yes ☐ No

If Yes, describe education:_____
_____
_____

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

☐ Yes ☐ No

If Yes, describe instruction:_____
_____
_____

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☐ Yes ☐ No

If yes, describe process(es)

☐ Pre-payment edits ☐ Post-payment edits ☐ Other

Explain—probe for basis of edits:_____
_____
_____
_____

If yes, how effective has this process been?

☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain:_____
_____
_____

If yes, how do you determine the effectiveness of these processes?_____
_____
_____
_____

5. Does [organization name] coordinate with MACs/carriers to ensure appropriate use of the AT modifier for chiropractic services?

☐ Yes ☐ No

Explain: _____
_____
_____
_____

6. Does [organization name] coordinate post-payment reviews with MAC-issued and carrier-issued LCDs regarding chiropractic services?

☐ Yes ☐ No

Explain:_____
_____
_____
_____

7. Has [organization name] conducted any reviews, investigations, and/or data analysis regarding the use of the AT modifier for chiropractic services?

☐ Yes ☐ No

If Yes, how many reviews/investigations/analyses were conducted?

_____

What was the nature of these?

_____
_____
_____
_____

What were the results?

_____
_____
_____
_____

How much was recovered?

_____

8. Is there anything we haven't discussed that you would like to share?

Carrier #_____

(b)(4)

Medicare Chiropractic Services: Payments for Maintenance Therapy Billed with the Acute Treatment (AT) Modifier
OEI-07-07-00390
Data Collection Instrument for Carriers

OBJECTIVE:
To determine (1) the extent to which chiropractic service claims allowed in 2006 for beneficiaries who received more than 12 services per year per provider were maintenance therapy, and (2) the Centers for Medicare & Medicaid Services (CMS) efforts to ensure that chiropractic service claims submitted with an AT modifier are not maintenance therapy.

1. What guidance has [organization name] received regarding use of the AT modifier for chiropractic services?

x Medicare Benefit Policy Manual	☐ Other
x Change Request 3449	
x MedLearn Matters Article 3449	☐ None *(confirm nothing received)*

If Other, describe guidance: Through the Carrier Advisory Committee (CAC) chiropractic societies and the chiropractic representative to our CAC provided advice. All of the guidance has been posted to their website.

2. Has CMS provided education on identifying misuse of the AT modifier for chiropractic services?

Yes x ☐ No

If Yes, describe education:_CR 3449 this seems to be the same question as number 1.

3. Has [organization name] instructed chiropractors regarding the use of the AT modifier?

X☐ Yes ☐ No

If Yes, describe instruction: Chiropractic workshops. Attended association meetings with AT modifier information. At first the information was very confusing for chiropractors. After more education, there is a better understanding about the use. Chiros have a pretty good understanding of

4. Does [organization name] have processes to ensure appropriate use of the AT modifier?

☐ Yes ☐ No

If yes, describe process(es)

X☐ Pre-payment edits X☐ Post-payment edits ☐ Other

Explain—probe for basis of edits _LCD states that the claim will be denied with inappropriate use of AT modfier. With post-pay review, findings are not good. Finding that maintenance therapy is being billed with AT modifier.

If yes, how effective has this process been?

X☐ Very Effective ☐ Somewhat Effective ☐ Not Effective

Explain Post-pay review is very effective. We have some providers with 100% error rate. For those providers, the carrier sends a follow up education later, with definition of AT modifier, definition of maintenance therapy. We then do a follow up review to see if they are still making errors. A copy of the letter is also sent to the contract representative noting that they are on "watch". Depends on what their services look like. We might do a face-to-face educational meeting. If they don't comply, we will send referral to PSC.

_____
_____
_____

5. Does [organization name] coordinate with PSCs to ensure appropriate use of the AT modifier for chiropractic services?

X☐ Yes ☐ No

Explain:_Refer chiropractors with continual misuse of AT modifier.

6. Has [organization name] implemented local coverage determinations (LCD) regarding chiropractic services?

☐x Yes ☐ No

If yes,
Describe the LCD?___

LCD Database ID Number	(b)(4)
LCD Title	Chiropractic Service

_____
_____
_____
_____

When? _____2000

_____

Why? Our initial policy developed in 1997 had caused utilization to more closely match national utilization rates. However utilization was rising once again toward previous levels. Therefore' the policy was rewritten.

Furthermore the policy was altered in 2001, 2002, 2004, 2005 and 2006. Some examples of reasons to alter the policy were changes in the language defining maintenance and the AT modifier use in CR 3499 All of changes and updates are part of LCD and can be viewed on the website.
Coding article for chiropractors in conjunction with LCD.
www.(b)(4)com Utilization is based on medical necessity. Over olicy, we base it on medical need. We give them three categories outlining severity of condition based on diagnoses. Review is done on a post-pay basis.

How does CMS determine whether the LCDs for chiropractic services are appropriate? (Probe for plan of implementation): The Comprehensive Error Rate Testing (CERT) program and the local utilization compared to national utilization averages serve as measurements of how our efforts to require proper billing for chiropractic services work compared to others as well as our own past utilization statistics

7. a. Has [organization name] experienced any changes in procedures for edits with the CMS transition to the use of Medicare Administrative Contractors (MACs)?

x Yes ☐ No

If Yes, please explain: Although it will not occur until the transition is complete to the (b)(4) Physician Services company our policy will remain in effect if it is the least restrictive policy in the States of (b)(4) and (b)(4) The MAC contract bidding process had this requirement. Has ienced changes specific to chiropractic services at this time.

b. Does [organization name] anticipate any changes in procedures for edits as CMS transitions to the use of MACs?

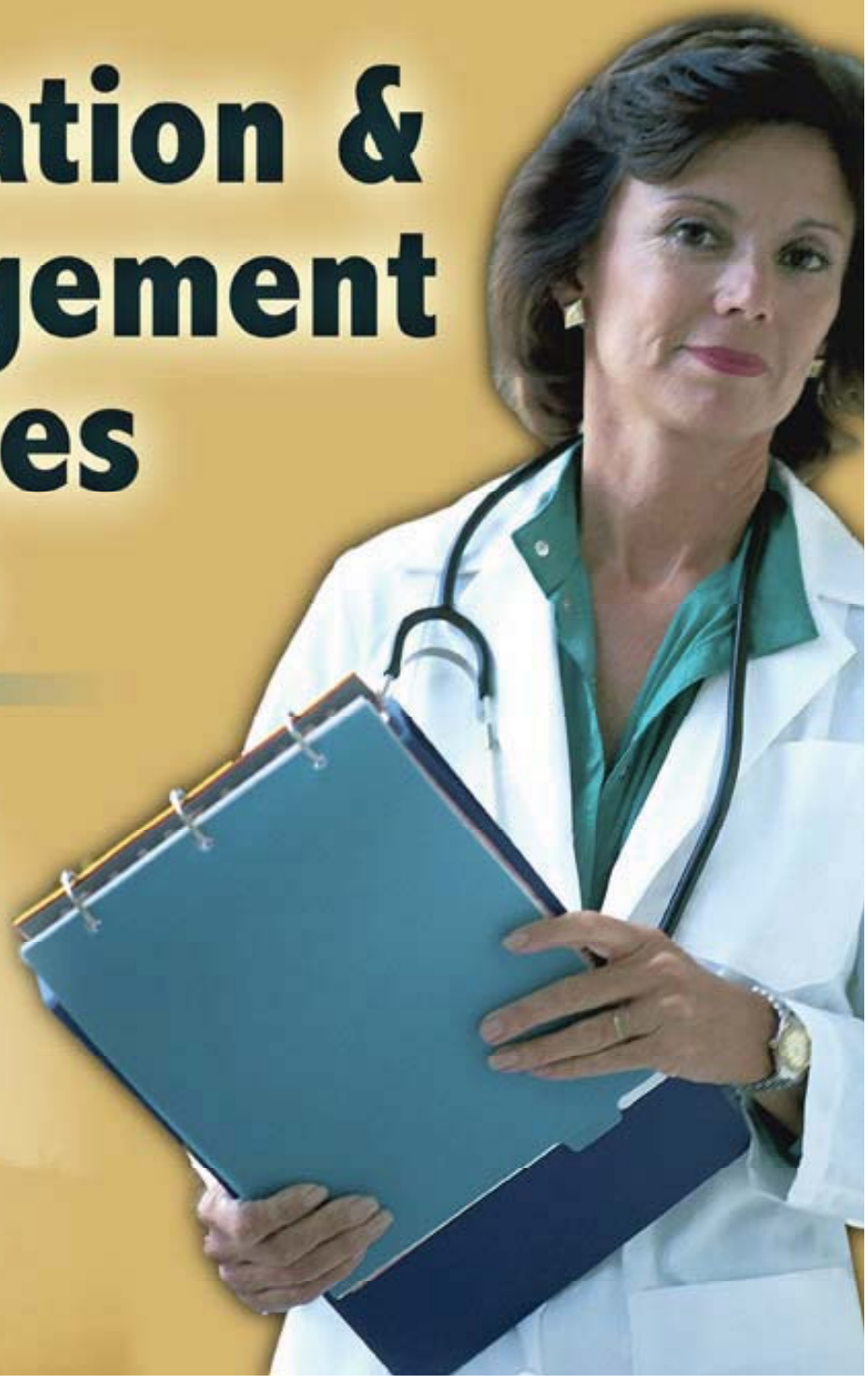
x Yes ☐ No

If Yes, please describe: The edits will be those which the new contractor (b)(4) institutes.

8. Is there anything we haven't discussed that you would like to share?

Our provider community, the majority, try to understand policy and try to comply. There are those who are going to do what they want to do regardless of education, etc. Their definition of maintenance therapy is different from CMS definition. There are those who bill inappropriately. More education might help.

Evaluation & Management Services Guide



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This guide was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

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The Medicare Learning Network (MLN) is the brand name for official CMS educational products and information for Medicare fee-for-service providers. For additional information visit the Medicare Learning Network's web page at *www.cms.hhs.gov/MLNGenInfo* on the CMS website.

ICD-9 NOTICE

The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) is published by the United States Government. A CD-ROM, which may be purchased through the Government Printing Office, is the only official Federal government version of the ICD-9-CM. ICD-9-CM is an official Health Insurance Portability and Accountability Act standard.

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PREFACE

This guide is offered as a reference tool and does not replace content found in the *1995 Documentation Guidelines for Evaluation and Management Services* and the *1997 Documentation Guidelines for Evaluation and Management Services*. It is recommended that health care providers refer to the *1995 Documentation Guidelines for Evaluation and Management Services* in order to identify differences between the two sets of guidelines.

This guide offers Medicare health care providers the following evaluation and management services information:

- Medical Record Documentation
  - Medical Record Documentation Background
  - Guidelines for Residents and Teaching Physicians

- International Classification of Diseases, 9th Revision, Clinical Modification and American Medical Association Current Procedural Terminology Codes

- Key Elements of Service
  - History
  - Examination
  - Medical Decision Making
  - Documentation of an Encounter Dominated By Counseling and/or Coordination of Care

It is recommended that providers refer to the following publications, which were used to prepare this guide:

- *1995 Documentation Guidelines for Evaluation and Management Services*, available at *www.cms.hhs.gov/MLNProducts/Downloads/1995dg.pdf* on the Centers for Medicare & Medicaid Services (CMS) website;
- *1997 Documentation Guidelines for Evaluation and Management Services*, available at *www.cms.hhs.gov/MLNProducts/Downloads/MASTER1.pdf* on the CMS website;
- Medicare Claims Processing Manual (Pub. 100-4), available at *www.cms.hhs.gov/Manuals/IOM/list.asp* on the CMS website; and
- *Current Procedural Terminology 2005* book, available from the American Medical Association (800-621-8335 or *www.amapress.org* on the Web).

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MEDICAL RECORD DOCUMENTATION

"If it isn't documented, it hasn't been done" is an adage that is frequently heard in the health care setting.

Medical Record Documentation Background

Concise medical record documentation is critical to providing patients with quality care as well as to receiving accurate and timely reimbursement for furnished services. It chronologically documents the care of the patient and is required to record pertinent facts, findings, and observations about the patient's health history including past and present illnesses, examinations, tests, treatments, and outcomes. Medical record documentation also assists physicians and other health care professionals in evaluating and planning the patient's immediate treatment and monitoring his or her health care over time.

Payers may require reasonable documentation that services are consistent with the insurance coverage provided in order to validate:

- The site of service;
- The medical necessity and appropriateness of the diagnostic and/or therapeutic services provided; and/or
- That services furnished have been accurately reported.

To ensure that medical record documentation is accurate, the following principles should be followed:

- The medical record should be complete and legible.
- The documentation of each patient encounter should include:
    - Reason for the encounter and relevant history, physical examination findings, and prior diagnostic test results
    - Assessment, clinical impression, or diagnosis
    - Medical plan of care
    - Date and legible identity of the observer.
- If not documented, the rationale for ordering diagnostic and other ancillary services should be easily inferred.
- Past and present diagnoses should be accessible to the treating and/or consulting physician.
- Appropriate health risk factors should be identified.
- The patient's progress, response to and changes in treatment, and revision of diagnosis should be documented.
- The Current Procedural Terminology (CPT) and International Classification of Diseases, 9th Revision, Clinical Modification codes reported on the health insurance claim form or billing statement should be supported by the documentation in the medical record.

Guidelines for Residents and Teaching Physicians

Both residents and teaching physicians may document physician services in the patient's medical record. The documentation must be dated and contain a legible signature or identity and may be:

- Dictated and transcribed;
- Typed;
- Hand-written; or
- Computer-generated.

The attending physician who bills Medicare for evaluation and management (E/M) services in the teaching setting must, at a minimum, personally document:

- His or her participation in the management of the patient; and
- That he or she performed the service or was physically present during the critical or key portion(s) of the service performed by the resident (the resident's certification that the attending physician was present is not sufficient).

Students may also document services in the patient's medical record. The teaching physician may refer only to a student's E/M documentation that is related to a review of systems and/or past, family, and/or social history. If the medical student documents E/M services, the teaching physician must verify and repeat documentation of the physical examination and medical decision making activities of the service.

Exception for Evaluation and Management Services Furnished in Certain Primary Care Centers

Medicare may grant a primary care exception within an approved Graduate Medical Education (GME) Program in which the teaching physician is paid for certain E/M services the resident performs when the teaching physician is not present. The primary care exception applies to the following lower and mid-level E/M services and the initial preventive physical examination (also known as the "Welcome to Medicare Physical"):

New Patient	Established Patient
CPT Code 99201®	CPT Code 99211
CPT Code 99202	CPT Code 99212
CPT Code 99203	CPT Code 99213

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Effective January 1, 2005, the following code is included under the primary exception:

- Healthcare Common Procedure Coding System code G3044:
  Initial Preventive Physical Examination: face-to-face visit, services limited to new beneficiary during the first six months of Medicare enrollment.

The range of services furnished by residents include the following:

- Acute care for undifferentiated problems or chronic care for ongoing conditions including chronic mental illness;
- Coordination of care furnished by other providers; and
- Comprehensive care not limited by organ system or diagnosis.

The types of residency programs most likely to qualify for the primary care exception include family practice, general internal medicine, geriatric medicine, pediatrics, and obstetrics/gynecology. Certain GME programs in psychiatry may qualify in special situations, such as when the program furnishes comprehensive care for chronically mentally ill patients.

A center must attest in writing that all of the following conditions are met for a particular residency program:

- The services must be furnished in a center located in the outpatient department of a hospital or another ambulatory care entity in which the time spent by residents in patient care activities is included in determining direct GME payments to a teaching hospital.
- Any resident furnishing the service without the presence of a teaching physician must have completed more than six months of an approved residency program.
- The teaching physician in whose name the payment is sought must not supervise more than four residents at any given time and must direct the care from such proximity as to constitute immediate availability. The teaching physician must:
  - Have no other responsibilities, including the supervision of other personnel, at the time of the service for which payment is sought
  - Assume management responsibility for those patients seen by the residents
  - Ensure that the services furnished are appropriate
  - Review the patient's medical history, physical examination, diagnosis, and record of tests and therapies with each resident during or immediately after each visit
  - Document the extent of his or her own participation in the review and direction of the services furnished to each patient.

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- The patients seen must be an identifiable group of individuals who consider the center to be the continuing source of their health care and in which services are furnished by residents under the medical direction of

teaching physicians. The residents must generally follow the same group of patients throughout the course of their residency program, but there is no requirement that the teaching physicians remain the same over any period of time.

INTERNATIONAL CLASSIFICATION OF DISEASES, 9TH REVISION, CLINICAL MODIFICATION AND AMERICAN MEDICAL ASSOCIATION CURRENT PROCEDURAL TERMINOLOGY CODES

When billing for a patient's visit, codes are selected that best represent the services furnished during the visit. The two common sets of codes used are:

- Diagnostic or International Classification of Diseases, 9th Revision, Clinical Modification codes; and
- Procedural or American Medical Association Current Procedural Terminology (CPT) codes.

These codes are organized into various categories and levels. It is the physician's responsibility to ensure that documentation reflects the services furnished and that the codes selected reflect those services. The more work performed by the physician, the higher the level of code he or she may bill within the appropriate category. The billing specialist or alternate source reviews the physician's documented services and assists with selecting codes that best reflect the extent of the physician's personal work necessary to furnish the services.

Evaluation and management (E/M) services refer to visits and consultations furnished by physicians. Billing Medicare for a patient visit requires the selection of a CPT code that best represents the level of E/M service performed. For example, there are five CPT codes that may be selected to bill for office or other outpatient visits for a new patient:

- 99201® – Usually the presenting problem(s) are self limited or minor and the physician typically spends 10 minutes face-to-face with the patient and/or family. E/M requires the following three key components:
    - Problem focused history
    - Problem focused examination
    - Straightforward medical decision making
- 99202 – Usually the presenting problem(s) are of low to moderate severity and the physician typically spends 20 minutes face-to-face with the patient and/or family. E/M requires the following three key components:
    - Expanded problem focused history
    - Expanded problem focused examination
    - Straightforward medical decision making

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- 99203 – Usually the presenting problem(s) are of moderate severity and the physician typically spends 30 minutes face-to-face with the patient and/or family. E/M requires the following three key components:
    - Detailed history
    - Detailed examination
    - Medical decision making of low complexity
- 99204 – Usually the presenting problem(s) are of moderate to high severity and the physician typically spends 45 minutes face-to-face with the patient and/or family. E/M requires the following three key components:
    - Comprehensive history
    - Comprehensive examination
    - Medical decision making of moderate complexity
- 99205 – Usually the presenting problem(s) are of moderate to high severity and the physician typically spends 60 minutes face-to-face with the patient and/or family. E/M requires the following three key components:
    - Comprehensive history
    - Comprehensive examination
    - Medical decision making of high complexity

KEY ELEMENTS OF SERVICE

To determine the appropriate level of service for a patient's visit, it is necessary to first determine whether the patient is new or already established. The physician then uses the presenting illness as a guiding factor and his or her clinical judgment about the patient's condition to determine the extent of key elements of service to be performed. The key elements of service are:

- History;
- Examination; and
- Medical decision making.

The key elements of service and documentation of an encounter dominated by counseling and/or coordination of care are discussed below.

I. History

The elements required for each type of history are depicted in the table below. Note that each history type requires more information as you read down the left hand column. For example, a problem focused history requires the documentation of the chief complaint (CC) and a brief history of present illness (HPI) and a detailed history requires the documentation of a CC, extended HPI, extended review of systems (ROS), and pertinent past, family and/or social history (PFSH).

Elements Required for Each Type of History

TYPE OF HISTORY	CHIEF COMPLAINT	HISTORY OF PRESENT ILLNESS	REVIEW OF SYSTEMS	PAST, FAMILY, AND/OR SOCIAL HISTORY
Problem Focused	Required	Brief	N/A	N/A
Expanded Problem Focused	Required	Brief	Problem Pertinent	N/A
Detailed	Required	Extended	Extended	Pertinent
Comprehensive	Required	Extended	Complete	Complete

The extent of information gathered for history is dependent upon clinical judgment and the nature of the presenting problem. Documentation of patient history includes some or all of the following elements:

A. Chief Complaint

A CC is a concise statement that describes the symptom, problem, condition, diagnosis, or reason for the patient encounter. The CC is usually stated in the patient's own words. For example, patient complains of upset stomach, aching joints, and fatigue.

B. History of Present Illness

HPI is a chronological description of the development of the patient's present illness from the first sign and/or symptom or from the previous encounter to the present. HPI elements are:

- Location. For example, pain in left leg;
- Quality. For example, aching, burning, radiating;
- Severity. For example, 10 on a scale of 1 to 10;
- Duration. For example, it started three days ago;
- Timing. For example, it is constant or it comes and goes;
- Context. For example, lifted large object at work;
- Modifying factors. For example, it is better when heat is applied; and
- Associated signs and symptoms. For example, numbness.

There are two types of HPIs:

1) Brief, which includes documentation of one to three HPI elements. In the following example, three HPI elements -- location, severity, and duration -- are documented:
    - CC: A patient seen in the office complains of left ear pain.
    - Brief HPI: Patient complains of dull ache in left ear over the past 24 hours.

2) Extended, which includes documentation of at least four HPI elements or the status of at least three chronic or inactive conditions. In the following example, five HPI elements -- location, severity, duration, context, and modifying factors -- are documented:
    - Extended HPI: Patient complains of dull ache in left ear over the past 24 hours. Patient states he went swimming two days ago. Symptoms somewhat relieved by warm compress and ibuprofen.

C. Review of Systems

ROS is an inventory of body systems obtained by asking a series of questions in order to identify signs and/or symptoms that the patient may be experiencing or has experienced. The following systems are recognized:

- Constitutional Symptoms (e.g., fever, weight loss);
- Eyes;
- Ears, Nose, Mouth, Throat;
- Cardiovascular;
- Respiratory;
- Gastrointestinal;
- Genitourinary;
- Musculoskeletal;
- Integumentary (skin and/or breast);
- Neurological;
- Psychiatric;
- Endocrine;
- Hematologic/Lymphatic; and
- Allergic/Immunologic.

There are three types of ROS:

1) Problem pertinent, which inquires about the system directly related to the problem identified in the HPI. In the following example, one system -- the ear -- is reviewed:

- CC: Earache.
- ROS: Positive for left ear pain. Denies dizziness, tinnitus, fullness, or headache.

2) Extended, which inquires about the system directly related to the problem(s) identified in the HPI and a limited number (two to nine) of additional systems. In the following example, two systems -- cardiovascular and respiratory -- are reviewed:

- CC: Follow up visit in office after cardiac catheterization. Patient states “I feel great.”
- ROS: Patient states he feels great and denies chest pain, syncope, palpitations, and shortness of breath. Relates occasional unilateral, asymptomatic edema of left leg.

3) Complete, which inquires about the system(s) directly related to the problem(s) identified in the HPI plus all additional (minimum of 10) body systems. In the following example, 10 signs and symptoms are reviewed:

- CC: Patient complains of "fainting spell."
- ROS:
    - Constitutional: weight stable, + fatigue.
    - Eyes: + loss of peripheral vision.
    - Ear, Nose, Mouth, Throat: no complaints.
    - Cardiovascular: + palpitations; denies chest pain; denies calf pain, pressure, or edema.
    - Respiratory: + shortness of breath on exertion.
    - Gastrointestinal: appetite good, denies heartburn and indigestion. + episodes of nausea. Bowel movement daily; denies constipation or loose stools.
    - Urinary: denies incontinence, frequency, urgency, nocturia, pain, or discomfort.
    - Skin: + clammy, moist skin.
    - Neurological: + fainting; denies numbness, tingling, and tremors.
    - Psychiatric: denies memory loss or depression. Mood pleasant.

D. Past, Family, and/or Social History

PFSH consists of a review of the patient's:

- Past history including experiences with illnesses, operations, injuries, and treatments;
- Family history including a review of medical events, diseases, and hereditary conditions that may place him or her at risk; and
- Social history including an age appropriate review of past and current activities.

The two types of PFSH are:

1) Pertinent, which is a review of the history areas directly related to the problem(s) identified in the HPI. The pertinent PFSH must document one item from any of the three history areas. In the following example, the patient's past surgical history is reviewed as it relates to the current HPI:

- Patient returns to office for follow up of coronary artery bypass graft in 1992. Recent cardiac catheterization demonstrates 50 percent occlusion of vein graft to obtuse marginal artery.

2) Complete, which is a review of two or all three of the areas, depending on the category of E/M service. A complete PFSH requires a review of all three history areas for services that, by their nature, include a comprehensive assessment or reassessment of the patient. A review of two history areas is sufficient for other services. At least one specific item from two of the three history areas must be documented for a complete PFSH for the following categories of E/M services:

- Office or other outpatient services, established patient;
- Emergency department;
- Domiciliary care, established patient; and
- Home care, established patient.

At least one specific item from each of the history areas must be documented for the following categories of E/M services:

- Office or other outpatient services, new patient;
- Hospital observation services;
- Hospital inpatient services, initial care;
- Consultations;
- Comprehensive Nursing Facility assessments;
- Domiciliary care, new patient; and
- Home care, new patient.

In the following example, the patient's genetic history is reviewed as it relates to the current HPI:

- Family history reveals the following:
    - Maternal grandparents: both + for coronary artery disease; grandfather deceased at age 69; grandmother still living
    - Paternal grandparents: grandmother - + diabetes, hypertension; grandfather - + heart attack at age 55
    - Parents: mother - + obesity, diabetes; father - + heart attack age 51, deceased age 57 of heart attack
    - Siblings: sister - + diabetes, obesity, hypertension, age 39; brother - + heart attack at age 45, living

II. Examination

An examination may involve several organ systems or a single organ system. The extent of the examination performed is based upon clinical judgment, the patient's history, and nature of the presenting problem.

The chart below depicts the body areas and organ systems that are recognized according to the Current Procedural Terminology (CPT) book:

Recognized Body Areas and Organ Systems

BODY AREAS	ORGAN SYSTEMS
Head, including face Neck Chest, including breasts and axilla Abdomen Genitalia, groin, buttocks Back Each extremity	Eyes Ears, Nose, Mouth, and Throat Cardiovascular Respiratory Gastrointestinal Genitourinary Musculoskeletal Skin Neurologic Hematologic/Lymphatic/Immunologic Psychiatric

There are two types of examinations that can be performed during a patient's visit:

1) General multi-system examination, which involves the examination of one or more organ systems or body areas. According to the *1997 Documentation Guidelines for Evaluation and Management Services* each body area or organ system contains two or more of the following examination elements:

- Constitutional Symptoms (e.g., fever, weight loss);
- Eyes;
- Ears, Nose, Mouth, Throat;
- Neck;
- Respiratory;
- Cardiovascular;
- Chest (breasts);
- Gastrointestinal;
- Genitourinary;
- Lymphatic;
- Musculoskeletal;
- Integumentary;
- Neurological; and
- Psychiatric.

2) Single organ system examination, which involves a more extensive examination of a specific organ system.

Both types of examinations may be performed by any physician, regardless of specialty. The chart below compares the elements of the **cardiovascular system/body area** for both a general multi-system and single organ system examination.

Cardiovascular System/Body Area

SYSTEM/ BODY AREA	GENERAL MULTI-SYSTEM EXAMINATION	SINGLE ORGAN SYSTEM EXAMINATION
Cardiovascular	Palpation of heart (e.g., location, size, thrills). Auscultation of heart with notation of abnormal sounds and murmurs. Examination of: • Carotid arteries (e.g., pulse amplitude, bruits) • Abdominal aorta (e.g., size, bruits); • Femoral arteries (e.g., pulse amplitude, bruits); • Pedal pulses (e.g., pulse amplitude); and • Extremities for edema and/or varicosities.	Palpation of heart (e.g., location, size, and forcefulness of the point of maximal impact; thrills; lifts; palpable S3 or S4). Auscultation of heart including sounds, abnormal sounds, and murmurs. Measurement of blood pressure in two or more extremities when indicated (e.g., aortic dissection, coarctation). Examination of: • Carotid arteries (e.g., waveform, pulse amplitude, bruits, apical-carotid delay); • Abdominal aorta (e.g., size, bruits); • Femoral arteries (e.g., pulse amplitude, bruits); • Pedal pulses (e.g., pulse amplitude); and • Extremities for peripheral edema and/or varicosities.

The elements required for each type of examination are depicted in the table below.

Elements Required for Each Type of Examination

TYPE OF EXAMINATION	DESCRIPTION
Problem Focused	A limited examination of the affected body area or organ system.
Expanded Problem Focused	A limited examination of the affected body area or organ system and any other symptomatic or related body area(s) or organ system(s).
Detailed	An extended examination of the affected body area(s) or organ system(s) and any other symptomatic or related body areas(s) or organ system(s).
Comprehensive	A general multi-system examination OR complete examination of a single organ system and other symptomatic or related body area(s) or organ system(s).

The elements required for general multi-system examinations are depicted in the following chart.

General Multi-System Examinations

TYPE OF EXAMINATION	DESCRIPTION
Problem Focused	Include performance and documentation of 1 - 5 elements identified by a bullet in 1 or more organ system(s) or body area(s).
Expanded Problem Focused	Include performance and documentation of at least 6 elements identified by a bullet in 1 or more organ system(s) or body area(s).
Detailed	Include at least 6 organ systems or body areas. For each system/area selected, performance and documentation of at least 2 elements identified by a bullet is expected. Alternatively, may include performance and documentation of at least 12 elements identified by a bullet in 2 or more organ systems or body areas.
Comprehensive	*1997 Documentation Guidelines for Evaluation and Management Services*: Include at least 9 organ systems or body areas. For each system/area selected, all elements of the examination identified by a bullet should be performed, unless specific directions limit the content of the examination. For each area/system, documentation of at least 2 elements identified by bullet is expected. *1995 Documentation Guidelines for Evaluation and Management Services*: Eight organ systems ***must*** be examined. If body areas are examined and counted, they must be over and above the 8 organ systems.

According to the *1997 Documentation Guidelines for Evaluation and Management Services*, the 10 single organ system examinations are:

- Cardiovascular;
- Ear, Nose, and Throat;
- Eye;
- Genitourinary;
- Hematologic/Lymphatic/Immunologic;
- Musculoskeletal;
- Neurological;
- Psychiatric;
- Respiratory; and
- Skin.

The elements required for single organ system examinations are depicted in the following chart.

Single Organ System Examinations

TYPE OF EXAMINATION	DESCRIPTION
Problem Focused	Include performance and documentation of 1 - 5 elements identified by a bullet, whether in a box with a shaded or unshaded border.
Expanded Problem Focused	Include performance and documentation of at least 6 elements identified by a bullet, whether in a box with a shaded or unshaded border.
Detailed	Examinations other than the eye and psychiatric examinations should include performance and documentation of at least 12 elements identified by a bullet, whether in a box with a shaded or unshaded border. Eye and psychiatric examinations include the performance and documentation of at least 9 elements identified by a bullet, whether in a box with a shaded or unshaded border.
Comprehensive	Include performance of all elements identified by a bullet, whether in a shaded or unshaded box. Documentation of every element in each box with a shaded border and at least 1 element in a box with an unshaded border is expected.

The chart below compares the elements that are required for both general multi-system and single organ system examinations.

Multi-System and Single Organ Examinations

TYPE OF EXAMINATION	MULTI-SYSTEM EXAMINATIONS	SINGLE ORGAN SYSTEM EXAMINATIONS
Problem Focused	1 - 5 elements identified by a bullet in 1 or more organ system(s) or body area(s).	1 - 5 elements identified by a bullet, whether in a box with a shaded or unshaded border.
Expanded Problem Focused	At least 6 elements identified by a bullet in one or more organ system(s) or body area(s).	At least 6 elements identified by a bullet, whether in a box with a shaded or unshaded border.
Detailed	At least 6 organ systems or body areas. For each system/area selected, performance and documentation of at least 2 elements identified by a bullet is expected. **OR** At least 12 elements identified by a bullet in 2 or more organ systems or body areas.	At least 12 elements identified by a bullet, whether in a box with a shaded or unshaded border. Eye and psychiatric: At least 9 elements identified by a bullet, whether in a box with a shaded or unshaded border.
Comprehensive	Include at least 9 organ systems or body areas. For each system/area selected, all elements of the examination identified by a bullet should be performed, unless specific directions limit the content of the examination. For each area/system, documentation of at least 2 elements identified by bullet is expected.	Perform all elements identified by a bullet, whether in a shaded or unshaded box. Document every element in each box with a shaded border and at least 1 element in a box with an unshaded border.

Some important points that should be kept in mind when documenting general multi-system and single organ system examinations are:

- Specific abnormal and relevant negative findings of the examination of the affected or symptomatic body area(s) or organ system(s) should be documented. A notation of “abnormal” without elaboration is not sufficient;
- Abnormal or unexpected findings of the examination of any asymptomatic body area(s) or organ system(s) should be described; and
- A brief statement or notation indicating “negative” or “normal” is sufficient to document normal findings related to unaffected area(s) or asymptomatic organ system(s). (However, an entire organ system should not be documented with a statement such as “negative.”)

III. Medical Decision Making

Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option, which is determined by considering the following factors:

- The number of possible diagnoses and/or the number of management options that must be considered;
- The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed and analyzed; and
- The risk of significant complications, morbidity, and/or mortality as well as comorbidities associated with the patient's presenting problem(s), the diagnostic procedure(s), and/or the possible management options.

The chart below depicts the elements for each level of medical decision making. Note that to qualify for a given type of medical decision making**,** two of the three elements must either be met or exceeded.

Elements of Medical Decision Making

TYPE OF DECISION MAKING	NUMBER OF DIAGNOSES OR MANAGEMENT OPTIONS	AMOUNT AND/OR COMPLEXITY OF DATA TO BE REVIEWED	RISK OF SIGNIFICANT COMPLICATIONS, MORBIDITY, AND/OR MORTALITY
Straightforward	Minimal	Minimal or None	Minimal
Low Complexity	Limited	Limited	Low
Moderate Complexity	Multiple	Moderate	Moderate
High Complexity	Extensive	Extensive	High

Number of Diagnoses or Management Options

The number of possible diagnoses and/or the number of management options that must be considered is based on:

- The number and types of problems addressed during the encounter;
- The complexity of establishing a diagnosis; and
- The management decisions that are made by the physician.

In general, decision making with respect to a diagnosed problem is easier than that for an identified but undiagnosed problem. The number and type of diagnosed tests performed may be an indicator of the number of possible diagnoses. Problems that are improving or resolving are less complex than those problems that are worsening or failing to change as expected. Another indicator of the complexity of diagnostic or management problems is the need to seek advice from other health care professionals.

Some important points that should be kept in mind when documenting the number of diagnoses or management options are:

- For each encounter, an assessment, clinical impression, or diagnosis should be documented which may be explicitly stated or implied in documented decisions regarding management plans and/or further evaluation.
    - For a presenting problem with an established diagnosis, the record should reflect whether the problem is:
        - Improved, well controlled, resolving, or resolved
        - Inadequately controlled, worsening, or failing to change as expected
    - For a presenting problem without an established diagnosis, the assessment or clinical impression may be stated in the form of differential diagnoses or as a “possible,” “probable,” or “rule out” diagnosis
- The initiation of, or changes in, treatment should be documented. Treatment includes a wide range of management options including patient instructions, nursing instructions, therapies, and medications.
- If referrals are made, consultations requested, or advice sought, the record should indicate to whom or where the referral or consultation is made or from whom advice is requested.

<u>Amount and/or Complexity of Data to be Reviewed</u>

The amount and/or complexity of data to be reviewed is based on the types of diagnostic testing ordered or reviewed. Indications of the amount and/or complexity of data being reviewed include:

- A decision to obtain and review old medical records and/or obtain history from sources other than the patient (increases the amount and complexity of data to be reviewed);
- Discussion of contradictory or unexpected test results with the physician who performed or interpreted the test (indicates the complexity of data to be reviewed); and
- The physician who ordered a test personally reviews the image, tracing, or specimen to supplement information from the physician who prepared the test report or interpretation (indicates the complexity of data to be reviewed).

Some important points that should be kept in mind when documenting amount and/or complexity of data to be reviewed include:

- If a diagnostic service is ordered, planned, scheduled, or performed at the time of the E/M encounter, the type of service should be documented.
- The review of laboratory, radiology, and/or other diagnostic tests should be documented. A simple notation such as "White blood count elevated" or "Chest x-ray unremarkable" is acceptable. Alternatively, the review may be documented by initialing and dating the report that contains the test results.
- A decision to obtain old records or obtain additional history from the family, caretaker, or other source to supplement information obtained from the patient should be documented.
- Relevant findings from the review of old records and/or the receipt of additional history from the family, caretaker, or other source to supplement information obtained from the patient should be documented. If there is no relevant information beyond that already obtained, this fact should be documented. A notation of “Old records reviewed” or “Additional history obtained from family” without elaboration is not sufficient.
- Discussion about results of laboratory, radiology, or other diagnostic tests with the physician who performed or interpreted the study should be documented.
- The direct visualization and independent interpretation of an image, tracing, or specimen previously or subsequently interpreted by another physician should be documented.

Risk of Significant Complications, Morbidity, and/or Mortality

The risk of significant complications, morbidity, and/or mortality is based on the risks associated with the following categories:

- Presenting problem(s);
- Diagnostic procedure(s); and
- Possible management options.

The assessment of risk of the presenting problem(s) is based on the risk related to the disease process anticipated between the present encounter and the next encounter. The assessment of risk of selecting diagnostic procedures and management options is based on the risk during and immediately following any procedures or treatment. The highest level of risk in any one category determines the overall risk.

The level of risk of significant complications, morbidity, and/or mortality can be:

- Minimal;
- Low;
- Moderate; or
- High.

Some important points that should be kept in mind when documenting level of risk are:

- Comorbidities/underlying diseases or other factors that increase the complexity of medical decision making by increasing the risk of complications, morbidity, and/or mortality should be documented;
- If a surgical or invasive diagnostic procedure is ordered, planned, or scheduled at the time of the E/M encounter, the type of procedure should be documented;
- If a surgical or invasive diagnostic procedure is performed at the time of the E/M encounter, the specific procedure should be documented; and
- The referral for or decision to perform a surgical or invasive diagnostic procedure on an urgent basis should be documented or implied.

The table on the following page may be used to assist in determining whether the level of risk of significant complications, morbidity, and/or mortality is minimal, low, moderate, or high. Because determination of risk is complex and not readily quantifiable, the table includes common clinical examples rather than absolute measures of risk.

TABLE OF RISK

Level of Risk	Presenting Problem(s)	Diagnostic Procedure(s) Ordered	Management Options Selected
Minimal	One self-limited or minor problem, eg, cold, insect bite, tinea corporis	Laboratory tests requiring venipuncture Chest x-rays EKG/EEG Urinalysis Ultrasound, eg, echocardiography KOH prep	Rest Gargles Elastic bandages Superficial dressings
Low	Two or more self-limited or minor problems One stable chronic illness, eg, well controlled hypertension, non-insulin dependent diabetes, cataract, BPH Acute uncomplicated illness or injury, eg, cystitis, allergic rhinitis, simple sprain	Physiologic tests not under stress, eg, pulmonary function tests Non-cardiovascular imaging studies with contrast, eg, barium enema Superficial needle biopsies Clinical laboratory tests requiring arterial puncture Skin biopsies	Over-the-counter drugs Minor surgery with no identified risk factors Physical therapy Occupational therapy IV fluids without additives
Moderate	One or more chronic illnesses with mild exacerbation, progression, or side effects of treatment Two or more stable chronic illnesses Undiagnosed new problem with uncertain prognosis, eg, lump in breast Acute illness with systemic symptoms, eg, pyelonephritis, pneumonitis, colitis Acute complicated injury, eg, head injury with brief loss of consciousness	Physiologic tests under stress, eg, cardiac stress test, fetal contraction stress test Diagnostic endoscopies with no identified risk factors Deep needle or incisional biopsy Cardiovascular imaging studies with contrast and no identified risk factors, eg, arteriogram, cardiac catheterization Obtain fluid from body cavity, eg lumbar puncture, thoracentesis, culdocentesis	Minor surgery with identified risk factors Elective major surgery (open, percutaneous or endoscopic) with no identified risk factors Prescription drug management Therapeutic nuclear medicine IV fluids with additives Closed treatment of fracture or dislocation without manipulation
High	One or more chronic illnesses with severe exacerbation, progression, or side effects of treatment Acute or chronic illnesses or injuries that pose a threat to life or bodily function, eg, multiple trauma, acute MI, pulmonary embolus, severe respiratory distress, progressive severe rheumatoid arthritis, psychiatric illness with potential threat to self or others, peritonitis, acute renal failure An abrupt change in neurologic status, eg, seizure, TIA, weakness, sensory loss	Cardiovascular imaging studies with contrast with identified risk factors Cardiac electrophysiological tests Diagnostic Endoscopies with identified risk factors Discography	Elective major surgery (open, percutaneous or endoscopic) with identified risk factors Emergency major surgery (open, percutaneous or endoscopic) Parenteral controlled substances Drug therapy requiring intensive monitoring for toxicity Decision not to resuscitate or to de-escalate care because of poor prognosis

IV. Documentation of an Encounter Dominated by Counseling and/or Coordination of Care

When counseling and/or coordination of care dominates (more than 50 percent of) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting, floor/unit time in the hospital, or Nursing Facility), time is considered the key or controlling factor to qualify for a particular level of E/M services. If the level of service is reported based on counseling and/or coordination of care, the total length of time of the encounter should be documented and the record should describe the counseling and/or activities to coordinate care. For example, if 25 minutes was spent face-to-face with an established patient in the office and more than half of that time was spent counseling the patient or coordinating his or her care, CPT code 99214® should be selected.

The Level I and Level II CPT books available from the American Medical Association list average time guidelines for a variety of E/M services. These times include work done before, during, and after the encounter. The specific times expressed in the code descriptors are averages and, therefore, represent a range of times that may be higher or lower depending on actual clinical circumstances.

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ACRONYMS

AMA	American Medical Association
CC	Chief Complaint
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
E/M	Evaluation and Management
GME	Graduate Medical Education
HPI	History of Present Illness
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
PFSH	Past, Family, and/or Social History
ROS	Review of Systems

REFERENCE MATERIALS

EMDOC (Evaluation and Management Documentation Guidelines)
Centers for Medicare & Medicaid Services
www.cms.hhs.gov/MLNEdWebGuide/25_EMDOC.asp

Internet-Only Manuals
Centers for Medicare & Medicaid Services
www.cms.hhs.gov/Manuals/IOM/list.asp

Medicare Learning Network Publications
Centers for Medicare & Medicaid Services
www.cms.hhs.gov/MLNProducts

Level I and Level II CPT Books
American Medical Association
(800) 621-8335
www.amapress.org

ICD-9-CM Book
American Medical Association
(800) 621-8335
www.amapress.org

ICN: 006764
Date: Revised July 2007

97810 Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient

CPT Assistant Jan 05:16-17; *CPT Changes: An Insider's View* 2005

►(Do not report 97810 in conjunction with 97813)◄

+▲ 97811 without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

CPT Assistant Jan 05:16; *CPT Changes: An Insider's View* 2005, 2006

►(Use 97811 in conjunction with 97810, 97813)◄

▲ 97813 with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient

CPT Assistant Jan 05:16-18; *CPT Changes: An Insider's View* 2005, 2006

►(Do not report 97813 in conjunction with 97810)◄

+▲ 97814 with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

CPT Assistant Jan 05:16; *CPT Changes: An Insider's View* 2005, 2006

►(Use 97814 in conjunction with 97810, 97813)◄

Osteopathic Manipulative Treatment

Osteopathic manipulative treatment (OMT) is a form of manual treatment applied by a physician to eliminate or alleviate somatic dysfunction and related disorders. This treatment may be accomplished by a variety of techniques.

Evaluation and Management services may be reported separately if, using modifier 25, the patient's condition requires a significant separately identifiable E/M service, above and beyond the usual preservice and postservice work associated with the procedure. The E/M service may be caused or prompted by the same symptoms or condition for which the OMT service was provided. As such, different diagnoses are not required for the reporting of the OMT and E/M service on the same date.

Body regions referred to are: head region; cervical region; thoracic region; lumbar region; sacral region; pelvic region; lower extremities; upper extremities; rib cage region; abdomen and viscera region.

CPT Assistant Nov 98:37-38

98925 Osteopathic manipulative treatment (OMT); one to two body regions involved

CPT Assistant May 96:10, Jan 97:8, 10, Jul 98:10, Aug 00:11, Dec 00:15

98926 three to four body regions involved

CPT Assistant May 96:10, Jan 97:8, Aug 00:11, Dec 00:15

98927 five to six body regions involved

CPT Assistant May 96:10, Jan 97:8, Aug 00:11, Dec 00:15

98928 seven to eight body regions involved

CPT Assistant May 96:10, Jan 97:8, Aug 00:11, Dec 00:15

98929 nine to ten body regions involved

CPT Assistant May 96:10, Jan 97:8, 10, Aug 00:11

Chiropractic Manipulative Treatment

Chiropractic manipulative treatment (CMT) is a form of manual treatment to influence joint and neurophysiological function. This treatment may be accomplished using a variety of techniques.

The chiropractic manipulative treatment codes include a pre-manipulation patient assessment. Additional Evaluation and Management services may be reported separately using modifier 25, if the patient's condition requires a significant separately identifiable E/M service, above and beyond the usual preservice and postservice work associated with the procedure. The E/M service may be caused or prompted by the same symptoms or condition for which the CMT service was provided. As such, different diagnoses are not required for the reporting of the CMT and E/M service on the same date.

For purposes of CMT, the five spinal regions referred to are: cervical region (includes atlanto-occipital joint); thoracic region (includes costovertebral and costotransverse joints); lumbar region; sacral region; and pelvic (sacro-iliac joint) region. The five extraspinal regions referred to are: head (including temporomandibular joint, excluding atlanto-occipital) region; lower extremities; upper extremities; rib cage (excluding costotransverse and costovertebral joints) and abdomen.

CPT Assistant Nov 98:38

98940 Chiropractic manipulative treatment (CMT); spinal, one to two regions

CPT Assistant Jan 97:7, 11, Feb 99:10, Dec 00:15

98941 spinal, three to four regions

CPT Assistant Jan 97:7, 11, Mar 97:10, Feb 99:10, Dec 00:15

98942 spinal, five regions

CPT Assistant Jan 97:7, 11, Feb 99:10, Dec 00:15

98943 extraspinal, one or more regions

CPT Assistant Jan 97:7, 11, Mar 97:10, Feb 99:10, Dec 00:15

Insurance

- Coding & Reimbursement
- Chiropractic Networks Action Center
- Insurance Resources
- Insurance Questions?
- Status of ACA Insurance Initiatives
- Ethical Practice

Clinical (Medical) Documentation: The Key To Reimbursement For Chiropra

Do insurers ask you repeatedly for patient records or for information that you have alrea
Is the administrative hassle frustrating you and costing you time and money? By followin
clinical documentation requirements recently endorsed by the American Chiropractic As
a group of major national insurers, you can simplify the reimbursement process and help
claims are handled fairly and efficiently.

Last year, representatives from 13 of the largest insurance companies in the United Stat
representatives during the second meeting of the ACA-sponsored Claim Solutions Work
insurers at the meeting, they too are frustrated by the documentation process and comp
chiropractic clinical documentation was often unreadable, non-specific and did not effect
improvement being made by the patient.

Based on the suggestions made during this meeting and on recent trends, ACA recomm
documentation requirements to be considered as appropriate in patient record keeping.
present at the meeting agreed that using these practices could reduce clinical record rec

How will ACA's agreement with national insurers on clinical documentation affect you in

- You can avoid medical record requests from insurers if you know and use these
patient documentation.
- You can tell insurers who ask for unnecessary medical records that you have co
nationally-accepted standards endorsed by the ACA. In addition, you can point c
requests for records with disregard to these recommendations represent unfair c

Use the recommendations on the reverse of this document to help you through the reiml
and to get insurers to comply with terms they themselves have proposed as claim handli

The ACA recommends that these basic requirements be considered as appropriate clini
documentation in patient record keeping. A concerted effort by the chiropractic professio
clinical (medical) documentation will improve the frustration level and reimbursement exp
exponentially.

1. The nationally accepted HCFA billing 1500 form must be completed in detail. Th
fields must be completed.
2. Subjective, objective, and treatment (if rendered) components should be incorpo
records on each visit. A customized format is not needed but these elements mu
Any significant changes in the clinical picture (e.g. significant patient improveme
should be noted.
3. All ICD-9-CM diagnosis codes and CPT treatment and procedure codes must be
patient chart and coordinated as to the diagnoses and treatment code descripto
4. Uniform chiropractic language should be used within the profession for describir
treatment. Non-standard abbreviations and indexes should be defined.
5. Documentation for the initial (new patient) visit, new injury or exacerbation shoul
history and physical and the anticipated patient treatment plan. The initial treatm
chronic cases, should not extend beyond a 30-45 day interval. Subsequent patie
include significant patient improvement or regression if demonstrated by the pat
the patient progresses, the treatment plan needs to be reevaluated and appropr
treating doctor of chiropractic (chiropractic physician) until the patient can be rel
appropriate.

6. If the patient is disabled, a statement(s) on the extent of disability and activity re initial and subsequent visits as appropriate over the course of care.

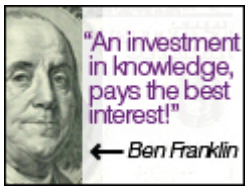
7. Records can be attached to each billing to pre-empt requests; however, it is not insurers should be contacted for preferences (i.e., No fault PIP insurers may req visit while health insurers may not).

8. All records must be legible and understandable, released within the authority giv a secure, confidential manner and in compliance with existing state (or federal) s

9. The patient name and initials of the person making the chart notation (especially offices) should appear on each page of the medical record.

10. If the above recommendations have been met, then the answers as to why the r continuing treatment are answered.

11. The insurance industry must improve their claim adjusting procedure by using cl consultants. The ACA can use its resources to assist in this initiative.



Insufficient documentation errors accounted for 0.6% of the total dollars allowed during period. This data breaks down as follows:

Carrier	DMERC	FI	QIO	Total
0.4%	0.0%	0.2%	0.0%	0.6%

In several cases of insufficient documentation, it was clear that Medicare beneficiaries re but the physician's orders or documentation supporting the beneficiary's medical conditi incomplete. While these errant claims did not meet Medicare reimbursement rules regard documentation, CMS could not conclude that the services were not provided.

In some instances, components of the medical documentation were located and maintain party facility. For instance, although a lab may have billed for a blood test, the physician the lab test maintained the medical record. If the billing provider failed to contact the thi third party failed to submit the documentation to the CERT Contractor, CMS counted the or partial insufficient documentation error.

Table 4b is a combined list of the services with the highest insufficient documentation pa rates for Carriers/DMERCs/FIs. This table does not include QIOs.

Table 4b: Top 20 Services with Insufficient Documentation: Carriers/DMERCs/FIs

Carriers (HCPCS), DMERCs (HCPCS), and FIs (Type of Bill)	Insufficient Documentatio	
	Paid Claims Error Rate	Projected Improper Payments
Hospital-outpatient (HHA-A also)(under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00) (13)	1.4%	$252,717,184
Subsequent hospital care (99232)	4.5%	$98,916,844
SNF-inpatient (including Part A) (21)	0.5%	$75,037,569
Subsequent hospital care (99233)	6.2%	$70,826,277
ESRD related svs 4+mo 20+yrs (G0317)	8.8%	$44,518,105
Chiropractic manipulation (98941)	11.3%	$41,814,339
Initial hospital care (99223)	5.0%	$35,249,167
Subsequent hospital care (99231)	7.9%	$34,753,978
Therapeutic exercises (97110)	4.4%	$28,636,453
Clinic-hospital based or independent renal dialysis facility (72)	0.5%	$25,997,646
SNF-inpatient or home health visits (Part B only) (22)	2.1%	$23,788,447
Office/outpatient visit, est (99213)	0.5%	$20,271,562
Office/outpatient visit, est (99211)	11.8%	$18,523,261
Chiropractic manipulation (98942)	20.4%	$16,035,608
Office/outpatient visit, est (99214)	0.4%	$15,418,735
Initial inpatient consult (99254)	2.1%	$14,252,568
HHA-outpatient (HHA-A also) (33)	0.3%	$13,101,799

Critical care, first hour (99291)	2.3%	$11,888,572
bls (A0428)	1.6%	$11,825,717
SNF-outpatient (HHA-A also) (23)	5.4%	$11,776,482
All Other Codes	0.6%	$550,547,101
Overall	**1.0%**	**$1,415,897,415**

The following is an example of an insufficient documentation error:

An FI paid an outpatient hospital $27.12 for three laboratory tests. CERT received the pl for the tests only. After repeated attempts by the CERT Contractor to obtain the supporti reports, the entire amount was considered an error as there was insufficient documentatic that the labs were performed.

Medically Unnecessary Services

Medically Unnecessary Services includes situations where the CERT or HPMP claim rev identifies enough documentation in the medical record to make an informed decision tha billed to Medicare were not medically necessary. In the case of inpatient claims, determi made with regard to the level of care; for example, in some instances another setting besi care may have been more appropriate. If a QIO determines that a hospital admission was due to not meeting an acute level of care, the entire payment for the admission is denied.

Medically Unnecessary Service errors accounted for 1.4% of the total dollars allowed du reporting period. This data breaks down as follows:

Carrier	DMERC	FI	QIO	Total
0.0%	0.1%	0.1%	1.2%	1.4%

For QIOs, this is predominantly related to hospital stays of short duration where services been rendered at a lower level of care. A smaller, but persistent amount of medically unn payment errors is due to unnecessary inpatient admissions associated with discharges to nursing facility.

Table 4c lists the top twenty medically unnecessary services for Carriers/DMERCs/FIs/C

Table 4c: Top 20 Medically Unnecessary Service: Carriers/DMERCs/FIs/QIOs

Addressing Misinformation Regarding Chiropractic Services and Medicare

Information for Medicare Fee-for-Service Health Care Professionals

Background

This fact sheet is being provided by the Centers for Medicare & Medicaid Services (CMS) to correct misinformation in the chiropractic community relating to Medicare and its regulations as they relate to chiropractic services. This fact sheet is informational only and represents no changes to existing Medicare policy.

In order to correct misinformation about Medicare and its regulations which exist in the chiropractic community, the American Chiropractic Association (ACA) works to check the validity of all claims and provide accurate information based on the Medicare manual system maintained by CMS, as well as information in regulatory and statutory language. CMS is providing this fact sheet which it hopes will clarify certain issues, around which there may be some confusion. The specific issues being addressed are:

Misinformation #1: There is a 12 visit cap or limit for chiropractic services.

Correction: There are no caps/limits in Medicare for covered chiropractic care rendered by chiropractors who meet Medicare's licensure and other requirements as specified in the *Medicare Benefit Policy Manual*, Chapter 15, Section 30.5. (This manual is available at *http://www.cms.hhs.gov/manuals/IOM/list.asp* on the CMS website.) There may be review screens (numbers of visits at which the Medicare Carrier or A/B MAC may require a review of documentation), but caps/limits are not allowed.

Misinformation #2: If you are a non-participating (non-par) provider, you do not have to worry about billing Medicare.

Correction: Being non-par does not mean you don't have to bill Medicare. All Medicare covered services must be billed to Medicare, or the provider could face penalties.

A non-par provider is actually a provider involved in the Medicare program who has enrolled to be a Medicare provider but chooses to receive payment in a different method and amount than Medicare providers classified as participating. Non-par providers may receive reimbursement for rendered services directly from their Medicare patients. They submit a bill to Medicare so the beneficiary may be reimbursed for the portion of the charges for which Medicare is responsible.

The Social Security Act

(Section 1862 (a)(1) at http://www.ssa.gov/OP_Home/ssact/title18/1862.htm on the Internet) provides that Medicare will only pay for items or services it determines to be "reasonable and necessary," and if those items or services can be shown to be "reasonable and necessary," then those items or services are covered and will be paid by Medicare.

It is important to note that non-par providers may choose to accept assignment, therefore, the amount paid by the beneficiary must be reported in Item 29 of the CMS 1500 claim form or its electronic equivalent. This ensures that the beneficiary is reimbursed (if applicable) prior to Medicare sending payment to the provider. Whether or not non-par providers choose to accept assignment on all claims or on a claim-by-claim basis, their Medicare reimbursement is five percent less than a participating provider, as reflected in the annual Medicare Physician Fee Schedule.

You can find a copy of the Medicare Participating Provider Agreement at *http://www.cms.hhs.gov/cmsforms/downloads/cms460.pdf* on the CMS website. The form contains important information regarding the participation process and the annual opportunity you have to make or change your participation decision. Additional information is available in the *Medicare Benefit Policy Manual* (Chapter 15; Covered Medical and Other Health Services) at *http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf* and the *Medicare Claims Processing Manual* (Chapter 12; Physician/Nonphysician Practitioners) at *http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf* on the CMS website.

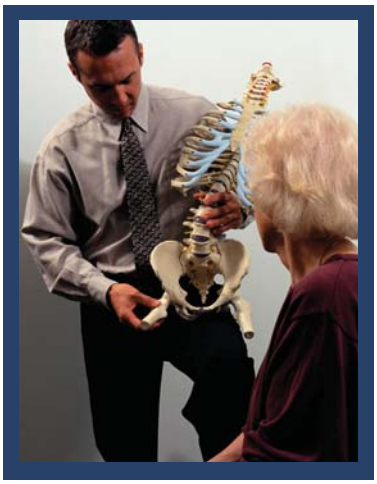
Misinformation #3: If you are a non-par provider, you will never be audited nor have claims reviewed, etc.

Correction: Any Medicare claim submitted can be audited/reviewed; the non-par or participating (par) status of the physician does not affect the possibility of this occurring. CMS audits/reviews are intended to protect Medicare trust funds and also to identify billing errors so providers and their billing staff can be alerted of errors and educated on how to avoid future errors. Correct coverage, reimbursement, and billing requirements are readily available to assist you in understanding Medicare requirements.

This information is in Medicare manuals that are at *http://www.cms.hhs.gov/Manuals/* on the CMS website. In addition, an excellent way to stay informed about changes to Medicare billing and coverage requirements is to monitor *MLN Matters Articles*, which are available at *http://www.cms.hhs.gov/MLNMattersArticles/* on the same site.

Misinformation #4: You can opt out of Medicare.

Correction: Opting out of Medicare is not an option for Doctors of Chiropractic. Note that opting out and being non-participating are not the same things. Chiropractors may decide to be participating or non-participating with regard to Medicare, but they may not opt out.

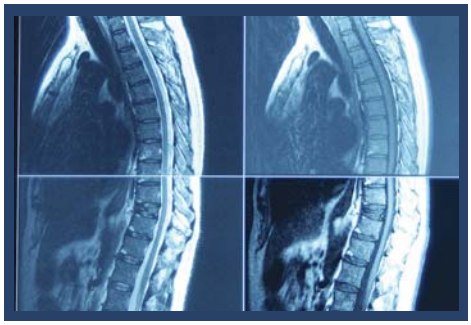


For further discussions of the Medicare "opt out" provision, see the *Medicare Benefit Policy Manual* (Chapter 15, Section 40; Definition of Physician/Practitioner) at *http://www.cms.hhs.gov/manuals/downloads/bp102c15.pdf* on the CMS website.

Misinformation #5: You should get an Advance Beneficiary Notification (ABN) signed once for each patient, and it will apply to all services, all visits.

Correction: The decision to deliver an **ABN must be based on a genuine reason to expect that Medicare will not pay for a particular service on a specific occasion** for that beneficiary due to lack of medical necessity for that service. The ABN then allows the beneficiary to make an informed decision about receiving and paying for the service. Should the beneficiary decide to receive the service, you must then submit a claim to Medicare even though you expect the beneficiary to pay and you expect that Medicare will deny the claim. For further information, see the *Medicare Claims Processing Manual* (Chapter 30) at *http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf* and

the *Medicare Benefit Policy Manual* (Chapter 15) at *http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf* on the CMS website. Also see "What Doctors Need to Know about the Advance Beneficiary Notice (ABN)" at *http://www.cms.hhs.gov/MLNProducts/downloads/ABN_READERS.pdf* on the CMS website.



Misinformation #6: Maintenance care is not a covered service under Medicare.

Correction: Spinal manipulation is a covered service under Medicare, no matter which phase of care you may be in; however, maintenance care is not **medically reasonable and necessary and therefore not reimbursable by Medicare.** Acute, chronic, and maintenance adjustments are all "covered" services, but only acute and chronic services are considered active care and may, therefore, be reimbursable. Maintenance therapy is defined (per Chapter 15, Section 30.5.B. of the *Medicare Benefit Policy Manual*) as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

See MM3449 (Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy) at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3449.pdf* on the CMS website. This article contains important information on completing claims and how to identify acute and chronic adjustments as opposed to maintenance adjustments. **The article also recommends you consider issuing an ABN to the Medicare beneficiary when you provide maintenance services.** Additional details are available in the *Medicare Benefit Policy Manual,* Chapter 15, Section 30.5 (Chiropractor's Services) at *http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf* on the CMS website.

Misinformation #7: Non-par providers do not have the same documentation requirements as par providers.

Correction: Chiropractic care has documentation requirements to show medical necessity. The participating status of the provider is irrelevant to the documentation requirements.

Specific details regarding documentation are in the *Medicare Benefit Policy Manual* (Chapter 15, Sections 30.5 and 240) at *http://www.cms.hhs.gov/manuals/downloads/bp102c15.pdf* on the CMS website. Also, see the *Medicare Claims Processing Manual* (Chapter 12, Section 220) at *http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf* on the CMS website.

Additional Information

If you have any questions regarding chiropractic issues and Medicare, please contact your Medicare Carrier or A/B MAC at its toll-free number, which may be found at *http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip* on the CMS website.

This fact sheet was prepared as a service to the public and is not intended to grant rights or impose obligations. This fact sheet may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

Medicare Benefit Policy - Basic Coverage Rules (PUB. 100-02)
Chapter 15 - Covered Medical and Other Health Services
240 - Chiropractic Services - General(Updated through Rev. 23; 10/08/04)

★ First Match

240 - Chiropractic Services - General(Updated through Rev. 23; 10/08/04)

(Rev. 1, 10-01-03)

B3-2250, B3-4118

The term “physician” under Part B includes a << chiropractor>> who meets the specified qualifying requirements set forth in §30.5 but only for treatment by means of manual manipulation of the spine to correct a subluxation.

Effective for claims with dates of services on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation.

Implementation of the chiropractic benefit requires an appreciation of the differences between chiropractic theory and experience and traditional medicine due to fundamental differences regarding etiology and theories of the pathogenesis of disease. Judgments about the reasonableness of chiropractic treatment must be based on the application of chiropractic principles. So that Medicare beneficiaries receive equitable adjudication of claims based on such principles and are not deprived of the benefits intended by the law, carriers may use chiropractic consultation in carrier review of Medicare chiropractic claims.

Payment is based on the physician fee schedule and made to the beneficiary or, on assignment, to the << chiropractor>> .

A - Verification of << Chiropractor>> ’s Qualifications

Carriers must establish a reference file of chiropractors eligible for payment as physicians under the criteria in §30.1. They pay only chiropractors on file. Information needed to establish such files is furnished by the CMS RO.

The RO is notified by the appropriate State agency which chiropractors are licensed and whether each meets the national uniform standards.

240.1 - Coverage of Chiropractic Services

(Rev. 1, 10-01-03)

B3-2251

240.1.1 - Manual Manipulation

(Rev. 1, 10-01-03)

B3-2251.1

Coverage of chiropractic service is specifically limited to treatment by means of manual manipulation, i.e., by use of the hands. Additionally, manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

No other diagnostic or therapeutic service furnished by a << chiropractor>> or under the << chiropractor>> 's order is covered. This means that if a << chiropractor>> orders, takes, or interprets an x-ray, or any other diagnostic test, the x-ray or other diagnostic test, can be used for claims processing purposes, but Medicare coverage and payment are not available for those services. This prohibition does not affect the coverage of x-rays or other diagnostic tests furnished by other practitioners under the program. For example, an x-ray or any diagnostic test taken for the purpose of determining or demonstrating the existence of a subluxation of the spine is a diagnostic x-ray test covered under §1861(s)(3) of the Act if ordered, taken, and interpreted by a physician who is a doctor of medicine or osteopathy.

Manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

Effective for claims with dates of service on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation. However, an x-ray may be used for this purpose if the << chiropractor>> so chooses.

The word "correction" may be used in lieu of "treatment." Also, a number of different terms composed of the following words may be used to describe manual manipulation as defined above:

- Spine or spinal adjustment by manual means;
- Spine or spinal manipulation;
- Manual adjustment; and
- Vertebral manipulation or adjustment.

In any case in which the term(s) used to describe the service performed suggests that it may not have been treatment by means of manual manipulation, the carrier analyst refers the claim for professional review and interpretation.

240.1.2 - Subluxation May Be Demonstrated by X-Ray or Physician's Exam

(Rev. 1, 10-01-03)

B3-2251.2

Subluxation is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact.

A subluxation may be demonstrated by an x-ray or by physical examination, as described below.

1. Demonstrated by X-Ray

An x-ray may be used to document subluxation. The x-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment. Unless more specific x-ray evidence is warranted, an x-ray is considered reasonably proximate if it was taken no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment. In certain cases of chronic subluxation (e.g., scoliosis), an older x-ray may be accepted provided the beneficiary's health record indicates the condition has existed longer than 12 months and there is a reasonable basis for concluding that the condition is permanent. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

2. Demonstrated by Physical Examination

Evaluation of musculoskeletal/nervous system to identify:

- Pain/tenderness evaluated in terms of location, quality, and intensity;
- Asymmetry/misalignment identified on a sectional or segmental level;
- Range of motion abnormality (changes in active, passive, and accessory joint movements resulting in an increase or a decrease of sectional or segmental mobility); and
- Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament.

To demonstrate a subluxation based on physical examination, two of the four criteria mentioned under "physical examination" are required, one of which must be asymmetry/misalignment or range of motion abnormality.

The history recorded in the patient record should include the following:

- Symptoms causing patient to seek treatment;
- Family history if relevant;
- Past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history);
- Mechanism of trauma;
- Quality and character of symptoms/problem;
- Onset, duration, intensity, frequency, location and radiation of symptoms;
- Aggravating or relieving factors; and

- Prior interventions, treatments, medications, secondary complaints.

A - Documentation Requirements: Initial Visit

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History as stated above.

2. Description of the present illness including:

   - Mechanism of trauma;
   - Quality and character of symptoms/problem;
   - Onset, duration, intensity, frequency, location, and radiation of symptoms;
   - Aggravating or relieving factors;
   - Prior interventions, treatments, medications, secondary complaints; and
   - Symptoms causing patient to seek treatment.

These symptoms must bear a direct relationship to the level of subluxation. The symptoms should refer to the spine (spondyle or vertebral), muscle (myo),bone (osseo or osteo), rib (costo or costal) and joint (arthro)and be reported as pain (algia), inflammation (itis), or as signs such as swelling, spasticity, etc. Vertebral pinching of spinal nerves may cause headaches, arm, shoulder, and hand problems as well as leg and foot pains and numbness. Rib and rib/chest pains are also recognized symptoms, but in general other symptoms must relate to the spine as such. The subluxation must be causal, i.e., the symptoms must be related to the level of the subluxation that has been cited. A statement on a claim that there is "pain" is insufficient. The location of pain must be described and whether the particular vertebra listed is capable of producing pain in the area determined.

3. Evaluation of musculoskeletal/nervous system through physical examination.

4. Diagnosis: The primary diagnosis must be subluxation, including the level of subluxation, either so stated or identified by a term descriptive of subluxation. Such terms may refer either to the condition of the spinal joint involved or to the direction of position assumed by the particular bone named.

5. Treatment Plan: The treatment plan should include the following:

   - Recommended level of care (duration and frequency of visits);
   - Specific treatment goals; and
   - Objective measures to evaluate treatment effectiveness.

6. Date of the initial treatment.

B - Documentation Requirements: Subsequent Visits

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History

    - Review of chief complaint;
    - Changes since last visit;
    - System review if relevant.

2. Physical exam

    - Exam of area of spine involved in diagnosis;
    - Assessment of change in patient condition since last visit;
    - Evaluation of treatment effectiveness.

3. Documentation of treatment given on day of visit.

240.1.3 - Necessity for Treatment

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2251.3

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam, as described above.

Most spinal joint problems fall into the following categories:

• Acute subluxation-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical exam as specified above. The result of chiropractic manipulation is expected to be an improvement in, *or arrest of progression,* of the patient's condition.
• Chronic subluxation-A patient's condition is considered chronic when it is not expected to *significantly improve or be resolved with further treatment* (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, *without expectation of additional objective clinical improvements,* further manipulative treatment is considered maintenance therapy and is not covered.

For Medicare purposes, a << chiropractor>> must place an AT modifier on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However the presence of the AT modifier may not in all instances indicate that the

service is reasonable and necessary. As always, contractors may deny if appropriate after medical review.

A - Maintenance Therapy

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, *or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied. Chiropractors who give or receive from beneficiaries an ABN shall follow the instructions in Pub. 100-04, Medicare Claims Processing Manual, Chapter 23, section 20.9.1.1 and include a GA (or in rare instances a GZ) modifier on the claim.*

B – Contraindications

Dynamic thrust is the therapeutic force or maneuver delivered by the physician during manipulation in the anatomic region of involvement. A relative contraindication is a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. The following are relative contraindications to dynamic thrust:

- Articular hyper mobility and circumstances where the stability of the joint is uncertain;
- Severe demineralization of bone;
- Benign bone tumors (spine);
- Bleeding disorders and anticoagulant therapy; and
- Radiculopathy with progressive neurological signs.

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

- Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis;
- Acute fractures and dislocations or healed fractures and dislocations with signs of instability;
- An unstable os odontoideum;
- Malignancies that involve the vertebral column;
- Infection of bones or joints of the vertebral column;
- Signs and symptoms of myelopathy or cauda equina syndrome;
- For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and
- A significant major artery aneurysm near the proposed manipulation.

240.1.4 - Location of Subluxation

(Rev. 1, 10-01-03)

B3-2251.4

The precise level of the subluxation must be specified by the << chiropractor>> to substantiate a claim for manipulation of the spine. This designation is made in relation to the part of the spine in which the subluxation is identified:

Area of Spine	Names of Vertebrae	Number of Vertebrae	Short Form or Other Name
Neck	Occiput	7	Occ, CO
	Cervical		C1 thru C7
	Atlas		C1
	Axis		C2
Back	Dorsal or	12	D1 thru D12
	Thoracic		T1 thru T12
	Costovertebral		R1 thru R12
	Costotransverse		R1 thru R12
Low Back	Lumbar	5	L1 thru L5
Pelvis	IIii, r and 1		I, Si
Sacral	Sacrum, Coccyx		S, SC

In addition to the vertebrae and pelvic bones listed, the Ilii (R and L) are included with the sacrum as an area where a condition may occur which would be appropriate for chiropractic manipulative treatment.

There are two ways in which the level of the subluxation may be specified.

- The exact bones may be listed, for example: C5, C6, etc.
- The area may suffice if it implies only certain bones such as: Occipito-atlantal (occiput and C1 (atlas)), lumbo-sacral (L5 and Sacrum), sacro-iliac (sacrum and ilium).

Following are some common examples of acceptable descriptive terms for the nature of the abnormalities:

- Off-centered
- Misalignment
- Malpositioning
- Spacing - abnormal, altered, decreased, increased
- Incomplete dislocation
- Rotation
- Listhesis - antero, postero, retro, lateral, spondylo

- Motion - limited, lost, restricted, flexion, extension, hyper mobility, hypomotility, aberrant

Other terms may be used. If they are understood clearly to refer to bone or joint space or position (or motion) changes of vertebral elements, they are acceptable.

240.1.5 - Treatment Parameters

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2251.5

The << chiropractor>> should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time. Acute subluxation (e.g., strains or sprains) problems may require as many as three months of treatment but some require very little treatment. In the first several days, treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.

Chronic spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already "set" and fibrotic tissue has developed. This condition may require a longer treatment time, but not with higher frequency.

Some chiropractors have been identified as using an "intensive care" concept of treatment. Under this approach multiple daily visits (as many as four or five in a single day) are given in the office or clinic and so-called room or ward fees are charged since the patient is confined to bed usually for the day. The room or ward fees are not covered and reimbursement under Medicare will be limited to not more than one treatment per day.

Section Revision History
240 - Chiropractic Services - General (Prior to Rev. 23; Eff. 10/01/04)
240 - Chiropractic Services - General (Prior to Rev. 18; Eff. 10/01/04)
240 - Chiropractic Services - General (Prior to Rev. 12; Eff. 10/01/04)

CMS

CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE ADMINISTRATIVE CONTRACTOR

WORKLOAD IMPLEMENTATION HANDBOOK

MEDICARE CONTRACTOR MANAGEMENT GROUP

03/01/07

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TABLE OF CONTENTS

Chapter 1: INTRODUCTION

1.1 Medicare Administrative Contractor Workload Implementation Handbook

This handbook was prepared by CMS to assist the Medicare Administrative Contractor (MAC) in moving data, records, and operational activities from current Medicare carriers and intermediaries in order to perform its Medicare contractual obligations. It represents a compilation of best practices, lessons learned, and over 25 years of CMS experience in overseeing Medicare workload transitions. The handbook describes the basic responsibilities and processes required for a MAC to assume Medicare claims administration functions. While both the MAC and the departing carriers and intermediaries are responsible for accomplishing various activities during the transition, this handbook is intended for use by the incoming MAC. A similar Carrier/Intermediary Closeout Handbook has been developed for outgoing Medicare carriers and intermediaries.

Every Medicare workload transition will vary depending on the unique circumstances and environment of this Medicare contractors involved. There may be activities and processes described in the handbook that will not be applicable to a specific implementation. There may also be activities that will need to be performed that the handbook does not cover. The handbook cannot identify and address all of the variations that may occur during a workload transition, nor all of the tasks for which the MAC will be responsible. However, it will provide the framework for a workload implementation and guidance in addressing situations as they arise.

1.1.1 Chapters

The handbook is comprised of 14 chapters and 9 exhibits as follows:

1. **Chapter 1**: **Introduction** provides an introduction to the Handbook and the goals for a successful workload transition.

2. **Chapter 2: CMS Organization** provides information on the duties and responsibilities of CMS's transition oversight staff.

3. **Chapter 3: Getting Started** describes the activities that are necessary to start the implementation process. It discusses establishment of the implementation team, kickoff meetings, and the organization and function of transition workgroups. The chapter also addresses initial notification activities.

4. **Chapter 4: Implementation Management** discusses the approach that a MAC may take for the implementation project. It includes the assessment of the outgoing contractor's Medicare operation and a discussion on information and deliverables required from the carrier/intermediary.

5. **Chapter 5: Obtaining Resources and Establishing Infrastructure** provides helpful information about personnel and facilities preparation. The chapter also covers hardware/software and telecommunication requirements, data center information, and electronic data interchange (EDI).

6. **Chapter 6: Transfer of Carrier/Intermediary Operations** describes the activities associated with moving the actual workload and Medicare functions of the carrier or intermediary. This includes analyzing the various functional areas, file transfer activities, asset inventory, and miscellaneous operational considerations.

7. **Chapter 7: Interaction with Other Transition Organizations** discusses the major organizations with which the MAC will work during the implementation and the basic responsibilities of each.

8. **Chapter 8: Testing** discusses the establishment of a test plan. It also describes the various tests that the MAC can perform in order to ensure that it will be able to process claims and perform its Medicare functions.

9. **Chapter 9: Cutover** covers the actual migration of records, files, and data (both physically and electronically) to the MAC, as well as any resources and infrastructure. The chapter also provides information on cutover plans, system dark days, and the reduction of the payment floor.

10. **Chapter 10: Post-Cutover** describes the activities that occur after cutover, including workload reporting and lessons learned.

11. **Chapter 11: CMS Monitoring Requirements** provides information on the various meetings that are necessary during a transition. It also describes the reporting requirements so that CMS may monitor the MAC's implementation progress.

12. **Chapter 12: Communications** discusses the approach and tasks associated with providing information about the transition to all direct and indirect stakeholders in the transition. This includes providers, beneficiaries, trading partners, medical and specialty groups, government officials, advocacy groups, and other interested parties.

13. **Chapter 13: Financial Processes** provides information on the financial activities required to move the Medicare workload. It discusses cash management and banking tasks, the accounts receivable reconciliation, and 1099 issues. There is also a section that provides information on vouching protocols.

14. **Chapter 14: Risk Management** discusses risk management processes including risk assessment, risk mitigation, and contingency plans.

1.1.2 Exhibits

Exhibit 1 Transition Phases and Terminology

Exhibit 2 MAC Contract Administrative Structure

Exhibit 3 Major Tasks and Activities Associated with a Workload Transition

Exhibit 4 Outgoing Contractor Information/Documentation

Exhibit 5 Files to be Transferred to a Medicare Administrative Contractor

Exhibit 6 Sample Workload Report

Exhibit 7 MAC Workload Implementation Meeting and Documentation Guide

Exhibit 8 Glossary

Exhibit 9 Abbreviations

1.2 Transition Phases

A Medicare workload transition involves three major participants: the incoming contractor (MAC), the outgoing contractor (carrier or intermediary) and CMS. Each transition has three major phases. For a MAC, the three major phases of a Medicare workload transition are identified as: pre-award, implementation, and post-cutover.

The **pre-award phase** is comprised of the activities associated with preparing and submitting a MAC proposal. The **implementation phase** covers the activities associated with establishing a MAC operation and the transfer of data, records, and functions from the various carriers and intermediaries within its jurisdiction. It begins with the award of a MAC contract and ends with the last cutover from an outgoing contractor. The **post-cutover phase** begins with the operational start date and continues for a period of time, usually three months. During this time CMS closely monitors MAC operations to determine if the implementation was successful and to ensure that all implementation issues have been resolved.

This handbook provides information that will assist the MAC in all three phases of the transition. However, its primary focus is on the **implementation** and **post-cutover** phases of the incoming contractor. **Exhibit 1** provides a graphic representation of terminology for the major transition participants.

1.3 Segment Implementations

The establishment of a fully operational MAC jurisdiction will involve a number of segment implementations, depending on the number of Medicare carriers and intermediaries that currently serve the states within the jurisdiction. Each segment implementation involves the movement of Medicare data, files, and functions from an existing Medicare carrier or intermediary to the MAC. In the past, workload implementation periods have ranged from 3-8 months, depending on the size of the outgoing contractor and numerous other factors. The length of the segment

implementations and the sequence of individual segment implementations must be developed using the requirements and assumptions provided in the MAC Request for Proposals (RFP) and incorporated into the MAC's Jurisdiction Implementation Project Plan, which will be approved by CMS.

The MAC will begin to perform Medicare functions as soon as the first segment cutover has occurred. This will be the Segment Operational Start Date. As each segment cutover in the MAC jurisdiction occurs, there will be another Segment Operational Start Date and the MAC's Medicare administrative responsibilities will expand over a wider area of its jurisdiction until it is fully operational in all states within its jurisdiction. This will be the Jurisdiction Operational Start Date, which is defined as the date when Medicare functions are no longer performed by any carrier or intermediary within the MAC jurisdiction.

1.4 Terminology

For purposes of this handbook, the term "**outgoing contractor**" refers to a carrier and/or fiscal intermediary (or simply intermediary) that is performing Medicare functions under Title XVIII of the Social Security Act. The terms "outgoing contractor" and "carrier/intermediary" are used interchangeably throughout this document.

The MAC who will be assuming the Medicare functions of the outgoing carrier or intermediary is referred to as the "**incoming contractor**." Both "MAC" and "incoming contractor" are used interchangeably.

The term "**provider**" is used in the broad sense of the word, meaning anyone providing a Medicare service; i.e., institutional provider, physician, non-physician practitioner, or supplier.

The term "**transition**" is defined as the period of time that encompasses the movement of Medicare operations from a carrier/intermediary to a MAC. The term "**implementation**" is used for those activities performed by the incoming MAC during a transition. The term "**closeout**" is used for those activities performed by the outgoing carrier/intermediary. However, in general usage, the term "transition" is often use to refer to MAC "implementation" and carrier/intermediary "closeout" activities.

Any reference to days in this handbook refers to **business days** unless otherwise noted.

1.5 Goals of a Successful Workload Transition

All of the organizations involved in a workload transition have a responsibility to ensure that the transition is conducted properly and that their contractual obligations are met. While each component has different roles and responsibilities during a transition, the goals remain the same:

- There is minimal disruption to beneficiaries;
- There is minimal disruption to providers, physicians and suppliers;

- There is no disruption of claims processing and Medicare operations;
- The transition is completed on schedule within the required time period;
- Actual costs represent effective and efficient use of resources; and,
- All parties with an interest in the transition (whether direct or indirect) are kept informed of the transition's status and progress.

In order to accomplish these goals, there must be proper project planning and management by the Medicare Administrative Contractor, maintenance of existing Medicare operations by the outgoing carrier or intermediary, and comprehensive oversight by CMS. All parties involved in the transition must cooperate fully and communicate constantly with all other parties at every level. This handbook will assist the MAC in achieving its transition goals and help it meet its contractual obligations during the operational period.

Chapter 2: CMS ORGANIZATION

CMS will have a number of individuals responsible for overseeing the implementation activities of the MAC and the closeout activities of the carrier/intermediary. Listed below are the CMS individuals who will monitor MAC implementation activities, along with a description of their responsibilities. Also discussed are the CMS individuals who will be responsible for the closeout activities of the outgoing carrier/intermediary's Title XVIII contract.

2.1 CMS MAC Contract Transition Personnel

The following individuals will be responsible for monitoring the implementation and/or operational activities of the Medicare Administrative Contractor. They may also interact with the carrier/intermediary in various meetings and workgroups. Except for the Segment Implementation Manager, CMS MAC contract personnel will not normally be involved with carrier/intermediary closeout activities during the transition. A CMS administrative organizational chart for the MAC contracts is shown in **Exhibit 2.**

2.1.1 MAC Contracting Officer

The MAC Contracting Officer (CO) has the overall responsibility for the incoming Medicare Administrative Contractor and is the only person authorized to enter into and bind the government by contract. He/she is the individual that negotiates and prepares the MAC contract document, modifies any terms or conditions of the contract, accepts delivered services, and approves vouchers for payment. While a single person could serve as both the carrier/intermediary CO and the MAC Contracting Officer, in the present CMS organizational structure they are two different people.

2.1.2 MAC Project Officer

The MAC Project Officer (PO) serves as the first point of contact for the MACs. He/she is the focal point for exchange of information and the receipt of programmatic approvals on deliverables and other work under the MAC contract. The PO is the technical representative of the MAC Contracting Officer and provides technical direction to the MAC, as necessary, in all the business functions contained in the MAC statement of work. He/she also monitors the performance of the MAC under the contract and reviews payment vouchers. The PO may designate various Business Function Leaders (BFLs) and technical monitors (TMs) to support his/her effort.

2.1.3 MAC Jurisdiction Transition Coordinator

The Jurisdiction Transition Coordinator (JTC) will serve as the PO's representative for the overall MAC jurisdiction implementation. The JTC will manage CMS's oversight of the jurisdiction transition and coordinate MAC implementation activities with the carrier/

intermediary Contractor Managers and the functional contract Project Officers. He/she will resolve issues involving the various segment transitions within the jurisdiction. In addition, the JTC will review vouchers for jurisdiction implementation activities and provide recommendations to the Project Officer. The JTC will also provide guidance to the MAC and the Segment Implementation Manager, perform problem solving/trouble shooting on a jurisdiction level, and be responsible for reporting to senior management.

2.1.4 MAC Segment Implementation Manager

For each segment transition within a jurisdiction, there will be a Segment Implementation Manager (SIM) who will be responsible for monitoring, trouble-shooting, problem solving, and reporting segment implementation activities. The SIM will work with the outgoing carrier/intermediary's Contractor Manager and Contracting Officer, as well as the MAC Project Officer, to manage and coordinate all of the segment transition activities of the carrier/intermediary and MAC. He/she will also provide input on technical issues, schedules, and payment vouchers.

2.1.5 Business Function Lead

Business Function Leads (BFLs) will assist the Project Officer and will serve as the technical representative for their specific business function within the MAC contract. They will assist the PO with specific functional inquires and technical issues. They will also monitor and analyze activities and deliverables. In addition, they will review monthly invoices and vouchers pertaining to their area and make payment recommendations to the PO. The BFL is not authorized to direct any technical changes or make any contractual commitments or changes on CMS's behalf.

2.1.6 Technical Monitor

Technical Monitors (TMs) may be designated to work with the BFL and/or the Project Officer on an as needed basis to monitor and evaluate specific activities within an overall functional area.

2.2 CMS Carrier/Intermediary Transition Personnel

The following are the key CMS individuals (along with the abovementioned Jurisdiction Transition Coordinator and Segment Implementation Manager) that the carrier/ intermediary will have contact with for the activities related to the transfer of its Medicare operations, files, and data to the incoming Medicare Administrative Contractor.

2.2.1 Carrier/Intermediary Contracting Officer

The carrier/intermediary Contracting Officer has the administrative responsibility for the outgoing contractor's Title XVIII Medicare contract. The carrier/intermediary Contracting Officer has overall responsibility for the carrier/intermediary's closeout activities and negotiating termination and transition costs.

2.2.2 Contractor Manager

The Contractor Manager is the CMS individual responsible for monitoring the day-to-day operational activities of the outgoing contractor. He/she will be responsible for ensuring that the carrier/intermediary continues to maintain its overall operation and performance during the closeout period. The Contractor Manager will work closely with the Segment Implementation Manager to ensure that the carrier/intermediary cooperates with the MAC during the transition and that all Medicare files, records, and data are successfully transferred to the incoming Medicare Administrative Contractor.

Chapter 3: GETTING STARTED

3.1 Contract Award

The MAC Contracting Officer will place a call to inform the MAC of contract award. This will start the implementation phase of the transition. Unsuccessful offerors will also be notified and CMS will issue a press release. The MAC may also want to issue its own press release.

3.2 Post-Award Orientation Conference

A post-award orientation conference with the MAC may be called by the Contracting Officer after notification of contract award. It will usually be held within 10 days after contract award. The CO will determine the time and location of the meeting, prepare the agenda, and notify the participants. The conference may be held in conjunction with the jurisdiction kickoff meeting (see **Chapter 3.6**).

The purpose of the conference is to achieve a clear and mutual understanding of all contractual provisions and requirements. The CO must ensure that the MAC understands the roles of Government personnel who will be involved in administering the MAC contract and the quality assurance procedures that will be applied. Participants may discuss special contract provisions, identify and resolve any potential problems, and review the implementation schedule. Procedures for vouchering and the processing of change orders will be reviewed. The upcoming jurisdiction and segment kickoff meetings may also be discussed.

Although the MAC will have proposed an implementation schedule based on the information provided in the Request for Proposal (RFP), it is possible that CMS may direct the MAC to revise its overall jurisdiction plan based on schedule changes or other considerations. Should this be necessary, CMS will negotiate with the MAC to reach agreement on a revised schedule and any additional costs associated with the changes. The contract will be modified accordingly.

3.3 Initial Transition Activities

The MAC will have a transition team as described in its proposal and composed of a Project Manager and staff who are responsible for the major implementation tasks shown in the Jurisdiction and Segment Implementation Project Plans. A team member will usually be assigned to be the lead for each major implementation task or workgroup and will report directly to the Project Manager.

An internal meeting with all key MAC transition members (project manager, transition analysts, potential workgroup leaders, subject matter experts) should be held after contract award to plan and prepare for the upcoming project, the kick-off meeting, and to

handle administrative details. Also, the project organization and workgroup structure may need to be revised and/or expanded. A final organization chart and contact list should be developed in preparation for the kickoff meeting. There may also be additional transition tasks or CMS-directed schedule date changes that are identified, and the MAC should begin to baseline the implementation project plan. Tools to assist the team in managing the project can be identified and discussed. Team training in project plan monitoring, financial tracking (data, cost analysis), and word processing (reports, general project communication) may be helpful. Internal procedures for meetings and communications should be agreed upon.

The outgoing carriers/intermediaries will also form a closeout team composed of a Project Manager and staff responsible for contract closeout activities. Information regarding the outgoing contractors' closeout team will be provided at the kickoff meeting. The outgoing contractors' closeout team shall work directly with the MAC for the orderly transfer of all Medicare functions.

CMS will also form a transition team as described in **Chapter 2.** CMS's contract administration structure for the MAC contract is graphically depicted in **Exhibit 2.**

3.4 Contact with Outgoing Contractor

After CMS has publicly announced the contract award and implementation schedule, contact may be made with the outgoing contractors in the jurisdiction. The contact is usually made by upper management, and will serve as an introduction to the MAC. Areas of discussion may include the outgoing contractor's plans for its Medicare employees, any proposed retention of staff by the incoming MAC, communication, commitment of the organizations, any schedule date changes that may have occurred after the RFP was issued, and any immediate problems or issues that need to be addressed before the kickoff meeting. The MAC may also make introductory calls to the major professional organizations (medical societies, hospital associations, specialty groups, etc.) in each of the segments within the jurisdiction, with follow-up calls as each segment implementation begins. Congressional contacts may also prove to be beneficial.

In the days immediately following the award announcement, the MAC must understand that it may difficult to have extensive contact with certain outgoing contractors because they may still be trying to deal with the loss of the jurisdiction contract. Those contractors may be assessing their options, addressing employee concerns, or preparing to protest the award, and there may be very little information initially provided. The incoming MAC must take this into consideration in regard to the timing of its initial contact and what it will be communicating. If an outgoing contractor did not bid for the jurisdiction, general communication should not be an issue.

3.5 Outgoing Contractor Employee Notification

After award announcement, the carriers and intermediaries who were not awarded the contract will begin to plan for their contract closeout. If the MAC has an interest in hiring any of the outgoing contractor's Medicare employees, it should inquire about the

carrier/intermediary's plans for those employees. If the outgoing contractor will not be retaining its Medicare staff, the MAC should inform the carrier/intermediary that it may be interested in making employment offers to some or all of the carrier/intermediary's employees. Plans should be coordinated with the carrier/intermediary to notify the employees affected and a face-to-face meeting should be scheduled as soon as possible. Employee commitment to the transition is critical and knowledge that they will be retaining their jobs will greatly facilitate the transition process and alleviate fears regarding employees' futures.

If the MAC will be hiring a significant number of outgoing contractor staff, a human resources representative from the MAC may be able to be located at the carrier/ intermediary's site to address employee concerns and provide detailed information on benefits and employment. An analysis of the outgoing contractor's employee benefits should be done as soon as possible and an explanation of the differences between the two organizations' benefits should be available to outgoing contractor staff. Meetings should be scheduled with staff to be hired to discuss differences in benefits and provide information on what will occur at cutover. The MAC may also be able to contribute transition-related articles to the outgoing contractor's employee newsletter.

3.6 Jurisdiction Kickoff Meeting

While the post-award orientation conference is a meeting between just CMS and the MAC, the jurisdiction kickoff meeting is intended for all parties involved in any of the segment transitions that will occur within the jurisdiction.

3.6.1 Purpose

The jurisdiction kickoff meeting provides the opportunity for all parties to meet face-to-face to discuss the approach to the project, go over the schedule, review roles and responsibilities, and address any concerns about the upcoming transitions. Teleconferencing should be available for individuals or organizations that will not attend in person.

3.6.2 Logistics

The jurisdiction kickoff meeting is generally held 10-15 days after contract award and after any post-award orientation conference (see **Chapter 3.2**). The meeting may be held in conjunction with the post-award orientation conference and/or a segment kickoff meeting (see **Chapter 3.7**). The MAC will be responsible for providing facilities for the meeting, providing toll-free phone lines for off-site participants, developing an agenda (with input from other participants), and notifying attendees, unless the meeting is held at the CMS headquarters building. If the meeting will be held at CMS, then CMS would be responsible for the facilities and other meeting logistics. Meeting minutes and an attendance sheet/contact list shall be prepared by the MAC and sent to all those in attendance.

3.6.3 Participants

All parties directly involved in the jurisdiction transition should be invited to attend: CMS, the MAC, the outgoing carriers and intermediaries, the Blue Cross and Blue Shield Association (for fiscal intermediaries with Plan agreements), any standard front end contractor, applicable data centers, any organization(s) that will be moving Medicare workload to the MAC during the transition or will process some portion of the outgoing contractors' workload, standard system maintainers, and functional contractors such as the Program Safeguard Contractor (PSC), Qualified Independent Contractor (QIC), and 1-800-MEDICARE. Attendance may be in person or via teleconference.

The purpose of the jurisdiction kickoff meeting is to understand, organize, and coordinate activities among all parties involved in the transition. While there may be some detailed technical discussion, the meeting is not intended to be at the level that would require all of the functional and technical leads that the MAC may be utilizing in its implementation effort; those individuals would be expected to attend the segment kickoff meetings. Attendance at the jurisdiction meeting would normally include the MAC's operational and implementation project directors, with a limited number of implementation project team members, such as the IT lead.

3.6.4 Topics of Discussion

The jurisdiction kickoff meeting will give a high level overview of the transition project. The MAC will be requested to make a corporate introduction and describe its Medicare organization and operation. The MAC should also discuss its implementation team/ organization, its implementation approach, and provide an overview of its Jurisdiction Implementation Project Plan (see **Chapter 4.3.1**). Much of the information presented would normally be drawn from the MAC's proposal or any oral presentations supporting the proposal. Other entities involved in the project will also provide an overview of their transition activities and interactions with the MAC. In addition, CMS will review implementation expectations and requirements and discuss its transition team organization.

Transition workgroups will be a key topic of discussion at the meeting (see **Chapter 3.8**). The MAC will be expected to work with the outgoing contractors and other attendees to establish jurisdiction-wide transition workgroups and agree on their basic responsibilities. These jurisdiction-wide workgroups and their functions should be in place for the entire jurisdiction implementation. All outgoing contractors involved in the transition will have to structure their closeout activities utilizing the workgroups. Therefore, it is critical that agreement be reached with all of the outgoing contractors as to what workgroups will be established and the major responsibilities for each.

Any Deliverables List, action item list, or problem/issue log that is developed as a result of the kickoff meeting should be distributed as soon as possible after the meeting. The Deliverables List will serve as documentation for all the information the outgoing contractors need to provide to the MAC (see **Chapter 4.13**). After the jurisdiction

kickoff meeting is completed, the MAC should review the project schedule, the Jurisdiction Implementation Project Plan (JIPP), upcoming Segment Implementation Project Plans, risk management plan, and communication plan and make any appropriate revisions based on the discussions that took place during the meeting.

3.7 Segment Kickoff Meeting

The segment kickoff meeting represents the formal start of the process of moving Medicare data, records, and operations from an outgoing carrier or intermediary to the MAC. It will be similar to the jurisdictional kickoff meeting in concept, but will be focused on the detailed technical and functional activities required for a specific segment transition.

3.7.1 Purpose

The segment kickoff meeting allows all parties involved in a segment transition to meet face-to-face to review the project expectations, discuss roles and responsibilities, and to organize and coordinate activities. The meeting will also help ensure that there is agreement among all participants regarding the tasks involved, project assumptions, and schedule. In addition, any emerging issues and/or changes that have occurred since contract award will be discussed, as will any lessons learned from prior segment transitions within the jurisdiction or other jurisdictions. Organizations that cannot attend in person may do so by teleconference.

3.7.2 Logistics

The MAC will be responsible for setting up the kickoff meeting for each segment implementation within its jurisdiction and shall consult with CMS regarding the time and location of such meetings. The meetings will generally be held at the proposed operational site of the MAC or in the vicinity of the outgoing contractor's operations. The first segment kickoff meeting will normally occur 10-15 days after contract award and may be held in conjunction with the jurisdiction kickoff meeting (see **Chapter 3.6**). Given the importance of the kickoff meeting, it is recommended that the MAC meet briefly with the CMS transition team prior to the segment kickoff meeting to discuss the agenda, materials to be handed out, and presentations that will be made.

All MACs will have to conduct multiple segment implementations in order to become fully operational. It is possible that there will be more than one segment implementation starting in the same month. If this occurs, the MAC will need to coordinate the scheduling of the kickoff meetings with CMS and the outgoing contractors of the segments. The kickoff meetings for segments that will begin after the first round of segment kickoff meetings should take place within 10 days of the scheduled start date of that segment implementation. Normally, each segment implementation will require its own kickoff meeting; however, it is possible that the integration of segments in the project plan would allow for one kickoff meeting to cover multiple segment implementations.

The MAC will be responsible for setting up the facilities for the meeting, providing toll-free phone lines for off-site participants, developing an agenda (with CMS input), and notifying attendees. Meeting minutes and an attendance/contact list shall be prepared by the MAC and sent to all those in attendance.

3.7.3 Participants

All parties directly involved in the segment transition should be invited to attend: CMS, the MAC, the outgoing segment contractor, any organization other than the MAC that will be responsible for processing a portion of the outgoing contractor's Medicare workload, representatives from the applicable data center(s), the standard system maintainer, the Blue Cross and Blue Shield Association (for fiscal intermediaries with Plan agreements), any standard front end contractor, IT services companies, and functional contractors (PSC, QIC, 1-800-MEDICARE, etc.). Attendance may be in person or via teleconference. All of the key members of the MAC's segment implementation team should be in attendance and most, if not all, of the anticipated workgroup heads present.

Since detailed information and operational procedures may be discussed, attendance at the segment kickoff meetings should include more technical and functional experts than necessarily would be in attendance at the jurisdiction kickoff meeting. The MAC must have representatives present with the authority to establish project commitments and approvals on behalf of the organization.

3.7.4 Topics of Discussion

The MAC will be requested to make a corporate introduction, describe its Medicare organization, and discuss its implementation team and structure. This presentation would be similar to the one made at the jurisdiction kickoff meeting, but geared to the specific segment implementation. The Segment Implementation Project Plan (SIPP) should be distributed (see **Chapter 4.3.2**) and an overview of the plan and the MAC's implementation approach provided. Input from the meeting attendees will be used by the MAC to prepare the "baseline" SIPP that will be submitted to CMS. The outgoing carrier/intermediary will also make a presentation regarding its organization, closeout plan, and closeout structure. Other involved parties will provide an overview of their activities and participation in the transition. CMS will discuss its transition organization and team and review reporting requirements (see **Chapter 11**). The meeting should also cover areas of the transition that need immediate attention, such as human resources, connectivity, and industry/provider communications.

The jurisdiction kickoff meeting will have already established the individual transition workgroups and the scope of their functions. During the segment kickoff meeting, there should be breakout sessions of the various workgroups with as many members as possible. If there are not enough workgroup members available, a date and time should be agreed upon for the group to initially meet and organize.

The breakout session will provide the opportunity for workgroup members to begin brainstorming, discuss transition strategy, and address any immediate issues. The group should also review implementation documents such as the JIPP and SIPP, deliverables that have been requested, dependencies, and any action items already identified in order to better define and develop the direction of the workgroup. Members should also discuss methods for accomplishing their workgroup tasks. The group should try to reach agreement on administrative details such as workgroup meeting/teleconference dates and times, if possible.

Any deliverable, action item, or issues log that is developed or added to an existing document as a result of the segment meeting should be distributed as soon as possible. After each segment kickoff meeting is completed, the MAC should review the project schedule, the implementation project plans, the risk management plan, and communication plan to make any necessary revisions based on the meeting discussions.

3.8 Transition Workgroups

Transition workgroups are the basic organizational structure for conducting the day-to-day activities of the transition. They have proven to be the key to successful workload transitions.

3.8.1 General

Transition workgroups are established to facilitate the process of transferring the outgoing contractor's Medicare workload to the MAC. The scope of a particular workgroup may vary from one workload transition to another for a variety of reasons, including the MAC's business structure, the jurisdiction project plan/approach, and outgoing contractor considerations. However, agreement must be reached with all of the outgoing contractors and the MAC regarding what workgroups will be established jurisdiction-wide and what their specific responsibilities will be. Workgroups are generally established for infrastructure activities (facilities, hardware, human resources, telecommunications, etc.), functional program areas (MSP, audit and reimbursement, medical review, etc.), and overall project administration tasks (project management, financial, etc.).

Since there could be a number of segment implementations occurring simultaneously, the MAC may find that it is necessary to have separate segment workgroups established within the overall jurisdiction-wide workgroup. Functional areas such as MSP, MR, or Provider Relations may have individual workgroups established for each segment implementation within the jurisdiction. If there are separate segment workgroups, the overall workgroup head must coordinate the activities of each to ensure consistency and schedule compliance.

3.8.2 Participants

Experienced staff from the MAC, the outgoing contractor, and other involved organizations should be assigned to the various workgroups that will be formed to oversee specific transition tasks or functional areas. Of course, members will only be assigned if the organization has some involvement with the workgroup's function. CMS will normally be represented on every workgroup. The MAC should try to keep the same workgroup members for the duration of the segment implementations, especially the workgroup heads.

The MAC will be responsible for appointing the workgroup head. Duties of the workgroup head include: 1) organizing, directing and coordinating all workgroup activities; 2) maintaining the applicable portions of the implementation project plan and associated action items; 3) analyzing and comparing workflow processes and documentation; 4) developing and responding to deliverables/action items; and 5) reporting and documentation.

The overall responsibilities of the various workgroups will remain the same throughout the transition. Participation in the workgroups amongst the outgoing contractor and other entities may vary; however, the workgroup should continue under MAC direction until all segments have been implemented and the MAC is fully operational**.**

Generally, there are three ways that an outgoing contractor (or other entity) may interact with the various workgroups: 1) it may be a part of a jurisdiction-wide workgroup, joining when its segment transition begins and leaving when its transition is completed; 2) it may participate in a specific segment workgroup under the aegis of the overall jurisdiction-wide workgroup; or 3) it may not participate at all in certain workgroups. For example, if no hardware or software is being transferred to the MAC, the outgoing contractor would not need to participate in that workgroup.

3.8.3 Scope

The scope or area of responsibility for the individual workgroups will vary depending on a number of factors such as the MAC's organization or business structure, size of the outgoing contractor, business processes, and workflow structure. The actual number of workgroups varies from transition to transition, but it has been found that 8-10 workgroups generally work best. Workgroups have been established for the areas shown below, but occasionally, more specialized workgroups have been established. Contractors have also combined workgroups based on convenience or practicality. Many contractors have found it advantageous to establish subgroups within a workgroup to focus on specific areas or issues.

- Project Management
- Communications
- Systems/IT
- Telecommunications

- Beneficiary/Provider Relations
- Audit and Reimbursement
- EMC/EDI
- Medical Review
- MSP
- Operations/Claims Processing
- Provider Enrollment
- Hardware/Software
- Facilities
- Human Resources
- Financial
- Print/Reports
- Cutover

An established workgroup may not necessarily correspond directly to a major task in the MAC's Jurisdiction or Segment Implementation Project Plan. For example, a financial workgroup may be established and function throughout the transition, but financial activities and tasks may be listed under the Project Management task in the Jurisdiction or Segment Implementation Project Plan.

3.8.4 Functions

Each workgroup will identify the steps and action items necessary to successfully transfer the Medicare records, data, and operations that relate to the specific workgroup. They will be responsible for monitoring and updating the tasks listed in the Jurisdiction or Segment Implementation Project Plans that are applicable to their workgroup. Throughout the transition period, the workgroup will report their progress to the MAC project manager, resolve policy and transition issues regarding their areas of expertise, and ensure that all specific activities and deliverables have been accomplished.

Each workgroup is charged with defining the basic functions of the workgroup and establishing a work plan to address its objectives, work responsibilities, ground rules, and reporting requirements. The workgroup should maintain an issues/action item list and a deliverables log throughout the transition to insure that all items relating to the workgroup are resolved. The workgroup must have a clear understanding of the information that it must provide to other entities, as well as information and deliverables that it has requested from others. It is important that requests are precise so that time will not be lost due to misunderstanding exactly what is being asked for. The workgroups should reach an understanding of the types of issues for which they have the authority to resolve and obtain approval from the project managers of those organizations represented in the workgroup.

While some workgroup activity may start at the jurisdiction kickoff meeting, most initial activity will begin at the segment kickoff meeting. If there are not enough participants available at that meeting, the MAC must schedule an organizational meeting for the workgroup at a later date.

Initial activities for the workgroups will include brainstorming, discussion of transition strategy, taking action on any immediate issues, identifying workgroup members, and reaching agreement on meeting dates and times. The workgroup should also discuss how they will accomplish their workgroup tasks. The group will review transition materials and meeting documentation, the Jurisdiction and Segment Implementation Project Plans, any deliverables that have been requested, dependencies, action items, etc. to better define and develop the direction of its workgroup. All of these activities will be coordinated through the MAC implementation project manager

3.8.5 Communication

Workgroups should generally meet on a weekly basis, either in person or via teleconference. It will be the responsibility of the MAC to provide toll-free teleconference capability for all participants in workgroup meetings, as well as any ad hoc teleconferences or meetings.

A comprehensive workgroup meeting schedule should be developed for each segment transition. The schedule should provide a listing of all the workgroups that have been established, the workgroup leads, members, meeting days and times (normally scheduled for one hour), and the call-in numbers with corresponding pass codes. Membership of the workgroups should be finalized within a week after the segment kickoff meeting.

A workgroup agenda should normally be distributed a day before the workgroup meeting. The agenda can be in a fixed format that can be used as a minutes document after conclusion of the meeting. Workgroup meeting notes or minutes should be distributed within two business days after a meeting to allow sufficient time for required decisions to be made before the next meeting. The development and distribution of the agenda and meeting minutes/notes are the responsibility of the MAC. The notes should be reviewed at the next meeting so that all parties understand the impact of any decisions.

It is absolutely essential that there be communication between the various workgroups to ensure that each group knows what issues have been identified and the progress being made towards resolution. In some instances, the same issue will arise in several workgroups. Therefore, workgroup meeting notes need to be exchanged among the different groups, particularly for those that are handling similar or related issues. A project management workgroup could serve as a clearinghouse or forum for sharing information among the workgroups.

Chapter 4: IMPLEMENTATION MANAGEMENT

4.1 Purpose

This chapter will provide general information and guidance regarding the management of the workload implementation process. It emphasizes a number of items that the MAC should consider and will provide the framework for completing the activities detailed in succeeding chapters so that the outgoing contractor's workload may be moved successfully into the MAC operational environment.

4.2 Project Management Approach

The MAC's implementation project management approach should be reflected in the Jurisdiction and Segment Implementation Plans and the various other plans used in the implementation. While there are numerous approaches to project management, the workgroup concept as discussed in **Chapter 3** should be utilized by the MAC. CMS does not mandate any particular method or software to be used in managing implementations. It does require, however, that project plans, reports, and materials are readable using Microsoft Project, Excel, Word, or Adobe.

The MAC may also wish to establish quality assurance (QA) support to internally monitor and review activities throughout the life of the implementation project. QA will help the MAC project manager oversee the quality effort and ensure that tasks are complete and accomplished in accordance with project requirements.

4.3 Project Plans

The MAC will be responsible for developing and maintaining an overall Jurisdiction Implementation Project Plan and associated Segment Implementation Project Plans. Both documents are CMS deliverables. An accurate and complete project plan is critical to the success of a transition.

4.3.1 Jurisdiction Implementation Project Plan (JIPP)

The Jurisdiction Implementation Plan (JIPP) must detail the steps and timeframes for accomplishing all of the work defined in the SOW, as it pertains to the transfer of Medicare workloads to the MAC. The JIPP will provide an overall administrative plan and a description of all major tasks and subtasks required to transfer Medicare data, records, and operations from each carrier and intermediary segment within the jurisdiction. It may also show tasks for assuming Medicare workload from other Medicare contractors outside of the MAC's jurisdiction (e.g., out-of-jurisdiction providers being transferred during the implementation) or for other associated implementation activities such as data center migration.

The JIPP is submitted as part of the MAC's proposal and developed using the information/dates provided in the Request for Proposals (RFP). The MAC project manager and staff must thoroughly review the plan after notification of contract award and after the initial outgoing contractor assessment (see **Chapter 4.9** below). Activities that the MAC or CMS may have identified subsequent to the submission of the JIPP must be incorporated. Tasks may need to be modified or deleted if they are no longer applicable. Timeframes must be revised to correlate to the contract award date or any transition schedule changes.

The MAC must discuss its JIPP revisions with CMS and create a "baseline" document. The baseline JIPP must be provided to CMS within 30 days of contract award. This will be the "master plan" for the project and will be used by the MAC and CMS to monitor the overall progress of the jurisdiction implementation. As each Segment Implementation Project Plan is developed, the appropriate sections of the JIPP will have to be updated to incorporate any changes in tasks and/or dates. CMS approval is required for the baseline JIPP and SIPP.

CMS understands that the JIPP and SIPP are dynamic documents that will change throughout the life of the project; however, it is imperative that changes to the plans are communicated promptly to CMS.

4.3.2 Segment Implementation Project Plan (SIPP)

For each segment implementation occurring within its jurisdiction, the MAC must develop a Segment Implementation Project Plan (SIPP). The SIPP will be, in effect, an expanded and more detailed description of the implementation activities shown in the Jurisdiction Implementation Project Plan that are specific to an individual segment. As a separate document, it will be used to monitor segment implementation activities.

The extent of a segment's individual tasks and the detail required for a segment implementation will be dependent on a number of factors, including the MAC's project management approach, the extent of integration of the jurisdiction implementation, availability of existing staff or facilities, the size of the outgoing contractor, etc. However, the SIPP should provide a more detailed level of segment activity than the overall JIPP and should be the most effective way to manage the implementation of a particular segment.

A great deal of outgoing contractor information is necessary for the complete development of the MAC's SIPP. However, much of this information will not be obtained until after contract award. A draft SIPP should be available at each segment kickoff meeting. The SIPP will continue to be refined as the result of the meeting and subsequent discussions with the outgoing contractor and other organizations involved in the transition. The MAC must ensure that the SIPP is coordinated with the outgoing contractor's closeout plan. A final "baseline" SIPP should be submitted to CMS for review no later than 30 days after each segment kickoff meeting.

Since some segment implementations may be scheduled to begin immediately after contract award, it may be helpful for the MAC to develop a "skeleton" SIPP during the pre-award period so that it can quickly prepare drafts to be available at the kickoff meetings for the first round of segment implementations.

4.3.3 Implementation Project Plan Structure

Exhibit 3, Major Tasks and Activities Associated with a Workload Transition, shows a breakout of the major areas of activity that are usually required for a workload implementation. The list is not all-inclusive, and tasks/activities could be added or deleted depending on the circumstances of each jurisdiction or segment. The Jurisdiction and Segment Project Plans should show a Work Breakdown Structure (WBS) to the level commensurate with the scope of the project. As an example, the JIPP could show the various segment implementation projects as Level 1, along with overarching jurisdiction tasks such as project management, facilities, and financial. The major implementation tasks of each segment would be shown as Level 2, and subtasks as Level 3. The SIPP, however, would show the major segment implementation tasks as Level 1, subtasks as Level 2, and would normally be developed to Level 3 or 4 (or beyond), depending on the major task category and the amount of detail the MAC (or CMS) finds necessary in order to properly track and cost the activity.

Major implementation tasks could be shown in the JIPP, SIPP, or both, depending on the MAC's proposed operations. For example, if the incoming MAC will consolidate all segment operations into one facility, the tasks necessary for site acquisition and facility preparation would be shown in the JIPP and not in the SIPP. However, if the MAC will maintain multiple facilities within its jurisdiction, then it may be more appropriate for facilities tasks to be listed in the appropriate SIPP.

The JIPP and SIPP should contain, at a minimum, the following data:

- Identification Number
- Task Name
- Task Dependencies
- Planned Start Date
- Planned Finish Date
- Actual Start Date
- Actual Finish Date
- Percent Completed
- Milestones
- Responsible Party
- Comments

The JIPP and SIPP must be updated on a biweekly basis with an accompanying list of tasks completed and tasks that are not on schedule (see **Chapter 11.2.2 and 11.2.5**).

4.4 Interaction with the Outgoing Contractor

It is important to stress communication and cooperation with the outgoing carrier or intermediary. It is an integral part of any transition. Without the outgoing contractor's cooperation and support, the transition will be in jeopardy, regardless of how much time, effort and resources the MAC commits to its implementation efforts. It must be remembered that the transition will be very stressful for the outgoing contractor's organization and employees. The carrier/intermediary may be ending its segment Medicare operations not by its own choice. It could have competed for the MAC jurisdiction and lost. It might be competing on future Request for Proposals (RFPs) and the incoming MAC may be a competitor. Staff could be losing their jobs. The collegial atmosphere among Medicare contractors that was present for many years may have vanished. Many factors can come into play in the relationship between the MAC and the outgoing contractor; the MAC must be cognizant of those factors in its approach to managing the implementation.

4.5 Nomenclature

As each segment implementation gets underway, the MAC and the outgoing contractor should discuss the terminology and nomenclature used in the outgoing contractor's operation. All terms, acronyms, and files need to be well defined and clearly understood by the parties involved in the project. This will help prevent project delays, duplication of effort, and unanticipated workload being transferred at cutover.

4.6 On-Site Presence

Depending on the circumstances of the transition, on-site presence of the MAC at the carrier/intermediary's site(s) could be beneficial. Any request for on-site presence will need to be discussed with the outgoing contractor to determine if it is desirable or feasible. The MAC will need to determine how much of an on-site presence it believes is warranted at the outgoing contractor's site(s) and the timing of such presence. The MAC must understand that it is possible that the carrier/intermediary will limit access to its operation and will not provide any working or meeting space for the incoming contractor. On-site access is the sole prerogative of the outgoing contractor and is not controlled by CMS.

In certain transitions, incoming contractors have been able to have an on-site presence of some type almost on a weekly basis and have leased lodging for staff use. The MAC's subject matter experts/workgroup heads will normally be on-site at various times throughout the implementation to gather information on current processes, monitor activities, and provide assistance to the segment project manager. The amount of on-site presence will be dependent on a number of factors, but a key factor is whether or not the MAC will be hiring the outgoing contractor's staff and/or maintain a presence in the area.

4.7 Communication

A transition is a complex undertaking involving many different organizations. It is a temporary partnership and all parties need to be working toward the common goal of a successful transition. It is critical that the MAC work closely with its partners and communicate at all levels. For its part, the MAC should ensure that there is a free flow of information among all parties. The meeting and reporting requirements detailed in **Chapter 11** provide a framework for that effort.

In some transitions the parties have found it helpful to have regular informal teleconferences with just the project heads of all the organizations involved (e.g., MAC, outgoing contractor, data center, BCBSA, CMS, PSC, etc.) to keep the lines of communication open, discuss overall progress, and ease the resolution of any issues or conflicts.

If the MAC believes there is a lack of cooperation and/or communication with any entity involved in the transition, it must contact the Segment Implementation Manager or Jurisdiction Transition Coordinator to resolve its concerns.

4.8 Identification Number

The MAC will be assigned specific jurisdiction identification numbers that will be used for CMS reporting and data exchange information. Each state within the MAC's jurisdiction will have an individual number or business segment identifier (BSI) that will allow Part A and Part B workload to be reported separately by state. The process for obtaining the new number will begin as soon as the MAC contract has been awarded. CMS will be responsible for providing the MAC with the identification numbers. The numbers will be formally distributed to all necessary parties through the CMS change management process; however, the MAC should inform its data center and CWF host site of the new number as soon as it is provided by CMS.

4.9 Operational Assessment of Outgoing Contractor / Due Diligence

It is important that the MAC gather as much information as possible regarding an outgoing contractor's current processes, activities, unique arrangements, assets, documentation, and overall business operations. This will facilitate the absorption of the workload into the MAC's operational environment, help ensure a smooth transition, and lessen any impact to beneficiary and providers. This activity is known by a number of different terms: operational assessment, operational analysis, due diligence, and gap analysis. All functional areas (audit and reimbursement, medical review, claims processing, provider education, Medicare Secondary Payment, financial, appeals, customer service, etc.) and all business operations and procedures need to be analyzed.

4.9.1 Initial Activity

It is important to begin an initial assessment as soon as possible after contract award so that the information obtained may be used by the transition workgroups. Changes to the MAC's implementation approach or project plan may also be made based on assessment activities. The MAC should contact the outgoing contractor to schedule a site visit. Agreement should be reached on such items as dates, times, frequency of visits, number of staff, and availability of on-site working space for the visiting MAC. There should be a discussion of the types of information that the MAC hopes to obtain and which operational areas it would like to review. Some incoming contractors use a special team for the initial assessment, while others will use the workgroup heads and perform the assessment as part of the initial activity of the applicable workgroup. After the initial assessment has been completed, the various workgroups will continue to examine the outgoing contractor's operations throughout the implementation period.

4.9.2 Areas of Focus

The assessment and documentation of the outgoing contractor's operation should include internal policies and procedures, business processes, work flow in each functional area, files, and staff analysis. This will help in refining the MAC's resource requirements. Standard operating procedures should be reviewed, along with quality assurance processes and standards. Procedural differences and/or local variations of the claims process should be noted. Any non-compliance discovered should be brought to the attention of CMS. Workload data and inventory statistics by functional area should be obtained. The outgoing contractor's productivity rates and production capacity may also be analyzed. The MAC should assess workload in progress and obtain specifics on the amount of Medicare files and records in storage, both on-site and at remote locations.

The MAC may want to obtain Contractor Performance Evaluation (CPE) or Report of Contractor Performance (RCP) documents for the outgoing contractor, as well as any audit findings. Any internal process improvement or CMS performance improvement plan (PIP) pertaining to the outgoing could also be reviewed to obtain information on performance or quality problems. If there is a problem obtaining any of these documents, the MAC should contact the CMS Project Officer. The MAC should also determine if there are any special CMS projects, initiatives, or activities that involve the outgoing contractor and the specific time frames for completion.

4.10 Specific Assessment Activities

The following are some of the areas or activities that are normally analyzed as part of the MAC's overall assessment/due diligence:

4.10.1 Local Coverage Determinations

The outgoing contractor will provide the MAC with any Local Coverage Determinations (LCDs), formerly known as Local Medical Review Policies (LMRPs). The MAC is required

to consolidate the existing LCDs of the outgoing carriers/intermediaries within its jurisdiction so that they are the same throughout the jurisdiction. The consolidation must be completed prior to the cutover of the first segment within the jurisdiction. Therefore, the MAC should begin to analyze all LCDs as soon as possible to determine their applicability jurisdiction-wide. In consolidating the LCDs, the incoming contractor must select the least restrictive LCD from the existing LCDs on a single topic. It must also consolidate the active edits in the system related to the consolidated LCDs

The MAC must provide a minimum comment period of 45 days on any proposed revision that restricts an existing LCD and it must ensure that the effective date for the LCD change (i.e., cutover) allows for a minimum notice period of 30 days. This allows time for educating affected providers through bulletins and/or meetings/training seminars.

4.10.2 Edits

Edits verify and validate claim data and are necessary to detect errors or potential errors. Various edits are in place for every type of claim and for every step in the claims flow and adjudication process. Every Medicare carrier and intermediary must maintain certain edits in its claims processing system. However, carriers/intermediaries have had discretion with other edits in the system (known as local edits) and may choose to suppress or modify them. This means that action taken on a claim may vary among the outgoing contractors. It is possible that the same claim may be denied by one carrier/intermediary, suspended by another, or returned to the submitter by a third carrier/intermediary.

CMS requires that the MAC consolidate the existing FISS shared system edits (reason codes, local business rules, etc.) of the outgoing fiscal intermediaries so that they will be the same for the entire jurisdiction. The consolidated edits for the jurisdiction will be implemented as each fiscal intermediary segment workload is cut over. Consolidation of the MCS shared system edits is not required, but a MAC may propose to do so during the implementation period as part of its proposal.

The MAC must analyze exiting edits and determine the final consolidated edits based on its proposed criteria. The criteria should include operational efficiency, minimization of disruption to the provider community, and other pertinent factors. The single set of edits will include a single defined action for each code. All final edits must be tested prior to their implementation.

Any changes to an outgoing contractor's edits must be analyzed to determine if there will be any impact to the provider community. The MAC must discuss and coordinate any edit consolidation with CMS. **The MAC must clearly communicate any edit/processing changes to providers and submitters early and often in bulletins, special newsletters, and/or training seminars/ workshops.**

4.10.3 Outgoing Contractor Workload and Inventory

As soon as the MAC award is made, CMS will begin monitoring each outgoing contractor's performance on a weekly basis. Data obtained will include:

- receipts,
- claims processed,
- claims pending,
- claims pending over 30/60/90 days,
- claims processing timeliness,
- correspondence,
- hearings,
- cost reports,
- appeals,
- telephone service, and
- compliance reviews.

CMS will provide this workload information to the MAC along with any outgoing contractor operational issues that arise. If necessary, the MAC will take appropriate action to modify its implementation activities or risk mitigation/contingency plans.

4.10.4 Staffing Levels

CMS will also monitor staffing levels of the outgoing contractor by the functional areas of its Medicare operation. The outgoing contractor will provide a weekly breakout of staffing showing staff losses by area, transfers within the Medicare operation or to other areas of the company, new hires (temporary or permanent), and staff in training. The MAC will be provided with a copy of the staff report. Based on workload and staffing reports, it is possible that CMS and the MAC may decide to move a particular function to the MAC sooner than expected. The project schedule and costs would be modified accordingly.

4.10.5 Internal Controls

Internal controls (also known as management controls) are addressed in many federal statutes and executive documents. For example, the Federal Managers' Financial Integrity Act (FMFIA) establishes specific requirements with regard to internal controls. FMFIA encompasses program, operational, and administrative areas as well as accounting and financial management. CMS (and by extension its MAC contractors) must establish controls that reasonably ensure that: 1) obligations and costs comply with applicable law; 2) assets are safeguarded against waste, loss, unauthorized use or misappropriation; and 3) revenues (e.g., overpayments) and expenditures are properly recorded and accounted for. In addition, the agencies and contractors must annually evaluate and report on the control and financial systems that protect the integrity of Federal programs.

The MAC should review the indicators of the outgoing contractor's internal controls, especially if the MAC intends to hire the outgoing contractor's management and staff or use them in a subcontracting/partnering arrangement. At a minimum, the MAC should review recent Chief Financial Officer (CFO) and Statement on Auditing Standards No. 70 (SAS 70) audit reports. The MAC may also request the outgoing contractor's own

reports on internal controls—such as the Certification Package for Internal Controls (CPIC).

4.10.6 Contractor Performance Evaluation

It is possible that there will be a Performance Improvement Plan (PIP) in place for deficiencies found at the outgoing contractor's operation as a result of a Contractor Performance Evaluation (CPE) review. The disposition of a PIP will depend on the relationship that the MAC will have with the outgoing contractor or its staff after cutover. CMS must also be aware of any performance issues or corrective action plans that the MAC may have in place at its own operation when it a segment implementation begins. This is to ensure that any items addressed in those corrective action plans are applied to the incoming workload as well.

4.10.6.1 Contractual Relationship

CMS will provide the MAC with information regarding the outgoing contractor's PIP if the MAC will have a contractual relationship with the outgoing contractor (e.g., subcontractor, partnering arrangement, etc.) or if it will be utilizing the outgoing contractor's staff and/or facilities, After reviewing the current status of the PIP with the MAC, CMS will determine if it can be closed because of the MAC's processes or procedures, either in place or proposed. If it cannot be closed, the MAC will be responsible for completing any outstanding parts of the plan once it becomes operational, or develop an alternative PIP with the approval of CMS.

There may also be a situation where a deficiency was found in an outgoing contractor's operation but no PIP was submitted. In such cases, the Segment Implementation Manager will review the nature of the deficiency with the outgoing contractor and the MAC and determine if the deficiency can be eliminated prior to cutover or if it will be necessary for the MAC to develop a post-cutover PIP.

4.10.6.2 No Contractual Relationship with Outgoing Contractor or Staff

If there will be no relationship with the outgoing contractor or if staff will not be retained, there should be no need for the MAC to become involved with the outgoing contractor's PIP, other than knowledge of its existence and if it may affect its own operation.

4.10.7 Outgoing Contractor Performance Waiver

Under its Title XVIII Medicare contract, an outgoing contractor may identify administrative or workload activities that it believes it can no longer perform (or makes sense to perform) due to the demands of the transition and its contract closeout. If a carrier/intermediary finds itself in such a situation, it may submit a request for a waiver from CMS. CMS will inform the MAC of the nature of any waiver request that it receives from the outgoing contractor, and if approval is granted, will meet with the MAC to discuss what effect it may have, if any, on the MAC during the transition.

4.11 Implementing Assessment/Due Diligence Findings

Based on its analysis of the outgoing contractor's operations and documentation, the MAC will determine if any changes should be made to its implementation approach, operational design, or project plan. The MAC may want to modify operational workflows, implement process improvements, review resource requirements, rearrange implementation tasks, and/or revise time estimates/dates of implementation activities. The operational assessment may also help the various workgroups in developing their issues log/action items list. The MAC may find the need to revise its risk mitigation and communication plans based on information from the outgoing contractor. Provider education and training may also need to be modified based on the assessment results. The MAC should update CMS on assessment activities and discuss any results and actions undertaken.

The MAC may determine that it is beneficial to move certain functions earlier than originally planned. For example, if there is a serious staff loss among auditors at the outgoing contractor, the MAC may propose to take the work prior to the planned cutover date. Any significant changes to the MAC's project plan must be discussed with CMS.

The MAC's operational assessment and information gathering will continue throughout the transition period as part of the work effort of the various transition workgroups. However, the MAC should make a concerted effort to complete an initial assessment within the first month of the start of the segment implementation so that any changes can be negotiated with CMS and incorporated into the "baseline" SIPP, which should be submitted to CMS within 30 days of the kickoff meeting.

4.12 Access to Outgoing Contractor Information

It is incumbent upon the MAC to ensure that any request for information and/or documents from the outgoing contractor is proper and necessary for the conduct of its implementation. Given all of the activity that will be required for contract closeout, the outgoing contractor will not have the time or resources to respond to requests for information or documents that are not appropriate to the circumstances of the transition nor essential to successful completion of the transition.

The amount of information/documentation that an outgoing contractor will provide is dependent upon a number of factors. If the carrier/intermediary is leaving the Medicare program, it may be willing to provide practically all information and documentation related to its Medicare operation, even proprietary information that is administrative, management, or cost-related in nature. If the carrier/intermediary will be in a partnering/ subcontracting arrangement, business information regarding personnel, work processes, and facilities may be provided, but other administrative or cost information may not be released. If the carrier/intermediary submitted an unsuccessful proposal for the Jurisdiction and/or will be submitting proposals for future MAC jurisdictions, it may not release any information that it considers proprietary or confidential. The outgoing

contractor may also not release information if it contemplates legal action regarding the Jurisdiction award.

Exhibit 4, **Outgoing Contractor Information/Documentation,** provides a list of some of the information and documents that incoming contractors will normally request from outgoing contractors. The exhibit shows information/ documentation that is considered non-proprietary and should be released to the incoming contractor if requested. It also shows proprietary documents or business information that an outgoing carrier/ intermediary does not have to release unless it chooses to do so.

If the MAC believes that the outgoing contractor is withholding non-proprietary information that is necessary for the successful completion of the implementation, or is not cooperating with its operational assessment/due diligence, it should contact the CMS Project Officer.

4.13 Deliverables List

The MAC may begin developing an initial Deliverables List in the pre-award period and discuss the contents at the Jurisdiction or Segment kickoff meeting. The list will be a formal record of information, documents, etc. that the MAC is requesting from the outgoing contractor or other parties involved in the transition. At the minimum, it should contain a description of what is being requested, the date of the request, the requester's name, to whom the request is being made, the due date, and the actual receipt date.

Any request for information and/or documents that is developed into a Deliverables List must be carefully reviewed to ensure that the items are appropriate and necessary. The MAC must consider the effort that the carrier/intermediary will need to expend in order to produce the information or respond to its request. Outgoing carrier/intermediary staff may not be available to gather information and the process may take longer than the MAC anticipates. The MAC will need to prioritize items on any Deliverables List as to their importance and when they will be needed in the implementation process. The MAC must also be able to provide rational for the items should there be an issue with the request.

As the MAC conducts its operational assessment/due diligence and workgroup activities, it should use the Deliverables List to request and control the receipt of information and/or documents. The workgroups will also develop Deliverables Lists for the outgoing contractor and other involved parties. The workgroup head must ensure that everyone understands exactly what is being requested, that the information is applicable to the purpose of the request, and that the timeframe for delivery is reasonable. The request should be noted on the Deliverables List and forwarded to the appropriate party. If certain information or documents are needed to assist the initial operational assessment/due diligence, there should be some type of indicator for a quick turnaround.

In the past, many implementation project managers have found it helpful to consolidate the individual workgroup Deliverables Lists into a master list. The master list will then

serve as a complete record of what has been requested and the project manager will be able to track the requests to receipt. The Deliverables List should be updated at least on a biweekly basis and a copy provided to CMS.

Chapter 5: OBTAINING RESOURCES AND ESTABLISHING INFRASTRUCTURE

5.1 Personnel

Human resources are critical to the success of any transition. The actions necessary to obtain resources for a MAC operation may vary for a variety of reasons, including proposed location(s), subcontracting/partnering arrangements, and the outgoing contractors' plans for its employees.

5.1.1 Recruitment of Outgoing Contractor Staff

If the MAC would like to hire any staff from the outgoing contractor, it should communicate that fact to the outgoing contractor's management immediately after contract award. If the outgoing contractor is agreeable to the MAC's employment proposal, it would be beneficial for the MAC to hold a meeting with affected employees as soon as possible to show the corporate commitment, allay employee fears, and provide them with information regarding the implementation. Rumors can run rampant during a transition, especially after announcement of the new MAC. They can also affect efforts to retain personnel--the longer uncertainty exists, the more attractive alternate employment becomes.

The MAC must work with the outgoing contractor to establish communication protocols with the employees that it is proposing to hire. Information such as when staff may be contacted, the process for obtaining approval and release of employee information, and whether or not MAC job postings can be placed in the outgoing contractor's site should be obtained. The outgoing contractor will need to provide the MAC with specific employee information such as: names and addresses of employees, dates of service, job titles, job grades, job descriptions, current salaries, review dates, and documentation of the current employee benefits.

If the MAC will be hiring a large number of the outgoing contractor's staff, it may be helpful to have a MAC human resources representative on-site to answer questions and provide detailed information on benefits and employment. A comparison of outgoing contractor's employee benefits versus the MAC's benefits should be made as soon as possible after award. Meetings should be scheduled with the outgoing contractor's staff to discuss differences in benefits, provide information on what employees may expect when the MAC hires them, and how the actual employment cutover will be handled. It may also be helpful for the MAC to contribute transition-related articles to the outgoing contractor's employee newsletter.

The outgoing contractor employees who will be hired by the MAC should receive an offer of employment with a required acceptance/rejection date. This will give the MAC

an idea of the number of positions that will need to be filled. Recruitment plans can then be adjusted accordingly. The MAC should work with the outgoing contractor to come up with a compatible plan or calendar for when employees will actually transfer to the MAC's employment. The plan must ensure that there is no degradation of service at the outgoing contractor's site due to the hiring schedule.

It is expected that the MAC will not try to hire any of the outgoing contractor's staff to perform work for the MAC prior to cutover unless it has been agreed to by the outgoing contractor and CMS.

5.1.2 General Recruitment

If the MAC is only hiring a portion of the outgoing contractor's staff, or none at all, CMS may request additional information regarding how new staff will be recruited, especially if a large number of employees are to be hired. CMS will review the MAC's HR approach, how potential employees will be found, methods of advertising and recruiting, schedules, and contingencies if labor sources are inadequate.

5.1.3 Employment Report

The incoming MAC will send to CMS a biweekly report of staff hired. The report should cover hiring activity for the jurisdiction, broken out by operational location(s). The report should show head counts for the various functional areas of the MAC's Medicare organization as well as the number of employees hired in those areas for the two-week reporting period. It should also show the total anticipated staff to be hired for that area. There should be a notation for employees that were hired from an outgoing contractor and the contractor should be identified. CMS will use the report to compare it with the staff listed in the MAC's proposal in order to verify that proposed staff was actually hired.

5.1.4 Training

CMS may request the MAC to provide detailed information on its training, especially if a large number of employees are to be hired and trained. The MAC should have a comprehensive approach for providing facilities and training resources for training new hires, as well as those hired from the outgoing contractor. Training information should specify the type of training, the duration of each phase of training, what staff will be trained, the facilities used, and if any training will be subcontracted.

The training materials that the MAC uses must be based on the requirements in the RFP and all applicable laws, regulations, and Medicare manuals. Particular attention should be given to manuals and materials dealing with coverage of services, eligibility, reimbursement, and appeals. During the implementation, CMS may review the MAC's training materials and curriculum, observe classes, and review testing results. The MAC must ensure that enough time is allotted in the schedule to adequately train all employees prior to cutover.

5.2 Site Acquisition/Facilities Preparation

CMS will be monitoring the activities associated with obtaining and preparing a facility for MAC operations. These activities include obtaining space, furnishing the operation, utilities, mail delivery, and support services (trash collection, security, cafeteria, etc.) CMS will verify that operational facilities are established as proposed and may perform an on-site inspection to confirm completion.

The MAC may be moving into a new facility (either buying or leasing an existing site, or new construction), moving operations into an existing MAC facility (which may require build-out or renovation), or moving into the outgoing contractor's facility. The MAC proposal will provide information on the location of its operational facility. If the MAC is proposing more than one operational location, it must identify what functions or workloads will be processed at each site and the expected staffing at each location. If the MAC proposes to acquire the outgoing contractor's facility, it needs to be sure that there are no problems with the outgoing contractor vacating or selling the property, or that the lease can be assumed. Existing contracts for security, food services, phones, off-site keying, etc. should also be reviewed to see if they can be assumed by the MAC.

Regardless of the facility approach, CMS may request to review any applicable permits, blueprints/floor plans, leases, etc. CMS may also perform on-site inspections to monitor renovation, expansion, or construction progress. CMS should be consulted if there is any change in regard to the facilities approach or plans during the implementation. The MAC must insure that the design for its operational workplace meets CMS requirements regarding access and security for certain functional areas; e.g., program integrity. The storage of Medicare files and records must also be taken into account when considering facility options. The MAC review of the outgoing contractor's operation will provide information on the outgoing contractor's storage arrangements so that the MAC can determine whether to keep existing arrangements or move the files to another location. All Medicare records and files (hardcopy and electronic) must be maintained in accordance with CMS manual instructions. See **Chapter 9.7.**

5.3 Hardware/Software

The MAC must provide the hardware and utility software necessary to communicate and operate with CMS-provided software and the CMS-designated Enterprise Data Center (EDC). The processes for obtaining and installing contractor-furnished hardware and software at the MAC operational site(s) will be described in the JIPP/SIPP. The tasks should cover all hardware and software that the MAC will need to become operational, including CPU upgrades, DASD, data bases, tapes, print/mail equipment (inserters/sorters/meters, etc.), PCs/laptops, LAN/WAN hardware and software, workstations, peripherals (printers, scanners, etc), and telephone equipment. The project plan must cover the main operational site, as well as any proposed field offices or satellite operations.

The MAC must ensure that hardware and software requirements for any necessary IT support of front end/back end and data services not provided by the EDC (i.e., non-base

services) are defined and agreed to with the organization providing the services. The MAC will also have to coordinate its equipment needs with its print/mail vendor if printing is subcontracted. It may be necessary to reassess equipment needs as the implementation progresses and as more information is obtained about the outgoing contractor's operations from the operational assessment or workgroups.

CMS will monitor the activities associated with obtaining hardware and software. CMS may request that the MAC submit verification of equipment orders and certification that equipment is in working order according to specifications. CMS may also perform an on-site inspection of the equipment and the operational readiness of the MAC.

5.4 Asset Inventory

The outgoing contractor retains legal control of assets acquired on behalf of the Medicare program. It is responsible for disposing of those assets as quickly as possible after cutover or whenever the assets are no longer needed for Medicare. The outgoing contractor will normally discontinue the acquisition of assets during its closeout unless it is absolutely essential to the success of the transition. Assets not specifically furnished by CMS are the property of the outgoing contractor and may be kept, sold, or disposed of in accordance with Federal Acquisition Regulations (FAR). CMS's preference is that these assets be made available for sale or transfer to the MAC.

As part of its closeout activities, the outgoing contractor is required by CMS to develop an inventory list showing its anticipated asset disposition. As part of this process, the outgoing contractor will provide the incoming MAC with a detailed inventory of all supplies, furniture, hardware, software, equipment, and other work-related items that may be available to the MAC. This should be done as early in the transition as possible so that the MAC will have time to analyze, negotiate, and transfer any asset that it will obtain from the outgoing contractor. The task of developing an inventory of assets should be placed on the Deliverables List with a mutually acceptable due date.

5.5 Telecommunications – Data

The MAC shall obtain network data communications services with CMS through the Medicare Data Communications Network (MDCN). CMS provides these network services through a contract with AT&T Government Solutions, which was formally known as AT&T Global Network Services (AGNS).

5.5.1 Background

All MDCN telecommunications services are frame-based T-1 services. The MAC must provide a gateway to their internal LANs in order to effectively interface with T-1, frame-based telecommunications technology, unless otherwise negotiated. MDCN data communications services may be used for:

- Internal Medicare communications across multiple sites supporting the MAC's Medicare contract;
- Communications between the MAC and its CMS-designated ED, other MACs, carriers/intermediaries, CWF Hosts, and standard system maintainers;
- Medicare communications between a MAC and any subcontractors (e.g., printing, front end, non-base data services); and,
- Communications between the MAC and CMS and any other CMS contractors; e.g., HIGLAS, PSCs, QIC, etc.

The MAC may not utilize the MDCN for providers to submit claims and/or inquiries, to receive payments or remittance advices, nor for any other communications with the providers.

5.5.2 Requirements

Medicare contractors previously requested network access through CMS's Office of Information Services (OIS) by accessing the MDCN mailbox. However, network connectivity must now be processed by CMS personnel through use of the Remedy system. If the MAC will need new connectivity, it must complete T-1 circuit forms (Circuit Request Form, Design Questionnaire, and Site Questionnaire) and forward them to the MAC Project Officer. The PO will then enter the request into the Remedy system.

OIS is responsible for the MDCN contract and will assist the PO as a liaison for all new/revised data communications needs. CMS will supply the incoming MAC with names of authorized Point of Contacts (POCs) within AT&T Government Solutions. OIS, AT&T Government Solutions, the MAC, and the CMS Segment Implementation Manager will establish regular teleconferences to assure that all data communications needs are communicated accurately and in a timely manner in order to ensure the most prompt installation.

The MAC must designate a program point-of-contact (POC) and a technical POC to handle ongoing communications and information exchange. These POCs will have the authority to represent/bind the MAC within the scope of data communications operations and supporting environments.

It is critical that the request for network services be made to CMS as soon as the kickoff meeting has occurred and implementation activities have begun.

The incoming MAC should request data communications services a minimum of ninety (90) calendar days before the expected operational delivery date for those services. The incoming MAC must also complete a technical information exchange with AT&T Government Solutions technical representatives within the first fifteen (15) calendar days following the request for services. When all specifications and requirements are complete, AT&T Government Solutions is contractually required to provide data communications within 60 calendar days.

5.5.3 Points of Emphasis

- **AT&T Government Solutions is dependent upon the local telephone company to install lines. The local telephone companies maintain their own schedules and may not be able to meet a customer's particular need for expedited installation and service.**
- Requirements gathering will include an interactive review process among the MAC, OIS, and AT&T Government Solutions representatives.
- The MAC should document all network connectivity requirements and specifications before the 60 day timeframe begins.
- The MAC should have any facility leases signed and arrangements made for the local telephone company and/or AT&T Government Solutions staff to have access to buildings to install lines and/or equipment. Turnaround time requirements on AT&T Government Solutions will not commence until this requirement is met.
- The MAC must grant AT&T Government Solutions access to equipment on its premises for installation, troubleshooting, and maintenance activities.
- The MAC is responsible for identifying any modifications to its data communications network requirements because of changes to its workload (e.g., obtaining additional workload or increased volumes of existing workload) and communicating those needs to the Project Officer.

5.6 Telecommunications – Voice

Voice communications are the responsibility of the MAC. The MDCN does not provide support for voice communications. The MAC must ensure that the telephone system that is in place at its operational site(s) meets the minimum design guidelines required by CMS and that it can connect with CMS-provided toll-free lines. The MAC should review the outgoing contractor's current inbound and outbound traffic to help assess needs, define phone system requirements, and determine how the additional workload will fit into its existing system. If the MAC is utilizing the outgoing contractor's facility, it must reach agreement with the carrier/intermediary regarding what telecommunications equipment the outgoing contractor is going to keep or is willing to sell to the MAC. IVR/ARU equipment must also be assessed and the application software reviewed for required modifications. Internal voice mail and call accounting system requirements will also need to be examined.

The MAC must be certain that the local telephone company is aware of its implementation schedule and that voice and data communication installations are coordinated. **It should be noted that the lead time for local phone system installation can vary widely; the MAC must allow sufficient time for system setup.**

5.7 Data Center

The MAC will utilize the services of a CMS-designated data center. This will normally be CMS's Enterprise Data Center (EDC). The EDC is an integral partner in the transition

process and a representative will be in attendance at the kickoff meeting. Data center personnel will participate in the appropriate transition workgroups. It is critical that there be an EDC point of contact for the MAC during the implementation. It is also critical that the MAC be familiar with the provisions of the contract between CMS and the EDC and understand the roles and responsibilities of each organization. The MAC may be required to enter into a Service Level Agreement (SLA) or some other type of agreement to formalize the requirements of each organization.

Data center connectivity must be established between the MAC's operational site(s), the EDC, and any IT facility supporting the MAC (e.g., if front-end and/or back-end services or non-base applications/services are being provided). The MAC must assess and document data center access, security protocols, and processes (test and production regions, operator control files, problem reporting, DDE access for providers, etc.). System access and IDs for authorized testers and production staff will need to be established. Access and system security must also be established with the CMS mainframe for CROWD, CSAMS reporting, PECOS, and other software applications. All areas must be tested to ensure that access is appropriate and that reports can be submitted timely.

The MAC must also verify that workload regions at the EDC are properly installed, populated, and tested. In addition, the MAC must determine that all interfaces are analyzed, properly established, and tested (e.g., bank files, ARU/IVR, crossover processing, CWF, EDI processes, PSC, QIC, financial reporting, print interfaces, 1099 processing, etc.). IT risks should be monitored as part of the MAC's overall risk management plan and mitigation/contingency plans invoked if necessary.

5.8 Electronic Data Interchange (EDI)

Providers must have the ability to submit claims electronically without disruption. The MAC must ensure that all providers and submitters understand the changes that will take place because of the implementation. They must have the opportunity to receive any necessary training and be able to test with the incoming MAC prior to cutover. The MAC must also provide technical support for any problems associated with claims submission and EDI if there is not a standard front end contractor.

5.8.1 General

EDI is the medium for the automated transfer of Medicare billing/claims (electronic media claims--EMC) and claims-related transactions. EDI technology facilitates the exchange of Medicare information between different computers by providing a standard communication mechanism. EDI is utilized by Medicare claims submitters (e.g., providers, physicians, suppliers, billing agencies, and clearinghouses) as well as other entities with which the MAC shares Medicare information (e.g., trading partners). Some institutional providers use direct data entry (DDE) access into Medicare shared systems for the purpose of submitting and correcting claims. These providers key data directly into a computer that serves as a remote extension of the EDC.

With limited exceptions, all initial claims for reimbursement under Medicare must be submitted electronically in the Health Insurance Portability and Accountability Act (HIPPA) standard format. Although MACs will receive non-electronic claims from certain providers (i.e., hard copies, faxes, and optical character recognition (OCR) claims), the ability of providers to submit electronic claims via EDI and DDE without disruption is critical to the success of a transition. If submitters cannot have their EMC and claims-related transactions submitted successfully, or if Medicare data cannot be provided to trading partners, it will adversely affect the incoming MAC's operations. Any problems with payment or the ability to submit claims will increase the customer service workload as submitters attempt to resolve EMC issues. In addition, the MAC may suffer adverse publicity and the possibility of complaints to CMS and/or Congress will increase.

The MAC must establish and maintain effective EDI processes for all claims submitters and trading partners. It must allow sufficient time prior to cutover to test EDC submitters to verify that they can accommodate the MAC's front-end requirements and bill successfully. This will reduce Return to Provider (RTP) claims and will assist the MAC in determining what training and/or informational bulletins need to be furnished to providers. The MAC must also coordinate EDI testing with its trading partners.

5.8.2 EDI Enrollment

Arrangements for Medicare EMC submission are specified in the CMS standard EDI Enrollment Form. When a submitter wishes to establish EDI capability with a MAC, it must complete the CMS standard EDI enrollment form and submit it to the MAC before the MAC will accept production claims from that submitter. However, current EDI submitters who have completed an EDI enrollment form with the outgoing contractor do not need to re-enroll and complete a new form. The existing EDI enrollment forms will be transferred to the incoming MAC at cutover. The MAC will make basic EMC software available free of charge to any new provider who wishes to enroll. A nominal fee may be charged to cover postage and handling for the PC software.

5.8.3 Connectivity

The Medicare Data Communications Network may not be used to provide connectivity between providers/submitters and the MAC. Consequently, MACs must support several connection methods for providers submitting electronic transactions. Providers may choose a direct dial-up connection from the provider's computer to the front end collection system, or they may choose to use a network service vendor to establish the connection. Providers are responsible for line costs for their use of EDI.

5.8.4 Front End System Translators

The EDI translator is part of the MAC's front end collection system and is used to:

- acknowledge receipt of transactions;
- detect errors in EDI transaction syntax;
- convert HIPAA X12N format and data into transactions that the shared claims processing system recognizes and can receive as input; and

By using reports generated by the front end collection system, submitters can confirm that the electronic files were received and determine whether any errors were identified within the file which prevented claims from being sent to the EDC for processing. CMS does not currently require that contractors use specific front-end system translator software; however, in view of the agency's move to standardized processes, such a requirement may be forthcoming.

5.8.5 EDI Assessment

As part of its review of the outgoing contractor's operations, the MAC should obtain a complete listing of all vendors, suppliers, providers, and trading partners who are currently submitting electronic transactions. This listing must identify whether submitters are transmitting claims via EDI or DDE and whether the format is HIPAA compliant. Electronic Remittance Notice (ERN) and Electronic Funds Transfer (EFT) information should be obtained, as should EMC submission rates.

The MAC must determine if there are any special carrier/intermediary claim edits that should be incorporated into its claims processing environment. The MAC must also determine if it interprets the standard format values differently than the outgoing contractor. The MAC needs to be aware of any information (other than claims) that is accepted by the outgoing contractor in a paperless manner and will need to determine whether or not it will be able to accept those items.

The MAC needs to determine as soon as possible if the outgoing contractor's EMC submission comes into the corporate network or directly to the Medicare operation. If EMC comes into the corporate network, the MAC needs to ascertain whether or not Medicare and corporate files are co-mingled. If so, the files will need to be separated so they can be furnished to the MAC.

5.8.6 EDI Communication

It is required that the MAC provide information, assistance, testing, and training to providers/submitters throughout the implementation period regarding EDI. Vendors, suppliers, and providers must understand any differences in EDI processes and front ends so that they will be able to make any changes necessary to their internal EDI processing systems. EDI must be emphasized in the MAC's implementation bulletins and in seminars/workshops. The MAC should also provide personal on-site assistance to submitters, if necessary. It is imperative that EMC/EDI issues are not ignored or minimized by the MAC or submitters. It is also important that the MAC be sensitive to provider concerns regarding any change.

The MAC must allow for sufficient time to test and verify that EMC submitters can accommodate the front end requirements and can successfully submit EDI transactions into the MAC's front end at cutover. This will help reduce Return to Provider claims and reduce provider inquiries. Testing will also help determine training needs or information bulletins that need to be furnished during the implementation and will help in planning telephone service support after cutover.

The MAC must remember that sufficient staff must be available to support the EDI/EMC activity. Incoming contractors normally have additional telephone and technical customer service personnel available immediately after cutover to accommodate questions/issues/problems regarding EDI transactions. It may also be necessary to provide on-site assistance if a submitter continues to have problems. EDI transactions, communications, and related customer service will be monitored closely by CMS after cutover to insure that entities are able to submit claims and receive proper notification and payment.

5.8.7 Electronic Funds Transfer

Electronic funds transfer (EFT) is the methodology by which Medicare payments are transferred electronically from the MAC's bank directly to the bank account of the provider or supplier. Providers and suppliers who wish to continue to receive Medicare payments via EFT from the incoming MAC must complete a new copy of Form CMS-588, Authorization Agreement for Electronic Funds Transfer prior to cutover. This is required even if the MAC's financial institution is the same as that of the outgoing carrier or intermediary.

The MAC will obtain and retain a signed form from each provider, physician, or supplier requesting EFT. It is essential that the requirement for the completion of a new CMS-588 be emphasized as part of the MAC's provider communications, special bulletins, and implementation workshops. CMS will be monitoring the percentage of completed EFT forms during the implementation. As cutover approaches, the MAC is expected to follow up and personally contact those providers who have not returned a completed CMS-588. Contact should be attempted numerous times, if necessary. Providers must be warned that failure to complete the CMS-588 by cutover will end the electronic deposit of funds to their bank accounts. The MAC should attempt to convince providers to accept direct deposit via EFT and inform them of the consequences if they do not.

If a provider refuses to accept electronic deposit, the only acceptable alternative to EFT is a paper check mailed by first class mail. Provider or supplier pick-up of checks, next day delivery, express mail, and courier services are not allowed unless there is a special situation that is authorized by CMS.

Chapter 6: TRANSFER OF CARRIER/INTERMEDIARY OPERATIONS

6.1 Overview

As the MAC is obtaining resources and preparing the infrastructure, it must also plan, organize, and control the orderly transfer of operations, workload, and documents from the outgoing contractor. The movement of a segment workload may establish the MAC's operation (i.e., it is the first Medicare workload that the MAC will have to process) or be a merger into the MAC's existing operation. The tasks required for the transfer of workload will vary between Part A and Part B and may vary among the carriers and intermediaries whose workload the MAC is assuming. The tasks will also vary depending on whether or not the MAC will have relationship with the outgoing contractor (e.g., partnership/subcontractor), will assume the outgoing contractor's employees or facility, or will maintain a presence in the area of the outgoing contractor.

Due diligence and workgroup activities will provide the structure to assess the various functions performed by the outgoing contractor. The MAC will need to get as much information as possible about the outgoing contractor's workload and business procedures for each operational area. This analysis will help the MAC to establish the parameters for what will need to be moved, and process flows will help determine how to move the workload and to where.

Depending on its assessment and the outgoing contractor's performance during the transition period, the MAC may propose to move certain functions earlier than scheduled. Should such a situation arise, CMS will discuss the proposal with all parties involved and reach agreement as to how to proceed. The MAC may also implement process improvements and/or operational changes based on its assessment, as well as reevaluate its staffing requirements. The MAC must be aware of all productivity, production capacity, and quality issues so that they may be addressed. It must also be aware of CMS contractual requirements and all manuals, performance requirements, transmittals, etc. as they relate to any implementation activity.

The MAC and the outgoing contractor must work closely to coordinate activities and monitor inventory and staffing changes throughout the transition. The MAC will need to verify that its system and Medicare operation is capable of supporting the workload that is being assumed and that the responsibility for interfaces and connections is established.

It will also need to ensure that any agreements and contracts between transition participants and other entities are negotiated and executed. The MAC must have a complete list of trading partners and make certain that trading partner agreements are updated to support operations. If the MAC will be assuming the outgoing contractor's facility or operation, it will need to review all contracts for services to determine if the contracts can be assumed or if they will have to be renegotiated.

6.2 Claims Processing

The MAC should analyze the outgoing contractor's workload data for all claims processing areas for the current and preceding year. High volume edits, returns, and rejects should be analyzed. Backlogs should be identified to see how they may affect the implementation schedule or require certain functions to be moved earlier than planned. The MAC must work closely with the outgoing contractor to understand how acceptable workload levels will be maintained and to provide assistance if necessary. Any unique processing requirements, special claims processing arrangements, or demonstration projects should be identified. Contract compliance and service issues should also be identified.

The MAC should request the outgoing contractor's claims operations documentation in order to review claims controls, reason codes, monitoring and reporting procedures, quality assurance processes, and the edit process. This will enable the MAC to determine procedural differences between its operation and the outgoing contractor's. Any applicable CPE results should be reviewed, as should all desk procedures and management reports.

6.2.1 Customer Service

The MAC will need to review provider service policies and procedures and determine procedural variances between it and the outgoing contractor. A listing of top reasons for inquires will provide helpful, as will a listing of providers (including provider number) with high call volumes. Also, a list of challenging providers with consistent issues should be obtained. The MAC should review complaint analysis summaries for the past year, if applicable, and evaluate the number of unresolved pending complaints. It should also obtain a historical analysis and trending reports for the past two years.

Workload data (open beneficiary/provider written and telephone inquiries) should be obtained. The MAC should also analyze data on call backs, email inquires, the logging and tracking of calls and written inquiries, quality call monitoring, and any walk-in activity. Copies of quality focused audits performed in past year and any CPE, OIG, or other external reviews should be reviewed by the MAC. The level of automation for correspondence generation should be assessed, and forms, listings, and any routine reports may also be examined.

The MAC must meet with the 1-800-MEDICARE contractor to obtain call data and to establish protocols for processing complex beneficiary inquiries (see **Chapter 7.5).** The MAC must also determine the impact of its ARU/IVR and make any necessary modifications to scripts to reflect the acquisition of the outgoing contractor's work. The outgoing contractor's workload reduction plan will be monitored throughout the implementation. Should customer service indicators show deterioration below acceptable standards, CMS may request that the MAC assume some or all of the customer service functions earlier than originally scheduled.

6.2.2 Medicare Secondary Payer (MSP)

The MAC will need to gather MSP documentation from the outgoing contractor and analyze current operations, desk procedures, and management reports. The MAC will need to obtain copies of MSP reports relative to workloads and pending caseload. A list of all open/active cases and correspondence will need to be obtained. The MAC should review MSP post-payment activities (pending subrogation liability cases, IRS/SSA/CMS data match files and outstanding cases, routine recovery) and MSP debt referral (DCIA process).

The outgoing contractor's current process of tracking accounts receivable (AR) will need to be reviewed. The MAC should determine the status of MSP accounts receivable and work with the outgoing contractor to move the current AR, both Group Health Plan (GHP) and non-GHP, to the MAC's financial system. It will need to determine the status of the MSP accounts receivable write-off and identify and reconcile MSP accounts receivable for 750/751 reporting.

6.2.3 Medical Review

The outgoing contractor should provide medical review (MR) policies, desk procedures, edits, and management reports to the incoming MAC. The MAC should review policies, articles, advisories, and mailings for compatibility and retention and archive this information for historical purposes. Medical records storage/retrieval and privacy act compliance should also be evaluated.

The MAC must review the MR/Local Provider Education and Training (LPET) strategy and the process and procedures of identifying program vulnerabilities. It must analyze progressive corrective action (PCA) procedures, reports, programs, data, and related activities. Data analysis methodology will also need to be assessed. This includes the number and type of edits, edit effectiveness, the number and type of probes, and software for trending reports. Statistics used to determine pattern analysis and other data analysis techniques should be reviewed. In addition, tracking techniques for monitoring effectiveness of edits and educational activities should also be analyzed. The MAC should prepare to receive any workload related to ongoing interventions addressing a prioritized problem from the outgoing contractor's MR/LPET strategy.

The MAC should monitor inventory and track the outgoing contractor's automated and manual workloads. Automated review tools should be analyzed and medical record storage/retrieval processes should be evaluated.

The MAC must meet with outgoing contractor's Medical Director and other MR staff to discuss Local Coverage Determinations (LCDs). The outgoing contractor must retain its LCDs and MR edits until cutover and will provide the historical record for each LCD to the MAC. Carrier/Intermediary Advisory Committee activities should also be discussed with the outgoing contractor.

The MAC must also discuss and coordinate its MR activities with the Quality Improvement Organization (QIO) and the Program Safeguard Contractor (PSC). In some jurisdictions, the PSC may perform MR activities for a segment. If that is the case, the PSC will be required to transfer MR functions and workload to the incoming MAC. The tasks required to accomplish the transfer must be incorporated into the IPP. Also see **Chapter 7.3.**

6.3 Appeals

The MAC will need to assess the outgoing contractor's appeal procedures and obtain the status of the first level appeals (redeterminations) that are currently in progress. The MAC will work with the outgoing contractor to develop an estimate of the redeterminations that will be completed prior to cutover and those that will be forwarded to the MAC. The MAC will also need to determine if there are any outstanding requests from the Qualified Independent Contractor (QIC) for reconsideration case files or any effectuations that are in progress. See **Chapter 7.6.**

6.4 Provider Audit and Reimbursement

The MAC will need to determine the location and status of cost reports and rate review files. It should evaluate workload volumes during the transition—desk reviews, audits, focus reviews, exception requests, re-openings, cost report appeals, settlements, and tentative settlements. It should also analyze the outgoing contractor's workload and operations—workflow, monitoring processes, internal controls, payment history, CFO reports, provider correspondence, and Freedom of Information Act requests. If applicable, the MAC should review and negotiate any cost report software vendor contract and evaluate any software that the outgoing contractor may have available for continued use. The MAC should also compare operational procedures and determine if any differences will require changes to its procedures.

6.4.1 Reimbursement

The MAC must make certain that it establishes accurate interim rates, provides key financial reporting, and collects overpayments timely. It will need to obtain current interim rate policies and procedures. It should also obtain provider schedules for interim rate review. The year-to-date accuracy of interim payments should be reviewed, as should the tracking of settlements and interim payments. Payment tolerances in the system will need to be established. The MAC must determine procedures for interim rate reviews beginning at cutover and for moving workload into the interim rate tracking system. It should also obtain an inventory of pending interim rate reviews.

The MAC will need to get TEFRA, Per Resident Amount (PRA), and Ambulance rates along with an inventory log of all historical rates and supporting calculations. It should also develop procedures for rate maintenance after cutover and incorporating rates into existing tracking logs. The MAC should obtain Sole Community Hospital (SCH) information, review cumulative target amounts for multiple years, establish files for SCH

worksheets, and update the existing SCH calculation database. Provider profile data, provider rates, and address information should also be verified.

The MAC will also have to obtain information on the outgoing contractor's debt collection and referral process. It should review the demand letters/tracking process, Provider Overpayment Report (POR) entry and reconciliation process, and the process for entering debts into the debt collection system. The MAC should also review correspondence on overpayments and obtain historical settlement data. The status of outstanding overpayments will have to be determined by reviewing the overpayment documentation and overpayment referrals. The MAC will have to review outstanding claims accounts receivables, extended repayment schedules, and outstanding accelerated payments. It will also need to evaluate internal accounting by analyzing monthly reporting, payment cycles, distribution of Remittance Advices, checks, EFTs, and balancing procedures.

6.4.2 Audit

The MAC will need to evaluate the current provider audit operations. This includes all activities relating to cost report acceptance through cost report settlement. It also includes all work related to re-openings and appeals.

The location and status of desk reviews and audit reviews will need to be obtained, as will exception requests, reopenings, appeals and settlements, wage index reviews, hospital audits and on-site reviews. The MAC must determine the audit data to be finalized by cutover and obtain an inventory of filed cost reports that will be unprocessed by cutover. It will also need to prepare cost report due date letters and demand letters for release after cutover.

The MAC should evaluate Cost Report acceptance, Tentative Settlement, and Cost-to-Charge Ratio policies and procedures to determine if there will be changes after cutover. Audit safeguard policies such as workload rotation policy and auditor independence should be evaluated, as well as the settlement and finalization process. The MAC should also determine how files are stored on-site and off-site and determine which will be shipped to its operational location.

The outgoing contractor's annual master audit plan should be analyzed. This would include all cost reports to be received, reviewed, audited and settled during the year. It would also include recurring, time-specific activities such as the wage index. This plan would be of benefit to the MAC in developing its master audit plan for the coming year.

6.5 Provider Enrollment

When cutover occurs, the MAC will need to ensure that the process for enrolling providers and verifying provider ownership and qualification data is functioning properly. The MAC should obtain the current provider enrollment inventory from the outgoing contractor and review enrollment procedures. Provider application processing

timeliness should be reviewed, as well as the provider application pending workload. The MAC should make certain that the latest 855 application form is in use. The MAC's provider enrollment processes must be in compliance with Pub.100-8, Chapter 10.

The MAC will coordinate with the outgoing contractor to determine when the cutoff for requests will be and when all applications will be forwarded to the MAC. Providers must be notified of when and where applications should be mailed. The MAC must ensure that it has provided for secured on-site storage space for applications and supporting documentation and that the files are properly transferred to its facility. The MAC must verify that it will have access to all PECOS files and records for the providers and supplier currently enrolled in each segment at the time of cutover.

6.6 Provider Education/Training

As described in **Chapter 12**, the MAC will be responsible for communicating information regarding the progress of the implementation to all stakeholders. A key element of the communication plan is provider education and training. For each segment implementation, the MAC must make sure that providers have a complete understanding of what will be required of them during the transition and the impact of any changes that will occur. Providers especially need to understand the activities associated with the cutover. The MAC needs to work closely with the outgoing contractor to be certain that transition information is transmitted clearly and frequently to providers using various means. When the outgoing contractor holds its regularly scheduled provider/association/ specialty group meetings, the MAC should attend so that it can be introduced and make a presentation. The MAC and outgoing contractor should continue joint meetings throughout the transition. It is expected that the MAC will conduct a number of provider workshops/seminars held at convenient locations throughout each state so that providers can be informed of the changes that will occur.

The MAC should obtain training history from the outgoing contractor. This includes the locations of meetings, topics, frequency, attendee mailing information, and telephone numbers. Training materials such as presentations, curriculum, and manuals/ handbooks should also be reviewed. The outgoing contractor's provider bulletins and newsletters from the past two years may be of benefit as the MAC develops its education and training plans. The MAC should also provide transition information to the outgoing contractor for inclusion on its website.

6.7 Print/Mail Operations

The MAC will need to analyze the outgoing contractor's mailroom workflow and operations to determine how mail functions will be transferred. These activities will be largely dependent on whether or not the MAC will assume existing space or have some presence in the outgoing contractor's geographical area. The MAC should request a breakout of the types of mail received and the average volumes by day. It will also need to know the volume of system generated and non-system generated mail. The MAC will

need to analyze what functions are performed at the mailroom (control, imaging, activation, etc.) and determine if it is a separate entity or part of the corporate mailroom.

A decision will have to be made regarding the number of locations mail will be received. The MAC will also need to determine how it will move the outgoing contractor's existing mail at cutover. The MAC must meet with post office representatives to explore its mail options. The post office can change the ownership of existing box(es), thereby keeping the same post office box number(s) for the MAC, or forward mail to other locations. The MAC may also want to have numerous boxes that will handle specific types of claims. The MAC should determine if it will need a mail services contractor for pick up, delivery, presorts, metering of letters, etc. It will also need to determine if additional mail handling, sorting, imaging, and/or metering equipment is needed.

The MAC must work with the outgoing contractor to determine how existing mail will be transferred at cutover. The organizations should also agree on arrangements for transferring mail that is received by the outgoing contractor after it leaves program. The MAC will need to determine how long old PO boxes will be kept open and how long mail will continue to be forwarded. Agreement will also need to be reached on how checks will be handled that are received by the outgoing contractor after cutover. Any new mailing arrangements must to be communicated to providers and submitters through bulletins, websites, and seminars as part of the MAC's implementation training.

The MAC must evaluate print requirements for each segment implementation. It should evaluate usage trends for letterheads, envelopes, and internal forms. It should analyze all print jobs and requirements, identify any changes, and evaluate any impact caused by obtaining the outgoing contractor's workload. Sample data for documents and reports should be printed and reviewed. Print format changes will then be made and form flashings modified. The MAC should conduct any training necessary for print and inserter operators and develop user documentation.

The print output should be thoroughly tested. Testing should include MSNs, provider remittance advices, and letter and report generation. The MAC must also test check generation, the check signing process, Magnetic Ink Character Recognition (MICR) check acceptance by banks, bar coding and sorting, and mail stuffing.

6.8 File Inventory

The MAC shall work with the outgoing carrier/intermediary (as well as any other organization such as a PSC or another carrier/intermediary outside of the jurisdiction) to identify all the files that will need to be transferred to the MAC during the implementation. The MAC should also be aware of any files that the outgoing carrier/intermediary may be splitting and moving to another MAC or other organization during the outgoing contractor's closeout.

6.8.1 General

The outgoing contractor (and any other organization that will be moving files during the transition) will develop an inventory of Medicare files in its possession (electronic data files, hardcopy, microfilm, microfiche, tape files, etc.). The inventory should include the file content description, data set information, tape and file processing methods, and record information. The inventory will be provided to CMS with a copy to the incoming MAC. The MAC will use the inventory to identify the files that it will need for its Medicare operation and will request those files from the outgoing contractor/other organization in the form of a Deliverables List. **Exhibit 5, Files to be Transferred to a Medicare Administrative Contractor,** provides a list of the types of files that a MAC would request from the outgoing contractor.

6.8.2 Disposition

As of the date of publication of this handbook, all Medicare contractors are under a Department of Justice decree not to destroy Medicare paper, electronic, and systems records regardless of the Medicare manual retention requirements. All Medicare files in the possession of the outgoing contractor must be transferred to the MAC. The only exceptions to this requirement are: 1) administrative financial files that the outgoing contractor must keep in order to prepare its final cost report, and 2) duplicates of files that are being transferred to the MAC. Any files that are not transferred to the custody of the MAC must be destroyed by the outgoing contractor and certified as such.

6.8.3 Mainframe

The movement of mainframe files may be internal or external, depending on where the files are located. The structure of all the files will need to be provided along with a description of each directory. Support files such as print/mail, EDI, financial, and ad-hoc interfaces must be included. Passwords will need to be removed from the files and the disk space determined. The actual transfer method/process must be established, with responsibilities acknowledged. Prior to cutover, the MAC should test that files can be transferred. After the actual transfer, the files should be reconciled with the directory.

The MAC should work with the EDC and/or standard system maintainer to determine if any files require conversion. If so, pre-conversion screen prints should be produced. After the file conversion is run, the results must be verified.

6.8.4 LAN/PC-Based Files

These files include Excel spreadsheets, access databases, and emails. The MAC should assess LAN file listings and establish transfer protocols similar to mainframe files.

6.8.5 Hardcopy

Prior to the actual transfer of files, the outgoing contractor must provide to CMS and the MAC a detailed inventory of hardcopy files, with an accompanying description of each file, including contents, size, etc. All paper files (archived and active, on and off-site) will be inventoried. Once the inventory has been prepared, the MAC will develop a schedule with shipping dates and work with the outgoing contractor to ensure that those dates can be accommodated.

The MAC must determine which hardcopy files will be moved and to what location. The outgoing contractor must provide information on any off-site storage sites: what files are stored, content, volume, and security. The MAC should schedule a meeting with the outgoing contractor and the storage facility to discuss transfer activities and access. The MAC will need to determine if any existing storage contract held by the outgoing contractor can be assumed, or if new storage agreements will need to be negotiated. When storage arrangements are made, the MAC will need to establish or review its storage and retrieval protocols.

Chapter 7: INTERACTION WITH OTHER TRANSITION ORGANIZATIONS

7.1 General

The MAC is required to interface with a number of different organizations in order to perform its contractual obligations. During the implementation, the level of interaction will these organizations will vary, depending on the extent of the interface. The following sections provide information on some of the key organizations that will have significant involvement with the MAC during its implementation.

7.2 Data Center

The MAC must utilize the services of a CMS-designated data center, normally CMS's Enterprise Data Center (EDC). The data center will provide all the necessary hardware, application software, resources and supplies necessary to properly process the MAC's Medicare claims.

The EDC will be a key participant in the MAC implementation effort. It will be a member of several transition workgroups and a data center point person must be identified for transition-related issues. It is expected that the data center will be present at all bi-weekly status meetings. The data center should have its own transition project plan, which will be coordinated with the MAC's JIPP/SIPP and the outgoing contractor's closeout plan. The MAC implementation tasks associated with data center activities must be incorporated into its JIPP/SIPP and may need to be revised once the data center has developed its transition plan.

The MAC must adhere to all operational processes and procedures the EDC establishes with its users. It may be helpful to obtain a copy of the contract between CMS and the data center to review and understand what hardware, software, and services for which the data center is contractually responsible. This may also help in defining implementation tasks for the JIPP/SIPP. Since the MAC will be required to enter into a Service Level Agreement (SLA) with the data center, the MAC should obtain a copy of an existing data center SLA to understand what services are covered and the performance requirements. The MAC may also use the sample as a basis for negotiating its SLA with the data center.

The EDC will work with the outgoing contractor's data center. It must also work with any IT facility that will support the MAC (e.g., front end and/or back end services not provided by the EDC or non-base applications/services). The MAC will also have to interact with another EDC/data center if it will be receiving workload from other contractors (i.e., PSC or out-of-jurisdiction providers). The MAC must assess and document EDC access, processes, and security protocols. It must work with the data center to establish system security and access for authorized testers and production staff.

The Enterprise Data Center will be heavily involved in the MAC's testing. The MAC must discuss its testing requirements with the EDC and coordinate its testing schedule. The MAC will need to verify that workload regions at the data center are properly installed, populated, and tested. It must also ensure that interfaces are established and tested. These include bank files, ARU/IVR, crossovers, CWF, EDI processes, print interfaces, and 1099s.

7.3 Program Safeguard Contractor (PSC)

The MAC must enter into a working relationship with the appropriate PSC that will be performing certain Medicare functions within its jurisdiction.

7.3.1 Background

The Medicare Integrity Program (MIP) was created under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This act gives CMS the authority to enter into contracts with Program Safeguard Contractors (PSCs) to promote the integrity of the Medicare program. The act allows PSCs to perform various functions: medical review, cost report auditing, data analysis, benefit integrity, and MIP provider education.

The functions that the PSCs perform vary from contract to contract; however, under Medicare Contracting Reform the PSCs will only be responsible for benefit integrity work. This means that for some segment transitions, the MAC will be required to assume some of the functions that are currently being performed by a PSC. In other segments, the PSC will just be performing benefit integrity functions; therefore, no workload will need to be transferred to the MAC. The MAC's implementation activities regarding the PSC must be incorporated into its Segment Implementation Project Plan.

7.3.2 Workgroups

The PSC implementation activities must be accounted for in the MAC's workgroups. There may be a separate workgroup established for the PSC or PSC activities may be incorporated into another MAC transition workgroup in order to conserve resources. Regardless of how it is organized, there should representation from CMS, the PSC, and the MAC on any workgroup responsible for PSC transition activities. The outgoing contractor may also participate. The MAC will be the lead for the workgroup and distribute meeting minutes. The outgoing contractor may decide to exit the workgroup if its attendance is not warranted.

7.3.3 PSC Contract Meetings

Since the contract for PSC activities is between CMS and the PSC, the CMS staff with oversight responsibility may require the MAC and the PSC to have meetings separate and apart from any transition workgroup meetings. These meetings would be held with the CMS Government Task Leaders (GTLs), the PSC, the MAC Segment Implementation Manager, and the outgoing contractor. The MAC Jurisdiction Transition Manager may

also participate in these meetings to provide jurisdiction-wide input and perspective. Weekly or bi-weekly conference calls would be conducted by PSC staff to discuss the PSC transition status of each organization.

7.3.4 Joint Operating Agreement

The MAC and the PSC must enter into a Joint Operating Agreement (JOA) to formalize the functions that each will perform. While the development of a JOA is the responsibility of the PSC, the MAC will need to be involved in the process. The JOA is an extremely important document that provides clarification of both contractors' roles, responsibilities, and respective duties. The PSC and the MAC should begin work on the JOA as soon as possible after contract award. There must be a high level of participation between the parties, since the JOA impacts the working relationship of both organizations. The outgoing contractor should also be involved in the process, especially if it will have a subcontracting/partnership arrangement with the MAC, since the work processes of the outgoing contractor and its staff may be utilized in the new operation. The MAC may want to review the current JOA between the outgoing contactor and the PSC to give it a basis for discussions with the PSC. Also, the MAC should recognize that the JOA is a document that may change during its existence due to changes in program requirements.

It should be noted that the MAC is responsible for referring all suspected fraud and abuse to the PSC regardless of the source, including provider inquiries, medical review, and complex inquiries referred from the BCC.

7.3.5 Communication/Coordination

The PSC and the MAC must coordinate their respective provider communications activities that occur during the transition. This coordination includes joint introductory newsletters and meetings with providers, subsequent provider newsletters, and information presented on the MAC's website. The MAC and PSC should also develop a joint Deliverables List since both parties will require some of the same deliverables from the outgoing contractor. This will prevent a duplication of effort for all parties.

The CMS GTL will closely monitor the PSC to ensure that as much of its workload as possible is completed prior to cutover so that the MAC does not receive an unanticipated backlog. Any remaining unfinished PSC work will be forwarded to the MAC in accordance with the MAC's cutover plan, which will be developed with PSC input. The PSC should allow sufficient time so that the MAC can review files and ask any questions prior to cutover. The CMS GTL will notify all relevant stakeholders (e.g. DOJ, FBI, OIG) of the functions (if any) that are being transferred and the roles and responsibilities under the new PSC JOA.

7.4 HIGLAS

HIGLAS is a comprehensive, unified general ledger accounting system that allows CMS to improve accountability for Medicare payments to providers and beneficiaries. It is replacing carrier and intermediary ad hoc, PC-based computer software that is fragmented and overlapping. HIGLAS provides four financial functions: accounts receivable, accounts payable, general ledger, and cash management. HIGLAS will eventually be used by all MAC contractors and for CMS administrative accounting. HIGLAS is a CMS-furnished application and the MAC will access it using a standard Web browser over the internet. MAC personnel will be able to access certain HIGLAS online functions to support their normal job functions.

At this time, it is not anticipated that the MAC will need to convert any outgoing contractor's financial system to HIGLAS during the implementation period. All outgoing contractors will be either using HIGLAS prior to cutover or will be converted to HIGLAS after the MAC is fully operational; i.e., after the Jurisdiction Operational Start Date. As such, the MAC will not be responsible for any HIGLAS conversion activity during the implementation period.

7.5 1-800- MEDICARE

The Medicare Modernization Act mandated that a toll-free number, 1-800-MEDICARE, be the single point of contact for Medicare beneficiary telephone inquires. This includes any specific question about a beneficiary's Medicare claim. Beneficiary-specific claims inquiries were formerly handled by the carrier or intermediary who processed the beneficiary's claim. When a beneficiary calls the toll-free 1-800-MEDICARE number and inquires about a specific claim, he/she will be routed to a customer service representative (CSR) trained to handle normal claim-specific questions. Written and electronic inquiries will also be handled in the same manner. Each CSR is equipped with the standard Next Generation Desktop (NGD), which provides them with access to the data systems necessary to answer Medicare inquiries.

CSRs will not have the expertise to answer complex beneficiary inquires. When the CSR cannot resolve the beneficiary's inquiry, it will electronically refer it to the MAC via the NGD. The MAC's research and referral staff will be responsible for investigating, resolving, and providing a direct response back to the beneficiary.

The MAC should meet with 1-800-MEDICARE during the implementation to determine the protocols for transferring telephone inquires and written/electronic correspondence. 1-800-MEDICARE must be aware of the MAC's implementation plan and a testing schedule should be developed. The MAC will also need to negotiate a Joint Operating Agreement (JOA) with 1-800-MEDICARE covering the interaction and responsibilities of both parties.

7.6 Qualified Independent Contractor (QIC)

Under the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act (BIPA) and the MMA appeals provisions, the MAC is

responsible for processing redeterminations, which are first level appeals. Qualified Independent Contractors (QICs) perform the second level claim appeal, which is known as a reconsideration of a redetermination. If a request for reconsideration is made, the MAC must ensure that all case files are forwarded to the QIC and that the files contain all relevant information and evidence, including medical documentation. The MAC must take all necessary action to forward cases, effectuate decisions received from the QIC or other subsequent level of appeal, and provide payment. It must also forward misrouted requests to the proper servicing QIC.

The MAC must meet with the QIC that is servicing the segment workload that is being transferred. The protocols for forwarding reconsideration requests and other information must be discussed and agreed upon. Any data network connections must be established and tested. The QIC should be aware of the MAC's implementation plan and schedule. It will need to know cutover dates to develop a plan for any outstanding work that it might have. The MAC and outgoing contractor will determine the date that the QIC should stop sending requests for information or effectuations to the outgoing contractor, so that the backlog can be reduced. The MAC will also need to negotiate a Joint Operating Agreement (JOA) with the QIC that will detail the activities and responsibilities of each party.

7.7 Quality Improvement Organization (QIO)

A Quality Improvement Organization (QIO), formerly known as Peer Review Organization (PRO), is a group of doctors and other health care experts that are paid by CMS to review and improve the care given to Medicare patients. QIOs review complaints about the quality of health care services given to Medicare beneficiaries in hospitals, skilled nursing facilities, CORFs, and home health agencies. QIOs also review cases from hospitals to make sure the care was medically necessary, provided in the appropriate setting, and coded correctly. In addition, QIOs provide assistance to hospitals, nursing homes, physician offices, and home health agencies in measuring and improving quality.

The MAC will make the appropriate referrals to the QIO for medical necessity determinations and accept referrals from the QIO. It will process payment adjustments submitted by the QIO based on medical necessity determinations and DRG validations, including corrections to the disposition code. The contractor will also receive all notification of billing errors from the QIO and resolve the error.

The MAC will need to contact the QIO that is servicing the segment workload being transferred to discuss the transition. The MAC should obtain a copy of the Joint Operating Agreement (JOA) between the QIO and the current intermediary and use it as a basis to negotiate a new JOA. The procedures for transferring and receiving data and information must be agreed upon. The network infrastructure must be established and tested. The QIO should be familiar with the MAC's implementation schedule and agreement must be reached among the parties as to the last date for referrals to be sent to the QIO and received by the outgoing contractor.

Chapter 8: TESTING

8.1 General

One of the most important activities in any workload implementation is testing. Testing is a large undertaking and various test activities will go on throughout the implementation period. Carriers and intermediaries who have gone through workload transitions in the past have continually stressed the importance of thorough and repeated testing—"an ounce of prevention is worth a pound of cure." The MAC should not underestimate the time and effort needed to create a test plan, develop test cases, and establish and train the test team prior to the actual start of testing. CMS will review test results and documentation throughout the implementation to ensure the proper functioning of the MAC's claims processing system and operational environment prior to cutover. Successful completion of testing activities will be necessary in order to obtain approval from CMS for each segment cutover.

8.2 Test Plan

The MAC must develop and maintain a comprehensive test plan for each segment implementation. The plan will provide a detailed narrative describing the activities necessary to test the MAC's processing environment and operational readiness. The test plan should encompass standard system and non-standard systems components. It must ensure that all activities are identified, roles and responsibilities are clear, rules for testing are established, and a consistent approach is used by all who support the testing effort. The associated major testing tasks will be incorporated into the Jurisdiction Implementation Project Plan (JIPP) and Segment Implementation Project Plan (SIPP).

An overall discussion of the MAC's testing activities should be submitted as part of the MAC's proposal. The plan should describe the MAC's general approach to testing and should discuss resources, types of tests, and schedules. A comprehensive segment test plan should be developed for each segment within 30 days of the segment kickoff meeting. The finalized segment test plan will be submitted to the CMS Segment Implementation Manager and Jurisdiction Transition Coordinator for review and approval. The segment test plan will be the basis for CMS's approval to begin each segment cutover, once all system and operational functions have been tested and any issues resolved.

The test plan should encompass the scope and approach, roles and responsibilities of the various entities involved, types of testing, resources and management, schedule, processes/documentation, and risks. These components are discussed below. The test plan should attempt to balance the scope and desired quality against the timeframes and available resources, while also minimizing risk to the project.

All entities interacting with the MAC's Medicare operation (data center, CWF, CMS, functional contractors (e.g., PSC), trading partners, and claims submitters) should be included within the scope of the plan. The MAC must meet with its data center and other entities to coordinate test schedules and to define roles and responsibilities during testing. Testing tasks will be updated as part of the overall SIPP bi-weekly Implementation Project Status Report.

8.2.1 Scope/Approach

The scope of the test plan should define what is to be tested and the approach that the MAC will take to perform testing activities. It should discuss any assumptions that are being made and constraints that may influence the project. The management approach of the testing activities should also be described. The following should be considered in defining the scope of the MAC's implementation testing:

- Communication and network facilities;
- Hardware; and
- Software. This would include the Standard System application, non-base system components such as interfaces and any standalone or proprietary non-base applications used by the MAC.

8.2.2 Roles and Responsibilities

The plan should detail the roles and responsibilities of all of the various entities involved in the testing. The MAC must ensure that all entities are in agreement with their participation and activities in the testing project.

8.2.3 Types of Tests

There are a number of different tests that may be used during an implementation to validate the areas defined in the scope of the testing project. Some of the tests that have been used for Medicare workload implementations are described below. Not all tests may be applicable to every segment implementation. The MAC testing activity in sum will determine the operational readiness of the MAC for cutover. Testing terminology may vary from entity to entity and several types of tests may be performed together. The MAC should ensure that everyone involved in the testing process understands the purpose and procedures for the test.

8.2.3.1 Connectivity/Standard System Validation

This area of testing will ensure that there is connectivity between the MAC operational site(s), the CMS-designated Enterprise Data Center (EDC), and any IT facility that will support the MAC (e.g., front-end and/or back-end applications or services). The MAC's access to CMS and other entities (PSC, QIC, keyshop, etc.) must also be established and tested. Testing must verify that regions are properly configured (production, test, training, etc.), that there is access to the regions, and that any supporting third party

software is installed in the proper regions. The MAC will also ensure that the online and batch components of the Medicare standard systems are properly installed and that data files are available to test.

The MAC must be make certain that all authorized individuals have proper access and that data center processes (regions, operation control files, problem reporting, etc.) and security protocols are in place. There should be verification of the various screens and transactions should be entered to ensure system stability. The batch portions of the standard system will also be tested by running multiple daily cycles (and weekly, monthly, and quarterly) to verify that the job flow is correctly established and that data files are present.

8.2.3.2 File Conversion

If there are any files or data to be converted during the implementation, the MAC must verify the data field values and test the converted files to insure that data is properly converted. This may be done via online and batch cycles. The MAC must work with the maintainers to resolve any conversion issues and verify any subsequent reconverted data.

8.2.3.3 System Testing

The system tests will test the full capabilities of the base standard systems and non-base "add-ons." It verifies that the system requirements are satisfied and that the system is functionally and operationally correct from the user's perspective. Daily/Weekly/ Monthly/Quarterly/Yearly cycles, through payment cycles, are run in the MAC's test region. MSNs and Remittance Advices are printed as necessary for those test cases requiring verification of printed output. It should cover all areas such as online entry, suspense, data validation, processing cycle and adjudication, correspondence, inquiry/customer service, CWF processing, financial processing, file maintenance, history, and reporting. All outputs are verified complete and correct. This type of testing may also be known as functional testing.

8.2.3.4 Interface Testing

Each interface to the standard systems must be tested. This is necessary to verify that all of the interrelated systems operate as intended within an operational environment. The MAC is responsible for the coordination and testing of all interfaces with other entities in order to ensure a correct data flow to and from the Medicare standard systems. Typical interfaces are shown below, but the list is by no means all-inclusive.

- CWF,
- Bank (EFT, check issues, check clears)
- OCR and imaging interfaces
- Trading partners,
- EMC formats,
- Claim and eligibility crossover formats,

- Local and remote printing and mailing,
- Provider telecommunications and bulletin board,
- ARU/IVR,
- NGD,
- Electronic remittance process,
- Report management systems, and
- 1099 process.

8.2.3.5 End-to-End Testing

In addition to the system and interface testing that verifies production readiness, the MAC must perform end-to-end testing. This test utilizes the EDC, any IT facility supporting the MAC, and external interfaces to insure that all components of the MAC's Medicare system environment operate properly and that Medicare claims can be processed from receipt to payment. This test may also be known as an Acceptance Test or Operational Readiness Test.

The MAC will develop specific test cases to ensure that full system functionality will be tested from beginning to end. The MAC is responsible for creating test scripts or test case scenarios, performing the test, documenting the results, resolving issues, retesting if necessary, and signing off upon completion.

The end-to-end test will mirror the MAC's production processes. It will transmit claims keyed locally and remotely (e.g., keyshop), OCR, and EMC claim files from the EDI front end to the MAC's EDC. The claims will be brought into the MCS or FISS system in the same manner as will occur in the live production environment after cutover. The files will be processed through the MCS or FISS base system, transmitted to CWF, and finalized. Files will be sent to trading partners and test checks, remittance notices, and MSNs will be produced. These will be sent to providers participating in the test and the MAC's financial institution. All system test output must be verified and all steps in the process must be fully documented. CMS will monitor test progress and review the resultant documentation. The end-to-end test will be one of the factors determining whether or not approval will be given for the MAC to proceed with the cutover. The MAC must ensure that planning for the end-to-end test begins early in the project and that all test entities have sufficient time to complete their testing and any necessary retesting prior to cutover.

8.2.3.6 Stress Test

The online stress test will verify that: 1) simultaneous user access has no significant impact on online response time; and 2) the CICS region and activity data files are properly sized to accommodate all users accessing the system at the same time. The test must be coordinated with the Enterprise Data Center and should last at least an hour. All clerical personnel should sign on to the Medicare standard system and enter a variety of transactions, as they would in normal operation. No data will be validated from this test. The EDC will monitor online access and response time during the test.

8.2.3.7 Volume Test

A volume test is basically a stress test for the claims processing system. The test is performed on the batch system to verify that data files are appropriately sized to accommodate the MAC's claim volume and that the EDC has the appropriate hardware to handle an abnormally large volume of claims. In its test plan, the MAC must identify the data to be used as input to the batch cycle and identify success factors. Generally a triple batch (i.e., three times the average batch size) is used for the test. Production files for electronic claims are used as input to the test.

8.2.3.8 Release Testing

Release testing involves testing the changes being made to the Medicare standard claims processing systems. Release testing follows a standard testing process which defines the specific steps that every system change must go through before it can be placed into the MAC's standard system production environment. During the segment implementations, the MAC may receive standard system releases that must be installed prior to, or concurrent with, a cutover. As such, the MAC will be required to develop release test plans and incorporate them into the overall implementation test plan.

8.2.3.9 EMC Testing

Regardless of the method of transmission of claims information, all submitters must electronically produce accurate claims. The testing of the EMC process is a critical part of the overall implementation test plan and it is during testing when submitters find errors, omissions, and conflicts within their systems. Testing allows these problems to be corrected before the actual standard transactions are used after cutover.

Testing with vendors, suppliers and providers involves exchanging files and validating that data integrity is maintained throughout the exchange. Submitters should send the MAC a test file containing a minimum of 25 claims, which are representative of their practice or service. The MAC will then subject the test claims to format and data edits. Format testing will validate the programming of the incoming files and includes file layout, record sequencing, balancing, alpha-numeric/numeric/date file conventions, field values, and relational edits. Data testing will validate data required for specific transactions, e.g., procedure/diagnosis codes, modifiers.

It is imperative that the MAC contact EMC submitters through its communication and educational plan to inform them about testing opportunities and protocols. The MAC should provide detailed information regarding submitter testing and coordinate test schedules. Continuous follow-up with the submitter should take place if it is found that testing is falling behind schedule. CMS will be monitoring EMC testing closely and will be especially concerned about the testing status of large providers.

If the MAC cannot perform sufficient testing due to time constraints or other considerations, it may be possible to arrange with the outgoing contractor to act as a

clearinghouse. The outgoing contractor would continue to receive claims after cutover until such time that the MAC can successfully accommodate all current and new EDI and DDE submitters. Using this contingency, the MAC would test with the outgoing contractor to ensure that all EMC claims are being received successfully.

8.2.4 Resources

The test plan should detail both physical and human resources needed for testing. It should describe the organizational structure of the testing team, the functions to be performed, and how many people are needed to satisfy the objectives of plan. Also, any training or preparation needs should be considered. The plan should describe any additional hardware, software, or security necessary for test activities. Other considerations to be addressed include: which standard system environment (test or production) will be used; if usage will differ depending on the type of test; and how often the system environments have to be available and at what specific times.

8.2.5 Schedule

The MAC needs to detail the tasks and schedule for test activities. The tasks, dependencies, duration and resources required for each task should be provided. The timing for tasks—start date, completion date, milestones dates, etc. must also be included. On a more detailed level, the MAC will need to coordinate the test cycle timing for the various areas to be tested such as EMC, batch cycles, payment cycles, CWF, crossovers, etc. The major test activity and tasks associated with them will be incorporated into the JIPP/SIPP.

8.2.6 Processes and Documentation

The plan must outline how the testing will be conducted. It should discuss the methodologies and procedures for conducting tests and any subsequent retesting. A test bed of cases and scripts for all areas should be developed with defined objectives and expected results. Management activities, such as how testing will be incorporated into the workgroup structure, internal meetings, reporting, and distribution, should be detailed. How issues/errors will be tracked, reported and resolved (i.e., problem log) must also be part of the plan. Deliverables and documentation (screen prints, file dumps, reports, EOMBs, MSNs, RAs, checks, correspondence, etc.) should be listed. The plan should also show who will review and approve test results and provide a description of any quality assurance activities.

8.2.7 Risks

The MAC should identify any test-related risks that may occur during the implementation and identify mitigation actions to reduce the likelihood that the risk will occur. The MAC will also need to develop contingency plans should mitigation actions not be effective.

Chapter 9: CUTOVER

9.1 Definitions

Cutover

The actual point at which the outgoing carrier or intermediary ceases Medicare operations and the MAC begins to perform those functions.

Cutover period

The period of time surrounding the actual cutover. It usually begins 10-14 days prior to the cutover and ends with the MAC's Segment Operational Start Date, defined as the day that the MAC begins normal Medicare operations for the segment workload that it assumed at cutover. During the cutover period the outgoing carrier/intermediary makes final preparations to shut down its operation and transfer its claims workload and administrative activities, and the MAC makes final preparations for the receipt and utilization of Medicare files, data, and acquired assets. The activities that occur within the cutover period and shown on the cutover plan (see **Chapter 9.2** below) are normally referred to as cutover tasks.

Post-Cutover

Post-cutover is a CMS-designated period of time beginning with the MAC's segment operational date. The post-cutover period is when CMS will monitor the MAC's operations and performance closely to ensure the timely and correct processing of claims for the workload that was transferred. CMS will also track any open SIPP/cutover plan issues and track resolution of any problems associated with the implementation. The post-cutover period is generally three months, but it may vary in length depending on the success of the implementation. Post-cutover activities are described in **Chapter 10** following.

9.2 Cutover Plan

The MAC will be required to submit a cutover plan for each segment workload that will be moved. The cutover plan is an expansion of the cutover tasks that are shown in the MAC's SIPP. The plan should be submitted to CMS for review no later than 45 days prior to the actual segment cutover. There are a number of factors that will influence the cutover plan; therefore, planning should be done well in advance to ensure a smooth transition.

The cutover plan shall be a separate document from the SIPP. It will contain very detailed and specific information, showing tasks at a very low level, and it may be

detailed to an hourly level at times. Many contractors use the plan as a checklist and to script the events and deliverable dates during the cutover period.

The cutover plan must be developed jointly with the outgoing contractor. There should also be input from the EDC, the PSC, and any other entity that will be playing a significant role in the actual transfer of the segment workload. The consolidated plan should show the responsible organization, any JIPP/SIPP task number, the responsible workgroup, the task description, start and finish times, status, and comments. All entities must agree on the schedule and tasks in order to avoid confusion about time frames, the specific cutover responsibilities for each party, items to be transferred, and terminology. The MAC has the responsibility for preparing the cutover plan and submitting it to CMS. The plan must be distributed to all involved parties, transition team members, and workgroups. The plan should be updated daily when the segment cutover period begins.

9.3 Cutover Workgroup

A cutover workgroup will normally be established to manage cutover activities. It should be composed of representatives from the MAC, outgoing carrier/intermediary, and other involved parties; e.g., EDC, PSC, etc. The workgroup will be responsible for cutover planning and scheduling, developing the cutover plan, and facilitating the data migration. As with all workgroups, it should be established in accordance with **Chapter 3.8.** Since the activities of the workgroup are centered on the cutover, the workgroup will not need to be established when the other workgroups are formed at the kickoff meeting. However, the MAC may find it helpful to have the workgroup lead designated at that time. The cutover workgroup will normally be formed three to four months prior to cutover.

The cutover workgroup will need to be aware of all of the other workgroups and their activities. It is important that all workgroup meeting minutes and issues/deliverables logs are forwarded to the cutover workgroup lead. The group must be informed of any decisions made by the MAC Segment Project Manager, the carrier/intermediary Closeout Project Manager, or other workgroups which will impact the manner or circumstances of the transfer of the segment workload. The other transition workgroups will provide input to the tentative cutover tasks and timing developed by the cutover workgroup. They will propose additions and/or deletions to the task list and recommend any schedule change. With the input from all of the other workgroups, the cutover workgroup will coordinate the cessation of activities (file changes, mail, etc.), determine the necessary production interruptions (EMC, OSA queries), establish dark days, and schedule and monitor the actual transfer of files and assets.

As with any other workgroup, cutover meetings will be held weekly and the agenda will follow the same format, including discussion of cutover issues, action items and accomplishments. Meetings should also discuss transition task progress, current inventories, risk evaluation, file transfer, and any facility or human resources updates. All issues that are identified by CMS, raised in the status reports or workgroup minutes,

or raised in any other forum, must be placed on the issues log documenting cutover issues and discussed at each workgroup call.

9.4 Daily Cutover Meeting

Approximately 10-14 days before cutover, the MAC should begin daily cutover teleconferences with the outgoing contractor and the other parties involved in the transition. The purpose of the meeting is to go over the cutover plan and the daily events that are scheduled to occur. Calls should be scheduled at the beginning of the day and normally will be brief in length. Participants will review the cutover plan checklist of activities scheduled for the day and determine if tasks scheduled for the prior day(s) have been accomplished. The meeting will also discuss activities for the upcoming day to ensure that everyone is in agreement as to what needs to be accomplished. In addition, the meeting should review any problem log or issues identified by any of the other workgroups that pertain to the cutover. Key personnel involved in the cutover should have a backup means of communication so that they may be able to be reached in case of an emergency. Cutover meetings will continue on a daily basis through at least the first week of post-cutover segment operation. At that point, CMS will make a decision as to the frequency of the meetings. The MAC should prepare a brief synopsis of the daily cutover meeting with any issues or action items and update the cutover plan prior to the next daily meeting.

9.5 Provider Progress Report

It is expected that the MAC will be monitoring the percentage of completed EFT forms during the implementation. Normally, when the cutover period begins, CMS will require the MAC to provide daily EFT statistics as part of a Provider Progress Report. The EFT statistics will show information such as the number of providers, the total number of forms returned, total verified, forms with missing information, percentages, etc. This information will help the MAC focus on its efforts to ensure that all EFT providers complete the necessary CMS-588 prior to cutover and will allow CMS to monitor progress and direct additional efforts if warranted.

The report should also provide CMS with the status of provider and trading partner EDI activities. This would include numbers and percentages of provider documentation received and testing information such as test/production set up and completion. In addition, for a Part A segment, the report should show any DDE provider information such as registrations received, security forms returned, and testing status.

9.6 System Dark Days

One of the issues for discussion and resolution by the cutover workgroup will be the number of system “dark” days that will occur during cutover. A dark day is defined as a day during the regular work week during which the Medicare claims processing system is not available for normal business operations. System dark days may occur between the

time that the outgoing contractor ends its regular claims processing activities and the MAC begins its first day of normal business operations for the segment.

The outgoing contractor must complete all billing cycles, validate payments, cut checks, and prepare financial reports prior cutover and the end of its Medicare contract. If the cutover occurs on a scheduled provider payment date, there must be additional time allowed for the carrier/intermediary to complete the billing cycle, validate payments, and cut claims payment checks prior to the end of its Medicare contract. Also, the MAC must verify that all telecommunications, hardware, software, and equipment are installed, tested, and properly functioning after the segment cutover. In addition, the MAC will also need to run limited cycles for checkout of the files and claims processing functions. The EDC will also be changing contractor numbers or identifiers for reports, database tables, etc.

The claims processing system cannot provide current information or process claims during the aforementioned cutover activities and is considered "dark." Because CMS wants to limit the number of dark workdays, cutover normally occurs around a weekend at the end of the month. However, most cutovers require more than just the two days that a weekend provides, which means that there will normally be at least one "dark" business day.

The outgoing contractor, Enterprise Data Center, and MAC must develop a cutover schedule that provides sufficient time to accomplish all of the cutover activities. Once this is done, then the number of dark days can be determined. The number of dark days necessary at cutover will vary depending on the calendar, the size of the outgoing contractor, the length of time required for the outgoing contractor's final cycles and closeout activities, and the various other cutover activities that have to be performed. Most cutovers will require 1-2 dark days, but some cutovers may require more. CMS must be involved in the dark day discussions. Acceptance of the cutover schedule and number of dark days will be reflected in CMS's approval of the cutover plan.

During dark days, providers and submitters may submit claims for payment, but those claims will be held and will be processed after cutover. Some EMC may be processed as part of system checkout, but most EMC will be entered on a staggered basis during the first week of normal operations. Staff will be able to perform limited functions. Claims may be entered, but they will be held until regular processing cycles have begun (unless they are entered as part of the system checkout). Customer service representatives can field inquiries, but they will be limited to information from the final run of the outgoing carrier/intermediary until the first MAC segment cycle is run. ARU/ IVR information will also be limited until completion of the MAC's first cycle. As part of its communications plan, the MAC must explain the cutover sequence and inform providers/submitters of scheduled dark days and their effect on claims submission and inquiries. This explanation must be provided frequently during the transition period.

9.7 Data Migration

During the cutover period, the outgoing contractor (and any other party that may be sending files to the MAC) will prepare and transfer all Medicare files and records to prescribed locations detailed in the file transfer plan. This plan will be developed by the carrier/intermediary and the MAC, with input from any other party that will be sending files to the MAC or who will be receiving files from the outgoing contractor during the transition.

9.7.1 Final Inventory

The outgoing contractor will provide the MAC with an inventory of all files and records that will be transferred to the MAC and any other organization involved in the transition (see **Chapter 6.8).** During the cutover period, the outgoing contractor will finalize the inventory and provide the document to CMS and the MAC. The final inventory will give a description of each file, including contents, size, etc. The inventory list will be used by the workgroups or project managers to determine where files and records will reside after cutover. If there is more than one operational site for the outgoing contractor, an inventory must be prepared for each site.

Once the records have been inventoried, they should be verified to determine the quality of the inventory results. If records are not electronic, physical sampling should be performed to confirm the accuracy of the information recorded on the inventory form. The MAC should also verify, to the extent possible, that all required updates to records have been made by the outgoing contractor prior to transfer.

9.7.2 File Transfer Plan

The MAC should determine what files will need to be transferred as early as possible in the transition process. This will enable the outgoing contractor to estimate the resources it will need to provide the data and to identify those that are in a proprietary format and will need to be converted to a standard or flat file format. The MAC and the outgoing contractor shall develop a file and record transfer plan using the outgoing contractor's finalized inventory. Files may be 1) transferred to the MAC's facility (or some other Medicare contractor) for support of its operation; 2) kept at the existing operational site or existing storage facility with transfer of ownership; 3) sent to a MAC storage facility or contracted storage facility; 4) transferred to another MAC (e.g., another MAC will have responsibility for storing and accessing co-mingled carrier/intermediary records; or 5) in the case of duplicative files, destroyed.

The file transfer plan should describe the files and records to be transferred by type (suspense, EMC, audit and reimbursement, MSP, etc.) and destination. It should also establish a schedule for the transfer of the workload with shipping dates and times. In addition, it should provide the cutoff dates that the outgoing contractor will stop updating or processing particular types of claims or files. The plan should also provide a description of the method of data transfer (e.g., tapes, NDM), transfer protocols,

manifesting, packaging, and labeling all claims and correspondence. Workload may be transferred in phases rather than all at one time, especially if there is serious staff attrition in certain areas of the outgoing contractor's operation. This possibility should be accounted for in the MAC's risk management plan. CMS must be provided a copy of the final file transfer plan at the beginning of the cutover period.

The MAC should work with the outgoing contractor to insure that all required updates to files are made prior to transfer. A test transfer of files should be made prior to cutover and the MAC must test transferred files as part of its system checkout at cutover.

9.7.3 File Format

Files scheduled to be transferred to an incoming MAC in an electronic format must not be in a proprietary format which would preclude the use of the data by the incoming contractor. The outgoing contractor must change any electronic files stored in a proprietary format to a standard or flat file format prior to transfer to the incoming contractor.

9.7.4 Packing

The transfer plan should provide for early packing of as many operational files as possible without any negative impact on the operations of the outgoing contractor. Normally, records are not all packed and moved at one time. The outgoing contractor will try to pack and ship as many operational files as early as possible while it has the resources to do so, thereby mitigating the possibility of records being packed and/or labeled improperly.

The outgoing contractor should use a labeling system so that boxes are routed correctly to the MAC for operational use or storage. At a minimum, the label of each box of files should display the title of the record series, and the earliest and latest dates of the records in the box. CMS will be monitoring the process of packing and labeling beginning early in the transition process. CMS and the incoming MAC representatives may make periodic on-site visits before files are shipped to make certain that the boxes are properly packed and labeled and that a detailed inventory has been prepared.

9.7.5 Transfer of Hardcopy Files and Physical Assets

The MAC will be responsible for the shipment of files and any physical assets (equipment, supplies, furniture, etc.) that it obtains from the outgoing contractor. The cost of conveyance will be borne by the MAC. It may be beneficial to have a representative at each of the outgoing contractor's locations from which items will be shipped. These representatives would sample files to verify content and proper labeling and would ensure that items are loaded for the proper destination with the proper invoices. They may also check assets against the acquisition list to verify that all are accounted for and in the proper condition.

9.8 Sequence of System Cutover Activities

The sequence at cutover of the segment will involve the following system activities:

9.8.1 System Closeout

The outgoing contractor will close out its system operations by performing its final batch cycle, final CWF queries, the final payment cycle, and the final weekly, monthly, quarterly, and yearly workload runs. A 1099 file will also be generated. Files will be purged in accordance with applicable instructions regarding time requirements for the retention of Medicare records.

9.8.2 Back Up

The outgoing contractor's data center will backup and verify the final data. The MAC and data center will determine how long the backup will be available for inquiry after cutover, should it be necessary.

9.8.3 Transfer and Installation

If there is a change in data centers during cutover, files will need to be transferred. This would include preparation of programs and JCL to load the files and data bases. Regardless of any data center change, the final data would be loaded and system changes (user file changes, base system changes to MCS or FISS, release changes, non-base system changes) will be made. Changes could include: MSN and remittance advices, identification number, print/mail interfaces, ARU/IVR scripts, etc.

9.8.4 Data Conversion

The MAC may receive files that will need to be converted during cutover. After conversion programs have been run and the production environment has been populated with converted data, the MAC will validate the conversion output.

9.8.5 Initial System Checkout

An initial system verification will be performed by the MAC. It will verify on-line connectivity and that production system can be accessed. The transfer and availability of files will be checked, as will customer interface processes. The MAC will also determine if hardware, software, and equipment is installed and operating properly.

9.8.6 Functional Validation of System

The MAC should run cycles over the cutover weekend to check out operational functionality. This would include on-line data entry, claims activation, file verification (files accessible, formats proper, information correct), inquiries, batch processing, and testing. The first validation cycle may run conversions for claims and correspondence that were pending after the outgoing contractor's last cycle. After the cycle data is

validated, another cycle may be run to process claims entered specifically for the validation, correspondence, and backdated EMC files that were received and held during the outgoing contractor's cutover activities. The MAC will verify system output after each cycle and will then make a decision to begin normal business operations for the segment.

9.8.7 First MAC Production Cycle

The first production cycle will be run after the first day of normal business operations and the output will be validated. The cycle will include input from all functional areas and any additional EMC held from the cutover period, as well as OCR/ICR and DDE. All aspects of the system should be verified; e.g. data entry, edits/audits, suspense, correspondence, adjustments, inquiry, etc. Interfaces and data output that will be transmitted must also be verified (EFT, EMC, CWF, etc.). All print/mail functions will be validated, including checks, remittance advices, MSNs, automated correspondence, and reports.

9.9 Reporting

The outgoing contractor is responsible for the completion of all monthly and quarterly reports through the end of its Medicare contract. If the outgoing contractor leaves before the end of a quarter, it must complete all reports through the month of cutover (or through the day of cutover if the outgoing contractor leaves mid-month.) The MAC is responsible for completing all quarterly reports beginning with its first cycle run after cutover. Therefore, if an outgoing contractor does not leave at the end of the quarter, an agreement must be reached with the outgoing contractor for the sharing of data so that the MAC can produce a quarterly report.

9.10 Cutover Communication

Communication with providers and submitters regarding the cutover and its impact is absolutely essential. This cannot be overstated. It can mean the difference between the provider community perceiving the transition to be a success or failure. Providers must be informed constantly and by numerous methods about the cutover and how their payments will be affected.

Cutover information should be part of any provider workshop/seminar and should be included in any provider bulletins or notices. A special mailing on optic-colored paper several weeks prior to cutover may be extremely helpful in reminding providers/ submitters about the upcoming cutover and the change of Medicare contractor. At a minimum, the following cutover information should be provided:

- Cutoff date for the submission of EMC and paper claims, redetermination requests; cost reports/appeals, audits, quarterly PIP data, etc., to the outgoing contractor;
- Last day the outgoing contractor will make bill/claim payment;

- Last date the outgoing contractor will have telephone, lobby and contact station service for providers and beneficiaries;
- The first day the MAC will accept EMC claims;
- The first day the MAC will accept paper claims;
- The date when the MAC will begin the bill/claim payment cycle; and
- The date when the MAC will begin customer service for beneficiaries and providers and the location of these services.

Chapter 10: POST-CUTOVER

10.1 General

Post-cutover is the period of time after cutover that CMS closely monitors the MAC's operations and performance to ensure that the implementation and cutover have not affected operations or performance. CMS will monitor workload and operational processes and will track any open issues or reported problems associated with the implementation. The post-cutover period is normally three months, but it may vary in length depending on how well the MAC has incorporated the segment workload into its operations.

10.2 First Day of Segment Operations

The MAC may find it helpful to have experienced management and/or clerical staff to walk the floors on the first day of normal operations. Floorwalkers have proven to be very helpful assisting staff in answering questions, navigating new screens, and helping with system security protocols and sign-on procedures. They can also be helpful to staff who have moved to a new facility and need to familiarize themselves with the location, obtain supplies and other work materials, or be trained on new equipment. Floorwalkers also will help identify potential problem areas and issues. A CMS representative may be on-site at the MAC location to check the status of cutover tasks and to monitor operations.

The MAC will be continuously monitoring all aspects of its operation and production during the first day. The phone system should be re-checked to be certain that numbers are in place and that communication equipment is functioning properly. Call volume and the nature of calls will also be assessed. Mailroom operations will be monitored to verify that mail is being received and that equipment such as OCR/ICR is functioning. The MAC should also check that forms are correctly formatted and that there are no problems with local printing. The ARU/IVR should be monitored to make sure that scripts have been changed and the device is communicating properly. It is possible that the MAC will also be receiving shipments of files and/or equipment during the first day of operation, which will necessitate storing or unpacking and verifying contents.

10.3 Post-Cutover Monitoring

During the weeks after cutover, the MAC will be closely monitoring all aspects of the segment operation. Production cycles, inventories, call volumes, denials, suspense, rejects, and other workload indicators should be monitored to determine if there are any implementation-related production problems. The MAC should analyze workload by the various areas and points within the system and take corrective action on problems that are causing excessive errors, rejects, or suspensions. The MAC will also track post-cutover

performance goals to determine if any triggers have been reached and implement the appropriate contingency plans detailed in its risk response plan.

A key activity during the first week will be to check financial output from the first post-cutover payment cycles. A sampling of checks should be performed to verify proper payment and printing. The timely mailing of checks released from the floor should be monitored, as should the transfer of electronic funds (EFT) to the appropriate banks. Other printing such as Remittance Advices and Medicare Summary Notices may also be evaluated. The MAC should finalize any asset transfer by reimbursing the outgoing contractor for the value of transferred assets and entering the transferred items on its depreciation schedule. In addition, the MAC may also perform quality assurance on work flow processes and procedure adherence. Report flow and accuracy may also be examined. During the week the MAC will assess whether any remedial training for staff is necessary and structure educational needs based on its findings.

Daily cutover teleconferences with all participants will continue for at least the first week. CMS will then make a determination if the daily calls will continue, or if a weekly meeting will be sufficient. There will normally be a few open issues that were not resolved prior to cutover that will need to be tracked. In addition, new issues may be found. Open issues must continue to be worked by the responsible parties until satisfactorily resolved. The MAC is responsible for continuing to track open issues during the post-cutover period and should provide an updated issues log to the transition participants. After the issues log has been completed, if any problem arises which is thought to be transition-related, it should be promptly relayed to the CMS Jurisdiction Transition Coordinator, who will determine if the issue warrants a resumption of daily/weekly teleconferences.

10.4 Workload Reporting

After cutover, CMS needs to ensure there is no degradation of performance to the provider/beneficiary communities. Therefore, the MAC must provide a daily workload report for at least two weeks after each segment cutover. At the end of two weeks, the frequency of the reporting will be assessed by CMS and a decision will be made either to continue daily reporting or begin weekly reporting. Weekly workload reporting will continue for three months after cutover unless directed by CMS.

Exhibit 6, Post-Cutover Workload Report, shows a sample of the type of workload information that CMS will require. The report will provide information on claims pending, claims processed, denials, correspondence inventory, days work on hand, call volumes, call service levels, all trunks busy, and average talk time, etc. CMS may also request additional performance data to be submitted by the MAC during the post-cutover period.

10.5 Assistance with Outgoing Contractor Closeout Activities

If the outgoing contractor's staff has been hired by the MAC (or if there is a subcontracting/partnering arrangement), the outgoing contractor may request that some of

its ex-employees be allowed to perform various contract closeout activities (mostly financial) that occur after the outgoing contractor has ceased operations. Usually this assistance is not that labor intensive or burdensome and incoming contractors have been willing to provide this help. However, a memorandum of understanding should be developed describing the activities to be performed, the staff required, and the associated costs to be borne by the outgoing contractor for this support.

10.6 Access to Files and Records after Cutover

The outgoing contractor may have a need to access Medicare files and records after the cutover in order to meet certain audit or reporting responsibilities or to respond to litigation that may be in process. If such is the case, the outgoing contractor will need to negotiate with the MAC regarding access to the Medicare files/records that were previously in its possession. A Memorandum of Understanding (MOU) regarding the protocols and responsibilities of each party and the associated costs should be executed. CMS must approve the MOU that is developed and must approve any request by the former carrier/intermediary for access to Medicare files/records.

10.7 Lessons Learned

When implementation issues have been resolved and operations stabilized, the MAC should develop a lessons learned document. Lessons learned are generally prepared 4-6 weeks after cutover. The MAC should conduct its internal review of the project with input from the workgroup heads and other key transition personnel. The lessons learned document should be structured using the major implementation tasks of the SIPP or the major areas reported on the bi-weekly segment project status report. The lessons learned should analyze what activities were successful and why, and discuss those activities that need improvement. The MAC will submit a copy of its lessons learned to CMS.

Other organizations that participated in the transition will also be asked to prepare lessons learned and forward them to the MAC. The MAC will then create a single lessons learned document that will be a compendium of the segment implementation activities that were successful and those that need improvement. This document will be the basis for discussion during a post-project review meeting (see **Chapter 10.8**) and used as a learning tool in future transitions. It should be distributed to all participants at least a week prior to the post-project review meeting. This will allow time for review, expedite the meeting, and facilitate discussion.

CMS encourages all participants to be honest and forthright in their assessment of the project. Although preparation of the document is one of the last tasks on the project schedule, lessons learned should be documented throughout the project as they occur, rather than waiting until the completion of the transition.

10.8 Post-Project Review

Approximately six weeks after cutover, a post-project review meeting will be held to discuss lessons learned from the transition. The meeting may be held in person at a mutually agreed upon site or by teleconference, depending on the circumstances of the transition. CMS will have the responsibility for organizing the meeting, obtaining any meeting space, and providing toll-free telephone lines. The meeting should cover each major area of the transition and focus on the actions, methods, and processes used during the transition. The consolidated lessons learned document developed by the MAC will be the basis for meeting. Those activities that went well should be reviewed and activities that need improvement should be discussed, along with suggested remedies. Hopefully, the meeting will provide insight and generate ideas for the improvement of future transitions. Discussion should be frank and honest, with no areas off limits. Feedback should focus on processes, not personalities. The participants should be able to discuss the impact of any action or problem encountered and provide suggestions for improvement.

10.9 Implementation Project Closeout

Once all open issues have been resolved, a final issues log containing all encountered and resolved project issues should be sent to CMS. This document will be placed on file along with the lessons learned document and shared with upcoming MACs for insight into potential problems and subsequent resolutions. The MAC should insure that all project documentation is completed and archived. In addition, the MAC may want to conduct an internal project closeout meeting with senior management.

Chapter 11: CMS MONITORING REQUIREMENTS

11.1 Meetings

The MAC will conduct or attend a variety of meetings throughout the transition period. These meetings will help ensure that all parties are informed of the progress of the implementation, are aware of the outstanding issues, and understand what actions need to be taken on their part for the successful outcome of the project.

Unless otherwise stated, the MAC should conduct the following meetings during the transition. For those meetings for which it has responsibility, the MAC shall organize, host, obtain facilities, provide toll-free teleconference lines, and prepare and distribute agendas and meeting minutes. Note that the term "biweekly" means every two weeks.

Exhibit 7, MAC Workload Implementation Meeting and Documentation Guide, provides a useful reference of the following meeting information in chart form.

11.1.1 Post-Award Orientation Conference

A post-award orientation conference may be called by the Contracting Officer (CO) if he/she believes that it is necessary. The purpose of the meeting would be to ensure a clear understanding of all contractual provisions and requirements. The CO may also want to discuss any schedule changes or modifications that would be necessary based on events that have transpired after the MAC's final proposal submission. If the meeting is held, it will normally be within 10 days of contract award. Meeting logistics are the responsibility of the CO. The conference may be held in conjunction the jurisdiction kickoff meeting. See **Chapter 3.2.**

11.1.2 Jurisdiction Kickoff Meeting

The jurisdiction kickoff meeting is a one-time meeting that brings together all of the participants in the transition. It provides the opportunity to meet face-to-face to discuss the overall approach and organization of the project. Participants will provide an overview of their companies and introduce their project team. The schedule will be reviewed, roles and responsibilities defined, and any concerns or issues addressed. The number and function of the transition workgroups will also be discussed and agreed upon. While the MAC has the responsibility to set up the meeting, CMS will host the meeting and work with the MAC to develop the agenda. The kickoff meeting is normally held 10-15 days after contract award. See **Chapter 3.6.**

11.1.3 Segment Kickoff Meeting

The segment kickoff meeting represents the formal start of the process of moving a carrier or intermediary's workload to the MAC. It is similar to the jurisdictional kickoff meeting in

concept, but is focused on the activities surrounding an individual segment transition. There will be a segment kickoff meeting for each segment transition within the jurisdiction. The incoming MAC will be responsible for the logistics of the segment kickoff meeting. However, CMS will host the meeting and will work with the MAC to develop an agenda. The first segment kickoff meeting should take place 10-15 days after contract award and may be held in conjunction with the jurisdiction kickoff meeting. Subsequent segment kickoff meetings should take place 10-15 days prior to the scheduled start date of that segment transition. See **Chapter 3.7.**

11.1.4 Jurisdiction Project Status Meeting

This is a biweekly meeting intended for the project leads of the parties involved in the transition, including the overall leads for the MAC jurisdiction, MAC segments, any jurisdiction-wide workgroup leads, outgoing contractors, data centers, PSC, and QIC. BCBSA should also be in attendance for those segments involving a fiscal intermediary. This meeting is intended to review the status of the overall jurisdiction transition, ensure that tasks and schedules are coordinated properly and tasks are on schedule, and resolve issues that involve multiple segments. These meetings are normally teleconferences, but it may be helpful to hold several meetings in person. The MAC should prepare an agenda at least one day prior to the meeting and distribute meeting documentation (list of attendees, minutes, action items, etc.) within three days after the meeting.

11.1.5 Segment Project Status Meeting

This biweekly meeting is intended for all parties involved in the segment transition to obtain an update on the progress of the project. The parties will review the major tasks of the Segment Implementation Project Plan (SIPP) and receive updates from each of the workgroups. Participants will go through the deliverables and issues logs and review workgroup items. The meeting will discuss issues that have arisen and determine appropriate action on delays in task completion, deliverables, and action items. The outgoing contractor's closeout plan will also be reviewed, along with the relevant activities of the other parties involved in the transition. The Segment Project Status Report (see **Chapter 11.2.6.** below) will be used as the basis for conducting the meeting. The segment project status meetings should not be held the same week as the jurisdiction project status meeting, thereby providing some type of project status meeting every week throughout the transition. The segment status meetings are generally held by conference call, although it may be beneficial to have a face-to-face meeting after the kickoff and again prior to cutover. The MAC should prepare an agenda at least one day prior to the meeting and distribute meeting documentation (list of attendees, minutes, action items, etc.) within three days after the meeting.

11.1.6 Transition Workgroup Meeting

The transition workgroup heads will be responsible for conducting weekly workgroup meetings. Workgroups may be established for individual segments, multiple segments, or for the entire jurisdiction. The meetings will be used to review the transition activities applicable to its function, track deliverables, and monitor action item resolution. Problems or issues will also be raised to the appropriate project lead. Workgroup

meetings are normally teleconferences, although some may be in person, especially in the beginning of the project or near cutover. See **Chapter 3.8**.

11.1.7 Cutover Meeting

Beginning approximately two weeks before each segment cutover, a daily cutover teleconference will be held. The meeting will review the cutover plan and activities scheduled for that day and resolve outstanding issues. The calls are normally held in the morning and are brief in length. See **Chapter 9.4.**

11.1.8 Post-Project Review Meeting (Lessons Learned)

After each segment transition, the MAC will conduct a post-project review meeting. This meeting will normally be via teleconference unless CMS believes that it should be a face-to-face meeting. The purpose of the meeting is to review those activities that were successful during the segment transition and those that need improvement. Attendees will review the lessons learned documents that will be prepared by all parties involved in the transition (see **Chapter 11.2.17** below). The meeting will take place approximately six weeks after the segment cutover. CMS will have the responsibility to organize the meeting and provide teleconference access. Also see **Chapter 10.8.**

11.2 Documentation

CMS will closely monitor the MAC and the outgoing carriers and intermediaries during the transition to ensure that the transition occurs on schedule and that all Medicare data and operations have been properly transferred. In addition to a number of documents described in other chapters, CMS requires that the MAC submit the following implementation documents. For convenience, CMS has prepared a comprehensive guide to all of the documentation required during an implementation. The **MAC Workload Implementation Meeting and Documentation Guide** is found in **Exhibit 7.**

This documentation is for the implementation period only. Operational deliverables and reporting requirements are specified in the MAC Statement of Work (SOW) and will normally be effective with the beginning of the operational phase of the contract. However, depending on the SOW, some reports and/or deliverables may be required during the implementation period.

11.2.1 Jurisdiction Implementation Project Plan

The Jurisdiction Implementation Project Plan (JIPP) is submitted with the MAC's proposal. The plan provides an overall description of the major tasks and subtasks required to transfer Medicare data and operations from all of the carriers and intermediaries within the jurisdiction. Changes that occur after the MAC has submitted its proposal and changes that are necessitated as the result of the MAC's contractor assessment/due diligence will need to be incorporated into the JIPP. The MAC must analyze any changes that have occurred since the submission of its JIPP and present a baseline document within 30 days of contract award.

This document will be the basis for CMS's monitoring of the implementation. The JIPP is a dynamic document and will be modified as events occur during the transition. The MAC must ensure that CMS is notified of any changes made to the JIPP. See **Chapter 4.3.1.**

11.2.2 Jurisdiction Implementation Project Plan Update

The JIPP will be updated on a bi-weekly basis. The update will be included with the Jurisdiction Implementation Project Status Report and submitted at least two days prior to the project status meeting. The updated plan should be accompanied by a list of tasks that were completed during the reporting period and a list of tasks that are not on schedule—either they have not started or have not been completed in accordance with the dates shown on the JIPP. When submitting an updated JIPP, many contractors highlight in red those tasks that are not on schedule. The update should also show any tasks that have been added to the plan and any that have been deleted, along with the reason.

11.2.3 Jurisdiction Implementation Project Status Report

This report provides all participants in the transition with an update on the MAC's jurisdiction-wide activities and an overview of the status of the segment implementations. The report should be organized by the major tasks of the JIPP and provide a narrative status of each task. It should also include a discussion of outstanding issues and deliverables. Problem resolution and risk mitigation/contingencies should be included in the report, if applicable. If there are tasks that are late, the MAC must discuss the reasons for the delay, the impact to the project, and the steps that are being taken to correct the situation. The Jurisdiction Implementation Project Status Report is due two days prior to the bi-weekly jurisdiction project status meeting (see **Chapter 11.1.4** above) and will be the basis of discussion for the meeting.

11.2.4 Segment Implementation Project Plan

The Segment Implementation Project Plan (SIPP) provides a detailed list of the major tasks and subtasks required to move the outgoing contractor's workload to the MAC. It should be developed in accordance with the instructions in **Chapter 4.3.2** and must be synchronized with the JIPP. A draft plan should be submitted to CMS 30 days prior to the scheduled start of the segment implementation. The draft should be submitted to all transition team members at least one week before the initial segment kickoff meeting. This will allow attendees time to review the plan and present comments at the meeting. After the kickoff meeting, the MAC will have 30 days to refine the draft Segment Implementation Project Plan and establish a baseline document that CMS will use for monitoring. CMS must approve the baseline plan. The segment implementation will not be static. Tasks will be being added or deleted and dates will be revised based on changes that occur during the implementation period. CMS must be aware of any changes to the tasks shown in the plan and the changes must be reflected in the bi-weekly SIPP update.

11.2.5 Segment Implementation Project Plan Update

The SIPP will be updated on a bi-weekly basis. The update will be sent in conjunction with the Segment Implementation Project Status Report and submitted at least two days prior to the scheduled segment project status meeting. There should be a list of tasks completed during the reporting period and a list of tasks that are not on schedule, and the updated plan should highlight those tasks in red. The update should also show new tasks that have been added to the plan and tasks that have been deleted, along with an explanation for the action.

11.2.6 Segment Project Status Report

This report is prepared bi-weekly and contains a narrative status of the segment implementation. The report should describe the activities that have taken place in each major implementation task area for the two week reporting period. It should also include a discussion of outstanding issues and the status of deliverables. If there are problems or potential problems, the MAC should provide detailed information and provide any resolution measures. Risk mitigation/contingency plans should also be reviewed, if appropriate. The MAC should discuss any tasks/subtasks that are not on schedule. This will be based on the SIPP update, which will be forwarded with the status report. The MAC must discuss the reasons for any schedule slippage, the impact it may have on the project, and the steps that are being taken to correct the situation. The Segment Implementation Project Status Report is due two days prior to the bi-weekly segment project status meeting (see **Chapter 11.1.5** above) and will be the basis of discussion for the meeting. The report is distributed to all organizations participating in the transition.

11.2.7 Workgroup Meeting Minutes

Workgroup meeting minutes should provide a concise summary of each workgroup's weekly meeting. It should provide the status of the specific implementation tasks for which the team is responsible and list accomplishments. It should discuss action items, the status of requested deliverables, and issues/problems that have arisen. The minutes should also list tasks overdue and any claims processing workload issues that are within the workgroup's purview. Minutes should be distributed within 2 days of the meeting to all members of the workgroup, other segment workgroup heads, the MAC jurisdiction and segment project managers, and CMS.

11.2.8 Segment and Jurisdiction Issues Log/Action Items

Throughout the implementation, each segment workgroup will prepare an issues log/action items list to assist with its transition activities. The MAC Segment Project Manager should prepare a "master" issues log/action items document that will be a compilation of all of the various segment workgroups issues/action items, plus any additional issues/action items that have been identified through other sources. The list should provide an identification number, the date created, a description of the issue/action required, the responsible party, an update of the status, the date of resolution, and any pertinent comments. The master document should be reviewed weekly and updated as required. It should be submitted with the bi-weekly Segment Project Status Report.

A similar jurisdiction issues log/action items list should be prepared for those issues or action items that apply to the implementation jurisdiction-wide, not to a specific segment. This document will contain the same type of information as the segment issues log/action items. It should also be updated as required, and submitted with the bi-weekly Jurisdiction Project Status Report.

11.2.9 Segment Test Plan

The MAC will discuss testing activities in its proposal, which should include a description of its general approach to testing, types of tests, and overall schedule. The MAC will develop a segment test plan for each segment implementation. The segment test plan will be a specific and detailed description of the scope, the roles and responsibilities of the various entities involved, the types of tests, resources, schedules and risks. The plan should be submitted within 30 days after the segment kickoff meeting.

11.2.10 Segment Test Plan Update

The segment test plan will be updated on a bi-weekly basis. The update will show the status of the various tests and percentages completed. There should be a discussion of any activity that is behind schedule and what is being done to correct the situation. The update should also discuss if the delay will have an impact on the implementation schedule or cutover. The update should be submitted as part of the Segment Project Status Report.

11.2.11 Segment Cutover Plan

A cutover plan will be developed for each segment cutover in the jurisdiction. The plan will be a very detailed day-by-day plan of cutover activities to be performed by the MAC and the outgoing contractor, as well as other participants in the transition (see **Chapter 9.2**). It will provide a checklist of systems and operational tasks, sometimes to the hourly level, for cutover personnel to follow. The plan should be submitted to CMS for review at least 45 days prior to the segment cutover date. It should be updated on a daily basis during the cutover period and used as the basis for the daily cutover meetings. See **Chapter 11.1.7** above.

11.2.12 Segment Production Workload Reports

After each segment cutover, CMS needs to ensure there is no degradation of performance to the provider/beneficiary community. Therefore, the MAC must provide a daily workload report for at least two weeks after segment cutover. At the end of two weeks, the frequency of reporting will be assessed by CMS and a decision will be made to continue daily reporting or begin weekly reporting. Daily/weekly reporting will continue for three months after the segment cutover unless directed by CMS. CMS will determine the workload data to be submitted by the contractor. A sample post-cutover workload report is shown in **Exhibit 6.**

11.2.13 Segment Communication Plan

The MAC will detail overall communication activities and tasks in its Jurisdiction Implementation Project Plan, which will be submitted as part of its proposal. After each segment kickoff meeting, as the MAC obtains additional information from the outgoing contractor, it will prepare a communication plan specific to that segment. This should be submitted 30 days after the segment kickoff meeting and is the document that CMS will use to track the MAC's communication activity. The plan should identify the various stakeholders, the type of communication activity, frequency, proposed dates, etc. See **Chapter 12.2**.

11.2.14 Segment Communication Plan Update

The segment communication plan will be updated bi-weekly. The update will show completed tasks and those that are behind schedule. There should be an explanation as to why the task has been delayed and what is being done to correct the situation. The update should also discuss if the delay will have an impact on the implementation or create a problem with the affected stakeholder's perception of the success of the transition. The update should be submitted with the Segment Implementation Project Status Report.

11.2.15 Risk Management Plan

The MAC will submit a risk management plan with its proposal. The plan should identify potential risks, the probability of occurrence, the impact on the transition, mitigation strategies, and possible contingency plans. As each segment implementation begins, any segment-specific risks obtained from the MAC's assessment/due diligence must be incorporated into the risk management plan within 30 days of the segment kickoff meeting. The modified plan should be submitted to CMS for review and will be used to monitor the MAC's risk management activities. See **Chapter 14.2.4.**

11.2.16 Risk Management Plan Update

The risk management plan should be assessed at least on a monthly basis. Any changes to the plan should be noted along with an explanation of the change. An updated risk management plan should be submitted on a monthly basis with the Jurisdiction Implementation Project Status Report. See **Chapter 14.2.5.**

11.2.17 Lessons Learned

After each segment implementation, the MAC will prepare a lessons learned document regarding its activities during the project. The document should be structured using the major implementation tasks in the SIPP or the major areas reported on the Segment Implementation Project Status Report. The lessons leaned should analyze what activities were successful and why, and discuss those activities that need improvement. The document should be submitted to CMS 4-6 weeks after cutover. The MAC will also receive lessons learned from other participants in the transition and will compile all

lessons learned into a single document that will be used as the basis for discussion during the post-project review meeting (see **Chapter 10.8**).

Chapter 12: COMMUNICATIONS

12.1 General

It is imperative that the MAC provide extensive and continuous communication with all stakeholders during its jurisdiction implementation. To put it simply, communication with all stakeholders should be "early and often." Communication regarding the transition should begin immediately after award and should continue into the operational period until all implementation related issues are resolved. The dissemination of information should be coordinated with CMS, which will review and approve newsletters, bulletins, notification language, etc. The MAC will need to determine the most effective methods and schedule for providing information throughout its jurisdiction, since a number of segment implementations will not begin immediately after contract award.

The outgoing contractor will be an integral part of a number of the MAC's communication activities. The outgoing contractor will be expected to provide information to beneficiaries and providers throughout the transition period. As such, it must be consulted when the MAC's refines its communication strategy after contract award. The outgoing contractor should include the MAC when it conducts its ongoing beneficiary and provider meetings. The MAC should also develop articles for the outgoing contractor's newsletters, provide language for MSNs and Remittance Advices, and help develop scripts for the ARU/IVR.

12.2 Communication Plan

The MAC will describe its overall jurisdictional communication activities in the Jurisdiction Implementation Project Plan that is submitted to CMS as part of its proposal. The plan will discuss the processes and procedures that the MAC will follow to ensure that all stakeholders are informed of the status of the implementation and its impact upon them. CMS will review the document as part of its evaluation process.

After each segment kickoff meeting, the MAC must develop a specific communication plan for that segment. The plan may be in chart, table, or WBS project plan format. Input is critical from the outgoing contractor. It is critical that the MAC work with the outgoing contractor when developing its communication plan, as well as other entities directly involved in the transition. The outgoing contractor will be of great assistance to the MAC and will have detailed practical information for communicating with the various provide groups, associations, government officials, and other stakeholders within the segment. The segment communication plan should be submitted to CMS within 30 days of the segment kickoff meeting. It should be updated on a bi-weekly basis and submitted with the Segment Project Status Report.

The segment communication plan should identify the:

- various stakeholders in the transition;
- type of communication activity;
- purpose;
- frequency;
- impact of transition on stakeholder;
- proposed dates/actual dates;
- medium utilized (mailings, meetings, website, etc.);
- responsible party for performing activity; and
- contact person for MAC and stakeholder.

12.3 Public Announcement

The MAC may want to provide a public announcement immediately upon notification of contract award. Generally, a press release would be sent to the major newspapers within each segment and to radio and/or television stations. For segments that are several months away from beginning implementation activities, the MAC may want to issue a short general press release and follow up with a more detailed one when implementation of each segment begins.

12.4 Congressional Contact

Given the high visibility of a Medicare workload transition, the incoming MAC must establish a relationship with each segment's Congressional delegation and continue that relationship throughout the transition. The MAC must be sensitive to the interests of Congressional delegations. Members of Congress must understand the impact of the MAC's contract award, especially on the outgoing contractor's staff, and they need to be aware of implementation plans and activities.

The MAC may find it beneficial to conduct a "meet and greet" session with Senators and Representatives at their Washington, D.C. offices. It should also meet with Congressional staff at local offices in each segment. These introductory meetings should take place as soon as possible after contract award. For MACs that have segment implementations that will not start for several months after contract award, the MAC may find it helpful to meet again shortly before the start of the segment implementation.

Regular updates to the progress of the implementation should be provided to members of Congress. The MAC must also discuss any policy or procedure changes that will impact the provider community because of the change in Medicare contractors.

12.5 State and Local Contact

The MAC should also hold introductory meetings with the Governors or staff of each state within its jurisdiction. Also, major city and county officials should be contacted,

especially those in the vicinity of any office or operational site. State officials will need to know the impact of the MAC's new contract from an economic standpoint and will be extremely sensitive to any change in operations or employment. The various state insurance commissioners must also be notified of the change. In addition, notification should be sent to the appropriate State Departments of Health, the Medicaid State Agencies, and any state/county organizations involved with the aging.

12.6 Provider Communication

Provider communication is the one of the most important activities during a transition. Providers are the most affected by implementation activities and they have a large financial stake in the project. As such, the MAC must ensure that it makes every effort to inform and properly educate providers about its implementation and any impact that it may have on them. The term "provider" is used in the broad sense of the word, meaning anyone providing a Medicare service; i.e., institutional providers (hospitals, skilled nursing facilities, rural health clinics, federally qualified health centers, home health agencies), physicians, non-physician practitioners, and suppliers.

12.6.1 Professional Organization Contact

It is important for the MAC to establish a relationship with the major professional and provider organizations in each of the segment areas. This will include organizations such as hospital associations, medical societies, and specialty groups. The MAC will work with the outgoing contractor to obtain information and contacts for provider groups within the state(s) it serves. The outgoing contractor should discuss its working relationship with these groups and provide the MAC with contact points. Each provider organization should be contacted as soon as possible after contract award. Personal contact, especially with the major associations and specialty groups, has proved beneficial in past transitions. Letters and phone calls may also be used, especially for follow-up communication.

The MAC should try to take advantage of any public relations opportunities that may present themselves by offering to attend regularly scheduled meetings held by the professional groups. The MAC should ask to be placed on the agenda in order to introduce itself, provide information on the impact of the transition, give the status of the implementation, and discuss any issues that have arisen. A request may also be made to place an article or announcement about the transition in the organization's professional journal or newsletter. In addition, the MAC could offer to make speakers available. The MAC should attend regularly scheduled provider meetings with the outgoing contractor, as well as Provider Advisory Group (PAG) and/or Provider Communication Advisory Group (PCOM) meetings.

The MAC should provide monthly status bulletins/newsletters to the major provider associations detailing the status of the transition and policy issues that may affect providers. The MAC should obtain provider input on subject areas to be discussed at workshop/seminars/training sessions. The outgoing contractor can prove helpful in

planning provider sessions and it may be able to offer suggestions on the best location and facilities for those meetings.

12.6.2 Provider Contact

For each segment, the MAC must work very closely with the outgoing contractor when developing a communication strategy for providers. A complete list of providers should be obtained. The list should include such information as name, address, contact person, email address, Employee Identification Number (EIN), and EMC information. An introductory letter to providers should be sent by the MAC as soon as possible after contract award. The MAC should provide information about the upcoming transition, the implementation schedule, and a contact person with telephone number. The MAC may wish to personally contact the largest billing providers in each segment. In addition, the MAC may establish a special transition provider hotline.

The MAC should work with the outgoing contractor to develop articles regarding the transition for the outgoing contractor's provider bulletins and other publications. In addition, beginning two months prior to cutover, the MAC should develop language for the outgoing contractor's Remittance Advices that will remind providers of the upcoming change in Medicare contractor and cutover activities. The MAC should also be a part of any provider advisory group that is currently in place.

In addition to using the outgoing contractor for provider communication, the MAC may also provide information on its own to providers. Monthly updates and reminders may be issued covering information such as the cutover schedule, upcoming provider workshops, and new post office boxes for claims submission. About a month prior to cutover, the MAC should send a special cutover reminder notice to all providers reminding them about payment procedures, dark days, and other changes. Some contractors have found it helpful to use colored or optic paper to insure that providers/submitters take notice of the information.

12.6.3 Provider Workshops/Seminars

Provider workshops or seminars have proven beneficial in previous workload transitions. The purpose is to supplement the information being provided about the transition through other vehicles, provide a more detailed and informative discussion of how changes will affect the billing process, and introduce the provider community to the MAC's provider relations representative. The MAC will be able to assess areas of provider concern and answer questions directly. The workshops can serve two different audiences: provider managers/executives and provider/submitter office and claims billing personnel.

Workshop sessions will review the calendar of transition events and the changes that providers can expect when the MAC assumes the segment workload. Topics will include EMC and front end changes, claims submission and address changes, interaction with the functional contractors, and dark days. Edits/LCDs and the possibility of increased suspension/rejection of claims may also be discussed. The MAC may also use the

workshop to distribute informational materials such as compact discs or new provider manuals.

The number and content of the workshops will vary depending on the implementation activity that will take place and the size of the workload segment that the MAC will assume. The location of the workshops should take into consideration major providers and population areas. The outgoing contractor should be able to provide input to the workshop schedule, content of the presentation, and proposed meeting locations. It should also have a representative present. Workshops are normally scheduled six to ten weeks before cutover, with additional meetings added if necessary.

12.7 Beneficiary Communication

While the 1-800-MEDICARE and Beneficiary Call Centers lessen the need for beneficiary contact with carriers and intermediaries, the MAC still must make every effort to inform the beneficiary community of the transition. This may be accomplished in a number of different ways:

- newspaper advertisements and public service announcements on radio and television;
- beneficiary associations and groups such as AARP;
- state and local government agencies dealing with the aged;
- Social Security Administration district offices;
- senior citizen centers;
- health fairs; and
- community centers/libraries/retirement centers.

A beneficiary information bulletin with the MAC's name, address, telephone number, new post office boxes for claims submission, and effective date of the change of contractors should be distributed when contacting the above. Any change to the beneficiary walk-in office or availability should be highlighted.

The outgoing contractor will also help the MAC disseminate transition information. The MAC should attend regularly scheduled beneficiary outreach and beneficiary advisory/ advocacy group meetings with the outgoing contractor. The outgoing contractor can help the MAC assess demographic and language needs, and help the MAC develop language for mail stuffers or MSN messages. Distribution of these messages should begin two months prior to cutover. Transition information would also be provided on ARU/IVR scripts and on the websites of the MAC and outgoing contractor.

12.8 Social Security Administration

The MAC should prepare a notice about the change of Medicare contractors and distribute it to the Social Security Administration (SSA) district offices within its jurisdiction. The MAC should ensure that informational signs and notices of the change are available at SSA offices. The notice should provide information such as the name,

address, and telephone number of the MAC, and the effective date of the change. Also, if existing walk-in offices will be reduced or eliminated, SSA will need to be aware of that fact so that it can make arrangements to handle any increase in district office walk-in traffic.

12.9 Transition Partners

Communication with the major participants in the implementation (outgoing contractor, data center, standard system maintainer, HIGLAS, PSC, QIC) will be thorough and continuous. Protocols for communication are discussed in **Chapter 7**, Interaction with other Organizations, and **Chapter 11**, CMS Monitoring Requirements. Other organizations that interface or have an interest in the transition (trading partners/ crossovers, QIOs, COB, other Medicare contractors, etc.) will need to be contacted to discuss expectations, implementation issues, interface protocols, case review, and workflow. The MAC should regularly provide these organizations with updates to the progress of the implementation, any schedule changes, and any issues that need to be addressed, especially regarding cutover.

12.10 Internal Communications

It is important that the MAC keep its employees informed about the progress of its segment implementations. This can be accomplished through regularly scheduled staff meetings and employee bulletins or newsletters. It is also important to provide implementation information to the outgoing contractor's staff if they will be employed by the MAC after cutover. The MAC may want to have a human resources person available on-site to answer employment questions and to provide general information on the progress of the implementation.

12.11 Website

As part of its communication efforts, the MAC should establish a website or add a transition area to its existing site. The site should be registered with internet search engines and temporary transition information should be prepared. CMS website design and content requirements must be adhered to. The site should be tested and placed into production as soon as possible and updated regularly.

The website will provide current information on the incoming MAC and give status updates on the implementation. It may also provide FAQs, display links to other Medicare informational sites, and discuss any changes that will occur at cutover. If both parties agree, the MAC can also utilize the outgoing contractor's website to provide transition information and links to the MAC's website. The MAC may also establish an e-mail mailbox for electronic inquiries and/or transition listservs for quick electronic updates.

12.12 ARU/IVR

Interactive Voice Response (IVR) and Automated Response Units (AUR) can be used to provide transition information to beneficiaries and providers. Scripts may be developed to provide the status of the implementation, key dates to remember, and reminders about the payment floor and dark days. Transition information can also be made available while beneficiaries and providers are on hold for a customer service representative.

12.13 Cutover

Communication with providers regarding cutover activities is essential. Providers must be aware of cutoff dates, payment cycles, and dark days. This specialized provider communication activity is discussed in **Chapter 9.10**, **Cutover Communication.**

Chapter 13: FINANCIAL PROCESSES

13.1 General

The MAC is responsible for the orderly transfer of financial accounts and documents from the outgoing contractor and the proper payment of claims for the segment workload that it is assuming. The MAC must establish a financial administration component which will be responsible for administering and monitoring Medicare program payments and reporting program expenditures using CMS reporting protocols. CMS will also advise the MAC of the identification numbers to be used for reporting benefit payments.

13.2 Banking

The MAC shall follow established CMS banking procedures or amend its current bank agreement to include the segment workload that it is assuming. The MAC, CMS, and the bank must enter into a tripartite agreement covering two types of accounts: benefits account and time account. The earnings from the time account are used to compensate the bank for services rendered.

CMS will issue a letter of credit to fund the MAC's estimated annual program benefit payments to providers and beneficiaries. This will flow through the benefits account. The letter of credit covers claims paid by the MAC that are drawn from the benefits account, either by check or electronic funds transfer (EFT.) It authorizes a Federal Reserve Bank to advance funds to the MAC's bank for deposit into the MAC's account for payment of processed claims. If the MAC will continue with its existing banking arrangements, it must coordinate with CMS to increase its current letter of credit to reflect the new workload it will be assuming.

13.3 Financial Coordination

The MAC will need to establish the payment dates and payment frequency for its operation. It should obtain the payment schedule of the outgoing contractors, as this may influence its payment decision. Payment days and frequency vary among carriers and intermediaries; some pay weekly, others several days a week, and some pay daily. If the MAC proposes to change the existing segment payment cycle, CMS should be consulted. Providers/submitters will need to be informed repeatedly of any changes to their payment date or frequency. The MAC and the outgoing contractor must also coordinate periodic interim payments (PIP) to providers when the payment cutoff date during cutover occurs within a PIP payment period.

After cutover, provisions must be made for the outgoing contractor to forward checks and other mail to the incoming MAC. The MAC must determine if its bank will cash a

countersigned check made out to the outgoing contractor. If it will not accept a countersigned check, the MAC must return the check to the provider for reissue.

At cutover, the MAC must obtain from the outgoing contractor a final listing of outstanding checks. The outgoing contractor must also provide a voided check register to the MAC. The MAC and the outgoing contractor will need to coordinate procedures for handling stop payments, voided checks, and the reissuance of old outstanding checks.

13.4 Accounts Receivable Reconciliation

13.4.1 General

Medicare accounts receivable are a significant balance on CMS's financial statements and they require the MAC's special attention. The majority of accounts receivable are comprised of overpayments made to providers, physicians, suppliers, beneficiaries, and insurers. Other receivables are incurred when Medicare paid claims as the primary payer and it is subsequently determined that Medicare should have been the secondary payer.

13.4.2 Accounts Receivable Reconciliation

The outgoing contractor is responsible for the reconciliation of the accounts receivable for the segment that will be transferred to the incoming MAC. After the segment implementation begins, CMS (or a contracted organization) will go on-site to conduct an accounts receivable review of the outgoing contractor. The MAC should attend the review sessions to understand the process and the documentation prepared to support the reconciliation.

The MAC should be notified in writing by the outgoing contractor of all outstanding accounts receivables being transferred 60 days prior to the effective date of the transfer. The written notification will include a transmittal document summarizing the number and value of Medicare accounts receivable being transferred and an acceptance statement to be signed by the MAC. In addition to this transmittal, the outgoing contractor will include a detailed listing showing each specific account receivable being transferred. The detailed listing must agree to the summary totals reflected on the transmittal document and will include the following data elements:

- Debtor's name, Medicare identification number (provider, physician, or supplier number) and EIN or TIN;
- Account receivable/overpayment amount being transferred that includes principal and interest;
- Account receivable types; e.g., Medicare Part A or B, MSP, or other;
- Type of account receivable; e.g., cost report overpayment - audit, medical review, duplicate payment, etc.;

- The current status of collection action; e.g., interim payments being offset, extended repayment schedule in effect, etc.; and,

- The cost report period or accounting period, if applicable.

The outgoing contractor should also send the permanent administrative file for each provider/debtor transferred to the MAC. This file must contain all relevant information to support the accounts receivable being transferred; e.g., identity of debtor, refund requests and documentation to clearly support each accounts receivable/overpayment determination.

The MAC will certify the receipt of the transmittal document and return the receipt to the outgoing contractor no later than 10 calendar days after the date of transfer, with a copy provided to CMS. The MAC will review and reconcile the accounts receivable transmittal document and the detailed listing with the administrative files transferred from the outgoing contractor. If the MAC identifies a discrepancy regarding specific accounts receivable, it must meet with the outgoing contractor and attempt to resolve the issue. If the discrepancy cannot be resolved, transfer accounts receivable to the CMS project officer for resolution. The MAC has one year to review and accept all transferred receivables.

13.4.3 Financial Reporting

The MAC must retain copies of all documentation related to the transfer of accounts receivable. If there is a discrepancy regarding a specific accounts receivable, the incoming MAC will contact the CMS project officer for resolution. The MAC will report the value of the receivables which have been accepted on the appropriate line of the CMS financial reporting form as well as any amounts transferred to CMS for resolution. Summary data should be included to identify the name of the outgoing contractor and the number and value of accounts receivable that were accepted as a result of transition activity. In the event that accounts receivables were transferred from multiple outgoing contractors, information should be included for each outgoing contractor. All MACs are subject to audit and may be required to provide supporting documentation for the accounts receivables values reported on CMS financial reports.

13.5 Voucher Submission and Protocol

The MAC will determine its need for periodic payment, but CMS expects that vouchers for contract cost reimbursement will be submitted on a monthly basis. The MAC will voucher in accordance with the FAR and any requirements specified in the MAC Request for Proposals. The MAC must use the voucher/financial management reporting system provided by CMS and will report implementation costs in accordance with the CMS instructions. System requirements and user instructions will be provided by CMS at contract award. Vouchers must include supporting documentation. If there are any questions or concerns with the voucher, CMS will contact the MAC for resolution prior to payment. Detailed documentation will facilitate the timely payment of vouchers.

13.6 Implementation Costs

After contract award, the MAC may need to refine and negotiate jurisdiction and segment implementation costs based on any schedule changes or additional information obtained from the outgoing contractor or through due diligence.

Implementation costs represent the efforts of the MAC during its jurisdiction implementation and are non-recurring in nature. Jurisdiction implementation costs may be incurred at any time from the date of contract award. Implementation costs will generally not be incurred to any great extent after the final segment cutover; i.e., the jurisdiction operational start date, unless there are significant problems associated with one (or more) of the segment implementations

To be considered an implementation cost the following criteria must be met:

- costs are non-recurring and would not have been incurred except for the MAC's implementation;
- costs are "used up" in the implementation; and
- costs do not represent ongoing operational costs and are not already included in the MAC's operational cost proposal.

Direct personal service costs of MAC employees working on an implementation may be considered as implementation costs but must be specifically identified and justified in the implementation cost proposal and any subsequent negotiations. The MAC will propose a separate implementation cost and will voucher according to CMS instructions.

13.7 1099 Responsibilities

The outgoing contractor shall retain responsibility for preparation and submission of the 1099's for the providers it serviced for the year of the transition (even if this period is less than one calendar year). This responsibility includes both the electronic reporting to the Internal Revenue Service (IRS) and the hard copy reporting statement for the providers. These items shall be released on the normal 1099 reporting cycle.

The outgoing carrier/intermediary shall produce separate 1099's for the Medicare line of business and shall modify the materials going to the providers to reference the incoming MAC's name, address and the telephone number for questions and any necessary restatement after the cutover date. If any provider reporting statements are returned as undeliverable mail, the outgoing carrier/intermediary shall forward them to the MAC.

The outgoing contractor shall notify the IRS of the transfer of its Medicare operation to the MAC. It shall also request a waiver from the IRS that would allow the incoming MAC to file 1099 corrections to the IRS on paper. The outgoing contractor and the MAC

shall enter an agreement wherein the MAC will be provided the authority to correct 1099s on behalf of the outgoing contractor.

Medicare claims data used to prepare original 1099s and to research and/or correct prior years' 1099s is subject to the Privacy Act. Therefore, the outgoing contractor shall complete any processing of claims data in preparation of the 1099s and shall forward the current and all prior year data to the incoming MAC no later than 60 days following the cutover.

The incoming MAC shall answer provider questions about 1099s prepared by the outgoing contractor for the transition year and all prior years. The incoming MAC shall prepare corrections to 1099s originally submitted by the outgoing contractor.

As part of its communication activities with providers, the MAC must remind providers that they will receive two 1099s for the year that the transition occurred—one from the carrier or intermediary, and one from the MAC.

Chapter 14: RISK MANAGEMENT

14.1 General

CMS has placed great emphasis on identifying and managing risks involved in a workload transition. Risk management is an important part of a workload transition and the MAC must be prepared to mitigate identified risks and implement contingency plans. Beneficiaries and providers must not be negatively impacted as the result of a transition. A well thought out approach to risk and a comprehensive risk management plan will help ensure that they are not.

14.2 Risk Management Processes

Risk management involves the systematic process of identifying, analyzing and responding to transition risks. The MAC must look at the overall transition project and the uncertainties that exist and develop risk response strategies to prevent these potential issues from becoming real problems that will adversely affect the transition. The activities listed below are the basic processes that should be followed for the management of risk during a transition.

14.2.1 Risk Identification

The MAC will identify which risks might affect the transition and document the characteristics of the risk. Identification may come from the MAC's experience in transitions, lessons learned from other transitions, industry experts or consultants, current performance, brainstorming, etc. Triggers or warning signs that a risk has occurred or is about to occur should also be identified.

14.2.2 Risk Analysis

Risk analysis will examine each identified risk to estimate the likelihood of it happening and to predict the impact on the transition. The probability of a risk occurring may be expressed in numbers or levels such as high—likely to occur during the transition; medium—a possibility of the risk occurring; or low—unlikely to happen.

The impact on the transition will normally focus on cost, schedule, technical, or operations. Impact assessment may also be expressed in numbers or levels: high—substantial impact on the cost, schedule, technical or operations; moderate—some impact; and low—minimal, if any, impact.

Once probability and impact have been categorized, a risk prioritization should be undertaken to show what risks require management attention and action.

14.2.3 Risk Response

The MAC should develop options for responding to the identified transition risks. Options include:

- The risk could possibly be avoided by changing tasks or the schedule of the JIPP/SIPP. Any change would require CMS review;
- The risk might be able to be transferred or shifted to another organization involved in the transition;
- The probability or impact of the risk may be able to be reduced or mitigated. This is the most common option that Medicare contractors take in their approach to transition risk and has been used successfully over the years. It is much more preferable than trying to deal with a risk's consequences after cutover; and
- If other risk options are not practical or beyond the scope of the MAC's contract, the risk must be accepted. If the MAC accepts a risk, then contingency plans should be developed, especially for high priority risks. Contingency plans may also be developed for risks with a mitigation plan in place, should the mitigation plan not be effective.

14.2.4 Risk Management Plan

Following the component steps outlined above, and as required by CMS, the MAC must develop a risk management plan (also known as a risk response plan) which should contain the following:

- The details of all identified risks, their descriptions, their causes, the probability of their occurrence, the areas of the transition affected, and what impact the risk may have on the transition goals (see **Chapter 1.4**);
- The organization/person that is responsible for risk and their responsibilities;
- The results of the risk analysis and prioritization;
- The risk responses (options) that have been selected for each risk identified;
- The specific actions identified to implement the risk option strategy (e.g., mitigation, contingency plans); and
- The level of risk expected to remain after the strategy is implemented.

The RFP requires that the MAC submit a jurisdiction risk management plan with its proposal. As each segment implementation begins, the MAC should analyze risks specific to that segment and incorporate any additional risks into the risk management plan. The segment-specific update should be submitted no later than 30 days after the segment kickoff meeting. This will allow time for the MAC to obtain information from the outgoing contractor and complete at least some of its assessment/due diligence. See **Chapter 11.2.15.**

The outgoing contractor will play a key role in the development of the MAC's risk management plan. This cannot be overemphasized. After contract award, it is critical the MAC meet with the outgoing contractor, as well as other organizations directly involved in the transition, to go through the risk processes, develop a plan, and to coordinate with the other risk management plans or activities.

14.2.5 Risk Monitoring

The MAC must keep track of the identified risks throughout the transition. It must monitor trigger events and ensure the execution of risk responses. It should also evaluate the effectiveness of the responses on an ongoing basis. The MAC must recognize new risks if they develop and monitor identified risks to see if they may change or disappear.

As an integral component of the risk management process, and as required by the RFP, the MAC shall periodically reassess its risk management activities and submit an update to its risk management plan to CMS on a monthly basis identifying any new risks, and describing the implementation of new risk responses including mitigation strategies and contingency plans. See Chapter **11.2.16.**

LIST OF EXHIBITS

Exhibit 1
Transition Phases and Terminology

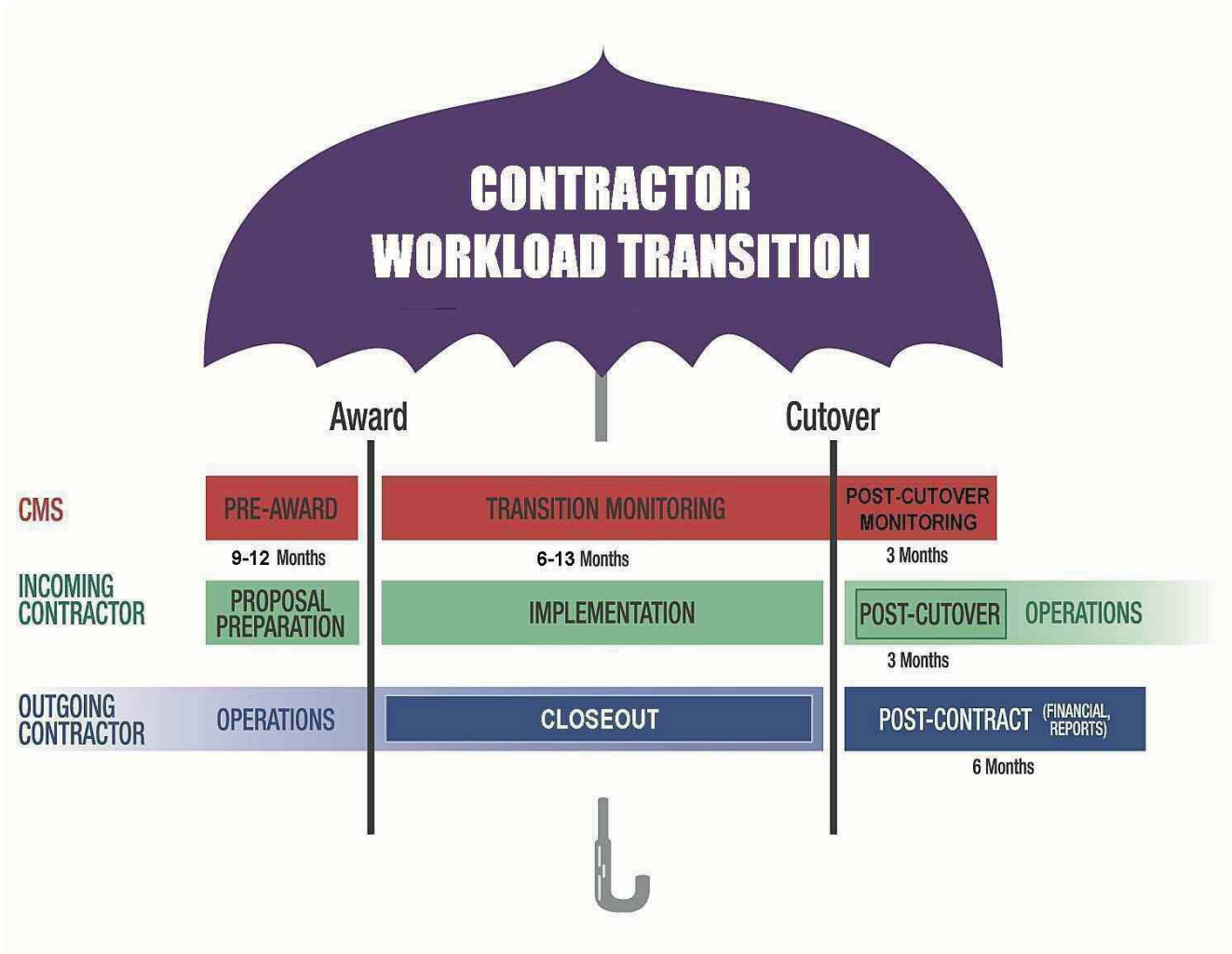

Exhibit 2
MAC Contract Administrative Structure

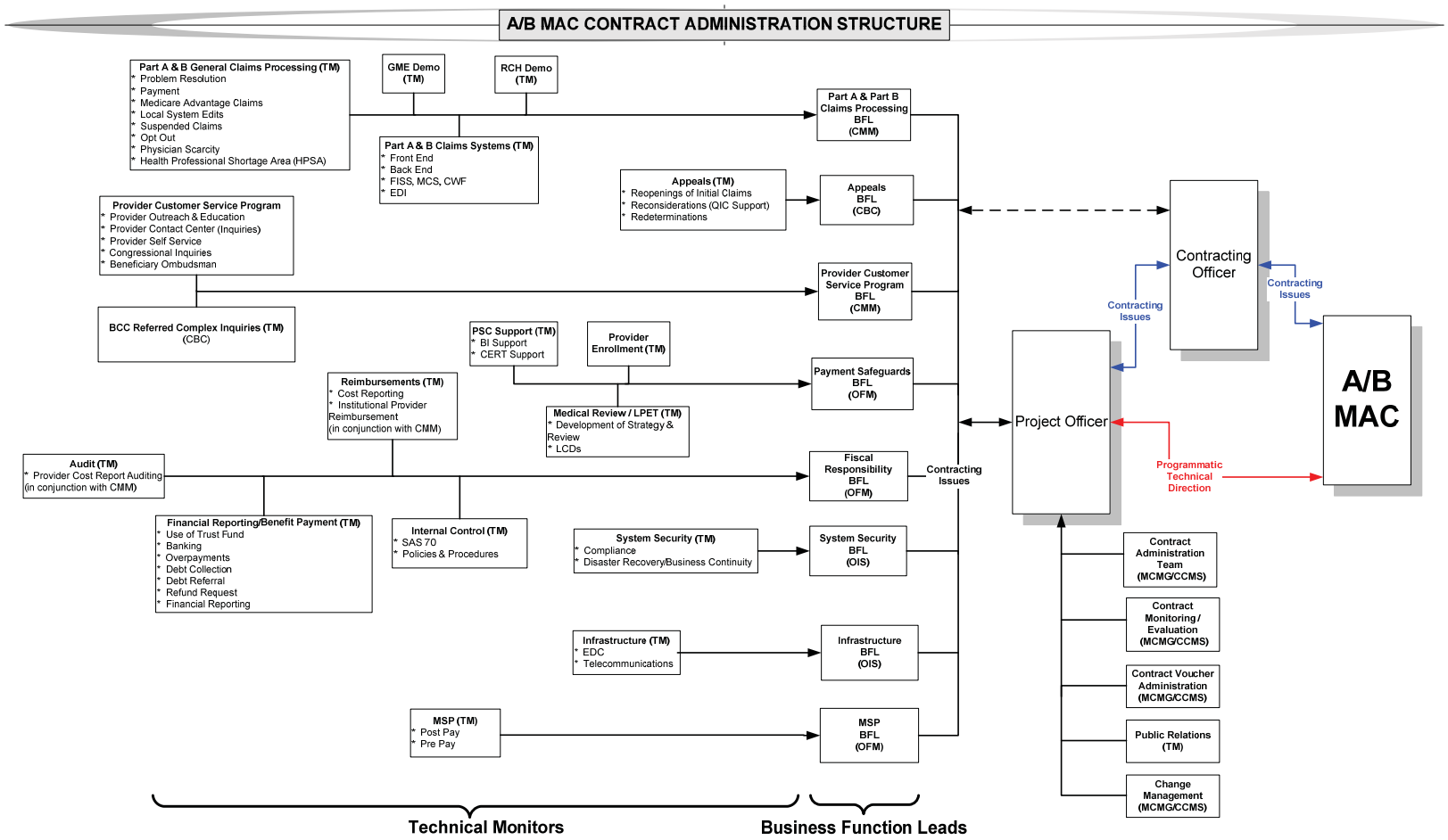

Exhibit 3
Major Tasks and Activities Associated with a Workload Transition

The following list is not all-inclusive.
All tasks listed may not be applicable in every implementation.

PROJECT MANAGEMENT

- Transition organization structure
- Establish/manage Workgroups
- Staffing
- Maintain Project plan
- Monitoring/issue log/deliverables
- Contract/subcontract administration
- Meetings
- Reports
- Communications: public, SSA, state/local, Congressional
- Risk analysis/mitigation/contingency
- Asset inventory analysis
- Financial/ project budget
- Vouchering

SITE ACQUISITION/PREPARATION

- Requirements
- Site acquisition
- Preparation/renovation
- Assess asset inventory
- Obtain/install furniture and equipment
- Miscellaneous—security, services, etc.

SOFTWARE ACQUISITION/INSTALLATION

- Requirements
- Acquisition
- Installation
- Testing

HARDWARE ACQUISTION/INSTALLATION

- Requirements
- Assess asset inventory
- Acquisition
- Installation
- Testing

Exhibit 3
Major Tasks and Activities Associated with a Workload Transition (Cont.)

CLAIMS PROCESSING/OPERATIONS ASSESSMENT

- Due diligence
- Assess/revise current operations/workflow—data entry/adjudication, MR, MSP, financial, hearings and appeals, reviews, pricing, correspondence, enrollment, etc.
- Documentation
- Special projects
- Performance deficiencies/PIPs
- Local issues/procedures/LMRP
- Special practices/best practices
- Corporate support functions (front end/back end, etc.)
- File review/transfer
- Print Functions
- Mail Operations/P.O. Boxes
- Forms/report analysis
- Records/storage

FINANCIAL

- Transition/operations budget development
- Cost reports/audit
- Accounts Receivable
- Banking agreements
- Letter of Credit
- Finance/Provider Payment?
- PIP coordination
- Provider and Physician/Supplier Overpayment Reports (POR/PSOR)
- CFO report
- EFT agreements

NETWORK / EDI / DATA CENTER CONNECTIVITY

- Determine voice/data requirements/configuration
- Order circuits/switches/equipment
- Install telecommunication equipment/software
- Establish/test connectivity
- LAN coordination (workstation support/servers/email)
- Data center agreements
- Websites

Exhibit 3
Major Tasks and Activities Associated with a Workload Transition (Cont.)

TESTING

- ☐ Unit
- ☐ Cycle/system
- ☐ End-to-end
- ☐ Contractor Acceptance
- ☐ Parallel
- ☐ Stress
- ☐ Volume
- ☐ Telecommunications
- ☐ CWF
- ☐ Interfaces
- ☐ Print/mail
- ☐ Forms/reports
- ☐ OCR/ICR
- ☐ ARU/IVR
- ☐ Front end/back end/ bulletin board
- ☐ Financial/banking (EFT, recon, clears, etc.)
- ☐ Trading partners
- ☐ EDI/DDE

INTERFACES/TRADING PARTNERS

- ☐ Identification/communication with trading partners
- ☐ Obtain crossover agreements
- ☐ Test eligibility and claims files
- ☐ EDI interfaces/migration to data center
- ☐ Front end/back end
- ☐ CWF
- ☐ EDI/DDE
- ☐ Banking/financial
- ☐ EFT agreements
- ☐ Print/mail
- ☐ 1099s

RECRUITING AND TRAINING

- ☐ Develop/refine staffing requirements
- ☐ Obtain HR information for retained staff
- ☐ Recruit/hire staff
- ☐ Establish training facilities
- ☐ Prepare training materials
- ☐ Conduct training
- ☐ Refresher training

Exhibit 3
Major Tasks and Activities Associated with a Workload Transition (Cont.)

BENEFICIARY RELATIONS

- Obtain beneficiary and organization data
- Develop communication plan
- Contact beneficiary groups, state agencies, SSA
- Meeting/seminar planning/preparation
- Conduct meetings/attend conferences
- Bulletins/newsletters/stuffer/media/website

PROFESSIONAL AND PROVIDER RELATIONS

- Obtain provider/association data
- Develop provider and professional communication plan
- Contact provider/medical organizations/large providers
- Workshop/seminar planning/preparation
- Conduct provider workshops/seminars
- Develop bulletins/newsletters/stuffers/provider manual/website

CUTOVER

- Cutover Plan
- Asset transfer
- Physical move
- Final run/copy files
- Verify copies of production/files/inventory
- System setup/conversion
- Initial cycle run
- Verify output, financial, and print/mail
- Telecommunications
- Records storage

POST- CUTOVER

- Monitor business/system operations
- Problem identification/analysis
- Problem resolution
- Workload reporting
- Lessons learned

Exhibit 4
Outgoing Contractor Information/Documentation

The following is a sample of Medicare information and documentation that is considered non-proprietary and that is normally requested by the incoming contractor during a transition:

- Copies of MSNs, Remittance Advices
- Copies of all notices and bulletins
- Outgoing contractor closeout plan
- Copies of fee schedules and payment schedules
- List of providers on 100% review, under investigation (including issues involved), and referrals to the Department of Justice
- Information on providers:
    - Name, telephone number, address, EIN of provider
    - List of providers on PIP/off PIP, with effective dates
    - Date of last interim rate payment review
    - EMC status
    - Current provider payment rates
    - Waiver of liability information, if applicable
    - Current program integrity information
    - Summary PS&R data
- Listing of historical provider issues and problems
- Unique procedure information
- Complete EMC information on all providers and submitters including:
    - Standard formats used
    - Vendors/billing houses/software used
    - Status of EDI agreements/contracts
    - EMC submission rates
    - Use of ERN and EFT
- A list of all special claims handling circumstances
- Beneficiary State Tape (BEST) or the Carrier Alphabetical State File (CASF).
- Inventory of all program materials and procedures that are available to the MAC, including any government owned property (equipment and supplies).
- List of assets available for purchase from the outgoing contractor.
- Key contacts: beneficiary, providers, Congress, specialty groups, associations.
- Staff attrition reports
- Storage information
- Status of key workload volumes
- Accounts receivable
- Enrollment inventory
- Status of cost Reports
- STAR databases
- Audit trails for Provider debt
- Workshop schedule

Exhibit 4
Outgoing Contractor Information/Documentation (Cont.)

The following is Medicare information/documentation that CMS has determined is proprietary in nature and does not have to be released by the outgoing contractor unless it chooses to do so:

- Annual Internal Audit Plan
- Business Continuity Plan
- Interim Expenditure Report/Notice of Budget Authorization
- Risk Assessment
- Lease agreements
- Subcontracts
- Off-site storage contract
- Personnel information
- Medicare organizational chart
- Disaster Recovery test results
- Production standards and performance requirements by functional area
- Internal controls/process manuals
- Training manuals and materials
- Claims processing guidelines
- List of CAPs/PIPs/CPE findings *
- CMS Regional Office Memorandum/Letters*
- Certification Package of Internal Controls *
- SAS 70 final report *
- CFO Audit final report *

* These documents may be obtained directly from CMS; however, proprietary business information and financial data will be deleted.

Exhibit 5
Files to be Transferred to a Medicare Administrative Contractor

This list is provides a sample of the types of files that will be transferred to an incoming Medicare contractor. It is not all-inclusive. Files to be transferred will vary depending on functions currently performed by the outgoing contractor and the functions that will be performed by the MAC.

Provider File

- Data File
- Index File
- Provider Mnemonic File
- Provider Overflow File
- Reasonable Charge File
- Physician ID File

Customary File

- Current Year File
- Previous Year File

Prevailing File

- Current Year File
- Previous Year File

Profile Procedure/Pricing Files

- Current Year File
- Previous Year File

Lowest Charge Level File

Limiting Charge Monitoring File

Beneficiary File

- On-line History Data Base File
- Off-line History Data Base File
- Index File
- Soundex File

Claim History/Conversion File

- Data File
- Beneficiary Inverted File
- Provider Inverted File

Exhibit 5
Files to be Transferred to a Medicare Administrative Contractor (Cont.)

Activity/Pended File

- Data File
- Master Pending File
- Index File
- Beneficiary Inverted File
- Provider Inverted File

Financial Files

- Accounting Master File
- Bank Reconciliation/Accounts Receivable File
- Inverted File

DME Files (DME MACs only)

Eligibility File

QA Files

Carrier Option File

Pending/ Finalized Audit and Reimbursement File

Personnel File

Correspondence Files

- On-line Correspondence History Data Base File
- Index File
- Inverted File
- Inverted Index File

Utilization (Post Payment) Review Files

Provider Development Systems (PDS) Files

- PDS Option File
- Base Year File
- Maximum Allowable Prevailing Charge File
- No Rollback File

Exhibit 5
Files to be Transferred to a Medicare Administrative Contractor (Cont.)

MSP Files

- Savings File
- Insurer File
- Data Match File

Government File

Coordination of Benefits File

HCPCS File

Pacemaster File

Miscellaneous Files

- SCC Files
- On-line and Update Reference Files
- Rolling Transaction File
- RPTTOTAL File
- OBFNEW File
- Batch Control File
- CICS Table Files
- Miscellaneous Transaction File
- Statistics File
- Replies Restart File
- Beneficiary Restart File
- HIC Restart File
- Procedure Frequency File
- PVSELECT File
- Provider Log File
- Procedure Diagnosis File
- Activity Restart File
- Daily/Weekly Check Number Files

Exhibit 6
Sample Post-Cutover Workload Report

Post-Cutover Workload Report													
MAC Name													
Date													
Date	Pending	Rec	Proc	CWF	Denied	Suspend	DOH Claims	DOH Corr	DOH Appeals	Bene Checks	Bene$	Prov Checks	Prov$
9/1/04													
9/2/04													
9/3/04													
9/6/04													
9/7/04													
9/8/04													
9/9/04													
9/10/04													
9/13/04													
9/14/04													
9/15/04													
9/16/04													
9/17/04													
9/20/04													
9/21/04													
9/22/04													
9/23/04													
9/24/04													
9/27/04													
9/28/04													
9/29/04													
9/30/04													

Exhibit 6
Sample Post-Cutover Workload Report (Cont.)

	Date	ACD Calls	DAILY % Service Level 60 Sec	MTD % Service Level 60 Sec	Average Talk Time	ATB	MTD - AVG ATB	Total Calls Answered (Calls that came into the IVR)	Calls Transferred to an Operator (opted out to rep)	Completed Calls (Completed in the IVR)
9/1/04										
9/2/04										
9/3/04										
9/4/04										
9/5/04										
9/6/04										
9/7/04										
9/8/04										
9/9/04										
9/10/04										
9/11/04										
9/12/04										
9/13/04										
9/14/04										
9/15/04										
9/16/04										
9/17/04										
9/18/04										
9/19/04										
9/20/04										
9/21/04										
9/22/04										
9/23/04										
9/24/04										
9/25/04										
9/26/04										
9/27/04										
9/28/04										
9/29/04										
9/30/04										
MTD:										

***Note: Callers have pre-IVR options to use the IVR or speak with a CSR. The numbers reflected on this report do not reflect those callers that opted to be routed to Customer Service.

Exhibit 7
MAC Workload Implementation Meeting and Documentation Guide

Blue shaded activities indicate face-to-face meetings or teleconferences.

Abbreviations:
CMS: CO—Contracting Officer; **PO**—Project Officer; **JTC**—Jurisdiction Transition Coordinator; **SIM**—Segment Implementation Manager
MAC: PM—Project Manager; **SPM**—Segment Project Manager; **Other: BCBSA**—Blue Cross and Blue Shield Association; **PSC**—Program Safeguard Contractor; **EDC—**Enterprise Data Center; **1-800-MEDICARE**—Call Center; **QIC**—Qualified Independent Contractor.

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
1.	*Post-Award Orientation Conference (if held).*	*Half-day meeting.*	*To review contract provisions, CMS contract administration, and vouchering.*	*One-time meeting within 10 days of contract award.*	*Face-to-face meeting.*	*CMS: CO, PO, JTC; MAC: PM, Project Team.*	*CMS Contracting Officer*	*3.2*
2.	*MAC Jurisdiction Transition Kickoff Meeting Agenda.*	*List of meeting topics with estimated times and dial-in teleconference number.*	*To provide participants with a description of topics to be discussed during the meeting .*	*One-time meeting. Due 3 days prior to meeting.*	*Memo via email.*	*CMS: CO, PO, JTC, SIM, Project Team; MAC: PM and Project Team; Outgoing Contractors; Data Centers; PSC; EDC; BCBSA; 1-800 MEDICARE; QIC, etc.*	*MAC Project Manager with CMS input.*	*3.6.2*
3.	*MAC Jurisdiction Transition Kickoff Meeting.*	*1 day meeting*	*To review the upcoming MAC jurisdiction implementation and associated carrier/ intermediary closeout activities.*	*One-time meeting scheduled 10-15 days after contract award.*	*Face-to-face meeting with telecon-ference capability.*	*CMS: CO,PO,JTC, SIM, Project Team; MAC: PM and Project Team; Outgoing Contractors; Data Centers; PSC; EDC; BCBSA; QIC; 1-800-MEDICARE, etc.*	*MAC Project Manager.*	*3.6*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
4.	*MAC Jurisdiction Transition Kickoff Meeting Documentation.*	*Minutes, record of discussion, issues/ action items.*	*To document the discussion and issues/action items from the kickoff meeting.*	*3 days following meeting.*	*Memo via electronic mail.*	*All attendees.*	*MAC Project Manager.*	*3.6.2*
5.	*Jurisdiction Transition Contact List.*	*List of kickoff meeting attendees and others to be involved in the project.*	*To ensure that appropriate transition personnel can be reached as needed throughout the transition.*	*Update and distribute as changes are made.*	*Spread-sheet via electronic mail*	*All Jurisdiction Kickoff Meeting attendees and others identified to be involved in the transition.*	*MAC Project Manager.*	*3.6.2*
6.	*Deliverables List.*	*List of documents, information, files, etc. requested by MAC to be provided by outgoing contractor.*	*To facilitate the transition from the carrier/ intermediary to the MAC environment.*	*Development begins at contract award. Maintained and updated throughout the implementation.*	*Memo via electronic mail.*	*Outgoing Contractor; CMS: PO, Jurisdiction Transition Coordinator, Segment Implementation Manager.*	*MAC Project Manager.*	*3.6.4 4.13*
7.	*MAC Segment Transition Kickoff Meeting Agenda.*	*List of meeting topics with estimated times and dial-in teleconference number.*	*To provide participants with a description of topics to be discussed during the meeting.*	*One-time meet-ing for each segment imple-mentation. Due 3 days prior to meeting.*	*Memo via electronic mail.*	*CMS: CO, PO, JTC, SIM; MAC: PM, Project Team leads; Outgoing Contractor; BCBSA; PSC; EDC; 1-800-MEDICARE; QIC, etc.*	*MAC Project Manager with input from CMS.*	*3.7.2*
8.	*MAC Segment Transition Kickoff Meeting.*	*1 day meeting.*	*To review the upcoming Segment implementation and carrier/intermediary closeout activities.*	*One-time meeting for each segment implementation.*	*Face-to-face meeting with teleconfer-ence capability.*	*CMS: CO, PO, JTC, SIM, workgroup heads; MAC: PM, workgroup leads; Outgoing Contractor; PSC; EDC; BCBSA; 1-800-MEDICARE; QIC, etc.*	*MAC Project Manager.*	*3.7*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
9.	*MAC Segment Transition Kickoff Meeting Documentation.*	*Minutes, record of discussion, and issues/action items.*	*To document the discussion and issues/action items from the Segment Kickoff Meeting.*	*3 days following meeting.*	*Memo via electronic mail.*	*All attendees.*	*MAC Project Manager.*	*3.7.2*
10.	*Segment Transition Contact List.*	*Contact list of segment kickoff meeting attendees and others to be involved in the project.*	*To ensure that appropriate segment transition personnel can be reached as needed throughout the transition.*	*Update and distribute as any changes are made.*	*Spread-sheet via electronic mail.*	*All attendees and workgroup members and others identified to be involved in the transition.*	*MAC Project Manager.*	*3.7.2*
11.	*Comprehensive Transition Workgroup Schedule/Calendar/ Contact List.*	*Document in calendar format showing all work-groups, heads, members, meeting times, and dial-in teleconference numbers.*	*To provide a reference calendar of all workgroup meetings and information.*	*Update and distribute as any changes are made.*	*Calendar format via electronic mail.*	*CMS: PO, JTC, SIM; MAC: Project Manager; all workgroup members.*	*MAC Project Manager*	*3.8.5*
12.	*Transition Workgroup Agenda.*	*Standardized outline of work-group topics with dial-in telecom-ference number*	*To provide participants with topics to be covered in the workgroup meeting.*	*One day prior to the meeting.*	*Memo via electronic mail.*	*CMS: JTC, SIM; MAC: PM; all workgroup members.*	*Workgroup Head.*	*3.8.5*
13.	*Transition Workgroup Meetings.*	*Meetings for the various functional workgroups.*	*To monitor transition tasks and issues of the functional area for which the work-group has responsibility.*	*Weekly meetings throughout the jurisdiction/seg-ment transition*	*Telecon-ference*	*All workgroup members.*	*Workgroup Head.*	*3.8.5*
14.	*Transition Workgroup Meeting Documentation.*	*Concise description of the workgroup meeting, issues, and action items.*	*To provide a record and to document issues and action items pertaining to the workgroup.*	*Two days after each meeting.*	*Memo via electronic mail.*	*All workgroup members; all other workgroup heads; CMS: JTC, SIM; MAC: PM.*	*Workgroup Head.*	*3.8.5*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
15.	*Jurisdiction Project Status Report.*	*Narrative of jurisdiction accomplishments by major tasks, issues/ concerns, action items, upcoming activities.*	*To communicate progress and performance against the project schedule, highlight issues, concerns, action items, etc. regarding the total jurisdiction implementation.*	*Biweekly alternating with the Segment Status Reports, at least 2 days prior to Jurisdiction Project Status Meeting.*	*Memo via electronic mail.*	*CMS: CO, PO, JTC, SIM; MAC: PM, SPM, Workgroup Heads; all other attendees of the Jurisdiction Kickoff Meeting/Contact List.*	*MAC Project Manager.*	*11.2.3*
16.	*Jurisdiction Project Status Meeting Agenda.*	*List of meeting topics with estimated times and dial-in teleconference number.*	*To provide participants with a description of topics to be discussed.*	*Biweekly at least 1 day before meeting.*	*Memo via electronic mail.*	*CMS: CO, PO, JTC, SIM; MAC: PM, SPM, Workgroup Heads; all other attendees of the Jurisdiction Kickoff Meeting/Contact List.*	*MAC Project Manager.*	*11.1.4*
17.	*Jurisdiction Project Status Meeting.*	*1-2 hour general status meeting.*	*To keep all parties involved in the transition informed about the overall transition status, to discuss progress and issues, track action items and deliverables, and to review the Jurisdiction Implementation Project Plan (JIPP).*	*Biweekly on the Segment Status Report/Meeting off-week*	*Conference call. Possible face-to-face meeting with tele-conference capability*	*CMS: CO, PO, JTC, SIM; MAC: PM, SPM, jurisdiction-wide workgroup leads; PSC; EDC; 1-800-MEDICARE; BCBSA; QIC, etc.*	*MAC Project Manager*	*11.1.4*
18.	*Jurisdiction Project Status Meeting Documentation.*	*List of attendees, discussion items, action items.*	*To provide a record and document the issues/action items from the bi-weekly jurisdiction project status meeting*	*3 days after meeting*	*Memo via electronic mail*	*All attendees*	*MAC Project Manager*	*11.1.4*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
19.	*Jurisdiction Implementation Project Plan (JIPP).*	*Project plan listing major tasks/ subtasks required for the MAC jurisdiction implementation, along with dates, duration, dependencies, and responsible parties.*	*To document all actions required for the MAC jurisdiction implementation, identify dependencies, and establish start/completion dates in order to monitor progress and to facilitate the communication process among the parties involved in the transition.*	*Submitted with proposal in accordance with Section L of the RFP. Baseline working document developed within 30 days after kickoff meeting.*	*Electronic. Project management software in, or convertible to, MS Project, MS Excel, or PDF format.*	*CMS: CO, PO, JTC, SIM; MAC: PM, SPM; outgoing carrier/intermediary; EDC; PSC; BCBSA; 1-800-MEDICARE; QIC; etc.*	*MAC Project Manager. Input from all involved entities necessary for baseline JIPP. Baseline JIPP approved by CMS.*	*4.3.1 4.3.3*
20.	*Jurisdiction Implementation Project Plan (JIPP) Update.*	*Current information on the JIPP regarding project tasks, start and finish dates, dependencies, and completion percentage, including a list of tasks completed and off schedule.*	*To provide up-to-date information regarding all project tasks. This will allow the MAC Project Manager and all involved parties to effectively monitor and manage the overall project to ensure completion as scheduled.*	*Biweekly on the Segment Status Report/Meeting off-week. Submitted with the Jurisdiction Project Status Report.*	*Electronic. Project management software in, or convertible to, MS Project, MS Excel, or PDF format.*	*CMS: CO, PO, JTC, SIM; MAC: PM, SPM; outgoing carrier/intermediary; EDC; PSC; BCBSA; 1-800-MEDICARE; QIC, etc.*	*MAC Project Manager.*	*11.2.6 4.3.3*
21.	*Segment Project Status Report.*	*Narrative description of segment accomplishments by major tasks, issues/ concerns, action items, upcoming activities.*	*To communicate progress and performance against the project schedule, highlight issues, concerns, action items, etc. regarding the segment implementation.*	*Biweekly alternating with the Jurisdiction Status Report, at least 2 days prior to Segment Project Status Meeting.*	*Memo via electronic mail.*	*CMS: JTC, SIM; MAC: PM, SPM, work-group team leads; outgoing carrier/intermediary; EDC; PSC; 1-800-MEDICARE; QIC, etc.*	*MAC Segment Manager.*	*11.2.6*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
22.	*Segment Project Status Meeting Agenda.*	*List of meeting topics with estimated times and dial-in teleconference number.*	*To provide participants with a description of topics to be discussed.*	*Biweekly for each segment, at least 1 day before meeting.*	*Memo via electronic mail.*	*CMS: JTC, SIM; MAC: PM, SPM, workgroup team leads; outgoing carrier/intermediary; EDC; BCBSA; PSC; 1-800-MEDICARE; QIC, etc.*	*MAC Segment Manager.*	*11.1.5*
23.	*Segment Project Status Meeting.*	*1-2 hour general status meeting.*	*To keep all parties informed about the segment transition status, to discuss progress and issues, track action items and deliverables, and to review the Segment Implementation Plan (SIPP).*	*Biweekly for each segment.*	*Conference call. Possible face-to-face meeting with with tele-conference capability.*	*CMS: SIM; MAC: SPM, workgroup team leads; outgoing carrier/intermediary; EDC; PSC; BCBSA; 1-800-MEDICARE; QIC, etc.*	*MAC Segment Project Manager*	*11.1.5*
24.	*Segment Project Status Meeting Documentation.*	*List of attendees, discussion items, action items.*	*To provide a record and document the issues/action items from the bi-weekly segment project status meeting.*	*3 days after meeting.*	*Memo via electronic mail.*	*All attendees.*	*MAC Segment Project Lead*	*11.1.5*
25.	*Segment Implementation Project Plan (SIPP).*	*Project plan listing major tasks/sub-tasks required for the MAC segment implementation, along with dates, duration, dependencies and responsible parties.*	*To document all actions required for the MAC segment implementation, identify dependencies, and establish start/completion dates in order to monitor progress and to facilitate the communication process among the parties involved in the transition*	*Draft due at segment kickoff meeting. Baseline document developed for each segment within 30 days of segment kickoff meeting.*	*Electronic. Project management software in, or convertible to, MS Project, MS Excel, or PDF format.*	*CMS:PO, JTC, SIM; MAC: PM, SPM; outgoing carrier/intermediary; BCBSA; EDC; PSC; QIC; 1-800-MEDICARE, etc.*	*MAC Segment Manager. Input from all involved entities necessary for baseline SIPP. Baseline SIPP approved by CMS.*	*4.3.2*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
26.	*Segment Implementation Project Plan (SIPP) Update.*	*Current information on the SIPP regarding project tasks, start and finish dates, dependencies, and completion percentage, including a list of tasks completed and off schedule.*	*To provide up-to-date information regarding all project tasks. This will allow the MAC Segment Manager and all involved parties to effectively monitor and manage the overall project to ensure completion as scheduled.*	*Biweekly on the Jurisdiction Status Report /Meeting off-week. Submitted with the Segment Project Status Report.*	*Electronic. Project management software in, or convertible to, MS Project, MS Excel, or PDF format.*	*CMS: PO, JTC, SIM; MAC: PM, SPM; outgoing carrier/ intermediary; EDC; PSC; BCBSA; QIC; 1-800-MEDICARE, etc.*	*MAC Segment Manager.*	*4.3.3 11.2.5*
27.	*Master List of Segment Issues Log/Action Items.*	*Comprehensive list that documents issues/action items for each segment including ID, date created, description, responsible party, status, date of resolution. Accumulated from the various segment workgroups.*	*To track segment transition issues and action items related to the project. Will be reviewed during the segment project status meetings.*	*Reviewed weekly and updated as required. Submitted with the biweekly Segment Project Status Report.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM; workgroup heads; outgoing carrier/intermediary.*	*MAC Segment Project Manager*	*11.2.8*
28.	*Master List of Jurisdiction Issues Log/Action Items.*	*A list that documents jurisdiction-wide issues/action items for the overall jurisdiction including ID, description, date created, responsible party, status, date of resolution.*	*To track jurisdiction-wide transition issues and action items related to the project. Will be reviewed during the jurisdiction project status meetings.*	*Reviewed weekly and updated as required. Submitted with the biweekly Jurisdiction Project Status Report.*	*Distributed by electronic mail.*	*CMS: JTC, SIM; MAC: PM, SPM; jurisdiction-wide workgroup heads; outgoing carrier/ intermediary.*	*MAC Project Manager*	*11.2.8*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
29.	*Segment Communication Plan.*	*A general description and detailed schedule of how the MAC will educated and keep all segment transition stakeholders in formed of the progress of the implementation and how any changes may affect them.*	*To monitor communication activities and schedules for each segment.*	*Overall communication plan submitted as part of MAC's proposal. Specific segment communication plans developed within 30 days of each segment kickoff meeting.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM; outgoing carrier/intermediary.*	*MAC Segment Project Manager with input from carrier/ intermediary.*	*12.2 11.2.13*
30.	*Segment Communication Plan. Update*	*Update on communication activities and schedules*	*To provide CMS with current information on communication activities and schedules.*	*Biweekly. Submitted with the Segment Implementation Project Status Report.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM; outgoing carrier/intermediary.*	*MAC Segment Project Manager.*	*12.2 11.2.14*
31.	*Segment Test Plan.*	*A specific and detailed description of the resources, types of tests and schedule for each segment.*	*To monitor the testing of the MAC's claims processing system and operational environment prior to each segment cutover.*	*Overall jurisdiction testing approach submitted with the MAC's proposal. Baseline segment test plan developed within 30 days of segment kickoff meeting.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM; appropriate workgroup heads.*	*MAC Segment Project Manager.*	*8.2 11.2.9*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
32.	*Segment Test Plan Update.*	*Update on testing activities and schedules.*	*To track schedule progress and provide current information on testing.*	*Updated on a bi-weekly basis and submitted with the Segment Implementation Project Status Report.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC:PM, SPM; appropriate workgroup heads.*	*MAC Segment Project Manager.*	*8.2 11.2.10*
33.	*Risk Management Plan.*	*A plan that identifies and analyzes jurisdiction and segment-specific risks, prioritizes them, and provides mitigation strategies and contingency plans.*	*To assist in managing and monitoring segment risks and mitigation activities.*	*Submitted with the MAC's proposal. Any segment-specific risks incorporated within 30 days of segment kickoff meeting.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM.*	*MAC Segment Project Manager.*	*14.2.4 11.2.15*
34.	*Risk Management Plan Update.*	*Update to risks based on periodic assessment or changed conditions.*	*To have up-to-date mitigation strategies and contingencies based on changes to the implementation environment.*	*As necessary, but at least monthly. Submitted with Jurisdiction Implementation Project Status Report.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM.*	*MAC Project Manager.*	*14.2.5 11.2.16*
35.	*Employment Report.*	*A report of MAC employees hired during the implementation, broken down by location, functional or organizational area.*	*To allow CMS to track employment hiring activity.*	*Biweekly report to be submitted with the Jurisdiction Project Status Report.*	*Distributed by electronic mail.*	*CMS: JTC, SIM; MAC: PM, SPM.*	*MAC Project Manager.*	*5.1.3*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
36.	*Segment Cutover Plan.*	*Day-by-day check-list of activities that need to be accomplished during the cutover period.*	*To assure that all tasks required for the transfer of Medicare files, records, equipment, etc. from the outgoing contractor are captured and tracked.*	*Submitted at least 45 days prior to the segment cutover date.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM; outgoing carrier/intermediary; EDC; BCBSA; PSC; 1-800-MEDICARE; QIC, etc.*	*MAC Segment Project Manager.*	*9.2*
37.	*Segment Cutover Plan Update.*	*Updates to the cutover plan reflecting tasks completed.*	*To provide an up-to-date status of tasks required for cutover.*	*Daily during the segment cutover period (10-14 days prior to cutover.)*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: SPM, PM; outgoing carrier/intermediary; EDC; BCBSA; PSC; 1-800-MEDICARE; QIC, etc.*	*MAC Segment Project Manager.*	*9.4*
38.	*Segment Cutover Meeting.*	*Status meeting generally one-half to one hour in length.*	*To review the Segment Cutover Plan and progress of activities, including action items, concerns, risks, and contingencies.*	*Daily during the segment cutover period (10-14 days prior to cutover) and continuing at least one week after cutover.*	*Telecon-ference.*	*CMS: SIM, JTC; MAC: SPM, PM; outgoing carrier/ intermediary; EDC; BCBSA; PSC; QIC; 1-800-MEDICARE, etc.*	*MAC Segment Project Manager.*	*9.4*
39.	*Cutover Meeting Documentation.*	*Brief synopsis of attendees, discussion items, and action items.*	*To document cutover meeting conference calls.*	*Prior to next daily meeting.*	*Memo via electronic mail.*	*All attendees of the Segment Cutover Meeting.*	*MAC Segment Project Manager.*	*9.4*
40.	*Provider Progress Report.*	*Daily report of numbers and percentages of providers completing EDI/ EFT/DDE processes.*	*To track progress of EFT form completion, DDE registration/security, and provider/trading partner EDI set up and testing. Assists MAC in focusing efforts for completion of processes.*	*Daily at the start of the segment cutover period (10-14 days prior to cutover).*	*Memo via electronic mail.*	*CMS: SIM; MAC: SPM; outgoing carrier/intermediary.*	*MAC Segment Project Manager.*	*9.5*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
41.	*File Transfer Plan.*	*Description of Medicare files and records to be transferred by type, how and where they will be moved, and schedule.*	*To assist CMS in monitoring file preparations and the relocation of files.*	*Submitted to CMS at the start of the cutover period (10-14 days prior to cutover).*	*Distributed by electronic mail*	*CMS: SIM; MAC: SPM; outgoing carrier/intermediary.*	*MAC Segment Project Manager with input from outgoing carrier/inter-mediary.*	*9.8.2*
42.	*Segment Production Workload Report.*	*Operational statistics from production, including claims, correspondence, appeals, and customer service as they pertain to the segment workload that has been cut over. Format and content specified by CMS.*	*To aid in monitoring operations and implementation issues in the post-cutover period as they pertain to the segment that has cut over.*	*Daily for at least the first 2 weeks after cutover. Frequency after the first 2 weeks will be determined by CMS.*	*Distributed by electronic mail.*	*CMS: PO, SIM; MAC: SPM*	*MAC Segment Project Manager.*	*10.4 Ex. 6*
43.	*Post Project Review (Lessons Learned).*	*A discussion of segment transition successes and areas that could be improved.*	*To document lessons leaned and suggested improvements for the next segment transition. A compilation of lessons learned from all parties involved in the transition will be used as the basis for the Post Project Review Meeting.*	*One time. Due 4-6 weeks after cutover of each segment. MAC will also compile lessons learned from other involved parties into a single document and distribute 1 week prior to the Post-Project Review Meeting.*	*Distributed by electronic mail.*	*CMS: SIM, JTC; MAC: PM, SPM; outgoing carrier/intermediary; EDC; BCBSA; PSC; 1-800-MEDICARE; QIC, etc.*	*MAC Project Manager with input from project leads of all parties involved in the transition.*	*10.5*

No.	Activity	Description	Purpose	Frequency	Media	Audience	Responsibility	Ref.
44.	*Post-Project Review Meeting (Lessons Learned).*	*3-4 hour meeting.*	*To discuss segment transition practices that worked well and areas for improvement for future transitions.*	*One time. Approximately 4- 6 weeks following each segment cutover.*	*Teleconfer-ence or possible face-to-face meeting.*	*CMS: SIM, JTC; MAC: PM, SPM; outgoing carrier/intermediary; EDC; BCBSA; PSC; 1-8000-MEDICARE; QIC, etc.*	*MAC Project Manager.*	*10.6*

Exhibit 8
Glossary

Closeout: The period of time from the MAC's contract award to the end of the outgoing contractor's Medicare business operations during which the carrier/intermediary carries out its plan to close down operations and transfer Medicare functions to the MAC.

Cutover: The actual point at which the outgoing Medicare carrier/intermediary ceases Medicare operations and the MAC begins to perform Medicare business functions.

Cutover Period: The period of time surrounding the actual cutover. The cutover period normally begins 10-14 days prior to the cutover and ends with the MAC's segment operational date; i.e., when the MAC begins normal business operations for the segment workload that it assumed at cutover. During the cutover period the outgoing contractor makes final preparations to shut down its operation and transfer the claims workload to the incoming contractor and the MAC makes final preparations for the receipt of Medicare files/data and the beginning of segment operations.

Implementation: The period of time beginning with the award of the MAC contract and ending with the operational date of the MAC. During this period, the MAC performs all of the activities specified in its implementation plan to ensure the effective transfer of Medicare functions from each outgoing carrier or intermediary within the jurisdiction.

Jurisdiction: The territory in which the Medicare Administrative Contractor will contractually perform its Medicare functions.

Medicare Administrative Contractor (MAC): The incoming contractor that will assume the Medicare Part A and B functions from a carrier or fiscal intermediary.

Medicare Data: Any representation of information, in electronic or physical form, pertaining to Medicare beneficiaries, providers, physicians, or suppliers, or necessary for the contractual administration thereof, that is received, maintained, processed, manipulated, stored, or provided to others in the performance of functions described in a Medicare contract.

Medicare Record: A collection of related items of Medicare data treated as a unit.

Medicare File: A set or collection of related Medicare records treated as a unit

Operational Date: The date that the MAC assumes all Medicare functions from an outgoing Medicare carrier or fiscal intermediary and is capable of processing Medicare claims.

Exhibit 8
Glossary (Cont.)

Outgoing Contractor: The Medicare carrier or fiscal intermediary whose functions will be assumed by the MAC.

Post-Contract Period: The six-month period beginning with the end of the outgoing carrier or intermediary's Medicare contract. During this time, the outgoing contractor maintains the Federal Health Insurance Benefits account, completes financial reporting and performs related closeout business activities.

Post-Cutover Period: generally the MAC's first three months of Medicare operation for a segment implementation, during which workload and performance are monitored and any problems associated with the implementation are resolved.

Pre-Award Phase: The period of time prior to award of the MAC contract where CMS is preparing for and conducting the MAC procurement and performing informational activities pertaining to the affected Medicare carriers and intermediaries.

Segment: The Medicare Part A or Part B workload which a carrier or intermediary processes and which will be transferred to the MAC. A segment workload is generally a state or portion thereof. All jurisdiction transitions will involve multiple segment transitions.

Transition: The entire scope of activities associated with moving the functions of Medicare fee-for-service carriers and intermediaries to the Medicare Administrative Contractors. It includes implementation activities of the MAC, closeout activities of the outgoing contractor, and the activities of other parties involved in the transition.

Transition Monitoring: A responsibility of CMS to ensure that Medicare functions are properly transferred from each outgoing Medicare carrier or fiscal intermediary to the MAC. Transition monitoring begins with the award of the MAC contract and ends three months after the operational date of the MAC for each outgoing contractor.

Exhibit 9
Abbreviations

BCBSA	Blue Cross and Blue Shield Association
BCC	Beneficiary Contact Center
BFE	Business Function Expert
CMM	Center for Medicare Management
CMS	Centers for Medicare and Medicaid Services
CO	Central Office
CO	Contracting Officer
COB	Coordination of Benefits
CROWD	Contractor Reporting of Operational and Workload Data
CSAMS	Customer Service Assessment and Management System
CTA	Cooperative Transition Agreement
CWF	Common Working File
DDE	Direct Data Entry
DHHS	Department of Health and Human Services
DMERC	Durable Medical Equipment Regional Carrier
EDC	Enterprise Data Center
EDI	Electronic Data Interchange
EFT	Electronic Funds Transfer
EMC	Electronic Media Claims
ERN	Electronic Remittance Notice
FAQ	Frequently Asked Question
FFS	Fee-for-service
FI	Fiscal Intermediary
FISS	Fiscal Intermediary Standard System
GFP	Government-furnished property
GTL	Government Task Leader
HIGLAS	Healthcare Integrated General Ledger Accounting System
HIPAA	Health Insurance Portability and Accountability Act
IT	Information Technology
IVR	Interactive Voice Response
JIPP	Jurisdiction Implementation Project Plan
JOA	Joint Operating Agreement
JOSD	Jurisdiction Operational Start Date
JTC	Jurisdiction Transition Coordinator
LCD	Local Coverage Determination
MAC	Medicare Administrative Contractor

Exhibit 9
Abbreviations (Cont.)

MCR	Medicare Contracting Reform
MCS	Multi-Carrier System
MDCN	Medicare Data Communications Network
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
MR	Medical Review
MSN	Medicare Summary Notice
MSP	Medicare Secondary Payer
NARA	National Archive and Record Administration
PECOS	Provider Enrollment, Chain and Ownership System
PI	Program Integrity
PO	Project Officer
POR	Provider Overpayment Reporting
PSC	Program Safeguard Contractor
QIO	Quality Improvement Organization
QIC	Qualified Independent Contractor
RFP	Request for Proposal
RHHI	Regional Home Health Intermediary
RO	Regional Office
SIPP	Segment Implementation Project Plan
SOSD	Segment Operational Start Date
SOW	Statement of Work
SSA	Social Security Administration
SSM	Shared System Maintainer
SIM	Segment Implementation Manager

Medicare Part A or B	Consolidated Billing Rules Apply?	Hospital May Bill For Outpatient Services?
Part A (Medicare Covered / PPS) Resident in Medicare-certified part of a SNF	Yes	No
Medicare Part B Resident in Medicare-certified part of a SNF	Yes	No
Medicare Part B Not a Resident in Medicare-certified part of a SNF	No	Yes

- A hospital may not send therapy staff to provide therapy services in non-residential health care settings and bill for the services as if they were provided at the hospital, even if the hospital owns the other facility or entity. Examples of such non-residential settings include CORFs, rehabilitation agencies, ORFs and offices of physicians/NPPs or other practitioners, such as physical therapists. For example, services furnished to patients of a CORF must be billed as CORF services and not as outpatient hospital services. Even if a CORF contracts with a hospital to furnish services to CORF patients, the hospital may not bill Medicare for the services as hospital outpatient services. However, the CORF could have the hospital furnish services to its patients under arrangements, in which case the CORF would bill for the services.

Psychiatric hospitals are treated the same as other hospitals for the purpose of therapy billing.

240 - Chiropractic Services - General

(Rev. 1, 10-01-03)
B3-2250, B3-4118

The term “physician” under Part B includes a chiropractor who meets the specified qualifying requirements set forth in §30.5 but only for treatment by means of manual manipulation of the spine to correct a subluxation.

Effective for claims with dates of services on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation.

Implementation of the chiropractic benefit requires an appreciation of the differences between chiropractic theory and experience and traditional medicine due to fundamental

differences regarding etiology and theories of the pathogenesis of disease. Judgments about the reasonableness of chiropractic treatment must be based on the application of chiropractic principles. So that Medicare beneficiaries receive equitable adjudication of claims based on such principles and are not deprived of the benefits intended by the law, carriers may use chiropractic consultation in carrier review of Medicare chiropractic claims.

Payment is based on the physician fee schedule and made to the beneficiary or, on assignment, to the chiropractor.

A. Verification of Chiropractor's Qualifications

Carriers must establish a reference file of chiropractors eligible for payment as physicians under the criteria in §30.1. They pay only chiropractors on file. Information needed to establish such files is furnished by the CMS RO.

The RO is notified by the appropriate State agency which chiropractors are licensed and whether each meets the national uniform standards.

240.1 - Coverage of Chiropractic Services

(Rev. 1, 10-01-03)
B3-2251

240.1.1 - Manual Manipulation

(Rev. 1, 10-01-03)
B3-2251.1

Coverage of chiropractic service is specifically limited to treatment by means of manual manipulation, i.e., by use of the hands. Additionally, manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

No other diagnostic or therapeutic service furnished by a chiropractor or under the chiropractor's order is covered. This means that if a chiropractor orders, takes, or interprets an x-ray, or any other diagnostic test, the x-ray or other diagnostic test, can be used for claims processing purposes, but Medicare coverage and payment are not available for those services. This prohibition does not affect the coverage of x-rays or other diagnostic tests furnished by other practitioners under the program. For example, an x-ray or any diagnostic test taken for the purpose of determining or demonstrating the existence of a subluxation of the spine is a diagnostic x-ray test covered under §1861(s)(3) of the Act if ordered, taken, and interpreted by a physician who is a doctor of medicine or osteopathy.

Manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

Effective for claims with dates of service on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation. However, an x-ray may be used for this purpose if the chiropractor so chooses.

The word "correction" may be used in lieu of "treatment." Also, a number of different terms composed of the following words may be used to describe manual manipulation as defined above:

- Spine or spinal adjustment by manual means;
- Spine or spinal manipulation;
- Manual adjustment; and
- Vertebral manipulation or adjustment.

In any case in which the term(s) used to describe the service performed suggests that it may not have been treatment by means of manual manipulation, the carrier analyst refers the claim for professional review and interpretation.

240.1.2 - Subluxation May Be Demonstrated by X-Ray or Physician's Exam

(Rev. 1, 10-01-03)
B3-2251.2

Subluxation is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact.

A subluxation may be demonstrated by an x-ray or by physical examination, as described below.

1. Demonstrated by X-Ray

An x-ray may be used to document subluxation. The x-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment. Unless more specific x-ray evidence is warranted, an x-ray is considered reasonably proximate if it was taken no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment. In certain cases of chronic subluxation (e.g., scoliosis), an older x-ray may be accepted provided the beneficiary's health record indicates the condition has existed longer than 12 months and there is a reasonable basis for concluding that the

condition is permanent. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

2. Demonstrated by Physical Examination

Evaluation of musculoskeletal/nervous system to identify:

Pain/tenderness evaluated in terms of location, quality, and intensity;

Asymmetry/misalignment identified on a sectional or segmental level;

Range of motion abnormality (changes in active, passive, and accessory joint movements resulting in an increase or a decrease of sectional or segmental mobility); and

Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament.

To demonstrate a subluxation based on physical examination, two of the four criteria mentioned under "physical examination" are required, one of which must be asymmetry/misalignment or range of motion abnormality.

The history recorded in the patient record should include the following:

Symptoms causing patient to seek treatment;

Family history if relevant;

Past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history);

Mechanism of trauma;

Quality and character of symptoms/problem;

Onset, duration, intensity, frequency, location and radiation of symptoms;

Aggravating or relieving factors; and

Prior interventions, treatments, medications, secondary complaints.

A. Documentation Requirements: Initial Visit

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History as stated above.

2. Description of the present illness including:

    Mechanism of trauma;

    Quality and character of symptoms/problem;

    Onset, duration, intensity, frequency, location, and radiation of symptoms;

    Aggravating or relieving factors;

    Prior interventions, treatments, medications, secondary complaints; and

    Symptoms causing patient to seek treatment.

These symptoms must bear a direct relationship to the level of subluxation. The symptoms should refer to the spine (spondyle or vertebral), muscle (myo), bone (osseo or osteo), rib (costo or costal) and joint (arthro) and be reported as pain (algia), inflammation (itis), or as signs such as swelling, spasticity, etc. Vertebral pinching of spinal nerves may cause headaches, arm, shoulder, and hand problems as well as leg and foot pains and numbness. Rib and rib/chest pains are also recognized symptoms, but in general other symptoms must relate to the spine as such. The subluxation must be causal, i.e., the symptoms must be related to the level of the subluxation that has been cited. A statement on a claim that there is "pain" is insufficient. The location of pain must be described and whether the particular vertebra listed is capable of producing pain in the area determined.

3. Evaluation of musculoskeletal/nervous system through physical examination.

4. Diagnosis: The primary diagnosis must be subluxation, including the level of subluxation, either so stated or identified by a term descriptive of subluxation. Such terms may refer either to the condition of the spinal joint involved or to the direction of position assumed by the particular bone named.

5. Treatment Plan: The treatment plan should include the following:

    Recommended level of care (duration and frequency of visits);

    Specific treatment goals; and

    Objective measures to evaluate treatment effectiveness.

6. Date of the initial treatment.

B. Documentation Requirements: Subsequent Visits

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History

   Review of chief complaint;

   Changes since last visit;

   System review if relevant.

2. Physical exam

   Exam of area of spine involved in diagnosis;

   Assessment of change in patient condition since last visit;

   Evaluation of treatment effectiveness.

3. Documentation of treatment given on day of visit.

240.1.3 - Necessity for Treatment

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam, as described above.

Most spinal joint problems fall into the following categories:

- Acute subluxation-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical exam as specified above. The result of chiropractic manipulation is expected to be an improvement in, or arrest of progression, of the patient's condition.

- Chronic subluxation-A patient's condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered.

For Medicare purposes, a chiropractor **must** place an AT modifier on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However the presence of the AT modifier may not in all instances indicate that the service is reasonable and necessary. As always, contractors may deny if appropriate after medical review.

A. Maintenance Therapy

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied. Chiropractors who give or receive from beneficiaries an ABN shall follow the instructions in Pub. 100-04, Medicare Claims Processing Manual, chapter 23, section 20.9.1.1 and include a GA (or in rare instances a GZ) modifier on the claim.

B. Contraindications

Dynamic thrust is the therapeutic force or maneuver delivered by the physician during manipulation in the anatomic region of involvement. A relative contraindication is a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. The following are **relative contraindications** to dynamic thrust:

> Articular hyper mobility and circumstances where the stability of the joint is uncertain;
>
> Severe demineralization of bone;
>
> Benign bone tumors (spine);
>
> Bleeding disorders and anticoagulant therapy; and
>
> Radiculopathy with progressive neurological signs.

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

> Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis;

Acute fractures and dislocations or healed fractures and dislocations with signs of instability;

An unstable os odontoideum;

Malignancies that involve the vertebral column;

Infection of bones or joints of the vertebral column;

Signs and symptoms of myelopathy or cauda equina syndrome;

For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and

A significant major artery aneurysm near the proposed manipulation.

240.1.4 – Location of Subluxation

(Rev. 1, 10-01-03)
B3-2251.4

The precise level of the subluxation must be specified by the chiropractor to substantiate a claim for manipulation of the spine. This designation is made in relation to the part of the spine in which the subluxation is identified:

Area of Spine	Names of Vertebrae	Number of Vertebrae	Short Form or Other Name
Neck	Occiput	7	Occ, CO
	Cervical		C1 thru C7
	Atlas		C1
	Axis		C2
Back	Dorsal or	12	D1 thru D12
	Thoracic		T1 thru T12
	Costovertebral		R1 thru R12
	Costotransverse		R1 thru R12
Low Back	Lumbar	5	L1 thru L5
Pelvis	IIii, r and 1		I, Si

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

Table of Contents

(Rev. 62, 12-22-06)

Transmittals for Chapter 15

Crosswalk to Old Manual

10 - Supplementary Medical Insurance (SMI) Provisions

(Rev. 37, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The supplementary medical insurance plan covers expenses incurred for the following medical and other health services under Part B of Medicare:

- Physician's services, including surgery, consultation, office and institutional calls, and services and supplies furnished incident to a physician's professional service;
- Outpatient hospital services furnished incident to physicians services;
- Outpatient diagnostic services furnished by a hospital;
- Outpatient physical therapy, outpatient occupational therapy, outpatient speech-language pathology services;
- Diagnostic x-ray tests, laboratory tests, and other diagnostic tests;
- X-ray, radium, and radioactive isotope therapy;
- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;
- Rental or purchase of durable medical equipment for use in the patient's home;
- Ambulance service;
- Prosthetic devices, other than dental, which replace all or part of an internal body organ;
- Leg, arm, back and neck braces and artificial legs, arms, and eyes including adjustments, repairs, and replacements required because of breakage, wear, loss, or change in the patient's physical condition;
- Certain medical supplies used in connection with home dialysis delivery systems;
- Rural health clinic (RHC) services;
- Federally Qualified Health Center (FQHC) services;
- Ambulatory surgical center (ASC) services;
- Screening mammography services;
- Screening pap smears and pelvic exams;
- Screening glaucoma services;
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines;
- Colorectal screening;
- Bone mass measurements;
- Diabetes self-management services;
- Prostate screening; and
- Home health visits after all covered Part A visits have been used.

See §250 for provisions regarding supplementary medical insurance coverage of certain of these services when furnished to hospital and SNF inpatients.

Payment may not be made under Part B for services furnished an individual if the individual is entitled to have payment made for those services under Part A. An individual is considered entitled to have payment made under Part A if the expenses incurred were used to satisfy a Part A deductible or coinsurance amount, or if payment would be made under Part A except for the lack of a request for payment or lack of a physician certification.

Some medical services may be considered for coverage under more than one of the above-enumerated categories. For example, electrocardiograms (EKGs) can be covered as physician's services or as other diagnostic tests. It is sufficient to determine that the requirements for coverage under one category are met to permit payment.

Membership dues, subscription fees, charges for service policies, insurance premiums, and other payments analogous to premiums which entitle enrollees to services or to repairs or replacement of devices or equipment or parts thereof without charge or at a reduced charge, are not considered expenses incurred for covered items or services furnished under such contracts or undertakings. Examples of such arrangements are memberships in ambulance companies, insurance for replacement of prosthetic lenses, and service contracts for durable medical equipment.

20 - When Part B Expenses Are Incurred

(Rev. 1, 10-01-03)

B3-2005

Part B expenses for items and services other than expenses for surgery and childbirth (see §20.1, below), are considered to have been incurred on the date the beneficiary received the item or service, regardless of when it was paid for or ordered. Therefore, when an individual orders an item prior to his or her entitlement to supplemental medical insurance (SMI) but receives the item after the effective date of SMI enrollment, the expense is considered incurred after entitlement began. However, if an item **not** custom-made for the beneficiary was ordered but not furnished, no reimbursement can be made. (See §20.3 for rules concerning custom-made items ordered but not furnished and the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for additional rules concerning the date of incurred expenses for durable medical equipment.)

20.1 - Physician Expense for Surgery, Childbirth, and Treatment for Infertility

(Rev. 1, 10-01-03)

B3-2005.l

A. Surgery and Childbirth

Skilled medical management is covered throughout the events of pregnancy, beginning with diagnosis, continuing through delivery and ending after the necessary postnatal care. Similarly, in the event of termination of pregnancy, regardless of whether terminated

spontaneously or for therapeutic reasons (i.e., where the life of the mother would be endangered if the fetus were brought to term), the need for skilled medical management and/or medical services is equally important as in those cases carried to full term. After the infant is delivered and is a separate individual, items and services furnished to the infant are not covered on the basis of the mother's eligibility.

Most surgeons and obstetricians bill patients an all-inclusive package charge intended to cover all services associated with the surgical procedure or delivery of the child. All expenses for surgical and obstetrical care, including preoperative/prenatal examinations and tests and post-operative/postnatal services, are considered incurred on the date of surgery or delivery, as appropriate. This policy applies whether the physician bills on a package charge basis, or itemizes the bill separately for these items.

Occasionally, a physician's bill may include charges for additional services not directly related to the surgical procedure or the delivery. Such charges are considered incurred on the date the additional services are furnished.

The above policy applies only where the charges are imposed by one physician or by a clinic on behalf of a group of physicians. Where more than one physician imposes charges for surgical or obstetrical services, all preoperative/prenatal and post-operative/postnatal services performed by the physician who performed the surgery or delivery are considered incurred on the date of the surgery or delivery. Expenses for services rendered by other physicians are considered incurred on the date they were performed.

B. Treatment for Infertility

Reasonable and necessary services associated with treatment for infertility are covered under Medicare. Infertility is a condition sufficiently at variance with the usual state of health to make it appropriate for a person who normally is expected to be fertile to seek medical consultation and treatment.

20.2 - Physician Expense for Allergy Treatment

(Rev. 1, 10-01-03)

B3-2005.2, B3-4145

Allergists commonly bill separately for the initial diagnostic workup and for the treatment (See §60.2). Where it is necessary to provide treatment over an extended period, the allergist may submit a single bill for all of the treatments, or may bill periodically. In either case the Form CMS-1500 claim shows the Healthcare Common Procedure Coding System (HCPCS) codes and from and through dates of service, or the Form CMS-1450 outpatient claim shows the HCPCS code and date of service (except for critical access hospital (CAH) claims).

20.3 - Artificial Limbs, Braces, and Other Custom Made Items Ordered But Not Furnished

(Rev. 1, 10-01-03)

B3-2005.3

A. Date of Incurred Expense

If a custom-made item was ordered but not furnished to a beneficiary because the individual died or because the order was canceled by the beneficiary or because the beneficiary's condition changed and the item was no longer reasonable and necessary or appropriate, payment can be made based on the supplier's expenses. (See subsection B for determination of the allowed amount.) In such cases, the expense is considered incurred on the date the beneficiary died or the date the supplier learned of the cancellation or that the item was no longer reasonable and necessary or appropriate for the beneficiary's condition. If the beneficiary died or the beneficiary's condition changed and the item was no longer reasonable and necessary or appropriate, payment can be made on either an assigned or unassigned claim. If the beneficiary, for any other reason, canceled the order, payment can be made to the supplier only.

B. Determination of Allowed Amount

The allowed amount is based on the services furnished and materials used, up to the date the supplier learned of the beneficiary's death or of the cancellation of the order or that the item was no longer reasonable and necessary or appropriate. The Durable Medical Equipment Regional Carrier (DMERC), carrier or intermediary, as appropriate, determines the services performed and the allowable amount appropriate in the particular situation. It takes into account any salvage value of the device to the supplier.

Where a supplier breaches an agreement to make a prosthesis, brace, or other custom-made device for a Medicare beneficiary, e.g., an unexcused failure to provide the article within the time specified in the contract, payment may not be made for any work or material expended on the item. Whether a particular supplier has lived up to its agreement, of course, depends on the facts in the individual case.

30 - Physician Services

(Rev. 1, 10-01-03)

B3-2020, B3-4142

A. General

Physician services are the professional services performed by a physician or physicians for a patient including diagnosis, therapy, surgery, consultation, and care plan oversight. The physician must render the service for the service to be covered. (See Publication 100-1, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, §70, for definition of physician.) A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc.

For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram reading that has been transmitted via telephone (i.e., electronically rather than by means of a verbal description) is a covered service.

Professional services of the physician are covered if provided within the United States, and may be performed in a home, office, institution, or at the scene of an accident. A

patient's home, for this purpose, is anywhere the patient makes his or her residence, e.g., home for the aged, a nursing home, a relative's home.

B. Telephone Services

Services by means of a telephone call between a physician and a beneficiary, or between a physician and a member of a beneficiary's family, are covered under Medicare, but carriers may not make separate payment for these services under the program. The physician work resulting from telephone calls is considered to be an integral part of the prework and postwork of other physician services, and the fee schedule amount for the latter services already includes payment for the telephone calls. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §270, for coverage of telehealth services.

C. Consultations

A consultation may be paid when the consulting physician initiates treatment on the same day as the consultation. It is only after a transfer of care has occurred that evaluation and management (E&M) services may not be billed as consultations; they must be billed as subsequent office/outpatient visits.

Therefore, if covered, a consultation is reimbursable when it is a professional service furnished a patient by a second physician at the request of the attending physician. Such a consultation includes the history and examination of the patient as well as the written report, which is furnished to the attending physician for inclusion in the patient's permanent medical record. These reports must be prepared and submitted to the provider for retention when they involve patients of institutions responsible for maintaining such records, and submitted to the attending physician's office for other patients.

To reimburse laboratory consultations, the services must:

- Be requested by the patient's attending physician;
- Relate to a test result that lies outside of the clinically significant normal or expected/established range relative to the condition of the patient;
- Result in a written narrative report included in the patient's medical record; and
- Require medical judgment by the consultant physician.

A consultation must involve a medical judgment that ordinarily requires a physician. Where a nonphysician laboratory specialist could furnish the information, the service of the physician is not a consultation payable under Part B.

The following indicators can ordinarily distinguish attending physician's claims:

- Therapeutic services are included on the bill in addition to an examination;
- The patient's history is before the examiner while the claim is reviewed and the billing physician has previously rendered other services to the patient; or
- Information in the file indicates that the patient was not referred.

The attending physician may remove himself from the care of the patient and turn the patient over to the person who performed a consultation service. In this situation, the

initial examination would be a consultation if the above requirements were met at that time.

D. Patient-Initiated Second Opinions

Patient-initiated second opinions that relate to the medical need for surgery or for major nonsurgical diagnostic and therapeutic procedures (e.g., invasive diagnostic techniques such as cardiac catheterization and gastroscopy) are covered under Medicare. In the event that the recommendation of the first and second physician differs regarding the need for surgery (or other major procedure), a third opinion is also covered. Second and third opinions are covered even though the surgery or other procedure, if performed, is determined not covered. Payment may be made for the history and examination of the patient, and for other covered diagnostic services required to properly evaluate the patient's need for a procedure and to render a professional opinion. In some cases, the results of tests done by the first physician may be available to the second physician.

E. Concurrent Care

Concurrent care exists where more than one physician renders services more extensive than consultative services during a period of time. The reasonable and necessary services of each physician rendering concurrent care could be covered where each is required to play an active role in the patient's treatment, for example, because of the existence of more than one medical condition requiring diverse specialized medical services.

In order to determine whether concurrent physicians' services are reasonable and necessary, the carrier must decide the following:

1. Whether the patient's condition warrants the services of more than one physician on an attending (rather than consultative) basis, and

2. Whether the individual services provided by each physician are reasonable and necessary.

In resolving the first question, the carrier should consider the specialties of the physicians as well as the patient's diagnosis, as concurrent care is usually (although not always) initiated because of the existence of more than one medical condition requiring diverse specialized medical or surgical services. The specialties of the physicians are an indication of the necessity for concurrent services, but the patient's condition and the inherent reasonableness and necessity of the services, as determined by the carrier's medical staff in accordance with locality norms, must also be considered. For example, although cardiology is a sub-specialty of internal medicine, the treatment of both diabetes and of a serious heart condition might require the concurrent services of two physicians, each practicing in internal medicine but specializing in different sub-specialties.

While it would not be highly unusual for concurrent care performed by physicians in different specialties (e.g., a surgeon and an internist) or by physicians in different sub-specialties of the same specialty (e.g., an allergist and a cardiologist) to be found medically necessary, the need for such care by physicians in the same specialty or sub-specialty (e.g., two internists or two cardiologists) would occur infrequently since in most cases both physicians would possess the skills and knowledge necessary to treat the patient. However, circumstances could arise which would necessitate such care. For example, a patient may require the services of two physicians in the same specialty or

sub-specialty when one physician has further limited his or her practice to some unusual aspect of that specialty, e.g., tropical medicine. Similarly, concurrent services provided by a family physician and an internist may or may not be found to be reasonable and necessary, depending on the circumstances of the specific case. If it is determined that the services of one of the physicians are not warranted by the patient's condition, payment may be made only for the other physician's (or physicians') services.

Once it is determined that the patient requires the active services of more than one physician, the individual services must be examined for medical necessity, just as where a single physician provides the care. For example, even if it is determined that the patient requires the concurrent services of both a cardiologist and a surgeon, payment may not be made for any services rendered by either physician which, for that condition, exceed normal frequency or duration unless there are special circumstances requiring the additional care.

The carrier must also assure that the services of one physician do not duplicate those provided by another, e.g., where the family physician visits during the post-operative period primarily as a courtesy to the patient.

Hospital admission services performed by two physicians for the same beneficiary on the same day could represent reasonable and necessary services, provided, as stated above, that the patient's condition necessitates treatment by both physicians. The level of difficulty of the service provided may vary between the physicians, depending on the severity of the complaint each one is treating and that physician's prior contact with the patient. For example, the admission services performed by a physician who has been treating a patient over a period of time for a chronic condition would not be as involved as the services performed by a physician who has had no prior contact with the patient and who has been called in to diagnose and treat a major acute condition.

Carriers should have sufficient means for identifying concurrent care situations. A correct coverage determination can be made on a concurrent care case only where the claim is sufficiently documented for the carrier to determine the role each physician played in the patient's care (i.e., the condition or conditions for which the physician treated the patient). If, in any case, the role of each physician involved is not clear, the carrier should request clarification.

F. Completion of Claims Forms

Separate charges for the services of a physician in completing a Form CMS-1500, a statement in lieu of a Form CMS-1500, or an itemized bill are not covered. Payment for completion of the Form CMS-1500 claim form is considered included in the fee schedule amount.

G. Care Plan Oversight Services

Care plan oversight is supervision of patients under care of home health agencies or hospices that require complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication with other health professionals not employed in the same practice who are involved in the patient's care, integration of new information into the care plan, and/or adjustment of medical therapy.

Such services are covered for home health and hospice patients, but are not covered for patients of skilled nursing facilities (SNFs), nursing home facilities, or hospitals.

These services are covered only if all the following requirements are met:

1. The beneficiary must require complex or multi-disciplinary care modalities requiring ongoing physician involvement in the patient's plan of care;
2. The care plan oversight (CPO) services should be furnished during the period in which the beneficiary was receiving Medicare covered HHA or hospice services;
3. The physician who bills CPO must be the same physician who signed the home health or hospice plan of care;
4. The physician furnished at least 30 minutes of care plan oversight within the calendar month for which payment is claimed. Time spent by a physician's nurse or the time spent consulting with one's nurse is not countable toward the 30-minute threshold. Low-intensity services included as part of other evaluation and management services are not included as part of the 30 minutes required for coverage;
5. The work included in hospital discharge day management (codes 99238-99239) and discharge from observation (code 99217) is not countable toward the 30 minutes per month required for work on the same day as discharge but only for those services separately documented as occurring after the patient is actually physically discharged from the hospital;
6. The physician provided a covered physician service that required a face-to-face encounter with the beneficiary within the six months immediately preceding the first care plan oversight service. Only evaluation and management services are acceptable prerequisite face-to-face encounters for CPO. EKG, lab, and surgical services are not sufficient face-to-face services for CPO;
7. The care plan oversight billed by the physician was not routine post-operative care provided in the global surgical period of a surgical procedure billed by the physician;
8. If the beneficiary is receiving home health agency services, the physician did not have a significant financial or contractual interest in the home health agency. A physician who is an employee of a hospice, including a volunteer medical director, should not bill CPO services. Payment for the services of a physician employed by the hospice is included in the payment to the hospice;
9. The physician who bills the care plan oversight services is the physician who furnished them;
10. Services provided incident to a physician's service do not qualify as CPO and do not count toward the 30-minute requirement;
11. The physician is not billing for the Medicare end stage renal disease (ESRD) capitation payment for the same beneficiary during the same month; and
12. The physician billing for CPO must document in the patient's record the services furnished and the date and length of time associated with those services.

30.1 - Provider-Based Physician Services

(Rev. 1, 10-01-03)

A3-3145, B3-2020.6, B3-8000-8099 (only instructions still applicable are included)

Providers may retain physicians on a full-time or part-time basis in, for example, the fields of pathology, psychiatry, anesthesiology, and radiology, and in many instances (especially in teaching hospitals) in other fields of medical specialization as well. Any one of these physicians may be engaged in a variety of activities including teaching, research, administration, supervision of professional or technical personnel, service on hospital committees, and other hospital-wide activities, as well as direct medical services to individual patients. The provider's arrangement may be with a single physician or with a group of physicians who assume joint responsibility for discharging agreed-upon duties.

It is necessary to distinguish between the medical and surgical services rendered by a physician to an individual patient, which are paid under Part B, and provider services (including a physician's services for the provider) which are paid under Part A. This is necessary because the payments are made from different trust funds, both intermediaries and carriers are involved in handling the claims, and the method of determining the payments for Part A benefits differs from the Part B payment calculation.

Provider-based physicians may include those on a salary, or a percentage arrangement, lessors of departments, etc.(whether or not they bill patients directly). The services to the patient are known as the professional component. The services to the provider are known as the provider component.

A. The Professional Component

The professional component of a provider-based physician's services pertains to that part of the physician's activities that is directly related to the medical care of the individual patient. It represents remuneration for the identifiable medical services by the physician that contribute to the diagnosis of the patient's condition or to his treatment. These services are covered under Part B. Claims for professional services are processed by the carrier and are paid, where applicable, under the fee schedule.

B. The Provider Component

The portion of the physician's activities representing services which are not directly related to an identifiable part of the medical care of the individual patient is the provider component. Payment for provider component services can be made only to a provider, and is included in the provider's prospective payment system (PPS) rate. Provider services include teaching, research conducted in conjunction with and as part of patient care (to the extent that such costs are not met by special research funds), administration, general supervision of professional or technical personnel, laboratory quality control activities, committee work, performance of autopsies, and attending conferences as part of the physician's provider service activities. Such services are covered under Part A where they relate to inpatient services.

30.2 - Teaching Physician Services

(Rev. 1, 10-01-03)

B3-2020.7, B3-8201, and B3-15016

Part B covers services that attending physicians (other than interns and residents) render in the teaching setting to individual patients. These include such services as reviewing the patient's history and physical exams, personally examining the patient within a reasonable time after admission, confirming or revising diagnoses, determining the course of treatment to be followed, assuring that any supervision needed by interns or residents is furnished, and making frequent review of the patient's progress. The medical record must contain signed or countersigned notes by the physician which show that the physician personally reviewed the patient's diagnoses, visited the patient at more critical times of the illness, and discharged the patient. For other services, such as surgical procedures, notes in the record by interns, residents, or nurses, which indicate that the physician was physically present when the service was rendered, are sufficient.

Note that, in order to pay a teaching physician under Part B, the teaching physician must at least be present during the key portion of a service rendered by a resident or intern. When a resident does a visit without teaching physician presence, the teaching physician must repeat the key portions of the visit and have his own documentation in order to get paid.

30.3 - Interns and Residents

(Rev. 1, 10-01-03)

B3-2020.8, A3-3115

For Medicare purposes, the terms "interns" and "residents" include physicians participating in approved postgraduate training programs and physicians who are not in approved programs but who are authorized to practice only in a hospital setting, e.g., individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. Where a senior resident has a staff or faculty appointment or is designated, for example, a "fellow," it does not change the resident's status for the purposes of Medicare coverage and payment. As a general rule, the intermediary pays for services of interns and residents as provider services.

A. Services Furnished by Interns and Residents Within the Scope of an Approved Training Program

Medical and surgical services furnished by interns and residents within the scope of their training program are covered as provider services. Effective with services furnished on or after July 1, 1987, provider services includes medical and surgical services furnished in a setting that is not part of the provider, where the hospital has agreed to incur all or substantially all of the costs of training in the nonprovider facility.

Where the provider does not incur all or substantially all of the training costs and the services are performed by a licensed physician, the services are payable under Part B by the carrier.

B. Services Furnished by Interns and Residents Outside the Scope of an Approved Training Program - Moonlighting

Medical and surgical services furnished by interns and residents that are not related to their training program, and are performed outside the facility where they have their training program, are covered as physician services where the requirements in the first two bullets below are met. Medical and surgical services furnished by interns and residents that are not related to their training program, and are performed in an outpatient department or emergency room of the hospital where they have their training program, are covered as physicians' services where all three of the following criteria are met:

- The services are identifiable physician services, the nature of which requires performance by a physician in person and which contribute to the diagnosis or treatment of the patient's condition;
- The intern or resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed; and
- The services performed can be separately identified from those services that are required as part of the training program.

When these criteria are met, the services are considered to have been furnished by the individuals in their capacity as physicians and not in their capacity as interns and residents.

30.4 - Optometrist's Services

(Rev. 1, 10-01-03)

B3-2020.25

Effective April 1, 1987, a doctor of optometry is considered a physician with respect to all services the optometrist is authorized to perform under State law or regulation. To be covered under Medicare, the services must be medically reasonable and necessary for the diagnosis or treatment of illness or injury, and must meet all applicable coverage requirements. See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," for exclusions from coverage that apply to vision care services, and the Medicare Claims Processing Manual, Chapter 12, "Physician/Practitioner Billing," for information dealing with payment for items and services furnished by optometrists.

A. FDA Monitored Studies of Intraocular Lenses

Special coverage rules apply to situations in which an ophthalmologist is involved in a Food and Drug Administration (FDA) monitored study of the safety and efficacy of an investigational Intraocular Lens (IOL). The investigation process for IOLs is unique in that there is a core period and an adjunct period. The core study is a traditional, well-controlled clinical investigation with full record keeping and reporting requirements. The adjunct study is essentially an extended distribution phase for lenses in which only limited safety data are compiled. Depending on the lens being evaluated, the adjunct study may be an extension of the core study or may be the only type of investigation to which the lens may be subject.

All eye care services related to the investigation of the IOL must be provided by the investigator (i.e., the implanting ophthalmologist) or another practitioner (including a doctor of optometry) who provides services at the direction or under the supervision of the investigator and who has an agreement with the investigator that information on the patient is given to the investigator so that he or she may report on the patient to the IOL manufacturer.

Eye care services furnished by anyone other than the investigator (or a practitioner who assists the investigator, as described in the preceding paragraph) are not covered during the period the IOL is being investigated, unless the services are not related to the investigation.

B. Concurrent Care

Where more than one practitioner furnishes concurrent care, services furnished to a beneficiary by both an ophthalmologist and another physician (including an optometrist) may be recognized for payment if it is determined that each practitioner's services were reasonable and necessary. (See §30.E.)

30.5 - Chiropractor's Services

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2020.26

A chiropractor must be licensed or legally authorized to furnish chiropractic services by the State or jurisdiction in which the services are furnished. In addition, a licensed chiropractor must meet the following uniform minimum standards to be considered a physician for Medicare coverage. Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation provided such treatment is legal in the State where performed. All other services furnished or ordered by chiropractors are not covered.

If a chiropractor orders, takes, or interprets an x-ray or other diagnostic procedure to demonstrate a subluxation of the spine, the x-ray can be used for documentation. However, there is no coverage or payment for these services or for any other diagnostic or therapeutic service ordered or furnished by the chiropractor. For detailed information on using x-rays to determine subluxation, see §240.1.2.

In addition, in performing manual manipulation of the spine, some chiropractors use manual devices that are hand-held with the thrust of the force of the device being controlled manually. While such manual manipulation may be covered, there is no separate payment permitted for use of this device.

A. Uniform Minimum Standards

Prior to July 1, 1974

Chiropractors licensed or authorized to practice prior to July 1, 1974, and those individuals who commenced their studies in a chiropractic college before that date must meet all of the following three minimum standards to render payable services under the program:

- Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;
- Graduation from a college of chiropractic approved by the State's chiropractic examiners that included the completion of a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance covering adequate course of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing, and adjusting; and
- Passage of an examination prescribed by the State's chiropractic examiners covering the subjects listed above.

After June 30, 1974

Individuals commencing their studies in a chiropractic college after June 30, 1974, must meet all of the above three standards and all of the following additional requirements:

- Satisfactory completion of 2 years of pre-chiropractic study at the college level;
- Satisfactory completion of a 4-year course of 8 months each year (instead of a 3-year course of 6 months each year) at a college or school of chiropractic that includes not less than 4,000 hours in the scientific and chiropractic courses specified in the second bullet under "**Prior to July 1, 1974**" above, plus courses in the use and effect of x-ray and chiropractic analysis; and
- The practitioner must be over 21 years of age.

B. Maintenance Therapy

Under the Medicare program, Chiropractic maintenance therapy is not considered to be medically reasonable or necessary, and is therefore not payable. Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. For information on how to indicate on a claim a treatment is or is not maintenance, see §240.1.3.

30.6 - Indian Health Service (IHS) Physician and Nonphysician Services

(Rev. 1, 10-01-03)

AB-02-150

Section 1880 of Title XVIII of the Social Security Act (the Act) provides an exception for Indian Health Service to the general prohibition of payment to Federal Agencies.

The following facilities, which were unable to bill for practitioner services prior to BIPA, may now be paid:

- Outpatient departments of IHS operated hospitals that meet the definition of provider-based in 42 CFR 413.65; and

- Outpatient clinics (freestanding) operated by the IHS.

The following facilities, which were limited by §1880 of the Act, may be paid for services under BIPA or may be paid under another authority under which it qualifies.

- Outpatient departments of tribally operated hospitals that are operated by a tribe or tribal organization; and
- Other outpatient facilities that are tribally operated regardless of ownership.

See the Medicare Claims Processing Manual Chapter 19 for a description of billing procedures.

Medicare does not pay IHS facilities for other Part B services. For example, the carrier does not pay IHS facilities for durable medical equipment, prosthetics, orthotics, and supplies, clinical laboratory services, ambulance services or any service paid on a reasonable charge basis.

For Medicare purposes, a tribally owned and operated facility is not considered a facility of the HIS.

40 - Effect of Beneficiary Agreements Not to Use Medicare Coverage

(Rev. 1, 10-01-03)

B3-3044, PM-B-97-17

Normally physicians and practitioners are required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. Also, they are not allowed to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished.

However, a physician or practitioner (as defined in §40.4) may opt out of Medicare. A physician or practitioner who opts out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare covered services.

Only physicians and practitioners that are listed in §40.4 may opt out.

- The **only** situation in which non-opt-out physicians or practitioners, or other suppliers, are not required to submit claims to Medicare for covered services is where a beneficiary or the beneficiary's legal representative refuses, of his/her own free will, to authorize the submission of a bill to Medicare. However, the limits on what the physician, practitioner, or other supplier may collect from the beneficiary continue to apply to charges for the covered service, notwithstanding the absence of a claim to Medicare.
- If an item or service is one that Medicare may cover in some circumstances but not in others, a non-opt-out physician/practitioner, or other supplier, must still submit a claim to Medicare. However, the physician, practitioner or other supplier may choose to provide the beneficiary, prior to the rendering of the item or service, an Advance Beneficiary Notice (ABN) as described in the Medicare Claims Processing Manual Chapter 30. (Also see §40.24 for a description of the difference between an ABN and a private contract.) An ABN notifies the beneficiary that Medicare is likely to deny the claim and that if Medicare does

deny the claim, the beneficiary will be liable for the full cost of the services. Where a valid ABN is given, subsequent denial of the claim relieves the non-opt-out physician/practitioner, or other supplier, of the limitations on charges that would apply if the services were covered.

Opt-out physicians and practitioners must not use ABNs, because they use private contracts for any item or service that is, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)).

Where a physician/practitioner, or other supplier, fails to submit a claim to Medicare on behalf of a beneficiary for a covered Part B service within one year of providing the service, or knowingly and willfully charges a beneficiary more than the applicable charge limits on a repeated basis, he/she/it may be subject to civil monetary penalties under §§1848(g)(1) and/or 1848(g)(3) of the Act. Congress enacted these requirements for the protection of all Part B beneficiaries. Application of these requirements cannot be negotiated between a physician/practitioner or other supplier and the beneficiary except where a physician/practitioner is eligible to opt out of Medicare under §40.4 and the remaining requirements of §§40.1 - 40.38 are met. Agreements with Medicare beneficiaries that are not authorized as described in these manual sections and that purport to waive the claims filing or charge limitations requirements, or other Medicare requirements, have no legal force and effect. For example, an agreement between a physician/practitioner, or other supplier and a beneficiary to exclude services from Medicare coverage, or to excuse mandatory assignment requirements applicable to certain practitioners, is ineffective.

The contractor will refer such cases to the OIG.

This subsection does not apply to noncovered charges.

40.1 - Private Contracts Between Beneficiaries and Physicians/Practitioners

(Rev. 1, 10-01-03)

B3-3044.1

Section 1802 of the Act, as amended by §4507 of the BBA of 1997, permits a physician/practitioner to opt out of Medicare and enter into private contracts with Medicare beneficiaries if specific requirements of this instruction are met.

40.2 - General Rules of Private Contracts

(Rev. 1, 10-01-03)

B3-3044.2

The following rules apply to physicians/practitioners who opt out of Medicare:

- A physician/practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare (provided the conditions in §40.1 are met).
- A physician/practitioner who enters into at least one private contract with a Medicare beneficiary (under the conditions of §40.1) and who submits one or

more affidavits in accordance with §40.9, opts out of Medicare for a 2-year period unless the opt-out is terminated early according to §40.35 or unless the physician/practitioner fails to maintain opt-out. (See §40.11.) The physician's or practitioner's opt out may be renewed for subsequent 2-year periods.

- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt out described in the second paragraph of this section are null and void if the physician/practitioner fails to properly opt out in accordance with the conditions of these instructions.
- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt out described in the second paragraph of this section are null and void for the remainder of the opt-out period if the physician/practitioner fails to remain in compliance with the conditions of these instructions during the opt-out period.
- Services furnished under private contracts meeting the requirements of these instructions are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly.

40.3 - Effective Date of the Opt-Out Provision

(Rev. 1, 10-01-03)

B3-3044.3

A physician/practitioner may enter into a private contract with a beneficiary for services furnished no earlier than January 1, 1998.

40.4 - Definition of Physician/Practitioner

(Rev. 62, Issued: 12-22-06, Effective: 11-13-06, Implementation: 04-02-07)

For purposes of this provision, the term "physician" is limited to doctors of medicine; doctors of osteopathy; doctors of dental surgery or of dental medicine; doctors of podiatric medicine; and doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the State in which such function or action is performed; no other physicians may opt out. Also, for purposes of this provision, the term "practitioner" means any of the following to the extent that they are legally authorized to practice by the State and otherwise meet Medicare requirements:

- Physician assistant;
- Nurse practitioner;
- Clinical nurse specialist;
- Certified registered nurse anesthetist;
- Certified nurse midwife;
- Clinical psychologist;
- Clinical social worker;
- *Registered dietitian; or*

- *Nutrition Professional*

The opt out law does not define “physician” to include chiropractors; therefore, they may not opt out of Medicare and provide services under private contract. Physical therapists in independent practice and occupational therapists in independent practice cannot opt out because they are not within the opt out law’s definition of either a “physician” or “practitioner”.

40.5 - When a Physician or Practitioner Opts Out of Medicare

(Rev. 1, 10-01-03)

B3-3044.5

When a physician/practitioner opts out of Medicare, Medicare covers no services provided by that individual and no Medicare payment can be made to that physician or practitioner directly or on a capitated basis. Additionally, no Medicare payment may be made to a beneficiary for items or services provided directly by a physician or practitioner who has opted out of the program.

EXCEPTION: In an emergency or urgent care situation, a physician/practitioner who opts out may treat a Medicare beneficiary with whom he/she does not have a private contract and bill for such treatment. In such a situation, the physician/practitioner may not charge the beneficiary more than what a nonparticipating physician/practitioner would be permitted to charge and must submit a claim to Medicare on the beneficiary’s behalf. Payment will be made for Medicare covered items or services furnished in emergency or urgent situations when the beneficiary has not signed a private contract with that physician/practitioner. (See §40.28.)

Under the statute, the physician/practitioner cannot choose to opt out of Medicare for some Medicare beneficiaries but not others; or for some services but not others. The physician/practitioner who chooses to opt out of Medicare may provide covered care to Medicare beneficiaries only through private agreements.

Medicare will make payment for covered, medically necessary services that are ordered by a physician/practitioner who has opted out of Medicare if the ordering physician/practitioner has acquired a unique provider identification number (UPIN) from Medicare and provided that the services are not furnished by another physician/practitioner who has also opted out. For example, if an opt-out physician/practitioner admits a beneficiary to a hospital, Medicare will reimburse the hospital for medically necessary care.

40.6 - When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner

(Rev. 1, 10-01-03)

B3-3044.6

Payment may be made to a beneficiary for services of an opt out in two cases:

- If the services are emergency or urgent care services furnished by an opt-out physician/practitioner to a beneficiary with whom he/she has a previously

existing private contract. (See §40.28 for further discussion of emergency and urgent care services by opt-out physicians and practitioners.); or

- If the opt-out physician/practitioner failed to privately contract with the beneficiary for services that they provided that were not emergency or urgent care services. The CMS expects this case to come to the carrier's attention only in the course of a request for reconsideration of a denied claim or as a result of a complaint from a beneficiary or the beneficiary's legal representative. If the carrier receives such a complaint, it must consider it to be a request for a reconsideration of the denial of payment for services of the opt-out physician/practitioner. It must follow the procedures outlined in §40.11 for cases in which the physician/ practitioner fails to maintain opt-out. If the physician/practitioner does not respond to the carrier's request for a copy of the private contract within 45 days, the carrier must make payment to the beneficiary based upon the payment for a nonparticipating physician/practitioner for that service. It must notify the beneficiary that the physician/practitioner who has opted out must privately contract with the beneficiary or the beneficiary's legal representative for services the physician/practitioner furnished and that no further payment will be made to the beneficiary for services furnished by the opt-out physician/practitioner after 15 days from the postmark of the notice.

40.7 - Definition of a Private Contract

(Rev. 1, 10-01-03)

B3-3044.7

A "private contract" is a contract between a Medicare beneficiary and a physician or other practitioner who has opted out of Medicare for two years for **all** covered items and services the physician/practitioner furnishes to Medicare beneficiaries. In a private contract, the Medicare beneficiary agrees to give up Medicare payment for services furnished by the physician/practitioner and to pay the physician/practitioner without regard to any limits that would otherwise apply to what the physician/practitioner could charge. Pursuant to the statute, once a physician/practitioner files an affidavit notifying the Medicare carrier that the he/she has opted out of Medicare, the physician/practitioner is out of Medicare for two years from the date the affidavit is signed (unless the opt-out is terminated early according to §40.35, or unless the he/she fails to maintain opt-out (See §40.11)). After those two years are over, a physician/practitioner could elect to return to Medicare or to opt out again. A beneficiary who signs a private contract with a physician/practitioner is not precluded from receiving services from other physicians and practitioners who have not opted out of Medicare.

Physicians or practitioners who provide services to Medicare beneficiaries enrolled in the new Medical Savings Account (MSA) demonstration created by the BBA of 1997 are not required to enter into a private contract with those beneficiaries and to opt out of Medicare under §1802 of the Act.

40.8 - Requirements of a Private Contract

(Rev. 1, 10-01-03)

B3-3044.8

A private contract under this section must:

- Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract;
- Clearly state whether the physician/practitioner is excluded from Medicare under §§1128, 1156 or 1892 of the Act;
- State that the beneficiary or the beneficiary's legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician/practitioner;
- State that the beneficiary or the beneficiary's legal representative understands that Medicare limits do not apply to what the physician/practitioner may charge for items or services furnished by the physician/practitioner;
- State that the beneficiary or the beneficiary's legal representative agrees not to submit a claim to Medicare or to ask the physician/practitioner to submit a claim to Medicare;
- State that the beneficiary or the beneficiary's legal representative understands that Medicare payment will not be made for any items or services furnished by the physician/practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted;
- State that the beneficiary or the beneficiary's legal representative enters into the contract with the knowledge that the beneficiary has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted out;
- State the expected or known effective date and expected or known expiration date of the opt-out period;
- State that the beneficiary or the beneficiary's legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare;
- Be signed by the beneficiary or the beneficiary's legal representative and by the physician/practitioner;
- Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician/practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with §40.28;)
- Be provided (a photocopy is permissible) to the beneficiary or to the beneficiary's legal representative before items or services are furnished to the beneficiary under the terms of the contract;

- Be retained (original signatures of both parties required) by the physician/practitioner for the duration of the opt-out period;
- Be made available to CMS upon request; and
- Be entered into for each opt-out period.

In order for a private contract with a beneficiary to be effective, the physician/practitioner must file an affidavit with all Medicare carriers to which the physician/practitioner would submit claims, advising that the physician/practitioner has opted out of Medicare. The affidavit must be filed within 10 days of entering into the first private contract with a Medicare beneficiary. Once the physician/practitioner has opted out, such physician/practitioner must enter into a private contract with each Medicare beneficiary to whom the physician/practitioner furnishes covered services (even where Medicare payment would be on a capitated basis or where Medicare would pay an organization for the physician's or practitioner's services to the Medicare beneficiary), with the exception of a Medicare beneficiary needing emergency or urgent care.

If a physician/practitioner has opted out of Medicare, the physician/practitioner must use a private contract for items and services that are, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)). An opt-out physician/practitioner is not required to use a private contract for an item or service that is definitely excluded from coverage by Medicare.

A non-opt-out physician/practitioner, or other supplier, is required to submit a claim for any item or service that is, or may be, covered by Medicare. Where an item or service may be covered in some circumstances, but not in others, the physician/practitioner, or other supplier, may provide an Advance Beneficiary Notice to the beneficiary, which informs the beneficiary that Medicare may not pay for the item or service, and that if Medicare does not do so, the beneficiary is liable for the full charge. (See §§40, 40.24)

40.9 - Requirements of the Opt-Out Affidavit

(Rev. 1, 10-01-03)

B3-3044.9

Under 1802(b)(3)(B) of the Act, a valid affidavit must:

- Be in writing and be signed by the physician/practitioner;
- Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number (if one has been assigned), uniform provider identification number (UPIN) if one has been assigned, or, if neither an NPI nor a UPIN has been assigned, the physician's or practitioner's tax identification number (TIN);
- State that, except for emergency or urgent care services (as specified in §40.28), during the opt-out period the physician/practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services;

- State that the physician/practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician/practitioner permit any entity acting on the physician's/practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in §40.28;
- State that, during the opt-out period, the physician/practitioner understands that the physician/practitioner may receive no direct or indirect Medicare payment for services that the physician/practitioner furnishes to Medicare beneficiaries with whom the physician/practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare+Choice plan;
- State that a physician/practitioner who opts out of Medicare acknowledges that, during the opt-out period, the physician's/practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the physician's/practitioner's services, directly or on a capitated basis;
- State on acknowledgment by the physician/practitioner to the effect that, during the opt-out period, the physician/practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the physician/practitioner has entered into;
- Acknowledge that the physician/practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician/practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the physician/practitioner has not previously privately contracted) without regard to any payment arrangements the physician/practitioner may make;
- With respect to a physician/practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;
- Acknowledge that the physician/practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if the physician/practitioner furnishes such services;
- Identify the physician/practitioner sufficiently so that the carrier can ensure that no payment is made to the physician/practitioner during the opt-out period. If the physician/practitioner has already enrolled in Medicare, this would include the physician/practitioner's Medicare uniform provider identification number (UPIN), if one has been assigned. If the physician/practitioner has not enrolled in Medicare, this would include the information necessary to be assigned a UPIN; and

- Be filed with all carriers who have jurisdiction over claims the physician/ practitioner would otherwise file with Medicare and be filed no later than 10 days after the first private contract to which the affidavit applies is entered into.

40.10 - Failure to Properly Opt Out

(Rev. 1, 10-01-03)

B3-3044.10

A. A physician/practitioner fails to properly opt out for any of the following reasons:

- Any private contract between the physician/practitioner and a Medicare beneficiary that was entered into before the affidavit described in §40.9 was filed does not meet the specifications of §40.8; or
- The physician/practitioner fails to submit the affidavit(s) in accordance with §40.9.

B. If a physician/practitioner fails to properly opt out in accordance with the above paragraphs of this section, the following will result:

- The physician's or practitioner's attempt to opt out of Medicare is nullified, and all of the private contracts between the physician/practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt out are deemed null and void;
- The physician/practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician/practitioner is subject to the limiting charge provision. For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the approved amount for nonparticipating physicians or practitioners. A participating physician/practitioner is subject to the limitations on charges of the participation agreement the physician/practitioner signed;
- The physician/practitioner may not reassign any claim except as provided in the Medicare Clams Processing Manual, Chapter 1, "General Billing Requirements," §§30.2.12 and 30.2.13;
- The physician/practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts; and
- The physician/practitioner may make another attempt to properly opt out at any time.

40.11 - Failure to Maintain Opt-Out

(Rev. 1, 10-01-03)

B3-3044.11

A physician/practitioner fails to maintain opt-out under this section if during the opt-out period one of the following occurs:

- The physician/practitioner has filed an affidavit in accordance with §40.9 and has signed private contracts in accordance with §40.8 but,
- The physician/practitioner knowingly and willfully submits a claim for Medicare payment (except as provided in §40.28); or
- Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in §40.28).
- The physician/practitioner fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into private contracts that fail to meet the specifications of §40.8; or
- The physician/practitioner fails to comply with the provisions of §40.28 regarding billing for emergency care services or urgent care services; or
- The physician/practitioner fails to retain a copy of each private contract that the physician/practitioner has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

If a physician/practitioner fails to maintain opt-out in accordance with the above paragraphs of this section, and fails to demonstrate within 45 days of a notice from the carrier of a violation of the first paragraph of this section that the physician/practitioner has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to the beneficiaries with whom the physician/practitioner did not sign a private contract), the following will result effective 46 days after the date of the notice, **but only for the remainder of the opt-out period.** (However, if the physician/practitioner did not privately contract and refunds coverage, the physician/practitioner may still maintain the opt-out):

- All of the private contracts between the physician/practitioner and Medicare beneficiaries are deemed null and void.
- The physician's or practitioner's opt-out of Medicare is nullified.
- The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.
- The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as stated above.
- The physician or practitioner is subject to the limiting charge provisions as stated in §40.10.
- The practitioner may not reassign any claim except as provided in the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §30.2.13.
- The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

- The physician or practitioner may not attempt to once more meet the criteria for properly opting out until the 2-year opt-out period expires.

40.12 - Actions to Take in Cases of Failure to Maintain Opt-Out

(Rev. 1, 10-01-03)

B3-3044.12

If the carrier becomes aware that the physician/practitioner has failed to maintain opt-out as indicated in §40.11, it must send the physician/practitioner a letter advising the physician/practitioner that it has received a claim and believes that the physician/practitioner may have inadvertently failed to maintain opt-out. It must describe the situation in §40.11 that it believes exists and its basis for its belief. It must ask the physician or practitioner to provide it with an explanation within 45 days of what happened and how the physician or practitioner will resolve it. (See the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §70.6, and the Medicare Program Integrity Manual for action when responses are not received within 45 days).

If the carrier received a claim from the opt-out physician/practitioner, it must ask the physician/practitioner if the received claim was: (a) an emergency or urgent situation, with missing documentation, **or** (b) filed in error. When the reason for the letter is that the physician/practitioner filed a claim that the physician/practitioner did not identify as an emergency or urgent care service, the carrier must request that the physician/practitioner submit the following information with the physician's/practitioner's response:

- Emergency/urgent care documentation if the claim was for a service furnished in an emergency or urgent situation but included no documentation to that effect; and/or
- If the claim was filed in error, the carrier must ask the physician/practitioner to explain whether the filing was an isolated incident or a systematic problem affecting a number of claims.

In the case of any potential failure to maintain opt-out (including but not limited to improper submission of a claim), the carrier must explain in its request to the physician or practitioner that it would like to resolve this matter as soon as possible. It must instruct the physician/practitioner to provide the information it requested within 45 days of the date of its development letter. It must provide the physician or practitioner with the name and telephone number of a contact person in case they have any questions.

If the violation was due to a systems problem, the carrier must ask the physician or practitioner to include with his or her response an explanation of the actions being taken to correct the problem and when the physician or practitioner expects the system error to be fixed. If the violation persists beyond the time period indicated in the physician's or practitioner's response, the carrier must contact the physician or practitioner again to ascertain why the problem still exists and when the physician or practitioner expects to have it corrected. It must repeat this process until the system problem is corrected.

Also, in the carrier's development request, it must advise the physician or practitioner that if no response is received by the due date, the carrier will assume that there has been

no correction of the failure to maintain opt-out and that this could result in a determination that the physician/practitioner is once again subject to Medicare rules.

In the case of wrongly filed claims, the carrier must hold the claim and any others it receives from the physician or practitioner in suspense until it hears from the physician or practitioner or the response date lapses. In this case, if the physician or practitioner responds that the claim was filed in error, the carrier must continue processing the claim, deny the claim, and send the physician or practitioner the appropriate Remittance Advice and send the beneficiary a Medicare Summary Notice (MSN) with the appropriate language explaining that the claim was submitted erroneously and the beneficiary is responsible for the physician's or practitioner's charge. In other words, the limiting charge provision does not apply and the beneficiary is responsible for all charges. This process will apply to all claims until the physician or practitioner is able to get the problem fixed.

If the carrier does not receive a response from the physician or practitioner by the development letter due date or if it is determined that the opt-out physician or practitioner knowingly and willfully failed to maintain opt-out, it must notify the physician or practitioner that the effects of failure to maintain opt-out specified in §40.11 apply. **It must formally notify the physician/practitioner of this determination and of the rules that again apply (e.g., mandatory submission of claims, limiting charge, etc.)**. It must specifically include in this letter each of the effects of failing to opt out that are identified in §40.11.

The act of claims submission by the beneficiary for an item or service provided by a physician or practitioner who has opted out is **not** a violation by the physician or practitioner and does not nullify the contract with the beneficiary. However, if there are what the carrier considers to be a substantial number of claims submissions by beneficiaries for items or services by an opt-out physician or practitioner, it must investigate to ensure that contracts between the physician or practitioner and the beneficiaries exist and that the terms of the contracts meet the Medicare statutory requirements outlined in this instruction. If noncompliance with the opt-out affidavit is determined, it must develop claims submission or limiting charge violation cases, as appropriate, based on its findings.

In cases in which the beneficiary files an appeal of the denial of a beneficiary-filed claim for services from an opt-out physician or practitioner, and alleges that there was no private contract, the carrier must ask the physician/practitioner to provide it with a copy of the private contract, but only if the beneficiary authorizes the carrier to do so. Where the physician or practitioner does not provide a copy of a private contract that was signed by the beneficiary before the service was furnished, the carrier must make payment to the beneficiary and proceed as described above.

40.13 - Physician/Practitioner Who Has Never Enrolled in Medicare

(Rev. 1, 10-01-03)

B3-3044.13

For a physician/practitioner who has never enrolled in the Medicare program and wishes to opt out of Medicare, the carrier must provide the physician/practitioner with a Unique

Physician Identification Number (UPIN). It can get the full name, address, license number, and tax identification number from this affidavit. All other data requirements should be developed from other data sources (e.g., the American Medical Association, State Licensing Board, etc.). The carrier must annotate its in-house provider file and update the UPIN Registry that the physician/practitioner has opted out of the program. The physician/practitioner must not receive payment during the opt-out period (except in the case of emergency or urgent care services). If the carrier needs additional data elements and cannot obtain that information from another source, it may contact the physician/practitioner directly. It must notify the physician or practitioner that in order to refer or order services for a Medicare patient, the physician or practitioner must have a UPIN.

If an opt-out physician/practitioner provides emergency or urgent care service to a beneficiary who has not signed a private contact with the physician or practitioner and the physician/practitioner submits an assigned claim, the physician or practitioner must complete Form CMS-855 and enroll in the Medicare program before receiving reimbursement. Under a similar circumstance, if the physician or practitioner submits an unassigned claim, the carrier must pay the beneficiary directly without requiring a completed Form CMS-855. It may use the information from the affidavit to begin the enrollment process.

40.14 - Nonparticipating Physicians or Practitioners Who Opt Out of Medicare

(Rev. 1, 10-01-03)

B3-3044.14

A nonparticipating physician or practitioner may opt out of Medicare at any time in accordance with the following:

- The 2-year opt-out period begins the date the affidavit meeting the requirements of §40.9 is signed, provided the affidavit is filed within 10 days after the physician or practitioner signs his or her first private contract with a Medicare beneficiary.
- If the physician or practitioner does not timely file any required affidavit, the 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

40.15 - Excluded Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.15

An excluded physician or practitioner may opt out of Medicare by submitting the required documentation in accordance with §40.9. When determining effective dates of the exclusion versus the opt-out, the date of exclusion always takes precedence over the

date the physician or practitioner opts out of Medicare. A physician or practitioner who has been excluded must comply with 42 CFR 1001.1901, "Scope and Effect of Exclusion."

If an excluded/opt-out physician or practitioner submits a claim to Medicare, the carrier must not make payment for services furnished, ordered, or prescribed on or after the effective date of the exclusion.

The carrier must not make payment to a beneficiary who submits claims for services rendered by an excluded/opt-out physician or practitioner (except where payment would otherwise be made in accordance with the Medicare Program Integrity Manual). It must deny the claim and send the physician or practitioner the appropriate remittance and send the beneficiary a MSN as explained in §40.39.

40.16 - Relationship Between Opt-Out and Medicare Participation Agreements

(Rev. 1, 10-01-03)

B3-3044.16

Participation agreements will terminate on the opt out effective date. See 40.17 for effective date provisions. Physicians and practitioners may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit. Nonparticipating physicians and practitioners may opt out at any time.

The carrier must updates carrier system files so that it may timely pay participating physicians and practitioners at the correct payment amounts in effect for that part of the fee schedule year before they opt out and to pay them as nonparticipating for emergency or urgent care as of their opt out effective date.

40.17 - Participating Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.17

Participating physicians and practitioners may opt out if they file an affidavit that meets the criteria and which is received by the carrier at least 30 days before the first day of the next calendar quarter showing an effective date of the first day in that quarter (i.e., January 1, April 1, July 1,October 1). They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit.

The 30-day notice is required to allow sufficient time for the carrier to accomplish the appropriate system file updates before the effective date. The carrier must make participating physician status changes no less frequently than at the beginning of each calendar quarter. Therefore, participating physicians or practitioners must provide the carrier with 30 days notice that they intend to opt out at the beginning of the next calendar quarter.

Participating physicians or practitioners may sign private contracts only after the effective date of affidavits filed in accordance with §40.9. They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit.

It is necessary to treat nonparticipating physicians or practitioners differently from participating physicians or practitioners in order to assure that participating physicians or practitioners are paid properly for the services they furnish before the effective date of the affidavit.

Participating physicians or practitioners are paid at the full fee schedule for the services they furnish to Medicare beneficiaries. However, the law sets the payment amount for nonparticipating physicians or practitioners at 95 percent of the payment amount for participating physicians or practitioners.

Participating physicians or practitioners who opt out are treated as nonparticipating physicians or practitioners as of the effective date of the opt-out affidavit. When a participating physician/practitioner opts out of Medicare, the carrier must pay the physician/practitioner at the higher participating physician/practitioner rate for services rendered in the period before the effective date of the opt-out; and at the nonparticipating rate for services rendered on and after the opt-out date.

40.18 - Physicians or Practitioners Who Choose to Opt Out of Medicare

(Rev. 1, 10-01-03)

B3-3044.18

If a physician/practitioner chooses to opt out of Medicare, it means that the physician/practitioner opts out for all covered items and services that he or she furnishes. Physicians and practitioners cannot have private contracts that apply to some covered services they furnish but not to others. For example, if a physician or practitioner provides laboratory tests or durable medical equipment incident to his or her professional services and chooses to opt out of Medicare, then the physician/practitioner has opted out of Medicare for payment of lab services and Durable Medical Equipment, Prosthetics, and Orthotics (DMEPOS) as well as for professional services. If a physician or practitioner who has opted out refers a beneficiary to a non-opt-out physician or practitioner for medically necessary services, such as laboratory, DMEPOS or inpatient hospitalization, Medicare would cover those services.

In addition, because suppliers of DMEPOS, independent diagnostic testing facilities, clinical laboratories, etc., cannot opt out, the physician or practitioner owner of such suppliers cannot opt out as such a supplier. Therefore, the participating physician or practitioner becomes a nonparticipating physician or practitioner for purposes of Medicare payment for emergency and urgent care services on the effective date of the opt-out. (See §40.28).

40.19 - Opt-Out Relationship to Noncovered Services

(Rev. 1, 10-01-03)

B3-3044.19

Because Medicare's rules do not apply to items or services that are categorically not covered by Medicare, a private contract is not needed to furnish such items or services to Medicare beneficiaries, and Medicare's claims filing rules and limits on charges do not apply to such items or services. For example, because Medicare does not cover hearing

aids, a physician or practitioner, or other supplier, may furnish a hearing aid to a Medicare beneficiary and would not be required to file a claim with Medicare; further, the physician, practitioner, or other supplier would not be subject to any Medicare limit on the amount they could collect for the hearing aid.

If the item or service is one that is not categorically excluded from coverage by Medicare, but may be noncovered in a given case (for example, it is covered only where certain clinical criteria are met and there is a question as to whether the criteria are met), a non-opt-out physician/practitioner or other supplier is **not** relieved of his or her obligation to file a claim with Medicare. If the physician or practitioner or other supplier has given a proper Advance Beneficiary Notice (ABN), they may collect from the beneficiary the full charge if Medicare does deny the claim.

Where a physician or practitioner has opted out of Medicare, he or she must provide covered services only through private contracts that meet the criteria specified in §40.8 (including items and services that are not categorically excluded from coverage but may be excluded in a given case). An opt-out physician or practitioner is prohibited from submitting claims to Medicare (except for emergency or urgent care services furnished to a beneficiary with whom the physician or practitioner did not have a private contract). (See §40.12.)

40.20 - Maintaining Information on Opt-Out Physicians

(Rev. 1, 10-01-03)

B3-3044.20

The carrier must maintain information on the opt-out physicians or practitioners. At a minimum, it must capture the name and UPIN of the physician or practitioner, the effective date of the opt-out affidavit, and the end date of the opt-out period. The carrier may also include other provider-specific information it may need. If cost effective, it may house this information on its provider file.

40.21 - Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 1, 10-01-03)

B3-3044.21

The carrier must develop data exchange mechanisms for furnishing Medicare managed care plans in its service area with timely information on physicians and practitioners who have opted out of Medicare. For example, it may wish to establish an Internet Web site "Home Page" which houses all of the information on physicians or practitioners who have opted out. It will need to negotiate appropriate opt out information exchange mechanisms with each managed care plan in its service area.

40.22 - Informing the National Supplier Clearinghouse (NSC) of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 1, 10-01-03)

B3-3044.22

The carrier must notify the NSC directly with timely information on physicians or practitioners who have opted out of Medicare. An Internet Web site "Home Page" is not an acceptable means of notifying the NSC. The NSC's address is as follows:

National Supplier Clearinghouse
P.O. Box 100142
Columbia, SC 29202-3142

40.23 - Organizations That Furnish Physician or Practitioner Services

(Rev. 1, 10-01-03)

B3-3044.23

The opt-out applies to all items or services the physician or practitioner furnishes to Medicare beneficiaries, regardless of the location where such items or services are furnished.

Where a physician or practitioner opts out and is a member of a group practice or otherwise reassigns his or her rights to Medicare payment to an organization, the organization may no longer bill Medicare or be paid by Medicare for services that the physician or practitioner furnishes to Medicare beneficiaries. However, if the physician or practitioner continues to grant the organization the right to bill and be paid for the services the physician or practitioner furnishes to patients, the organization may bill and be paid by the beneficiary for the services that are provided under the private contract. The decision of a physician or practitioner to opt out of Medicare does not affect the ability of the group practice or organization to bill Medicare for the services of physicians and practitioners who have not opted out of Medicare.

Corporations, partnerships, or other organizations that bill and are paid by Medicare for the services of physicians or practitioners who are employees, partners, or have other arrangements that meet the Medicare reassignment-of-payment rules cannot opt out because they are neither physicians nor practitioners. Of course, if every physician and practitioner within a corporation, partnership, or other organization opts out, then such corporation, partnership, or other organization would have, in effect, opted out.

40.24 - The Difference Between Advance Beneficiary Notices (ABN) and Private Contracts

(Rev. 1, 10-01-03)

B3-3044.24

An Advance Beneficiary Notice (ABN) allows a beneficiary to make an informed consumer decision by knowing in advance that the beneficiary may have to pay out-of-pocket. An ABN is not needed where the item or service is categorically excluded from Medicare coverage or outside the scope of the benefit.

An ABN is used when the physician/practitioner believes that Medicare will not make payment, while private contracts are used for services that are covered by Medicare and for which payment might be made if a claim were to be submitted.

See the Medicare Claims Processing Manual, chapter 30, for a description of the ABN.

40.25 - Private Contracting Rules When Medicare is the Secondary Payer

(Rev. 1, 10-01-03)

B3-3044.25

The opt-out physician/practitioner must have a private contract with a Medicare beneficiary for all Medicare-covered services (see §40.7), notwithstanding that Medicare would be the secondary payer in a given situation. No Medicare primary **or** secondary payments will be made for items and services furnished by a physician/practitioner under the private contract.

40.26 - Registration and Identification of Physicians or Practitioners Who Opt Out

(Rev. 1, 10-01-03)

B3-3044.26

The carrier must use the Unique Provider Identification Number (UPIN) Registry to identify opt-out physicians or practitioners nationwide. The Registry can be accessed at http://www.cms.hhs.gov/providers/enrollment/upin/upintoc.asp.

40.27 - System Identification

(Rev. 1, 10-01-03)

B3-3044.27

The carrier must ensure that its system can automatically identify claims that include services furnished by providers or practitioners who have opted out of Medicare. It must not make payment to any opt-out physician/practitioner for items or services furnished on or after the effective date of the physician's or practitioner's opt out affidavit unless there are emergency or urgent care situations involved. In an emergency or urgent care situation, payment can be made for services furnished to a Medicare beneficiary if the beneficiary has no contract with the opt-out physician/practitioner. See the following section for related instructions.

40.28 - Emergency and Urgent Care Situations

(Rev. 1, 10-01-03)

B3-3044.28

Payment may be made for services furnished by an opt-out physician or practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician opted out.

Where a physician or a practitioner who has opted out of Medicare treats a beneficiary with whom the physician or practitioner does not have a private contract in an emergency or urgent situation, the physician or practitioner may not charge the beneficiary more than the Medicare limiting charge for the service and must submit the claim to Medicare on

behalf of the beneficiary for the emergency or urgent care. Medicare payment may be made to the beneficiary for the Medicare covered services furnished to the beneficiary.

In other words, where the physician or practitioner provides emergency or urgent services to the beneficiary, the physician or practitioner must submit a claim to Medicare, and may collect no more than the Medicare limiting charge in the case of a physician, or the deductible and coinsurance in the case of a practitioner. This implements §1802(b)(2)(A)(iii) of the Act, which specifies that the contract may not be entered into when the beneficiary is in need of emergency or urgent care. Because the services are excluded from coverage under §1862(a)(19) of the Act only if they are furnished under private contract, CMS concludes that they are not excluded in this case where there in no private contract, notwithstanding that they were furnished by an opt-out physician or practitioner. Hence, they are covered services furnished by a nonparticipating physician or practitioner, and the rules in effect absent the opt-out would apply in these cases. Specifically, the physician or practitioner may choose to take assignment (thereby agreeing to collect no more than the Medicare deductible and coinsurance based on the allowed amount from the beneficiary) or not to take assignment (and to collect no more than the Medicare limiting charge), but the practitioner must take assignment under §1842(b)(18) of the Act.

Therefore, in this circumstance the physician or practitioner must submit a completed Medicare claim on behalf of the beneficiary with the appropriate HCPCS code and HCPCS modifier that indicates the services furnished to the Medicare beneficiary were emergency or urgent and the beneficiary does not have a private agreement with the physician or practitioner. If the physician or practitioner did not submit **GJ** national HCPCS modifier, then the carrier must deny the claim so that the beneficiary can appeal.

GJ = Opt-out physician/practitioner EMERGENCY OR URGENT SERVICES

This modifier must be used on claims for services rendered by an opt-out physician/ practitioner for an emergency/urgent service. The use of this modifier indicates that the service was furnished by an opt-out physician/practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician/practitioner opted out.

The carrier must deny payment for emergency or urgent care items and services to both an opt-out physician or practitioner and the beneficiary if these parties have previously entered into a private contract, i.e., prior to the furnishing of the emergency or urgent care items or services but within the physician's or practitioner's opt out period.

Under the emergency and urgent care situation where an opt-out physician or practitioner renders emergency or urgent service to a Medicare beneficiary (e.g., a fractured leg) who has not entered into a private agreement with the physician or practitioner, as stated above the physician or practitioner is required to submit a claim to Medicare with the appropriate modifier (GJ and 54 as discussed further below) and is subject to all the rules and regulations of Medicare including limiting charge. However, if the opt-out physician or practitioner asks the beneficiary, with whom the physician or practitioner has no private contract, to return for a follow up visit (e.g., return within five to six weeks to remove the cast and examine the leg) the physician or practitioner must ask the

beneficiary to sign a private contract. In other words, once a beneficiary no longer needs emergency or urgent care (i.e., nonurgent follow up care), Medicare cannot pay for the follow up care and the physician or practitioner can and must, under the opt-out affidavit agreement, ask the beneficiary to sign a private agreement as a condition of further treatment.

The way this would work in the fractured leg example (see previous paragraph) is that the physician or practitioner would bill Medicare for the setting of the fractured leg with the emergency opt out CMS modifier **(GJ)** and the surgical care only modifier (54) to ensure that CMS does not pay the Evaluation and Management (E&M) that is in the global fee for the procedure. The physician or practitioner would then either have the beneficiary sign the private contract or refer the beneficiary to a Medicare physician or practitioner who would bill Medicare using the post op only modifier to be paid for the post op care in the global period.

If the beneficiary continues to be in a condition that requires emergency or urgent care (i.e., unconscious or unstable after surgery for an aneurysm) follow up care would continue to be paid under emergency or urgent care until such time as the beneficiary no longer needed such care. In the absence on controvertible evidence CMS recommends accepting what the physician or practitioner says via the modifiers and doing post-pay records review of frequent users of the opt-out modifier.

40.29 - Definition of Emergency and Urgent Care Situations

(Rev. 1, 10-01-03)

B3-3044.29

Emergency services are defined as being services furnished to an individual who has an emergency medical condition as defined in 42 CFR 424.101. The CMS has adopted the definition of emergency medical condition in that section of the Code of Federal Regulations (CFR). However, it seemed clear that Congress intended that the term "emergency or urgent care services" not be limited to emergency services since they also included "urgent care services." Urgent Care Services are defined in 42 CFR 405.400 as services furnished within 12 hours in order to avoid the likely onset of an emergency medical condition. For example, if a beneficiary has an ear infection with significant pain, CMS would view that as requiring treatment to avoid the adverse consequences of continued pain and perforation of the eardrum. The patient's condition would not meet the definition of emergency medical condition because **immediate care** is not needed to avoid placing the health of the individual in serious jeopardy or to avoid serious impairment or dysfunction. However, although it does not meet the definition of emergency care, the beneficiary needs care within a relatively short period of time (which CMS defines as 12 hours) to avoid adverse consequences, and the beneficiary may not be able to find another physician or practitioner to provide treatment within 12 hours.

40.30 - Denial of Payment to Employers of Opt-Out Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.30

If an opt-out physician or practitioner is employed in a hospital setting and submits bills for which payment is prohibited, the Part B carrier usually detects and investigates the situation. However, in some instances an opt-out physician or practitioner may have a salary arrangement with a hospital or clinic or work in a group practice and may not directly submit bills for payment. If the carrier detects this situation, it must recover the payment made for the opt-out physician/practitioner from the hospital/clinic/group practice, after appropriate notification.

40.31 - Denial of Payment to Beneficiaries and Others

(Rev. 1, 10-01-03)

B3-3044.31

If a beneficiary submits a claim that includes items or services furnished by an opt-out physician or practitioner on dates on or after the effective date of opt out by such physician or practitioner, the carrier must deny such items or services. (See §40.6.) However, see §40.11 in cases in which the beneficiary appeals the denial on the basis that no private contract was signed.

40.32 - Payment for Medically Necessary Services Ordered or Prescribed by an Opt-out physician or Practitioner

(Rev. 1, 10-01-03)

B3-3044.32

If claims are submitted for any items or services ordered or prescribed by an opt out physician or practitioner under §1802 of the Act, the carrier may pay for medically necessary services of the furnishing entity, provided the furnishing entity is not also a physician or practitioner that has opted out of the Medicare program.

40.33 - Mandatory Claims Submission

(Rev. 1, 10-01-03)

B3-3044.33

Section 1848(g)(4) of the Act, "Physician/Practitioner Submission of Claims," regarding mandatory claims submission, does not apply once a physician or practitioner signs and submits an affidavit to the Medicare carrier opting out of the Medicare program, for the duration of the physician's or practitioner's opt out period, unless the physician or practitioner knowingly and willfully violates a term of the affidavit.

40.34 - Renewal of Opt-Out

(Rev. 1, 10-01-03)

B3-3044.34

A physician or practitioner may renew an opt out without interruption by filing an affidavit with each carrier to which an affidavit was submitted for the first opt out (as specified in §40.9), and to each carrier to which a claim was submitted under §40.28 during the previous opt out period, provided the affidavits are filed within 30 days after the current opt-out period expires.

40.35 - Early Termination of Opt-Out

(Rev. 1, 10-01-03)

B3-3044.35

If a physician or practitioner changes his or her mind after the carrier has approved the affidavit, the opt-out may be terminated within 90 days of the effective date of the affidavit. To properly terminate an opt out, a physician or practitioner must:

- Not have previously opted out of Medicare;
- Notify all Medicare carriers, with which the physician or practitioner filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period;
- Refund to each beneficiary with whom the physician or practitioner has privately contracted all payment collected in excess of:
    - The Medicare limiting charge (in the case of physicians or practitioners);or
    - The deductible and coinsurance (in the case of practitioners).
- Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt out and of the beneficiaries' rights to have claims filed on their behalf with Medicare for services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

When the physician or practitioner properly terminates opt-out in accordance with the second bullet above, the physician or practitioner will be reinstated in Medicare as if there had been no opt-out, and the provision of §40.3 must not apply unless the physician or practitioner subsequently properly opts out.

40.36 - Appeals

(Rev. 1, 10-01-03)

B3-3044.36

A determination by CMS that a physician or practitioner has failed to properly opt out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, or failed to properly terminate opt-out is an initial determination for purposes of 42 CFR 405.803.

A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted out is an initial determination for purposes of 42 CFR 405.803.

See the Medicare Claims Processing Manual, Chapter 29, "Appeals of Claims Decisions," for additional information on appeals.

40.37 - Application to Medicare+Choice Contracts

(Rev. 1, 10-01-03)

B3-3044.37

The Medicare Managed Care Manual contains instructions for M+C organizations about the impact on managed care.

The manual provides in general that M+C organizations:

- Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted out of Medicare.
- Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted out of Medicare, except for emergency or urgent care services furnished to a beneficiary who has not previously entered into a private contract with the physician or practitioner, in accordance with §40.28.

The carrier must maintain mutually agreeable means of advising M+C organizations of who has opted out. Disputes with M+C organizations about the provision of opt out information should be referred to the regional office staff for resolution.

40.38 - Claims Denial Notices to Opt-Out Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.38

To ensure that the notice denying payment to the opt-out physician or practitioner indicates the proper reason for denial of payment, the carrier must include language in the notice appropriate to particular circumstances as follows:

- When the claim is submitted **inadvertently** by the opt-out physician/practitioner, the carrier must use claim adjustment reason code 28 (coverage not in effect at the time service was provided) at the claim level with group code PR (patient responsibility) and the remark code MA47:

  > Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies furnished. As a result, we cannot pay this claim. The patient is responsible for payment."

- The carrier uses the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner. It must use claim adjustment reason code 28 (coverage not in effect at the time service was provided) at the claim level with group code PR (patient responsibility) and the claim level remark code MA56:

  > Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies furnished. As a result, we cannot pay this claim. The patient is responsible for payment. Under Federal law you cannot charge more than the limiting charge amount.

40.39 - Claims Denial Notices to Beneficiaries

(Rev. 1, 10-01-03)

B3-3044.39

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, the carrier must include language in the notice appropriate to particular circumstances as follows:

- It must use the following MSN message when the claim is submitted **inadvertently** by the opt-out physician/practitioner:

  MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."

- It must use the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner:

  MSN # 21.19 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge. Under Federal law your doctor cannot charge you more than the limiting charge amount."

- It must use the following message when the claim is submitted by the beneficiary for a service furnished by an opt-out physician/practitioner:

  MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."

40.40 - Reporting

(Rev. 1, 10-01-03)

B3-3044.40

The carrier must compile cumulative data for CMS on the number of physicians and practitioners who sign up to privately contract with Medicare beneficiaries. It must prepare a quarterly "Private Contracting" report and submit it to central office and a copy to its regional office. It must send quarterly reports to:

Centers for Medicare & Medicaid Services
Center for Health Plans and Providers
Provider Purchasing and Administration Group
Division of Practitioner Claims Processing
7500 Security Boulevard
Baltimore MD, 21244-1850

Reports may be faxed to (410) 786-0330, Attn: CMM, PPAG, DPCP, in lieu of mailing a hard copy report. The carrier must prepare a separate report for each contract jurisdiction.

NOTE: For reporting purposes, CMS is interested only in valid/approved affidavits. The carrier must not count affidavits it receives that are invalid/not approved and must be returned to the physician/practitioner for clarification, incompleteness, etc.

The carrier must use the following report format:

Name of Report: Private Contracting Data

1. Carrier name;
2. Carrier number;
3. Quarter: (beginning and ending date); and
4. Number of "private contracting" affidavits received during report period.

For detail information: (use the following format)

Specialty	Name/Address	PIN	UPIN	Par Status	Affidavit Receipt Date	Effective Date

NOTE: The "Affidavit Receipt Date" column of the report is optional. Because the affidavit receipt date may not be currently available in all systems, it may not be possible to give CMS a quarterly count of the number of private contracting affidavits received. If the carrier's system has the capability to supply CMS with the affidavit receipt date, the carrier must enter the correct date in the "Affidavit Receipt Date" column. If its system cannot supply CMS with the affidavit receipt date, it must leave the "Affidavit Receipt Date" column blank.

The carrier must sort the report data by physician/practitioner specialty.

The report is due 30 days after the end of each quarter (e.g., a report for the quarter April1, 2003, through June 30, 2003, is due July 30, 2003).

The CMS will notify the carrier if and when this report is either discontinued or put on the CROWD system.

50 - Drugs and Biologicals

(Rev. 1, 10-01-03)

B3-2049, A3-3112.4.B, HO-230.4.B

The Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals (see §50.1);
- They are of the type that are not usually self-administered. (see §50.2);
- They meet all the general requirements for coverage of items as incident to a physician's services (see §§50.1 and 50.3);
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §50.4);
- They are not excluded as noncovered immunizations (see §50.4.4.2); and

- They have not been determined by the FDA to be less than effective. (See §§50.4.4).

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §110.3 for coverage of drugs, which are necessary to the effective use of Durable Medical Equipment (DME) or prosthetic devices.)

50.1 - Definition of Drug or Biological

(Rev. 1, 10-01-03)

B3-2049.1

Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental Association (AOA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.

50.2 - Determining Self-Administration of Drug or Biological

(Rev. 1, 10-01-03)

AB-02-072, AB-02-139, B3-2049.2

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act to redefine this exclusion. The prior statutory language referred to those drugs “which cannot be self-administered.” Implementation of the BIPA provision requires interpretation of the phrase “not usually self-administered by the patient”.

A. Policy

Fiscal intermediaries and carriers are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

B. Administered

The term "administered" refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Only injectable (including intravenous) drugs are eligible for inclusion under the "incident to" benefit. Other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are all considered to be usually self-administered by the patient.

C. Usually

For the purposes of applying this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered.

Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, CMS offers the following guidance for each contractor's consideration in making this determination in the absence of such data:

1. Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.
2. Absent evidence to the contrary, presume that drugs delivered by intramuscular injection are not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self-administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:
3. Absent evidence to the contrary, presume that drugs delivered by subcutaneous injection are self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:

    A. **Acute Condition -** Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.

    B. **Frequency of Administration -** How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

D. Definition of Acute Condition

For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment consisting of scheduled injections lasting less than two weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug administration (FDA) approval language, package inserts, drug compendia, and other information.

E. By the Patient

The term "by the patient" means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses,

friends, or other care-givers are not considered the patient). The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The carrier ignores all instances when the drug is administered on an inpatient basis.

The carrier makes this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for "self-administered by the patient" was based; for example, an early onset of dementia.

F. Evidentiary Criteria

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Please note that prior to the August 1, 2002, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label contained instructions for self-administration. However, CMS notes that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.

G. Provider Notice of Noncovered Drugs

Contractors must describe on their Web site the process they will use to determine whether a drug is usually self-administered and thus does not meet the "incident to" benefit category. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208.

Contractors must provide notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice.

Contractors must not develop local medical review policies (LMRPs) for this purpose because further elaboration to describe drugs that do not meet the 'incident to' and the 'not usually self-administered' provisions of the statute are unnecessary. Current LMRPs

based solely on these provisions must be withdrawn. LMRPs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LMRPs to describe reasonable and necessary uses of drugs that are not usually self-administered.

H. Conferences Between Contractors

Contractors' Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

I. Beneficiary Appeals

If a beneficiary's claim for a particular drug is denied because the drug is subject to the "self-administered drug" exclusion, the beneficiary may appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.

J. Provider and Physician Appeals

A physician accepting assignment may appeal a denial under the provisions found in Chapter 29 of the Medicare Claims Processing Manual.

K. Reasonable and Necessary

Carriers and fiscal intermediaries will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient's condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician's office visit was reasonable and necessary. However, contractors should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician's office or outpatient hospital setting. That is, while a physician's office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

L. Reporting Requirements

Each carrier and intermediary must report to CMS, every September 1 and March 1, its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered. The CMS anticipates that contractors will review injectable drugs on a rolling basis and publish their list of excluded drugs as it is developed. For example, contractors should not wait to publish this list until every drug has been reviewed.

Contractors must send their exclusion list to the following e-mail address: drugdata@cms.hhs.gov a template that CMS will provide separately, consisting of the following data elements in order:

1. Carrier Name
2. State
3. Carrier ID#
4. HCPCS
5. Descriptor
6. Effective Date of Exclusion
7. End Date of Exclusion
8. Comments

Any exclusion list not provided in the CMS mandated format will be returned for correction.

To view the presently mandated CMS format for this report, open the file located at:

http://cms.hhs.gov/manuals/pm_trans/AB02_139a.zip

50.3 - Incident-to Requirements

(Rev. 1, 10-01-03)

B3-2049.3

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:

- Be of a form that is not usually self-administered;
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements. (See §§170, 180, 190 and 200 for specific instructions.)

Whole blood is a biological, which cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied and the blood deductible has been met.

50.4 - Reasonableness and Necessity

(Rev. 1, 10-01-03)

B3-2049.4

50.4.1 - Approved Use of Drug

(Rev. 1, 10-01-03)

B3-2049.4

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

The carrier, DMERC, or intermediary will deny coverage for drugs and biologicals, which have not received final marketing approval by the FDA unless it receives instructions from CMS to the contrary. For specific guidelines on coverage of Group C cancer drugs, see the Medicare National Coverage Determinations Manual.

If there is reason to question whether the FDA has approved a drug or biological for marketing, the carrier or intermediary must obtain satisfactory evidence of FDA's approval. Acceptable evidence includes:

- A copy of the FDA's letter to the drug's manufacturer approving the new drug application (NDA);
- A listing of the drug or biological in the FDA's "Approved Drug Products" or "FDA Drug and Device Product Approvals";
- A copy of the manufacturer's package insert, approved by the FDA as part of the labeling of the drug, containing its recommended uses and dosage, as well as possible adverse reactions and recommended precautions in using it; or
- Information from the FDA's Web site.

When necessary, the regional office (RO) may be able to help in obtaining information.

50.4.2 - Unlabeled Use of Drug

(Rev. 1, 10-01-03)

B3-2049.3

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §50.5.

These decisions are made by the contractor on a case-by-case basis.

50.4.3 - Examples of Not Reasonable and Necessary

(Rev. 1, 10-01-03)

B3-2049.4

Determinations as to whether medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice:

1. Not for Particular Illness

Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations). Charges for medications, e.g., vitamins, given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage.

2. Injection Method Not Indicated

Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration. For example, the accepted standard of medical practice for the treatment of certain diseases is to initiate therapy with parenteral penicillin and to complete therapy with oral penicillin. Carriers exclude the entire charge for penicillin injections given after the initiation of therapy if oral penicillin is indicated unless there are special medical circumstances that justify additional injections.

3. Excessive Medications

Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered. For example, the accepted standard of medical practice in the maintenance treatment of pernicious anemia is one vitamin B-12 injection per month. Carriers exclude the entire charge for injections given in excess of this frequency unless there are special medical circumstances that justify additional injections.

Carriers will supplement the guidelines as necessary with guidelines concerning appropriate use of specific injections in other situations. They will use the guidelines to screen out questionable cases for special review, further development, or denial when the injection billed for would not be reasonable and necessary. They will coordinate any type of drug treatment review with the Quality Improvement Organization (QIO).

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge (i.e., for both the drug and its administration). Also, carriers exclude from payment any charges for other services (such as office visits) which were primarily for the purpose of administering a noncovered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

50.4.4 - Payment for Antigens and Immunizations

(Rev. 1, 10-01-03)

50.4.4.1 - Antigens

(Rev. 1, 10-01-03)

B3-2049.4

Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)

50.4.4.2 - Immunizations

(Rev. 1, 10-01-03)

A3-3157.A, B3-2049.4, HO-230.4.C

Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as anti-rabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered. However, pneumococcal, hepatitis B, and influenza virus vaccines are exceptions to this rule. (See items A, B, and C below.) In cases where a vaccination or inoculation is excluded from coverage, related charges are also not covered.

A. Pneumococcal Pneumonia Vaccinations

Effective for services furnished on or after May 1, 1981, the Medicare Part B program covers pneumococcal pneumonia vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. This includes revaccination of patients at highest risk of pneumococcal infection. Typically, these vaccines are administered once in a lifetime except for persons at highest risk. Effective July 1, 2000, Medicare does not require for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician’s order and without physician supervision.

An initial vaccine may be administered only to persons at high risk (see below) of pneumococcal disease. Revaccination may be administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least five years have [passed since the previous doe of pneumococcal vaccine.

Persons at high risk for whom an initial vaccine may be administered include all people age 65 and older; immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness (e.g., cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks); and individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

Persons at highest risk and those most likely to have rapid declines in antibody levels are those for whom revaccination may be appropriate. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. It is not appropriate for routine revaccination of people age 65 or older that are not at highest risk.

Those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient's verbal history to determine prior vaccination status. If the patient is uncertain about his or her vaccination history in the past five years, the vaccine should be given. However, if the patient is certain he/she was were vaccinated in the last five years, the vaccine should not be given. If the patient is certain that the vaccine was given more than five years ago, revaccination is covered only if the patient is at high risk.

B. Hepatitis B Vaccine

Effective for services furnished on or after September 1, 1984, P.L. 98-369 provides coverage under Part B for hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. This coverage is effective for services furnished on or after September 1, 1984. High-risk groups currently identified include (see exception below):

- ESRD patients;
- Hemophiliacs who receive Factor VIII or IX concentrates;
- Clients of institutions for the mentally retarded;
- Persons who live in the same household as an Hepatitis B Virus (HBV) carrier;
- Homosexual men; and
- Illicit injectable drug abusers.

Intermediate risk groups currently identified include:

- Staff in institutions for the mentally retarded; and
- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

EXCEPTION: Persons in both of the above-listed groups in paragraph B, would not be considered at high or intermediate risk of contracting hepatitis B, however, if there were laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For Medicare program purposes, the vaccine may be administered upon the order of a doctor of medicine or osteopathy, by a doctor of medicine or osteopathy, or by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, and persons recognized under the incident to physicians' services provision of law.

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

C. Influenza Virus Vaccine

Effective for services furnished on or after May 1, 1993, the Medicare Part B program covers influenza virus vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. Typically, these vaccines are administered once a year in the fall or winter. Medicare does not require, for coverage purposes, that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

50.4.5 - Unlabeled Use for Anti-Cancer Drugs

(Rev. 1, 10-01-03)

B3-2049.4.C

Effective January 1, 1994, unlabeled uses of FDA approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen for a medically accepted indication are evaluated under the conditions described in this paragraph. A regimen is a combination of anti-cancer agents which has been clinically recognized for the treatment of a specific type of cancer. An example of a drug regimen is: Cyclophosphamide + vincristine + prednisone (CVP) for non-Hodgkin's lymphoma.

In addition to listing the combination of drugs for a type of cancer, there may be a different regimen or combinations which are used at different times in the history of the cancer (induction, prophylaxis of CNS involvement, post remission, and relapsed or refractory disease). A protocol may specify the combination of drugs, doses, and schedules for administration of the drugs. For purposes of this provision, a cancer treatment regimen includes drugs used to treat toxicities or side effects of the cancer treatment regimen when the drug is administered incident to a chemotherapy treatment.

Contractors must not deny coverage based solely on the absence of FDA approved labeling for the use, if the use is supported by one of the following and the use is **not**

listed as "not indicated" in any of the three compendia. (See note at the end of this subsection.)

A. American Hospital Formulary Service Drug Information

Drug monographs are arranged in alphabetical order within therapeutic classifications. Within the text of the monograph, information concerning indications is provided; including both labeled and unlabeled uses. Unlabeled uses are identified with daggers. The text must be analyzed to make a determination whether a particular use is supported.

B. American Medical Association Drug Evaluations

Drug evaluations are organized into sections and chapters that are based on therapeutic classifications. The evaluation of a drug provides information concerning indications, including both labeled and unlabeled uses. Unlabeled uses are not specifically identified as such. The text must be analyzed to make a determination whether a particular use is supported. In making these determinations, also refer to the "AMA Drug Evaluations Subscription," Volume III, section 17 (Oncolytic Drugs), chapter 1 (Principles of Cancer Chemotherapy), tables 1 and 2.

Table 1, Specific Agents Used In Cancer Chemotherapy, lists the anti-neoplastic agents which are currently available for use in various cancers. The indications presented in this table for a particular anti-cancer drug include labeled and unlabeled uses (although they are not identified as such). Any indication appearing in this table is considered to be a medically accepted use.

Table 2, Clinical Responses To Chemotherapy, lists some of the currently preferred regimens for various cancers. The table headings include (1) type of cancer, (2) drugs or regimens currently preferred, (3) alternative or secondary drugs or regimens, and (4) other drugs or regimens with reported activity.

A regimen appearing under the preferred or alternative/secondary headings is considered to be a medically accepted use.

A regimen appearing under the heading "Other Drugs or Regimens With Reported Activity" is considered to be for a medically accepted use provided:

- The preferred and alternative/secondary drugs or regimens are contraindicated;
- A preferred and/or alternative/secondary drug or regimen was used but was not tolerated or was ineffective; or
- There was tumor progression or recurrence after an initial response.

C. United States Pharmacopoeia Drug Information (USPDI)

Monographs are arranged in alphabetic order by generic or family name. Indications for use appear as accepted, unaccepted, or insufficient data. An indication is considered to be a medically accepted use only if the indication is listed as accepted. Unlabeled uses are identified with brackets. A separate indications index lists all indications included in USPDI along with the medically accepted drugs used in treatment or diagnosis.

D. A Use Supported by Clinical Research That Appears in Peer Reviewed Medical Literature

This applies only when an unlabeled use does not appear in any of the compendia or is listed as insufficient data or investigational. If an unlabeled use of a drug meets these criteria, the carrier will contact the compendia to see if a report regarding this use is forthcoming. If a report is forthcoming, the carrier uses this information as a basis for making decisions. The compendium process for making decisions concerning unlabeled uses is very thorough and continuously updated. Peer reviewed medical literature includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

In determining whether there is supportive clinical evidence for a particular use of a drug, carrier medical staff (in consultation with local medical specialty groups) will evaluate the quality of the evidence in published peer reviewed medical literature. When evaluating this literature, they will consider (among other things) the following:

- The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate. While a 20 percent response rate may be adequate for highly prevalent disease states, a lower rate may be adequate for rare diseases or highly unresponsive conditions.
- The effect on the patient's well-being and other responses to therapy that indicate effectiveness, e.g., a significant increase in survival rate or life expectancy or an objective and significant decrease in the size of the tumor or a reduction in symptoms related to the tumor. Stabilization is not considered a response to therapy.
- The appropriateness of the study design. The carrier will consider:
    1. Whether the experimental design in light of the drugs and conditions under investigation is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.);
    2. That nonrandomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and
    3. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

The carrier will use peer reviewed medical literature appearing in the following publications:

- American Journal of Medicine;
- Annals of Internal Medicine;
- The Journal of the American Medical Association;

- Journal of Clinical Oncology;
- Blood;
- Journal of the National Cancer Institute;
- The New England Journal of Medicine;
- British Journal of Cancer;
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Drugs;
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
- Lancet; or
- Leukemia.

The carrier is not required to maintain copies of these publications. If a claim raises a question about the use of a drug for a purpose not included in the FDA approved labeling or the compendia, the carrier will ask the physician to submit copies of relevant supporting literature.

Unlabeled uses may also be considered medically accepted if determined by the carrier to be medically accepted generally as safe and effective for the particular use.

NOTE: If a use is identified as not indicated by CMS or the FDA, or if a use is specifically identified as not indicated in one or more of the three compendia mentioned or if the carrier determines, based on peer reviewed medical literature, that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered.

50.4.6 - Less Than Effective Drug

(Rev. 1, 10-01-03)

B3-2049.4.C.5

This is a drug that has been determined by the Food and Drug Administration (FDA) to lack substantial evidence of effectiveness for all labeled indications. Also, a drug that has been the subject of a Notice of an Opportunity for a Hearing (NOOH) published in the "Federal Register" before being withdrawn from the market, and for which the Secretary has not determined there is a compelling justification for its medical need, is considered less than effective. This includes any other drug product that is identical, similar, or related. Payment may not be made for a less than effective drug.

Because the FDA has not yet completed its identification of drug products that are still on the market, existing FDA efficacy decisions must be applied to all similar products once they are identified.

50.4.7 - Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act

(Rev. 1, 10-01-03)

B3-2049.4.C.6

The Food and Drug Administration (FDA) has found that, from time to time, firms established as retail pharmacies engage in mass production of compounded drugs, beyond the normal scope of pharmaceutical practice, in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). By compounding drugs on a large scale, a company may be operating as a drug manufacturer within the meaning of the FFDCA, without complying with requirements of that law. Such companies may be manufacturing drugs which are subject to the new drug application (NDA) requirements of the FFDCA, but for which FDA has not approved an NDA or which are misbranded or adulterated. If the FDA has not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs these companies are producing are safe and effective. The safety and effectiveness issues pertain to such factors as chemical stability, purity, strength, bioequivalency, and biovailability.

Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to by covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.

In those cases in which the FDA has determined that a company is producing compounded drugs in violation of the FFDCA, Medicare does not pay for the drugs because they do not meet the FDA approval requirements of the Medicare program. In addition, Medicare does not pay for the DME or prosthetic device used to administer such a drug if FDA determines that a required NDA has not been approved or that the drug is misbranded or adulterated.

The CMS will notify the carrier when the FDA has determined that compounded drugs are being produced in violation of the FFDCA. The carrier does not stop Medicare payment for such a drug unless it is notified that it is appropriate to do so through a subsequent instruction. In addition, if the carrier or Regional Offices (ROs) become aware that other companies are possibly operating in violation of the FFDCA, the carrier or RO notifies:

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Blvd.
Baltimore, MD 21244-1850

50.5 - Self-Administered Drugs and Biologicals

(Rev. 1, 10-01-03)

B3-2049.5

Medicare Part B does not cover drugs that are usually self-administered by the patient unless the statute provides for such coverage. The statute explicitly provides coverage, for blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, certain oral anti-cancer drugs and anti-emetics used in certain situations.

50.5.1 - Immunosuppressive Drugs

(Rev. 1, 10-01-03)

A3-3112.4.B.3, HO-230.4.B.3, AB-01-10

Until January 1, 1995, immunosuppressive drugs were covered under Part B for a period of one year following discharge from a hospital for a Medicare covered organ transplant. The CMS interpreted the 1-year period after the date of the transplant procedure to mean 365 days from the day on which an inpatient is discharged from the hospital. Beneficiaries are eligible to receive additional Part B coverage **within** 18 months after the discharge date for drugs furnished in 1995; **within** 24 months for drugs furnished in 1996; **within** 30 months for drugs furnished in 1997; and **within** 36 months for drugs furnished after 1997.

For immunosuppressive drugs furnished on or after December 21, 2000, this time limit for coverage is eliminated.

Covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. (This is an exception to the standing drug policy which permits coverage of FDA approved drugs for **nonlabeled** uses, where such uses are found to be reasonable and necessary in an individual case.)

Covered drugs also include those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. Therefore, antibiotics, hypertensives, and other drugs that are not directly related to rejection are not covered.

The FDA has identified and approved for marketing the following specifically labeled immunosuppressive drugs. They are:

Sandimmune (cyclosporine), Sandoz Pharmaceutical;

Imuran (azathioprine), Burroughs Wellcome;

Atgam (antithymocyte globulin), Upjohn;

Orthoclone OKT3 (Muromonab-CD3), Ortho Pharmaceutical;

Prograf (tacrolimus), Fujisawa USA, Inc;

Celicept (mycophenolate mefetil, Roche Laboratories;

Daclizumab (Zenapax);

Cyclophosphamide (Cytoxan);

Prednisone; and

Prednosolone.

The CMS expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs.

50.5.2 - Erythropoietin (EPO)

(Rev. 1, 10-01-03)

A3-3112.4.B.4, HO-230.4.B.4

The statute provides that EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis. Coverage is available regardless of whether the drug is administered by the patient or the patient's caregiver. EPO is a biologically engineered protein which stimulates the bone marrow to make new red blood cells.

NOTE: Non-ESRD patients who are receiving EPO to treat anemia induced by other conditions such as chemotherapy or the drug zidovudine (commonly called AZT) must meet the coverage requirements in §50.

EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis when:

- It is administered in the renal dialysis facility; or
- It is self-administered in the home by any dialysis patient (or patient caregiver) who is determined competent to use the drug and meets the other conditions detailed below.

NOTE: Payment may not be made for EPO under the incident to provision when EPO is administered in the renal dialysis facility.

Also, in the office setting, reimbursement will be made for the administration charge only for non-ESRD patients receiving EPO.

50.5.2.1 - Requirements for Medicare Coverage for EPO

(Rev. 1, 10-01-03)

B3-2049.5

Medicare covers EPO and items related to its administration for dialysis patients who use EPO in the home when the following conditions are met:

A. Patient Care Plan

A dialysis patient who uses EPO in the home must have a current care plan (a copy of which must be maintained by the designated backup facility for Method II patients) for monitoring home use of EPO that includes the following:

1. Review of diet and fluid intake for aberrations as indicated by hyperkalemia and elevated blood pressure secondary to volume overload;
2. Review of medications to ensure adequate provision of supplemental iron;
3. Ongoing evaluations of hematocrit and iron stores;

4. Reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume;
5. Method for physician and facility (including backup facility for Method II patients) follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results;
6. Training of the patient to identify the signs and symptoms of hypotension and hypertension; and
7. The decrease or discontinuance of EPO if hypertension is uncontrollable.

B. Patient Selection

The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

1. Preselection Monitoring

The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

2 Conditions the Patient Must Meet

The assessment must find that the patient meets the following conditions:

a. Is a dialysis patient;

b. Has a hematocrit (or comparable hemoglobin level) that is as follows:

- For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. Patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.
- For a patient who has been receiving EPO from the facility or the physician, between 30 and 36 percent.

c. Is under the care of:

- A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and
- A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

3. The assessment must find that the patient or a caregiver meets the following conditions:

- Is trained by the facility to inject EPO and is capable of carrying out the procedure;

- Is capable of reading and understanding the drug labeling; and
- Is trained in, and capable of observing, aseptic techniques.

4. Care and Storage of Drug

The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

C. Responsibilities of Physician or Dialysis Facility

The patient's physician or dialysis facility must:

- Develop a protocol that follows the drug label instructions;
- Make the protocol available to the patient to ensure safe and effective home use of EPO;
- Through the amounts prescribed, ensure that the drug on hand at any time does not exceed a 2-month supply;
- Maintain adequate records to allow quality assurance for review by the Network and State Survey Agencies. For Method II patients, current records must be provided to and maintained by the designated backup facility; and
- The dialysis facility must submit claims for EPO, if the facility provides it.

See the Medicare Claims Processing Manual, Chapter 11, "End Stage Renal Disease," for instructions for billing and processing claims for EPO under Method 1 and Method 2. Note that hematocrit readings are required on claims. It is expected that the ESRD facility or hospital outpatient department will maintain the following information in each patient's medical record to permit the review of the medical necessity of EPO.

1. Diagnostic coding;
2. Most recent creatinine prior to initiation of EPO therapy;
3. Date of most recent creatinine prior to initiation of EPO therapy;
4. Most recent hematocrit (HCT) prior to initiation of EPO therapy;
5. Date of most recent hematocrit (HCT) prior to initiation of EPO therapy;
6. Dosage in units/kg;
7. Weight in kgs; and
8. Number of units administered.

50.5.2.2 - Medicare Coverage of Epoetin Alfa (Procrit) for Preoperative Use

(Rev. 1, 10-01-03)

PM-AB-99-59, Dated 8/1/99

This instruction pertains exclusively to the preoperative surgical indication of the drug Procrit, in which it is administered to specific patients prior to surgery to reduce risk of

transfusion. It does not affect Medicare policies related to other Food and Drug Administration (FDA) approved uses of Procrit. **It is not a national coverage decision**.

Procrit as Preventive Service

The carrier may determine that Procrit is covered for individuals who:

1. Are undergoing hip or knee surgery
2. Have an anemia with a hemoglobin between 10 and 13 mg/dL;
3. Are not a candidate for autologous blood transfusion;
4. Are expected to lose more than 2 units of blood; and
5. Have had a workup so that their anemia appears to be that of chronic disease.

The preoperative use of Procrit may be afforded to these individuals when carriers, exercising their discretion, determine that this treatment is reasonable and necessary. In other cases, Procrit is considered a preventive service and therefore not covered.

50.5.3 - Oral Anti-Cancer Drugs

(Rev. 1, 10-01-03)

A3-3112.4.B.5, HO-230.4.B.5

Effective January 1, 1994, Medicare Part B coverage is extended to include oral anti-cancer drugs that are prescribed as anti-cancer chemotherapeutic agents providing they have the same active ingredients and are used for the same indications as anti-cancer chemotherapeutic agents which would be covered if they were not self-administered and they were furnished incident to a physician's service as drugs and biologicals.

For an oral anti-cancer drug to be covered under Part B, it must:

- Be prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents;
- Be a drug or biological that has been approved by the Food and Drug Administration (FDA);
- Have the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's "Approved Drug Products" (Orange Book), "Physician's Desk Reference" (PDR), or an authoritative drug compendium;
- Be used for the same indications, including unlabeled uses, as the non-self-administrable version of the drug; and
- Be reasonable and necessary for the individual patient.

50.5.4 - Oral Anti-Nausea (Anti-Emetic) Drugs

(Rev. 1, 10-01-03)

PM AB-97-26

Effective January 1, 1998, Medicare also covers self-administered anti-emetics which are necessary for the administration and absorption of the anti-neoplastic chemotherapeutic agents when a high likelihood of vomiting exists. The anti-emetic drug is covered as a necessary means for administration of the antineoplastic chemotherapeutic agents. Oral drugs prescribed for use with the primary drug, which enhance the anti-neoplastic effect of the primary drug or permit the patient to tolerate the primary anti-neoplastic drug in higher doses for longer periods are not covered. Self-administered anti-emetics to reduce the side effects of nausea and vomiting brought on by the primary drug are not included beyond the administration necessary to achieve drug absorption.

Section 1861(s)(2) of the Act extends coverage to oral anti-emetic drugs that are used as full replacement for intravenous dosage forms of a cancer regimen under the following conditions:

- Coverage is provided only for oral drugs approved by the Food and Drug Administration (FDA) for use as anti-emetics;
- The oral anti-emetic must either be administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen;
- Oral anti-emetic drugs administered with a particular chemotherapy treatment must be initiated within two hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time;
- The oral anti-emetic drugs provided must be used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of the chemotherapy treatment.

Only drugs pursuant to a physician's order at the time of the chemotherapy treatment qualify for this benefit. The dispensed number of dosage units may not exceed a loading dose administered within two hours of the treatment, plus a supply of additional dosage units not to exceed 48 hours of therapy.

Oral drugs that are not approved by the FDA for use as anti-emetics and which are used by treating physicians adjunctively in a manner incidental to cancer chemotherapy are not covered by this benefit and are not reimbursable within the scope of this benefit.

It is recognized that a limited number of patients will fail on oral anti-emetic drugs. Intravenous anti-emetics may be covered (subject to the rules of medical necessity) when furnished to patients who fail on oral anti-emetic therapy.

More than one oral anti emetic drug may be prescribed and may be covered for concurrent use if needed to fully replace the intravenous drugs that otherwise would be given.

50.5.5 - Hemophilia Clotting Factors

(Rev. 1, 10-01-03)

A3-3112.4.B.2, HO-230.4.B.2

Section 1861(s)(2)(I) of the Act provides Medicare coverage of blood clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. Hemophilia, a blood disorder characterized by prolonged coagulation time, is caused by deficiency of a factor in plasma necessary for blood to clot. For purposes of Medicare Part B coverage, hemophilia encompasses the following conditions:

- Factor VIII deficiency (classic hemophilia);
- Factor IX deficiency (also termed plasma thromboplastin component (PTC) or Christmas factor deficiency); and
- Von Willebrand's disease.

Claims for blood clotting factors for hemophilia patients with these diagnoses may be covered if the patient is competent to use such factors without medical supervision.

The amount of clotting factors determined to be necessary to have on hand and thus covered under this provision is based on the historical utilization pattern or profile developed by the contractor for each patient. It is expected that the treating source, e.g., a family physician or comprehensive hemophilia diagnostic and treatment center, have such information. From this data, the contractor is able to anticipate and make reasonable projections concerning the quantity of clotting factors the patient will need over a specific period of time. Unanticipated occurrences involving extraordinary events, such as automobile accidents or inpatient hospital stays, will change this base line data and should be appropriately considered. In addition, changes in a patient's medical needs over a period of time require adjustments in the profile.

50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

(Rev. 6, 01-23-04)

Beginning for dates of service on or after January 1, 2004, The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides coverage of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2) in the home. The corresponding HCPCS codes are J1563 and J1564. The Act defines "intravenous immune globulin" as an approved pooled plasma derivative for the treatment of primary immune deficiency disease. It is covered under this benefit when the patient has a diagnosed primary immune deficiency disease, it is administered in the home of a patient with a diagnosed primary immune deficiency disease, and the physician determines that administration of the derivative in the patient's home is medically appropriate. The benefit does not include coverage for items or services related to the administration of the derivative. For coverage of IVIG under this benefit, it is not necessary for the derivative to be administered through a piece of durable medical equipment.

60 - Services and Supplies

(Rev. 1, 10-01-03)

B3-2050

A. Noninstitutional Setting

For purposes of this section a noninstitutional setting means all settings other than a hospital or skilled nursing facility

Medicare pays for services and supplies (including drug and biologicals which are not usually self-administered) that are furnished incident to a physician's or other practitioner's services, are commonly included in the physician's or practitioner's bills, and for which payment is not made under a separate benefit category listed in §1861(s) of the Act. Carriers and intermediaries must not apply incident to requirements to services having their own benefit category. Rather, these services should meet the requirements of their own benefit category. For example, diagnostic tests are covered under §1861(s)(3) of the Act and are subject to their own coverage requirements. Depending on the particular tests, the supervision requirement for diagnostic tests or other services may be more or less stringent than supervision requirements for services and supplies furnished incident to physician's or other practitioner's services. Diagnostic tests need not also meet the incident to requirement in this section. Likewise, pneumococcal, influenza, and hepatitis B vaccines are covered under §1861(s)(10) of the Act and need not also meet incident to requirements. (Physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical psychologists, clinical social workers, physical therapists and occupational therapists all have their own benefit categories and may provide services without direct physician supervision and bill directly for these services. When their services are provided as auxiliary personnel (see under direct physician supervision, they may be covered as incident to services, in which case the incident to requirements would apply.

For purposes of this section, physician means physician or other practitioner (physician, physician assistant, nurse practitioner, clinical nurse specialist, nurse midwife, and clinical psychologist) authorized by the Act to receive payment for services incident to his or her own services.

To be covered incident to the services of a physician or other practitioner, services and supplies must be:

- An integral, although incidental, part of the physician's professional service (see §60.1);
- Commonly rendered without charge or included in the physician's bill (see §60.1A);
- Of a type that are commonly furnished in physician's offices or clinics (see §60.1A);
- Furnished by the physician or by auxiliary personnel under the physician's direct supervision (see §60.1B).

B. Institutional Setting

Hospital services incident to physician's or other practitioner's services rendered to outpatients (including drugs and biologicals which are not usually self-administered by

the patient), and partial hospitalization services incident to such services may also be covered.

The hospital's intermediary makes payment for these services under Part B to a hospital.

60.1 - Incident to Physician's Professional Services

(Rev. 1, 10-01-03)

B3-2050.1

Incident to a physician's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness.

A. Commonly Furnished in Physicians' Offices

Services and supplies commonly furnished in physicians' offices are covered under the incident to provision. Where supplies are clearly of a type a physician is not expected to have on hand in his/her office or where services are of a type not considered medically appropriate to provide in the office setting, they would not be covered under the incident to provision.

Supplies usually furnished by the physician in the course of performing his/her services, e.g., gauze, ointments, bandages, and oxygen, are also covered. Charges for such services and supplies must be included in the physicians' bills. (See §50 regarding coverage of drugs and biologicals under this provision.) To be covered, supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing fir he services or supplies. For example, where a patient purchases a drug and the physician administers it, the cost of the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

B. Direct Personal Supervision

Coverage of services and supplies incident to the professional services of a physician in private practice is limited to situations in which there is direct physician supervision of auxiliary personnel.

Auxiliary personnel means any individual who is acting under the supervision of a physician, regardless of whether the individual is an employee, leased employee, or independent contractor of the physician, or of the legal entity that employs or contracts with the physician. Likewise, the supervising physician may be an employee, leased employee or independent contractor of the legal entity billing and receiving payment for the services or supplies.

However, the physician personally furnishing the services or supplies or supervising the auxiliary personnel furnishing the services or supplies must have a relationship with the legal entity billing and receiving payment for the services or supplies that satisfies the requirements for valid reassignment. As with the physician's personal professional services, the patient's financial liability for the incident to services or supplies is to the

physician or other legal entity billing and receiving payment for the services or supplies. Therefore, the incident to services or supplies must represent an expense incurred by the physician or legal entity billing for the services or supplies.

Thus, where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician.

This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment. (However, the direct supervision requirement must still be met with respect to every nonphysician service.)

Direct supervision in the office setting does not mean that the physician must be present in the same room with his or her aide. However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services.

If auxiliary personnel perform services outside the office setting, e.g., in a patient's home or in an institution (other than hospital or SNF), their services are covered incident to a physician's service only if there is direct supervision by the physician. For example, if a nurse accompanied the physician on house calls and administered an injection, the nurse's services are covered. If the same nurse made the calls alone and administered the injection, the services are not covered (even when billed by the physician) since the physician is not providing direct supervision. Services provided by auxiliary personnel in an institution (e.g., nursing, or convalescent home) present a special problem in determining whether direct physician supervision exists. The availability of the physician by telephone and the presence of the physician somewhere in the institution does not constitute direct supervision. (See §70.3 of the Medicare National Coverage Determinations Manual for instructions used if a physician maintains an office in an institution.) For hospital patients and for SNF patients who are in a Medicare covered stay, there is no Medicare Part B coverage of the services of physician-employed auxiliary personnel as services incident to physicians' services under §1861(s)(2)(A) of the Act. Such services can be covered only under the hospital or SNF benefit and payment for such services can be made to only the hospital or SNF by a Medicare intermediary. (See §80 concerning physician supervision of technicians performing diagnostic x-ray procedures in a physician's office.)

60.2 - Services of Nonphysician Personnel Furnished Incident to Physician's Services

(Rev. 1, 10-01-03)

B3-2050.2

In addition to coverage being available for the services of such auxiliary personnel as nurses, technicians, and therapists when furnished incident to the professional services of a physician (as discussed in §60.1), a physician may also have the services of certain nonphysician practitioners covered as services incident to a physician's professional services. These nonphysician practitioners, who are being licensed by the States under various programs to assist or act in the place of the physician, include, for example, certified nurse midwives, clinical psychologists, clinical social workers, physician assistants, nurse practitioners, and clinical nurse specialists. (See §§150 through 200 for coverage instructions for various allied health/nonphysician practitioners' services.)

Services performed by these nonphysician practitioners incident to a physician's professional services include not only services ordinarily rendered by a physician's office staff person (e.g., medical services such as taking blood pressures and temperatures, giving injections, and changing dressings) but also services ordinarily performed by the physician such as minor surgery, setting casts or simple fractures, reading x-rays, and other activities that involve evaluation or treatment of a patient's condition.

Nonetheless, in order for services of a nonphysician practitioner to be covered as incident to the services of a physician, the services must meet all of the requirements for coverage specified in §§60 through 60.1. For example, the services must be an integral, although incidental, part of the physician's personal professional services, and they must be performed under the physician's direct supervision.

A nonphysician practitioner such as a physician assistant or a nurse practitioner may be licensed under State law to perform a specific medical procedure and may be able (see §§190 or 200, respectively) to perform the procedure without physician supervision and have the service separately covered and paid for by Medicare as a physician assistant's or nurse practitioner's service. However, in order to have that same service covered as incident to the services of a physician, it must be performed under the direct supervision of the physician as an integral part of the physician's personal in-office service. As explained in §60.1, this does not mean that each occasion of an incidental service performed by a nonphysician practitioner must always be the occasion of a service actually rendered by the physician. It does mean that there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part, and there must be subsequent services by the physician of a frequency that reflects the physician's continuing active participation in and management of the course of treatment. In addition, the physician must be physically present in the same office suite and be immediately available to render assistance if that becomes necessary.

Note also that a physician might render a physician's service that can be covered even though another service furnished by a nonphysician practitioner as incident to the physician's service might not be covered. For example, an office visit during which the physician diagnoses a medical problem and establishes a course of treatment could be covered even if, during the same visit, a nonphysician practitioner performs a noncovered service such as acupuncture.

60.3 - Incident to Physician's Service in Clinic

(Rev. 1, 10-01-03)

B3-2050.3

Services and supplies incident to a physician's service in a physician directed clinic or group association are generally the same as those described above.

A physician directed clinic is one where:

1. A physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open;
2. Each patient is under the care of a clinic physician; and
3. The nonphysician services are under medical supervision.

In highly organized clinics, particularly those that are departmentalized, direct physician supervision may be the responsibility of several physicians as opposed to an individual attending physician. In this situation, medical management of all services provided in the clinic is assured. The physician ordering a particular service need not be the physician who is supervising the service. Therefore, services performed by auxiliary personnel and other aides are covered even though they are performed in another department of the clinic.

Supplies provided by the clinic during the course of treatment are also covered. When the auxiliary personnel perform services outside the clinic premises, the services are covered only if performed under the direct supervision of a clinic physician. If the clinic refers a patient for auxiliary services performed by personnel who are not supervised by clinic physicians, such services are not incident to a physician's service.

60.4 - Services Incident to a Physician's Service to Homebound Patients Under General Physician Supervision

(Rev. 1, 10-01-03)

B3-2051

A. When Covered

In some medically underserved areas there are only a few physicians available to provide services over broad geographic areas or to a large patient population. The lack of medical personnel (and, in many instances, a home health agency servicing the area) significantly reduces the availability of certain medical services to homebound patients. Some physicians and physician-directed clinics, therefore, call upon nurses and other paramedical personnel to provide these services under general (rather than direct) supervision. In some areas, such practice has tended to become the accepted method of delivery of these services.

The Senate Finance Committee Report accompanying the 1972 Amendments to the Act recommended that the direct supervision requirement of the "incident to" provision be modified to provide coverage for services provided in this manner.

Accordingly, to permit coverage of certain of these services, the direct supervision criterion in §60.2 above is **not** applicable to individual or intermittent services outlined in this section when they are performed by personnel meeting any pertinent State

requirements (e.g., a nurse, technician, or physician extender) and where the criteria listed below also are met:

1 The patient is homebound; i.e., confined to his or her home (see §60.4.1 for the definition of a "homebound" patient and §110.1 (D) for the definition of patient's "place of residence."

2 The service is an integral part of the physician's service to the patient (the patient must be one the physician is treating), and is performed under general physician supervision by employees of the physician or clinic. General supervision means that the physician need not be physically present at the patient's place of residence when the service is performed; however, the service must be performed under his or her overall supervision and control.

The physician orders the service(s) to be performed, and contact is maintained between the nurse or other employee and the physician, e.g., the employee contacts the physician directly if additional instructions are needed, and the physician must retain professional responsibility for the service. All other "incident to" requirements must be met (see §§60-60.4).

3 The services are included in the physician's/clinic's bill, and the physician or clinic has incurred an expense for them (see §60.2).

4 The services of the paramedical are required for the patient's care; that is, they are reasonable and necessary as defined in the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20.

5 When the service can be furnished by an HHA in the local area, it **cannot** be covered when furnished by a physician/clinic to a homebound patient under this provision, except as described in §60.4.C.

B. Covered Services

Where the requirements in §60.4.A are met, the direct supervision requirement in §60.2 is not applicable to the following services:

1. Injections;
2. Venipuncture;
3. EKGs;
4. Therapeutic exercises;
5. Insertion and sterile irrigation of a catheter;
6. Changing of catheters and collection of catheterized specimen for urinalysis and culture;
7. Dressing changes, e.g., the most common chronic conditions that may need dressing changes are decubitus care and gangrene;
8. Replacement and/or insertion of nasogastric tubes;
9. Removal of fecal impaction, including enemas;

10. Sputum collection for gram stain and culture, and possible acid-fast and/or fungal stain and culture;
11. Paraffin bath therapy for hands and/or feet in rheumatoid arthritis or osteoarthritis;
12. Teaching and training the patient for:
    a. The care of colostomy and ileostomy;
    b. The care of permanent tracheostomy;
    c. Testing urine and care of the feet (diabetic patients only); and
    d. Blood pressure monitoring.

Teaching and training services (also referred to as educational services) can be covered only where they provide knowledge essential for the chronically ill patient's participation in his or her own treatment and only where they can be reasonably related to such treatment or diagnosis. Educational services that provide more elaborate instruction than is necessary to achieve the required level of patient education are not covered. After essential information has been provided, the patient should be relied upon to obtain additional information on his or her own.

C. Relation to Home Health Benefits

This coverage should not be considered as an alternative to home health benefits where there is a participating home health agency in the area which could provide the needed services on a timely basis. For example, two of the three services initially included under this coverage - injections and venipuncture - are skilled nursing services that could be covered as home health services (EKG is not a covered Home Health Agency (HHA) service) if the patient is eligible for home health benefits and there is a home health agency available. Thus, postpayment review of these claims will include measures to assure that physicians and clinics do not provide a substantial number of services under this coverage when they could otherwise have been performed by a home health agency.

In these circumstances, the physician or clinic is expected to assist the patient in obtaining such skilled services together with the other home health services (such as aide services). However, HHA services are not considered available where the HHA cannot respond on a timely basis or where the physician could not have foreseen that intermittent services would be needed.

Refer to the Medicare Claims Processing Manual, Chapter 10, "Home Health Agency Billing," for a more in depth discussion of home health services.

60.4.1 - Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit

(Rev. 1, 10-01-03)

B3-2051.1

This definition applies to homebound for purposes of the Medicare home health benefit. An individual does not have to be bedridden to be considered as confined to home. However, the condition of these patients should be such that there exists a normal

inability to leave home and, consequently, leaving his or her home would require a considerable and taxing effort. If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration. It is expected that in most instances absences from the home will be for the purpose of receiving medical treatment. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block, a drive attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the individual is not homebound if absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

The above examples are not all-inclusive and are meant to be illustrative of the kinds of infrequent or unique events a patient may attend. Generally speaking, a beneficiary will be considered to be homebound if the beneficiary has a condition due to an illness or injury which restricts ability to leave the residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers, the use of special transportation, or the assistance of another person or if the beneficiary has a condition which is such that leaving home is medically contraindicated. The following are some examples of homebound patients:

- A beneficiary paralyzed from a stroke who is confined to a wheelchair or who requires the aid of crutches in order to walk;
- A beneficiary who is blind or senile and, therefore, requires the assistance of another person in leaving his or her residence;
- A beneficiary who has lost the use of the upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and therefore, requires the assistance of another individual in leaving his or her place of residence;
- A beneficiary who has just returned from a hospital stay involving surgery who may be suffering from resultant weakness and pain and, therefore, his or her actions may be restricted by the physician to certain specified and limited activities such as getting out of bed only for a specified period of time, or walking stairs only once a day;
- A beneficiary with arteriosclerotic heart disease of such severity that the beneficiary must avoid all stress and physical activity;
- A beneficiary with a psychiatric problem if the illness is manifested in part by a refusal to leave the home environment or it is not considered safe for the beneficiary to leave home unattended, even if he/she had no physical limitations, and
- A beneficiary in the late stages of ALS or a neurodegenerative disability.

In determining whether the patient has the general inability to leave the home and leaves the home only infrequently or for periods of short duration, it is necessary (as is the case in determining whether skilled nursing services are intermittent) to look at the patient's condition over a period of time rather than for short periods within the home health stay.

For example, a patient may leave the home (under the conditions described above, e.g., with severe and taxing effort, with the assistance of others) more frequently during a short period when, for example, the presence of visiting relatives provides a unique opportunity for such absences, than is normally the case. So long as the patient's overall condition and experience is such that he or she meets these qualifications, he or she should be considered confined to the home.

The aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age is not considered confined to home for purposes of this reimbursement unless the person's condition is analogous to those above.

If for any reason a question is raised as to whether an individual is confined to home, the carrier will ask the physician to furnish the information necessary to establish if the beneficiary is homebound, as defined above.

70 - Sleep Disorder Clinics

(Rev. 1, 10-01-03)

B3-2055

Sleep disorder clinics are facilities in which certain conditions are diagnosed through the study of sleep. Such clinics are for diagnosis, therapy, and research. Sleep disorder clinics may provide some diagnostic or therapeutic services which are covered under Medicare. These clinics may be affiliated either with a hospital or a freestanding facility. Whether a clinic is hospital-affiliated or freestanding, coverage for diagnostic services under some circumstances is covered under provisions of the law different from those for coverage of therapeutic services.

A. Criteria for Coverage of Diagnostic Tests

All reasonable and necessary diagnostic tests given for the medical conditions listed in subsection B are covered when the following criteria are met:

- The clinic is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics may be covered even in the absence of direct supervision by a physician;
- Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician's orders; and
- The need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.

Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

B. Medical Conditions for Which Testing is Covered

Diagnostic testing is covered only if the patient has the symptoms or complaints of one of the conditions listed below. Most of the patients who undergo the diagnostic testing are not considered inpatients, although they may come to the facility in the evening for

testing and then leave after testing is over. The overnight stay is considered an integral part of these tests.

1. Narcolepsy - This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks (e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness. The sleep disorder clinic must submit documentation that this condition is severe enough to interfere with the patient's well being and health before Medicare benefits may be provided for diagnostic testing. Ordinarily, a diagnosis of narcolepsy can be confirmed by three sleep naps. If more than three sleep naps are claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional test(s). It will use HCPCS procedure codes 95828 and 95805.

2. Sleep Apnea - This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing. Ordinarily, a single polysomnogram and electroencephalogram (EEG) can diagnose sleep apnea. If more than one such testing session is claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional tests. It will use HCPCS procedure codes 95807, 95810, and 95822.

3. Impotence - Diagnostic nocturnal penile tumescence testing may be covered, under limited circumstances, to determine whether erectile impotence in men is organic or psychogenic. Although impotence is not a sleep disorder, the nature of the testing requires that it be performed during sleep. The tests ordinarily are covered only where necessary to confirm the treatment to be given (surgical, medical, or psychotherapeutic). Ordinarily, a diagnosis may be determined by two nights of diagnostic testing. If more than two nights of testing are claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional tests. It will have its medical staff review questionable cases to ensure that the tests are reasonable and necessary for the individual. It will use HCPCS procedure code 54250. (See the Medicare National Coverage Determinations Manual, Chapter 1, for policy on coverage of diagnosis and treatment of impotence.)

4. Parasomnia - Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis. The carrier must use HCPCS procedure codes 95807, 95810, and/or 95822.

C. Polysomnography for Chronic Insomnia Is Not Covered.

Evidence at the present time is not convincing that polysomnography in a sleep disorder clinic for chronic insomnia provides definitive diagnostic data or that such information is useful in patient treatment or is associated with improved clinical outcome. The use of polysomnography for diagnosis of patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

D. Coverage of Therapeutic Services.

Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services may be covered in a hospital outpatient setting or in a freestanding facility provided they meet the pertinent requirements for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct supervision of a physician.

80 - Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

(Rev. 51, Issued: 06-23-06, Effective: 01-01-05, Implementation: 09-21-06)

This section describes the levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is not a hospital inpatient or outpatient. Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule, with certain exceptions listed in the regulation, have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare. The regulation defines these levels of physician supervision for diagnostic tests as follows:

General Supervision - means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

Direct Supervision - in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

Personal Supervision - means a physician must be in attendance in the room during the performance of the procedure.

One of the following numerical levels is assigned to each CPT or HCPCS code in the Medicare Physician Fee Schedule Database:

0 Procedure is not a diagnostic test or procedure is a diagnostic test which is not

subject to the physician supervision policy.

1	Procedure must be performed under the general supervision of a physician.
2	Procedure must be performed under the direct supervision of a physician.
3	Procedure must be performed under the personal supervision of a physician.
4	Physician supervision policy does not apply when procedure is furnished by a qualified, independent psychologist or a clinical psychologist or furnished under the general supervision of a clinical psychologist; otherwise must be performed under the general supervision of a physician.
5	Physician supervision policy does not apply when procedure is furnished by a qualified audiologist; otherwise must be performed under the general supervision of a physician.
6	Procedure must be performed by a physician or by a physical therapist (PT) who is certified by the American Board of Physical Therapy Specialties (ABPTS) as a qualified electrophysiologic clinical specialist and is permitted to provide the procedure under State law.
6a	Supervision standards for level 66 apply; in addition, the PT with ABPTS certification may supervise another PT but only the PT with ABPTS certification may bill.
7a	Supervision standards for level 77 apply; in addition, the PT with ABPTS certification may supervise another PT but only the PT with ABPTS certification may bill.
9	Concept does not apply.
21	Procedure must be performed by a technician with certification under general supervision of a physician; otherwise must be performed under direct supervision of a physician.
22	Procedure may be performed by a technician with on-line real-time contact with physician.
66	Procedure must be performed by a physician or by a PT with ABPTS certification and certification in this specific procedure.
77	Procedure must be performed by a PT with ABPTS certification or by a PT without certification under direct supervision of a physician, or by a technician with certification under general supervision of a physician.

Nurse practitioners, clinical nurse specialists, and physician assistants are not defined as physicians under §1861(r) of the Act. Therefore, they may not function as supervisory

physicians under the diagnostic tests benefit (§1861(s)(3) of the Act). However, when these practitioners personally perform diagnostic tests as provided under §1861(s)(2)(K) of the Act, §1861(s)(3) does not apply and they may perform diagnostic tests pursuant to State scope of practice laws and under the applicable State requirements for physician supervision or collaboration.

Because the diagnostic tests benefit set forth in §1861(s)(3) of the Act is separate and distinct from the incident to benefit set forth in §1861(s)(2) of the Act, diagnostic tests need not meet the incident to requirements. Diagnostic tests may be furnished under situations that meet the incident to requirements but this is not required. However, carriers must not scrutinize claims for diagnostic tests utilizing the incident to requirements.

80.1 - Clinical Laboratory Services

(Rev. 1, 10-01-03)

B3-2070.1

Section 1833 and 1861 of the Act provides for payment of clinical laboratory services under Medicare Part B. Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner, as described in 42 CFR 410.32(a)(3).

See the Medicare Claims Processing Manual Chapter 16 for related claims processing instructions.

80.1.1 - Certification Changes

(Rev. 1, 10-01-03)

B3-2070.1.E

Each page of the lists of approved specialties also includes a column “Certification Changed” in which the following codes are used:

“C” indicates a change in the laboratory’s approved certification since the preceding listing.

“A” discloses an accretion.

“TERM” - Laboratory not approved for payment after the indicated date which follows the code. The reason for termination also is given in the following codes:

1. Involuntary termination - no longer meets requirements
2. Voluntary withdrawal

3. Laboratory closed, merged with other interests, or organizational change
4. Ownership change with new ownership participating under different name
5. Ownership change with new owner not participating
6. Change in ownership - new provider number assigned
7. Involuntary termination - failure to abide by agreement
8. Former “emergency” hospital now fully participating

80.1.2 - Carrier Contacts With Independent Clinical Laboratories

(Rev. 1, 10-01-03)

B3-2070.1.F

An important role of the carrier is as a communicant of necessary information to independent clinical laboratories. Experience has shown that the failure to inform laboratories of Medicare regulations and claims processing procedures may have an adverse effect on prosecution of laboratories suspected of fraudulent activities with respect to tests performed by, or billed on behalf of, independent laboratories. United States Attorneys often have to prosecute under a handicap or may simply refuse to prosecute cases where there is no evidence that a laboratory has been specifically informed of Medicare regulations and claims processing procedures.

Carriers must follow the Provider Education and Training (PET) guidelines to assure that laboratories are aware of Medicare regulations and the carrier’s policy when any changes are made in coverage policy or claims processing procedures. The PET guidelines require carriers to use various methods of communication (such as print, Internet, face-to-face instruction). Newsletters/bulletins that contain program and billing information must be produced at least quarterly and posted on the carrier Web site where duplicate copies may be obtained.

Some items which should be communicated to laboratories and responsibilities that laboratories are required to perform are:

- The requirements to have the same fee schedule for Medicare and private patients;
- To specify whether the tests are manual or automated;
- To document fully the medical necessity for pickup of specimens from a skilled nursing facility or a beneficiary’s home, and
- In cases when a laboratory service is referred from one independent laboratory to another independent laboratory, to identify the laboratory actually performing the test.

Additionally, when carrier professional relations representatives make personal contacts with particular laboratories, the representative should prepare and retain reports of contact indicating dates, persons present, and issues discussed. Finally, carriers should inform independent laboratories that the Medicare National Coverage Determinations Manual as well as other guidelines contained in the manual for determining medical necessity are on the Web site. Carriers should also publish local guidelines on its Web

site; the carrier should not duplicate national instructions here. Timely paper or electronic communications concerning the Internet publications to independent laboratories new to the carrier's service area are essential.

80.1.3 - Independent Laboratory Service to a Patient in the Patient's Home or an Institution

(Rev. 1, 10-01-03)

B3-2070.1.G

Where it is medically necessary for an independent laboratory to visit a patient to obtain a specimen, the service would be covered in the following circumstances:

1. Patient Confined to Home

If a patient is confined to the home or other place of residence used as his or her home (see §60.4.1 for the definition of a "homebound patient"), medical necessity would exist (e.g., where a laboratory technician draws a blood specimen). However, where the specimen is a type which would require only the services of a messenger and would not require the skills of a laboratory technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary.

2. Place of Residence is an Institution

Medical necessity could also exist where the patient's place of residence is an institution, including a skilled nursing facility that does not perform venipunctures. This would apply even though the institution meets the basic definition of a skilled nursing facility and would not ordinarily be considered a beneficiary's home. (This policy is intended for independent laboratories only and does not expand the range of coverage of services to homebound patients under the incident to provision.) A trip by an independent laboratory technician to a facility (other than a hospital) for the purpose of performing a venipuncture is considered medically necessary only if:

a. The patient was confined to the facility; and

b. The facility did not have on duty personnel qualified to perform this service.

When facility personnel actually obtained and prepared the specimens for the independent laboratory to pick them up, the laboratory provides this pickup service as a service to the facility in the same manner as it does for physicians.

80.2 - Psychological Tests and Neuropsychological Tests

(Rev. 55, Issued: 09-29-06, Effective: 01-01-06, Implementation: 12-28-06)

Medicare Part B coverage of psychological tests and neuropsychological tests is authorized under section 1861(s)(2)(C) of the Social Security Act. Payment for psychological and neuropsychological tests is authorized under section 1842(b)(2)(A) of the Social Security Act. The payment amounts for the new psychological and neuropsychological tests (CPT codes 96102, 96103, 96119 and 96120) that are effective January 1, 2006, and are billed for tests administered by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings.

Additionally, there is no authorization for payment for diagnostic tests when performed on an "incident to" basis.

Under the diagnostic tests provision, all diagnostic tests are assigned a certain level of supervision. Generally, regulations governing the diagnostic tests provision require that only physicians can provide the assigned level of supervision for diagnostic tests. However, there is a regulatory exception to the supervision requirement for diagnostic psychological and neuropsychological tests in terms of who can provide the supervision. That is, regulations allow a clinical psychologist (CP) or a physician to perform the general supervision assigned to diagnostic psychological and neuropsychological tests.

In addition, nonphysician practitioners such as nurse practitioners (NPs), clinical nurse specialists (CNSs) and physician assistants (PAs) who personally perform diagnostic psychological and neuropsychological tests are excluded from having to perform these tests under the general supervision of a physician or a CP. Rather, NPs and CNSs must perform such tests under the requirements of their respective benefit instead of the requirements for diagnostic psychological and neuropsychological tests. Accordingly, NPs and CNSs must perform tests in collaboration (as defined under Medicare law at section 1861(aa)(6) of the Act) with a physician. PAs perform tests under the general supervision of a physician as required for services furnished under the PA benefit.

Furthermore, physical therapists (PTs), occupational therapists (OTs) and speech language pathologists (SLPs) are authorized to bill three test codes as "sometimes therapy" codes. Specifically, CPT codes 96105, 96110 and 96111 may be performed by these therapists. However, when PTs, OTs and SLPs perform these three tests, they must be performed under the general supervision of a physician or a CP.

Who May Bill for Diagnostic Psychological and Neuropsychological Tests

- CPs – see qualifications under chapter 15, section 160 of the Benefits Policy Manual, Pub. 100-02.

- NPs –to the extent authorized under State scope of practice. See qualifications under chapter 15, section 200 of the Benefits Policy Manual, Pub. 100-02.

- CNSs –to the extent authorized under State scope of practice. See qualifications under chapter 15, section 210 of the Benefits Policy Manual, Pub. 100-02.

- PAs – to the extent authorized under State scope of practice. See qualifications under chapter 15, section 190 of the Benefits Policy Manual, Pub. 100-02.

- Independently Practicing Psychologists (IPPs)

- PTs, OTs and SLPs – see qualifications under chapter 15, sections 220-230.6 of the Benefits Policy Manual, Pub. 100-02.

Psychological and neuropsychological tests performed by a psychologist (who is not a CP) practicing independently of an institution, agency, or physician's office are covered when a physician orders such tests. An IPP is any psychologist who is licensed or certified to practice psychology in the State or jurisdiction where furnishing services or, if the jurisdiction does not issue licenses, if provided by any practicing psychologist. (It is CMS' understanding that all States, the District of Columbia, and Puerto Rico license psychologists, but that some trust territories do not. Examples of psychologists, other than CPs, whose psychological and neuropsychological tests are covered under the diagnostic tests provision include, but are not limited to, educational psychologists and counseling psychologists.)

The carrier must secure from the appropriate State agency a current listing of psychologists holding the required credentials to determine whether the tests of a particular IPP are covered under Part B in States that have statutory licensure or certification. In States or territories that lack statutory licensing or certification, the carrier checks individual qualifications before provider numbers are issued. Possible reference sources are the national directory of membership of the American Psychological Association, which provides data about the educational background of individuals and indicates which members are board-certified, the records and directories of the State or territorial psychological association, and the National Register of Health Service Providers. If qualification is dependent on a doctoral degree from a currently accredited program, the carrier verifies the date of accreditation of the school involved, since such accreditation is not retroactive. If the listed reference sources do not provide enough information (e.g., the psychologist is not a member of one of these sources), the carrier contacts the psychologist personally for the required information. Generally, carriers maintain a continuing list of psychologists whose qualifications have been verified.

NOTE: When diagnostic psychological tests are performed by a psychologist who is not practicing independently, but is on the staff of an institution, agency, or clinic, that entity bills for the psychological tests.

The carrier considers psychologists as practicing independently when:

- They render services on their own responsibility, free of the administrative and professional control of an employer such as a physician, institution or agency;
- The persons they treat are their own patients; and
- They have the right to bill directly, collect and retain the fee for their services.

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions exist:

- The office is confined to a separately-identified part of the facility which is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and

- The psychologist conducts a private practice, i.e., services are rendered to patients from outside the institution as well as to institutional patients.

Payment for Diagnostic Psychological and Neuropsychological Tests

Expenses for diagnostic psychological and neuropsychological tests are not subject to the outpatient mental health treatment limitation, that is, the payment limitation on treatment services for mental, psychoneurotic and personality disorders as authorized under Section 1833(c) of the Act. The payment amount for the new psychological and neuropsychological tests (CPT codes 96102, 96103, 96119 and 96120) that are billed for tests performed by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings. CPs, NPs, CNSs and PAs are required by law to accept assigned payment for psychological and neuropsychological tests. However, while IPPs are not required by law to accept assigned payment for these tests, they must report the name and address of the physician who ordered the test on the claim form when billing for tests.

CPT Codes for Diagnostic Psychological and Neuropsychological Tests

The range of CPT codes used to report psychological and neuropsychological tests is 96101-96120. CPT codes 96101, 96102, 96103, 96105, 96110, and 96111 are appropriate for use when billing for psychological tests. CPT codes 96116, 96118, 96119 and 96120 are appropriate for use when billing for neuropsychological tests.

All of the tests under this CPT code range 96101-96120 are indicated as active codes under the physician fee schedule database and are covered if medically necessary.

Payment and Billing Guidelines for Psychological and Neuropsychological Tests

The technician and computer CPT codes for psychological and neuropsychological tests include practice expense, malpractice expense and professional work relative value units. Accordingly, CPT psychological test code 96101 should not be paid when billed for the same tests or services performed under psychological test codes 96102 or 96103. CPT neuropsychological test code 96118 should not be paid when billed for the same tests or services performed under neuropsychological test codes 96119 or 96120. However, CPT codes 96101 and 96118 can be paid separately on the rare occasion when billed on the same date of service for different and separate tests from 96102, 96103, 96119 and 96120.

Under the physician fee schedule, there is no payment for services performed by students or trainees. Accordingly, Medicare does not pay for services represented by CPT codes 96102 and 96119 when performed by a student or a trainee. However, the presence of a

student or a trainee while the test is being administered does not prevent a physician, CP, IPP, NP, CNS or PA from performing and being paid for the psychological test under 96102 or the neuropsychological test under 96119.

80.3 - Otologic Evaluations

(Rev. 1, 10-01-03)

B3-2070.3, PM-B-01-34, B-02-004, PM AB-02-080

Diagnostic testing, including hearing and balance assessment services, performed by a qualified audiologist is covered as "other diagnostic tests" under §1861(s)(3) of the Act when a physician orders such testing for the purpose of obtaining information necessary for the physician's diagnostic evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem. Services are excluded by virtue of §1862(a)(7) of the Act when the diagnostic information required to determine the appropriate medial or surgical treatment is already known to the physician, or the diagnostic services are performed only to determine the need for or the appropriate type of hearing aid.

Diagnostic services performed by a qualified audiologist and meeting the above requirements are payable as "other diagnostic tests". The payment for these services is determined by the reason the tests were performed, rather than the diagnosis or the patient's condition. Payment for these services is based on the physician fee schedule amount except for audiology services furnished in a hospital outpatient department which are paid under the Outpatient Prospective Payment System. Nonhospital entities billing for the audiologist's services may accept assignment under the usual procedure or, if not accepting assignment, may charge the patient and submit a nonassigned claim on their behalf.

If a physician refers a beneficiary to an audiologist for evaluation of signs or symptoms associated with hearing loss or ear injury, the audiologist's diagnostic services should be covered even if the only outcome is the prescription of a hearing aid. If a beneficiary undergoes diagnostic testing performed by an audiologist without a physician referral, the tests are not covered even if the audiologist discovers a pathologic condition.

80.3.1 - Definition of Qualified Audiologist

(Rev. 1, 10-01-03)

B3-2070.3

Section 1861(ll)(3) of the Act, provides that a qualified audiologist is an individual with a master's or doctoral degree in audiology and who:

- Is licensed as an audiologist by the State in which the individual furnishes such services; or
- In the case of an individual who furnishes services in a State which does not license audiologists has:
    - Successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience),

Performed not less than nine months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and

- Successfully completed a national examination in audiology approved by the Secretary.

To determine whether a particular audiologist is qualified under the above definition, the carrier will need to check individual qualifications. Possible reference sources for determining an audiologist's professional qualifications are the national directory published annually by the American Speech and Hearing Association (which indicates which individuals are certified) and records and directories, which may be available from the State Speech and Hearing Associations. In addition, carriers in states which have statutory licensure or certification should secure from the appropriate State agency a current listing of audiologists holding the required credentials.

NOTE: There is no provision for direct payment to audiologists for therapeutic services.

80.4 - Coverage of Portable X-Ray Services Not Under the Direct Supervision of a Physician

(Rev. 1, 10-01-03)

B3-2070.4

80.4.1 - Diagnostic X-Ray Tests

(Rev. 1, 10-01-03)

B3-2070.4.A

Diagnostic x-ray services furnished by a portable x-ray supplier are covered under Part B when furnished in a place or residence used as the patient's home and in nonparticipating institutions. These services must be performed under the general supervision of a physician, the supplier must meet FDA certification requirements, and certain conditions relating to health and safety (as prescribed by the Secretary) must be met.

Diagnostic portable x-ray services are also covered under Part B when provided in participating SNFs and hospitals, under circumstances in which they cannot be covered under hospital insurance, i.e., the services are not furnished by the participating institution either directly or under arrangements that provide for the institution to bill for the services. (See §250 for Part B services furnished to inpatients of participating and nonparticipating institutions.)

80.4.2 - Applicability of Health and Safety Standards

(Rev. 1, 10-01-03)

B3-2070.4.B

The health and safety standards apply to all suppliers of portable x-ray services, except physicians who provide immediate personal supervision during the administration of diagnostic x-ray services. Payment is made only for services of approved suppliers who have been found to meet the standards. Notice of the coverage dates for services of approved suppliers are given to carriers by the RO.

When the services of a supplier of portable x-ray services no longer meet the conditions of coverage, physicians having an interest in the supplier's certification status must be notified. The notification action regarding suppliers of portable x-ray equipment is the same as required for decertification of independent laboratories, and the procedures explained in §80.1.3 are followed.

80.4.3 - Scope of Portable X-Ray Benefit

(Rev. 1, 10-01-03)

B3-2070.4.C

In order to avoid payment for services which are inadequate or hazardous to the patient, the scope of the covered portable x-ray benefit is defined as:

- Skeletal films involving arms and legs, pelvis, vertebral column, and skull;
- Chest films which do not involve the use of contrast media (except routine screening procedures and tests in connection with routine physical examinations); and
- Abdominal films which do not involve the use of contrast media.

80.4.4 - Exclusions From Coverage as Portable X-Ray Services

(Rev. 1, 10-01-03)

B3-2070.4.D

Procedures and examinations which are not covered under the portable x-ray provision include the following:

- Procedures involving fluoroscopy;
- Procedures involving the use of contrast media;
- Procedures requiring the administration of a substance to the patient or injection of a substance into the patient and/or special manipulation of the patient;
- Procedures which require special medical skill or knowledge possessed by a doctor of medicine or doctor of osteopathy or which require that medical judgment be exercised;
- Procedures requiring special technical competency and/or special equipment or materials;
- Routine screening procedures; and
- Procedures which are not of a diagnostic nature.

80.4.5 - Electrocardiograms

(Rev. 1, 10-01-03)

B3-2070.4.F

The taking of an electrocardiogram tracing by an approved supplier of portable x-ray services may be covered as an "other diagnostic test." The health and safety standards

referred to in §80.4.2 are applicable to such diagnostic EKG services, e.g., the technician must meet the personnel qualification requirements in the conditions for coverage of portable x-ray services.

80.5 - Bone Mass Measurements (BMMs)

80.5.1 - Background

80.5.2 - Authority

80.5.3 - Definition

80.5.4 - Conditions for Coverage

80.5.5 - Frequency Standards

80.5.6 - Beneficiaries Who May be Covered

80.5.7 - Noncovered BMMs

80.5.8 - Claims Processing

80.5.9 - National Coverage Determinations (NCDs)

90 - X-Ray, Radium, and Radioactive Isotope Therapy

(Rev. 1, 10-01-03)

B3-2075

These services also include materials and services of technicians.

X-ray, radium, and radioactive isotope therapy furnished in a nonprovider facility require direct personal supervision of a physician. The physician need not be in the same room, but must be in the area and immediately available to provide assistance and direction throughout the time the procedure is being performed. This level of physician involvement does not represent a physician's service and cannot be billed as a Part B service. The physician would have to furnish a reasonable and necessary professional service as defined in §§30 of this chapter, in order for the physician's activity to be covered.

However, effective for radiation therapy services furnished on or after April 1, 1989, radiologists' weekly treatment management services are covered.

A separate charge for the services of a physicist is not recognized unless such services are covered under the "incident to" provision (§60.1 of this chapter) or the services are included as part of a technical component service billed by a freestanding radiation therapy center. The incident to provision may also be extended to include all necessary and appropriate services supplied by a radiation physicist assisting a radiologist when the physicist is in the physician's employ and working under his or her direct supervision.

100 - Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

(Rev. 1, 10-01-03)

B3-2079, A3-3110.3, HO-228.3,

Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional to the extent permissible under State law. In addition, surgical dressings required after debridement of a wound are also covered, irrespective of the type of debridement, as long as the debridement was reasonable and necessary and was performed by a health care professional acting within the scope of his/her legal authority when performing this function. Surgical dressings are covered for as long as they are medically necessary.

Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. Items such as adhesive tape, roll gauze, bandages, and disposable compression material are examples of secondary dressings. Elastic stockings, support hose, foot coverings, leotards, knee supports, surgical leggings, gauntlets, and pressure garments for the arms and hands are examples of items that are not ordinarily covered as surgical dressings. Some items, such as transparent film, may be used as a primary or secondary dressing.

If a physician, certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner. (See §§60.1, 180, 190, 200, and 210.) When surgical dressings are not covered incident to the services of a health care practitioner and are obtained by the patient from a supplier (e.g., a drugstore, physician, or other health care practitioner that qualifies as a supplier) on an order from a physician or other health care professional authorized under State law or regulation to make such an order, the surgical dressings are covered separately under Part B.

Splints and casts, and other devices used for reductions of fractures and dislocations are covered under Part B of Medicare. This includes dental splints.

110 - Durable Medical Equipment - General

(Rev. 1, 10-01-03)

B3-2100, A3-3113, HO-235, HHA-220

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and

- The equipment is used in the patient's home.

The decision whether to rent or purchase an item of equipment generally resides with the beneficiary, but the decision on how to pay rests with CMS. For some DME, program payment policy calls for lump sum payments and in others for periodic payment. Where covered DME is furnished to a beneficiary by a supplier of services other than a provider of services, the DMERC makes the reimbursement. If a provider of services furnishes the equipment, the intermediary makes the reimbursement. The payment method is identified in the annual fee schedule update furnished by CMS.

The CMS issues quarterly updates to a fee schedule file that contains rates by HCPCS code and also identifies the classification of the HCPCS code within the following categories.

Category Code	Definition
IN	Inexpensive and Other Routinely Purchased Items
FS	Frequently Serviced Items
CR	Capped Rental Items
OX	Oxygen and Oxygen Equipment
OS	Ostomy, Tracheostomy & Urological Items
SD	Surgical Dressings
PO	Prosthetics & Orthotics
SU	Supplies
TE	Transcutaneous Electrical Nerve Stimulators

The DMERCs, carriers, and intermediaries, where appropriate, use the CMS files to determine payment rules. See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices," for a detailed description of payment rules for each classification.

Payment may also be made for repairs, maintenance, and delivery of equipment and for expendable and nonreusable items essential to the effective use of the equipment subject to the conditions in §110.2.

See the Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease," for hemodialysis equipment and supplies.

110.1 - Definition of Durable Medical Equipment

(Rev. 1, 10-01-03)

B3-2100.1, A3-3113.1, HO-235.1, HHA-220.1, B3-2100.2, A3-3113.2, HO-235.2, HHA-220.2

Durable medical equipment is equipment which:

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be durable medical equipment.

The following describes the underlying policies for determining whether an item meets the definition of DME and may be covered.

A. Durability

An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented. Medical supplies of an expendable nature, such as incontinent pads, lambs wool pads, catheters, ace bandages, elastic stockings, surgical facemasks, irrigating kits, sheets, and bags are not considered "durable" within the meaning of the definition. There are other items that, although durable in nature, may fall into other coverage categories such as supplies, braces, prosthetic devices, artificial arms, legs, and eyes.

B. Medical Equipment

Medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. In most instances, no development will be needed to determine whether a specific item of equipment is medical in nature. However, some cases will require development to determine whether the item constitutes medical equipment. This development would include the advice of local medical organizations (hospitals, medical schools, medical societies) and specialists in the field of physical medicine and rehabilitation. If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the design, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

1. Equipment Presumptively Medical

Items such as hospital beds, wheelchairs, hemodialysis equipment, iron lungs, respirators, intermittent positive pressure breathing machines, medical regulators, oxygen tents, crutches, canes, trapeze bars, walkers, inhalators, nebulizers, commodes, suction machines, and traction equipment presumptively constitute medical equipment. (Although hemodialysis equipment is covered as a prosthetic device (§120), it also meets the definition of DME, and reimbursement for the rental or purchase of such equipment for use in the beneficiary's home will be made only under the provisions for payment applicable to DME. See the Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease," §30.1, for coverage of home use of hemodialysis.) **NOTE:** There is a

wide variety in types of respirators and suction machines. The DMERC's medical staff should determine whether the apparatus specified in the claim is appropriate for home use.

2. Equipment Presumptively Nonmedical

Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.

Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment (such as an exercycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature.

3. Special Exception Items

Specified items of equipment may be covered under certain conditions even though they do not meet the definition of DME because they are not primarily and customarily used to serve a medical purpose and/or are generally useful in the absence of illness or injury. These items would be covered when it is clearly established that they serve a therapeutic purpose in an individual case and would include:

a. Gel pads and pressure and water mattresses (which generally serve a preventive purpose) when prescribed for a patient who had bed sores or there is medical evidence indicating that they are highly susceptible to such ulceration; and

b. Heat lamps for a medical rather than a soothing or cosmetic purpose, e.g., where the need for heat therapy has been established.

In establishing medical necessity for the above items, the evidence must show that the item is included in the physician's course of treatment and a physician is supervising its use.

NOTE: The above items represent special exceptions and no extension of coverage to other items should be inferred

C. Necessary and Reasonable

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be

necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

See the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements;" §60, regarding the rules for providing advance beneficiary notices (ABNs) that advise beneficiaries, before items or services actually are furnished, when Medicare is likely to deny payment for them. ABNs allow beneficiaries to make an informed consumer decision about receiving items or services for which they may have to pay out-of-pocket and to be more active participants in their own health care treatment decisions.

1. Necessity for the Equipment

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DMERC will be sufficient to establish that the equipment serves this purpose.

2. Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3. Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee cannot charge the beneficiary the differential attributable to the equipment actually furnished.

4. Establishing the Period of Medical Necessity

Generally, the period of time an item of durable medical equipment will be considered to be medically necessary is based on the physician's estimate of the time that his or her patient will need the equipment. See the Medicare Program Integrity Manual, Chapters 5 and 6, for medical review guidelines.

D. Definition of a Beneficiary's Home

For purposes of rental and purchase of DME a beneficiary's home may be his/her own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution. However, an institution may not be considered a beneficiary's home if it:

- Meets at least the basic requirement in the definition of a hospital, i.e., it is primarily engaged in providing by or under the supervision of physicians, to inpatients, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, and sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
- Meets at least the basic requirement in the definition of a skilled nursing facility, i.e., it is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Thus, if an individual is a patient in an institution or distinct part of an institution which provides the services described in the bullets above, the individual is not entitled to have separate Part B payment made for rental or purchase of DME. This is because such an institution may not be considered the individual's home. The same concept applies even if the patient resides in a bed or portion of the institution not certified for Medicare.

If the patient is at home for part of a month and, for part of the same month is in an institution that cannot qualify as his or her home, or is outside the U.S., monthly payments may be made for the entire month. Similarly, if DME is returned to the provider before the end of a payment month because the beneficiary died in that month or because the equipment became unnecessary in that month, payment may be made for the entire month.

110.2 - Repairs, Maintenance, Replacement, and Delivery

(Rev. 30, Issued 02-18-05, Effective/Implementation: Not Applicable)

Under the circumstances specified below, payment may be made for repair, maintenance, and replacement of medically required DME, including equipment which had been in use before the user enrolled in Part B of the program. However, do not pay for repair, maintenance, or replacement of equipment in the frequent and substantial servicing or oxygen equipment payment categories. In addition, payments for repair and maintenance may not include payment for parts and labor covered under a manufacturer's or supplier's warranty.

A. Repairs

To repair means to fix or mend and to put the equipment back in good condition after damage or wear. Repairs to equipment which a beneficiary owns are covered when necessary to make the equipment serviceable. However, do not pay for repair of previously denied equipment or equipment in the frequent and substantial servicing or

oxygen equipment payment categories. If the expense for repairs exceeds the estimated expense of purchasing or renting another item of equipment for the remaining period of medical need, no payment can be made for the amount of the excess. (See subsection C where claims for repairs suggest malicious damage or culpable neglect.)

Since renters of equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out, separately itemized charges for repair of rented equipment are not covered. This includes items in the frequent and substantial servicing, oxygen equipment, capped rental, and inexpensive or routinely purchased payment categories which are being rented.

A new Certificate of Medical Necessity (CMN) and/or physician's order is not needed for repairs.

For replacement items, see Subsection C below.

B. Maintenance

Routine periodic servicing, such as testing, cleaning, regulating, and checking of the beneficiary's equipment, is not covered. The owner is expected to perform such routine maintenance rather than a retailer or some other person who charges the beneficiary. Normally, purchasers of DME are given operating manuals which describe the type of servicing an owner may perform to properly maintain the equipment. It is reasonable to expect that beneficiaries will perform this maintenance. Thus, hiring a third party to do such work is for the convenience of the beneficiary and is not covered. However, more extensive maintenance which, based on the manufacturers' recommendations, is to be performed by authorized technicians, is covered as repairs for medically necessary equipment which a beneficiary owns. This might include, for example, breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary. Do not pay for maintenance of purchased items that require frequent and substantial servicing or oxygen equipment.

Since renters of equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out, separately itemized charges for maintenance of rented equipment are generally not covered. Payment may not be made for maintenance of rented equipment other than the maintenance and servicing fee established for capped rental items. For capped rental items which have reached the 15-month rental cap, contractors pay claims for maintenance and servicing fees after 6 months have passed from the end of the final paid rental month or from the end of the period the item is no longer covered under the supplier's or manufacturer's warranty, whichever is later. See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for additional instruction and an example.

A new CMN and/or physician's order is not needed for covered maintenance.

C. Replacement

Replacement refers to the provision of an identical or nearly identical item. Situations involving the provision of a different item because of a change in medical condition are not addressed in this section.

Equipment which the beneficiary owns or is a capped rental item may be replaced in cases of loss or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item.

Irreparable wear refers to deterioration sustained from day-to-day usage over time and a specific event cannot be identified. Replacement of equipment due to irreparable wear takes into consideration the reasonable useful lifetime of the equipment. If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment's useful lifetime, the beneficiary may elect to obtain a new piece of equipment. Replacement may be reimbursed when a new physician order and/or new CMN, when required, is needed to reaffirm the medical necessity of the item.

The reasonable useful lifetime of durable medical equipment is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment, but in no case can it be less than 5 years. Computation of the useful lifetime is based on when the equipment is delivered to the beneficiary, not the age of the equipment. Replacement due to wear is not covered during the reasonable useful lifetime of the equipment. During the reasonable useful lifetime, Medicare does cover repair up to the cost of replacement (but not actual replacement) for medically necessary equipment owned by the beneficiary. (See subsection A.)

Charges for the replacement of oxygen equipment, items that require frequent and substantial servicing or inexpensive or routinely purchased items which are being rented are not covered.

Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment should be investigated and denied where the DMERC determines that it is unreasonable to make program payment under the circumstances. DMERCs refer such cases to the program integrity specialist in the RO.

D. Delivery

Payment for delivery of DME whether rented or purchased is generally included in the fee schedule allowance for the item. See Pub. 100-04, Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for the rules that apply to making reimbursement for exceptional cases.

110.3 - Coverage of Supplies and Accessories

(Rev. 1, 10-01-03)

B3-2100.5, A3-3113.4, HO-235.4, HHA-220.5

Payment may be made for supplies, e.g., oxygen, that are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment, e.g., tumor chemotherapy agents used with an infusion pump or heparin used with a home

dialysis system. However, the coverage of such drugs or biologicals does not preclude the need for a determination that the drug or biological itself is reasonable and necessary for treatment of the illness or injury or to improve the functioning of a malformed body member.

In the case of prescription drugs, other than oxygen, used in conjunction with durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) or prosthetic devices, the entity that dispenses the drug must furnish it directly to the patient for whom a prescription is written. The entity that dispenses the drugs must have a Medicare supplier number, must possess a current license to dispense prescription drugs in the State in which the drug is dispensed, and must bill and receive payment in its own name. A supplier that is not the entity that dispenses the drugs cannot purchase the drugs used in conjunction with DME for resale to the beneficiary. Reimbursement may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment.

110.4 - Miscellaneous Issues Included in the Coverage of Equipment

(Rev. 1, 10-01-03)

B3-2100.6, A3-3113.5, HO-235.5, HHA-220.6

Payment can be made for the purchase of DME even though rental payments may have been made for prior months. This could occur where, because of a change in his/her condition, the beneficiary feels that it would be to his/her advantage to purchase the equipment rather than to continue to rent it.

A beneficiary may sell or otherwise dispose of equipment for which they have no further use, for example, because of recovery from the illness or injury that gave rise to the need for the equipment. (There is no authority for the program to repossess the equipment.) If after such disposal there is again medical need for similar equipment, payment can be made for the rental or purchase of that equipment.

However, where an arrangement is motivated solely by a desire to create artificial expenses to be met by the program and to realize a profit thereby, such expenses would not be covered under the program. The resolution of questions involving the disposition and subsequent acquisition of durable medical equipment must be made on a case-by-case basis.

Cases where it appears that there has been an attempt to create an artificial expense and realize a profit thereby should be developed and when appropriate denied. After adjudication the DMERC would refer such cases to the program integrity specialist in the RO.

When payments stop because the beneficiary's condition has changed and the equipment is no longer medically necessary, the beneficiary is responsible for the remaining noncovered charges. Similarly, when payments stop because the beneficiary dies, the beneficiary's estate is responsible for the remaining noncovered charges.

Contractors do not get involved in issues relating to ownership or title of property.

110.5 - Incurred Expense Dates for Durable Medical Equipment

(Rev. 1, 10-01-03)

A3-3113.7.B, HO-235.7.B, B3-3011

The date of service on the claim must be the date that the beneficiary or authorized representative received the DMEPOS item. If the date of delivery is not specified on the bill, the contractor should assume, in the absence of evidence to the contrary, that the date of purchase was the date of delivery.

For mail order DMEPOS items, the date of service on the claim must be the shipping date.

The date of service on the claim must be the date that the DMEPOS item(s) was received by the nursing facility if the supplier delivered it or the shipping date if the supplier utilized a delivery/shipping service.

An exception to the preceding statements concerning the date of service on the claim occurs when items are provided in anticipation of discharge from a hospital or nursing facility. If a DMEPOS item is delivered to a patient in a hospital up to two days prior to discharge to home and it is for the benefit of the patient for purposes of fitting or training of the patient on its use, the supplier should bill the date of service on the claim as the date of discharge to home and should use POS=12.

See the Medicare Program Integrity Manual, Chapter 5, "Items and Services Having Special DMERC Review Considerations," for additional information pertaining to the date of service on the claim. Also see the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Surgical dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices," for additional DME billing and claims processing information.

110.6 - Determining Months for Which Periodic Payments May Be Made for Equipment Used in an Institution

(Rev. 1, 10-01-03)

A3-3113.7.D, HO-235.7.C

If a patient uses equipment subject to the monthly payment rule in an institution, which does not qualify as his or her home, the used months during which the beneficiary was institutionalized are not covered.

110.7 - No Payment for Purchased Equipment Delivered Outside the United States or Before Beneficiary's Coverage Began

(Rev. 1, 10-01-03)

A3-3113.7.C

In the case of equipment subject to the lump sum payment rules, the beneficiary must have been in the United States and must have had Medicare coverage at the time the item was delivered. Therefore, where an item of durable medical equipment paid for as a lump sum was delivered to an individual outside the United States or before his or her coverage period began, the entire expense of the item would be excluded from coverage.

Payment cannot be made in such cases even though the individual later uses the item inside the United States or after his or her coverage begins.

If the individual is outside the U.S. for more than 30 days and then returns to the U.S., the DMERC determines medical necessity as in an initial case before resuming payments.

120 - Prosthetic Devices

(Rev. 1, 10-01-03)

B3-2130, A3-3110.4, HO-228.4, A3-3111, HO-229

A. General

Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order. This does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met. (Such a device may also be covered under §60.l as a supply when furnished incident to a physician's service.)

Examples of prosthetic devices include artificial limbs, parenteral and enteral (PEN) nutrition, cardiac pacemakers, prosthetic lenses (see subsection B), breast prostheses (including a surgical brassiere) for postmastectomy patients, maxillofacial devices, and devices which replace all or part of the ear or nose. A urinary collection and retention system with or without a tube is a prosthetic device replacing bladder function in case of permanent urinary incontinence. The foley catheter is also considered a prosthetic device when ordered for a patient with permanent urinary incontinence. However, chucks, diapers, rubber sheets, etc., are supplies that are not covered under this provision. Although hemodialysis equipment is a prosthetic device, payment for the rental or purchase of such equipment in the home is made only for use under the provisions for payment applicable to durable medical equipment.

An exception is that if payment cannot be made on an inpatient's behalf under Part A, hemodialysis equipment, supplies, and services required by such patient could be covered under Part B as a prosthetic device, which replaces the function of a kidney. See the Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease," for payment for hemodialysis equipment used in the home. See the Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §10, for additional instructions on hospitalization for renal dialysis.

NOTE: Medicare does not cover a prosthetic device dispensed to a patient prior to the time at which the patient undergoes the procedure that makes necessary the use of the device. For example, the carrier does not make a separate Part B payment for an intraocular lens (IOL) or pacemaker that a physician, during an office visit prior to the actual surgery, dispenses to the patient for his or her use. Dispensing a prosthetic device in this manner raises health and safety issues. Moreover, the need for the device cannot be clearly established until the procedure that makes its use possible is successfully

performed. Therefore, dispensing a prosthetic device in this manner is not considered reasonable and necessary for the treatment of the patient's condition.

Colostomy (and other ostomy) bags and necessary accouterments required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care, whether the attachment of a bag is required.

Accessories and/or supplies which are used directly with an enteral or parenteral device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device may also be covered under the prosthetic device benefit subject to the additional guidelines in the Medicare National Coverage Determinations Manual.

Covered items include catheters, filters, extension tubing, infusion bottles, pumps (either food or infusion), intravenous (I.V.) pole, needles, syringes, dressings, tape, Heparin Sodium (parenteral only), volumetric monitors (parenteral only), and parenteral and enteral nutrient solutions. Baby food and other regular grocery products that can be blenderized and used with the enteral system are not covered. Note that some of these items, e.g., a food pump and an I.V. pole, qualify as DME. Although coverage of the enteral and parenteral nutritional therapy systems is provided on the basis of the prosthetic device benefit, the payment rules relating to lump sum or monthly payment for DME apply to such items.

The coverage of prosthetic devices includes replacement of and repairs to such devices as explained in subsection D.

Finally, the Benefits Improvement and Protection Act of 2000 amended §1834(h)(1) of the Act by adding a provision (1834 (h)(1)(G)(i)) that requires Medicare payment to be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary.

Payment may be made for the replacement of a prosthetic device that is an artificial limb, or replacement part of a device if the ordering physician determines that the replacement device or part is necessary because of any of the following:

1. A change in the physiological condition of the patient;
2. An irreparable change in the condition of the device, or in a part of the device; or
3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

This provision is effective for items replaced on or after April 1, 2001. It supersedes any rule that that provided a 5-year or other replacement rule with regard to prosthetic devices.

B. Prosthetic Lenses

The term "internal body organ" includes the lens of an eye. Prostheses replacing the lens of an eye include post-surgical lenses customarily used during convalescence from eye

surgery in which the lens of the eye was removed. In addition, permanent lenses are also covered when required by an individual lacking the organic lens of the eye because of surgical removal or congenital absence. Prosthetic lenses obtained on or after the beneficiary's date of entitlement to supplementary medical insurance benefits may be covered even though the surgical removal of the crystalline lens occurred before entitlement.

1. Prosthetic Cataract Lenses

One of the following prosthetic lenses or combinations of prosthetic lenses furnished by a physician (see **§30.4** for coverage of prosthetic lenses prescribed by a doctor of optometry) may be covered when determined to be reasonable and necessary to restore essentially the vision provided by the crystalline lens of the eye:

- Prosthetic bifocal lenses in frames;
- Prosthetic lenses in frames for far vision, and prosthetic lenses in frames for near vision; or
- When a prosthetic contact lens(es) for far vision is prescribed (including cases of binocular and monocular aphakia), make payment for the contact lens(es) and prosthetic lenses in frames for near vision to be worn at the same time as the contact lens(es), and prosthetic lenses in frames to be worn when the contacts have been removed.

Lenses which have ultraviolet absorbing or reflecting properties may be covered, in lieu of payment for regular (untinted) lenses, if it has been determined that such lenses are medically reasonable and necessary for the individual patient.

Medicare does not cover cataract sunglasses obtained in addition to the regular (untinted) prosthetic lenses since the sunglasses duplicate the restoration of vision function performed by the regular prosthetic lenses.

2. Payment for Intraocular Lenses (IOLs) Furnished in Ambulatory Surgical Centers (ASCs)

Effective for services furnished on or after March 12, 1990, payment for intraocular lenses (IOLs) inserted during or subsequent to cataract surgery in a Medicare certified ASC is included with the payment for facility services that are furnished in connection with the covered surgery.

Refer to the Medicare Claims Processing Manual, Chapter 14, "Ambulatory Surgical Centers," for more information.

3. Limitation on Coverage of Conventional Lenses

One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery with insertion of an IOL is covered.

C. Dentures

Dentures are excluded from coverage. However, when a denture or a portion of the denture is an integral part (built-in) of a covered prosthesis (e.g., an obturator to fill an opening in the palate), it is covered as part of that prosthesis.

D. Supplies, Repairs, Adjustments, and Replacement

Supplies are covered that are necessary for the effective use of a prosthetic device (e.g., the batteries needed to operate an artificial larynx). Adjustment of prosthetic devices required by wear or by a change in the patient's condition is covered when ordered by a physician. General provisions relating to the repair and replacement of durable medical equipment in §110.2 for the repair and replacement of prosthetic devices are applicable. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §40.4, for payment for devices replaced under a warranty.) Replacement of conventional eyeglasses or contact lenses furnished in accordance with §120.B.3 is not covered.

Necessary supplies, adjustments, repairs, and replacements are covered even when the device had been in use before the user enrolled in Part B of the program, so long as the device continues to be medically required.

130 - Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes

(Rev. 1, 10-01-03)

B3-2133, A3-3110.5, HO-228.5, AB-01-06 dated 1/18/01

These appliances are covered under Part B when furnished incident to physicians' services or on a physician's order. A brace includes rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Back braces include, but are not limited to, special corsets, e.g., sacroiliac, sacrolumbar, dorsolumbar corsets, and belts. A terminal device (e.g., hand or hook) is covered under this provision whether an artificial limb is required by the patient. Stump stockings and harnesses (including replacements) are also covered when these appliances are essential to the effective use of the artificial limb.

Adjustments to an artificial limb or other appliance required by wear or by a change in the patient's condition are covered when ordered by a physician.

Adjustments, repairs and replacements are covered even when the item had been in use before the user enrolled in Part B of the program so long as the device continues to be medically required.

140 - Therapeutic Shoes for Individuals with Diabetes

(Rev. 1, 10-01-03)

B3-2134

Coverage of therapeutic shoes (depth or custom-molded) along with inserts for individuals with diabetes is available as of May 1, 1993. These diabetic shoes are covered if the requirements as specified in this section concerning certification and prescription are fulfilled. In addition, this benefit provides for a pair of diabetic shoes even if only one foot suffers from diabetic foot disease. Each shoe is equally equipped so that the affected limb, as well as the remaining limb, is protected. Claims for therapeutic

shoes for diabetics are processed by the Durable Medical Equipment Regional Carriers (DMERCs).

Therapeutic shoes for diabetics are not DME and are not considered DME nor orthotics, but a separate category of coverage under Medicare Part B. (See §1861(s)(12) and §1833(o) of the Act.)

A. Definitions

The following items may be covered under the diabetic shoe benefit:

1. Custom-Molded Shoes

Custom-molded shoes are shoes that:

- Are constructed over a positive model of the patient's foot;
- Are made from leather or other suitable material of equal quality;
- Have removable inserts that can be altered or replaced as the patient's condition warrants; and
- Have some form of shoe closure.

2. Depth Shoes

Depth shoes are shoes that:

- Have a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;
- Are made from leather or other suitable material of equal quality;
- Have some form of shoe closure; and
- Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.)

3. Inserts

Inserts are total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot and that are made of a suitable material with regard to the patient's condition.

B. Coverage

1. Limitations

For each individual, coverage of the footwear and inserts is limited to one of the following within one calendar year:

- No more than one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts; or

- No more than one pair of depth shoes and three pairs of inserts (not including the noncustomized removable inserts provided with such shoes).

2. Coverage of Diabetic Shoes and Brace

Orthopedic shoes, as stated in the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices," generally are not covered. This exclusion does not apply to orthopedic shoes that are an integral part of a leg brace. In situations in which an individual qualifies for both diabetic shoes and a leg brace, these items are covered separately. Thus, the diabetic shoes may be covered if the requirements for this section are met, while the brace may be covered if the requirements of §130 are met.

3. Substitution of Modifications for Inserts

An individual may substitute modification(s) of custom-molded or depth shoes instead of obtaining a pair(s) of inserts in any combination. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled. The following is a list of the most common shoe modifications available, but it is not meant as an exhaustive list of the modifications available for diabetic shoes:

- **Rigid Rocker Bottoms** - These are exterior elevations with apex positions for 51 percent to 75 percent distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapered off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel;
- **Roller Bottoms (Sole or Bar)** - These are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole;
- **Metatarsal Bars** - An exterior bar is placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose;
- **Wedges (Posting)** - Wedges are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight bearing upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance; and
- **Offset Heels** - This is a heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.

Other modifications to diabetic shoes include, but are not limited to flared heels, Velcro closures, and inserts for missing toes.

4. Separate Inserts

Inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which

the insert can be placed. This footwear must meet the definitions found above for depth shoes and custom-molded shoes.

C. Certification

The need for diabetic shoes must be certified by a physician who is a doctor of medicine or a doctor of osteopathy and who is responsible for diagnosing and treating the patient's diabetic systemic condition through a comprehensive plan of care. This managing physician must:

- Document in the patient's medical record that the patient has diabetes;
- Certify that the patient is being treated under a comprehensive plan of care for diabetes, and that the patient needs diabetic shoes; and
- Document in the patient's record that the patient has one or more of the following conditions:
    - Peripheral neuropathy with evidence of callus formation;
    - History of pre-ulcerative calluses;
    - History of previous ulceration;
    - Foot deformity;
    - Previous amputation of the foot or part of the foot; or
    - Poor circulation.

D. Prescription

Following certification by the physician managing the patient's systemic diabetic condition, a podiatrist or other qualified physician who is knowledgeable in the fitting of diabetic shoes and inserts may prescribe the particular type of footwear necessary.

E. Furnishing Footwear

The footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, an orthotist, or a prosthetist. The certifying physician may not furnish the diabetic shoes unless the certifying physician is the only qualified individual in the area. It is left to the discretion of each carrier to determine the meaning of "in the area."

150 - Dental Services

(Rev. 1, 10-01-03)

B3-2136

As indicated under the general exclusions from coverage, items and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth are not covered. "Structures directly supporting the teeth" means the periodontium, which includes the gingivae, dentogingival junction, periodontal membrane, cementum of the teeth, and alveolar process.

In addition to the following, see Pub 100-01, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, Definitions and Pub 3, the Medicare

National Coverage Determinations Manual for specific services which may be covered when furnished by a dentist. If an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion is covered.

EXAMPLE 1:

The reconstruction of a ridge performed primarily to prepare the mouth for dentures is a noncovered procedure. However, when the reconstruction of a ridge is performed as a result of and at the same time as the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service.

EXAMPLE 2:

Medicare makes payment for the wiring of teeth when this is done in connection with the reduction of a jaw fracture.

The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is also covered. This is an exception to the requirement that to be covered, a noncovered procedure or service performed by a dentist must be an incident to and an integral part of a covered procedure or service performed by the dentist. Ordinarily, the dentist extracts the patient's teeth, but another physician, e.g., a radiologist, administers the radiation treatments.

When an excluded service is the primary procedure involved, it is not covered, regardless of its complexity or difficulty. For example, the extraction of an impacted tooth is not covered. Similarly, an alveoplasty (the surgical improvement of the shape and condition of the alveolar process) and a frenectomy are excluded from coverage when either of these procedures is performed in connection with an excluded service, e.g., the preparation of the mouth for dentures. In a like manner, the removal of a torus palatinus (a bony protuberance of the hard palate) may be a covered service. However, with rare exception, this surgery is performed in connection with an excluded service, i.e., the preparation of the mouth for dentures. Under such circumstances, Medicare does not pay for this procedure.

Dental splints used to treat a dental condition are excluded from coverage under 1862(a)(12) of the Act. On the other hand, if the treatment is determined to be a covered medical condition (i.e., dislocated upper/lower jaw joints), then the splint can be covered.

Whether such services as the administration of anesthesia, diagnostic x-rays, and other related procedures are covered depends upon whether the primary procedure being performed by the dentist is itself covered. Thus, an x-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered. However, a single x-ray or x-ray survey taken in connection with the care or treatment of teeth or the periodontium is not covered.

Medicare makes payment for a covered dental procedure no matter where the service is performed. The hospitalization or nonhospitalization of a patient has no direct bearing on the coverage or exclusion of a given dental procedure.

Payment may also be made for services and supplies furnished incident to covered dental services. For example, the services of a dental technician or nurse who is under the direct supervision of the dentist or physician are covered if the services are included in the dentist's or physician's bill.

150.1 - Treatment of Temporomandibular Joint (TMJ) Syndrome

(Rev. 1, 10-01-03)

PASS memo Read.014

There are a wide variety of conditions that can be characterized as TMJ, and an equally wide variety of methods for treating these conditions. Many of the procedures fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services and appliances used to treat TMJ fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment "for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth...." For these reasons, a diagnosis of TMJ on a claim is insufficient. The actual condition or symptom must be determined.

160 - Clinical Psychologist Services

(Rev. 51, Issued: 06-23-06, Effective: 01-01-05, Implementation: 09-21-06)

A. Clinical Psychologist (CP) Defined

To qualify as a clinical psychologist (CP), a practitioner must meet the following requirements:

Hold a doctoral degree in psychology;

Be licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

B. Qualified Clinical Psychologist Services Defined

Effective July 1, 1990, the diagnostic and therapeutic services of CPs and services and supplies furnished incident to such services are covered as the services furnished by a physician or as incident to physician's services are covered. However, the CP must be legally authorized to perform the services under applicable licensure laws of the State in which they are furnished.

C. Types of Clinical Psychologist Services That May Be Covered

Diagnostic and therapeutic services that the CP is legally authorized to perform in accordance with State law and/or regulation. Carriers pay all qualified CPs based on the physician fee schedule for the diagnostic and therapeutic services. (Psychological tests by practitioners who do not meet the requirements for a CP may be covered under the provisions for diagnostic tests as described in §80.2.

Services and supplies furnished incident to a CP's services are covered if the requirements that apply to services incident to a physician's services, as described in §60 are met. These services must be:

- Mental health services that are commonly furnished in CPs' offices;
- An integral, although incidental, part of professional services performed by the CP;
- Performed under the direct personal supervision of the CP; i.e., the CP must be physically present and immediately available;
- Furnished without charge or included in the CP's bill; and
- Performed by an employee of the CP (or an employee of the legal entity that employs the supervising CP) under the common law control test of the Act, as set forth in 20 CFR 404.1007 and §RS 2101.020 of the Retirement and Survivors Insurance part of the Social Security Program Operations Manual System.
- Diagnostic psychological testing services when furnished under the general supervision of a CP.

Carriers are required to familiarize themselves with appropriate State laws and/or regulations governing a CP's scope of practice.

D. Noncovered Services

The services of CPs are not covered if the service is otherwise excluded from Medicare coverage even though a clinical psychologist is authorized by State law to perform them. For example, §1862(a)(1)(A) of the Act excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member." Therefore, even though the services are authorized by State law, the services of a CP that are determined to be not reasonable and necessary are not covered. Additionally, any therapeutic services that are billed by CPs under CPT psychotherapy codes that include medical evaluation and management services are not covered.

E. Requirement for Consultation

When applying for a Medicare provider number, a CP must submit to the carrier a signed Medicare provider/supplier enrollment form that indicates an agreement to the effect that, contingent upon the patient's consent, the CP will attempt to consult with the patient's attending or primary care physician in accordance with accepted professional ethical norms, taking into consideration patient confidentiality.

If the patient assents to the consultation, the CP must attempt to consult with the patient's physician within a reasonable time after receiving the consent. If the CP's attempts to consult directly with the physician are not successful, the CP must notify the physician within a reasonable time that he or she is furnishing services to the patient. Additionally, the CP must document, in the patient's medical record, the date the patient consented or declined consent to consultations, the date of consultation, or, if attempts to consult did not succeed, that date and manner of notification to the physician.

The only exception to the consultation requirement for CPs is in cases where the patient's primary care or attending physician refers the patient to the CP. Also, neither a CP nor a primary care nor attending physician may bill Medicare or the patient for this required consultation.

F. Outpatient Mental Health Services Limitation

All covered therapeutic services furnished by qualified CPs are subject to the outpatient mental health services limitation in Pub 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30, (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

G. Assignment Requirement

Assignment is required.

170 - Clinical Social Worker (CSW) Services

(Rev. 1, 10-01-03)

B3-2152

See the Medicare Claims Processing Manual Chapter 12, Physician/Nonphysician Practitioners, §150, "Clinical Social Worker Services," for payment requirements.

A. Clinical Social Worker Defined

Section 1861(hh) of the Act defines a "clinical social worker" as an individual who:

- Possesses a master's or doctor's degree in social work;
- Has performed at least two years of supervised clinical social work; and
- Is licensed or certified as a clinical social worker by the State in which the services are performed; or
- In the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting such as a hospital, SNF, or clinic.

B. Clinical Social Worker Services Defined

Section 1861(hh)(2) of the Act defines "clinical social worker services" as those services that the CSW is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed for the diagnosis and treatment of mental illnesses. Services furnished to an inpatient of a hospital or an inpatient of a SNF that the SNF is required to provide as a requirement for participation are not included. The services that are covered are those that are otherwise covered if furnished by a physician or as incident to a physician's professional service.

C. Covered Services

Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law). The services of a CSW may be covered under Part B if they are:

- The type of services that are otherwise covered if furnished by a physician, or as incident to a physician's service. (See §30 for a description of physicians' services and §70 of Pub 100-1, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, for the definition of a physician.);
- Performed by a person who meets the definition of a CSW (See subsection A.); and
- Not otherwise excluded from coverage.

Carriers should become familiar with the State law or regulatory mechanism governing a CSW's scope of practice in their service area.

D. Noncovered Services

Services of a CSW are not covered when furnished to inpatients of a hospital or to inpatients of a SNF if the services furnished in the SNF are those that the SNF is required to furnish as a condition of participation in Medicare. In addition, CSW services are not covered if they are otherwise excluded from Medicare coverage even though a CSW is authorized by State law to perform them. For example, the Medicare law excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."

E. Outpatient Mental Health Services Limitation

All covered therapeutic services furnished by qualified CSWs are subject to the outpatient psychiatric services limitation in Pub 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30, (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

F. Assignment Requirement

Assignment is required.

180 - Nurse-Midwife (CNM) Services

(Rev. 1, 10-01-03)

B3-2154

A. General

Effective on or after July 1, 1988, the services provided by a certified nurse-midwife or incident to the certified nurse-midwife's services are covered. Payment is made under assignment only.

See the Medicare Claims Processing Manual, Chapter 12, "Physician and Nonphysician Practitioners," §130, for payment methodology for nurse midwife services.

B. Certified Nurse-Midwife Defined

A certified nurse-midwife is a registered nurse who has successfully completed a program of study and clinical experience in nurse-midwifery, meeting guidelines prescribed by the Secretary, or who has been certified by an organization recognized by the Secretary. The Secretary has recognized certification by the American College of Nurse-Midwives and State qualifying requirements in those States that specify a program of education and clinical experience for nurse-midwives for these purposes. A nurse-midwife must:

- Be currently licensed to practice in the State as a registered professional nurse; and
- Meet one of the following requirements:
    1. Be legally authorized under State law or regulations to practice as a nurse-midwife and have completed a program of study and clinical experience for nurse-midwives, as specified by the State; or
    2. If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, the nurse-midwife must:
        a. Be currently certified as a nurse-midwife by the American College of Nurse-Midwives;
        b. Have satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives; or
        c. Have successfully completed a formal education program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and have practiced as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976, to July 16, 1982.

C. Covered Services

1. General - Effective January 1, 1988, through December 31, 1993, the coverage of nurse-midwife services was restricted to the maternity cycle. The maternity cycle is a period that includes pregnancy, labor, and the immediate postpartum period.

Beginning with services furnished on or after January 1, 1994, coverage is no longer limited to the maternity cycle. Coverage is available for services furnished by a nurse-midwife that he or she is legally authorized to perform in the State in which the services are furnished and that would otherwise be covered if furnished by a physician, including obstetrical and gynecological services.

2. Incident To - Services and supplies furnished incident to a nurse midwife's service are covered if they would have been covered when furnished incident to the services of a doctor of medicine or osteopathy, as described in §60.

D. Noncovered Services

The services of nurse-midwives are not covered if they are otherwise excluded from Medicare coverage even though a nurse-midwife is authorized by State law to perform them. For example, the Medicare program excludes from coverage routine physical checkups and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

Coverage of service to the newborn continues only to the point that the newborn is or would normally be treated medically as a separate individual. Items and services furnished the newborn from that point are not covered on the basis of the mother's eligibility.

E. Relationship With Physician

Most States have licensure and other requirements applicable to nurse-midwives. For example, some require that the nurse-midwife have an arrangement with a physician for the referral of the patient in the event a problem develops that requires medical attention. Others may require that the nurse-midwife function under the general supervision of a physician. Although these and similar State requirements must be met in order for the nurse-midwife to provide Medicare covered care, they have no effect on the nurse-midwife's right to personally bill for and receive direct Medicare payment. That is, billing does not have to flow through a physician or facility.

See §60.2 for coverage of services performed by nurse-midwives incident to the service of physicians.

F. Place of Service

There is no restriction on place of service. Therefore, nurse-midwife services are covered if provided in the nurse-midwife's office, in the patient's home, or in a hospital or other facility, such as a clinic or birthing center owned or operated by a nurse-midwife.

G. Assignment Requirement

Assignment is required.

190 - Physician Assistant (PA) Services

(Rev. 1, 10-01-03)

B3-2156

Effective for services rendered on or after January 1, 1998, any individual who is participating under the Medicare program as a physician assistant for the first time may have his or her professional services covered if he or she meets the qualifications listed below and he or she is legally authorized to furnish PA services in the State where the services are performed. PAs who were issued billing provider numbers prior to January 1, 1998 may continue to furnish services under the PA benefit.

See the Medicare Claims Processing Manual, Chapter 12, "Physician and Nonphysician Practitioners," §110, for payment methodology for PA services. Payment is made under assignment only.

A. Qualifications for PAs

To furnish covered PA services, the PA must meet the conditions as follows:

1. Have graduated from a physician assistant educational program that is accredited by the Accreditation Review Commission on Education for the Physician Assistant (its predecessor agencies, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the Committee on Allied Health Education and Accreditation (CAHEA); or

2. Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA); and

3. Be licensed by the State to practice as a physician assistant.

B. Covered Services

Coverage is limited to the services a PA is legally authorized to perform in accordance with State law (or State regulatory mechanism provided by State law).

1. General

The services of a PA may be covered under Part B, if all of the following requirements are met:

- They are the type that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO);
- They are performed by a person who meets all the PA qualifications,
- They are performed under the general supervision of an MD/DO;
- The PA is legally authorized to perform the services in the state in which they are performed; and
- They are not otherwise precluded from coverage because of one of the statutory exclusions.

2. Incident To

If covered PA services are furnished, services and supplies furnished incident to the PA's services may also be covered if they would have been covered when furnished incident to the services of an MD/DO, as described in §60.

3. Types of PA Services That May Be Covered

State law or regulation governing a PA's scope of practice in the State in which the services are performed applies. Carriers should consider developing lists of covered services. Also, if authorized under the scope of their State license, PAs may furnish services billed under all levels of CPT evaluation and management codes, and diagnostic tests if furnished under the general supervision of a physician.

Examples of the types of services that PAs may provide include services that traditionally have been reserved to physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition.

See §60.2 for coverage of services performed by PAs incident to the services of physicians.

4. Services Otherwise Excluded From Coverage

The PA services may not be covered if they are otherwise excluded from coverage even though a PA may be authorized by State law to perform them. For example, the Medicare law excludes from coverage routine foot care, routine physical checkups, and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Therefore, these services are precluded from coverage even though they may be within a PA's scope of practice under State law.

C. Physician Supervision

The PA's physician supervisor (or a physician designated by the supervising physician or employer as provided under State law or regulations) is primarily responsible for the overall direction and management of the PA's professional activities and for assuring that the services provided are medically appropriate for the patient. The physician supervisor (or physician designee) need not be physically present with the PA when a service is being furnished to a patient and may be contacted by telephone, if necessary, unless State law or regulations require otherwise.

D. Employment Relationship

Payment for the services of a PA may be made only to the actual qualified employer of the PA that is eligible to enroll in the Medicare program under existing Medicare provider/supplier categories. If the employer of the PA is a professional corporation or other duly qualified legal entity (such as a limited liability company or a limited liability partnership), properly formed, authorized and licensed under State laws and regulations, that permits PA ownership in such corporation nor entity as a stockholder or member, that corporation or entity as the employer may bill for PA services even if a PA is a stockholder or officer of the entity, as long as the entity is entitled to enroll as a "provider of services" or a supplier of services in the Medicare program. Physician Assistants may not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporate to bill for their services. Leasing agencies and staffing companies do not qualify under the Medicare program as "providers of services" or suppliers of services.

200 - Nurse Practitioner (NP) Services

(Rev. 1, 10-01-03)

B3-2158

Effective for services rendered after January 1, 1998, any individual who is participating under the Medicare program as a nurse practitioner (NP) for the first time ever, may have his or her professional services covered if he or she meets the qualifications listed below, and he or she is legally authorized to furnish NP services in the State where the services are performed. NPs who were issued billing provider numbers prior to January 1, 1998 may continue to furnish services under the NP benefit.

Payment for NP services is effective on the date of service, that is, on or after January 1, 1998, and payment is made on an assignment-related basis only.

A. Qualifications for NPs

In order to furnish covered NP services, an NP must meet the conditions as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; or
- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner by December 31, 2000.

The following organizations are recognized national certifying bodies:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- National Certification Board of Pediatric Nurse Practitioners and Nurses;
- Oncology Nurses Certification Corporation; and
- Critical Care Certification Corporation.

The NPs applying for a Medicare billing number for the first time on or after January 1, 2001, must meet the requirements as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and
- Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

The NPs applying for a Medicare billing number for the first time on or after January 1, 2003, must meet the requirements as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law;
- Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; and
- Possess a master’s degree in nursing.

B. Covered Services

Coverage is limited to the services an NP is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law).

1. General

The services of an NP may be covered under Part B if all of the following conditions are met:

- They are the type that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO);
- They are performed by a person who meets the definition of an NP (see subsection A);
- The NP is legally authorized to perform the services in the State in which they are performed;
- They are performed in collaboration with an MD/DO (see subsection D); and
- They are not otherwise precluded from coverage because of one of the statutory exclusions. (See subsection C.2.)

2. Incident To

If covered NP services are furnished, services and supplies furnished incident to the services of the NP may also be covered if they would have been covered when furnished incident to the services of an MD/DO as described in §60.

C. Application of Coverage Rules

1. Types of NP Services That May Be Covered

State law or regulation governing an NP's scope of practice in the State in which the services are performed applies. Consider developing a list of covered services based on the State scope of practice. Examples of the types of services that NP's may furnish include services that traditionally have been reserved to physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition. Also, if authorized under the scope of their State license, NPs may furnish services billed under all levels of evaluation and management codes and diagnostic tests if furnished in collaboration with a physician.

See §60.2 for coverage of services performed by NPs incident to the services of physicians.

2. Services Otherwise Excluded From Coverage

The NP services may not be covered if they are otherwise excluded from coverage even though an NP may be authorized by State law to perform them. For example, the Medicare law excludes from coverage routine foot care, routine physical checkups, and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Therefore, these services are precluded from coverage even though they may be within a NP's scope of practice under State law.

D. Collaboration

Collaboration is a process in which a NP works with one or more physicians (MD/DO) to deliver health care services, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished. In the absence of

State law governing collaboration, collaboration is to be evidenced by NPs documenting their scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice.

The collaborating physician does not need to be present with the NP when the services are furnished or to make an independent evaluation of each patient who is seen by the NP.

E. Direct Billing and Payment

Direct billing and payment for NP services may be made to the NP.

F. Assignment

Assignment is mandatory.

210 - Clinical Nurse Specialist (CNS) Services

(Rev. 1, 10-01-03)

B3-2160

Effective for services rendered after January 1, 1998, any individual who is participating under the Medicare program as a clinical nurse specialist (CNS) for the first time ever, may have his or her professional services covered if he or she meets the qualifications listed below and he or she is legally authorized to furnish CNS services in the State where the services are performed. CNSs who were issued billing provider numbers prior to January 1, 1998, may continue to furnish services under the CNS benefit.

Payment for CNS services is effective on the date of service, that is, on or after January 1, 1998, and payment is made on an assignment-related basis only.

A. Qualifications for CNSs

In order to furnish covered CNS services, a CNS must meet the conditions as follows:

1. Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to furnish the services of a clinical nurse specialist in accordance with State law;
2. Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and
3. Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

B. Covered Services

Coverage is limited to the services a CNS is legally authorized to perform in accordance with State law (or State regulatory mechanism provided by State law).

1. General

The services of a CNS may be covered under Part B if all of the following conditions are met:

- They are the types of services that are considered as physician's services if furnished by an MD/DO;

- They are furnished by a person who meets the CNS qualifications (see subsection A);
- The CNS is legally authorized to furnish the services in the State in which they are performed;
- They are furnished in collaboration with an MD/DO as required by State law (see subsection C); and
- They are not otherwise excluded from coverage because of one of the statutory exclusions. (See subsection C.)

2. Types of CNS Services that May be Covered

State law or regulations governing a CNS' scope of practice in the State in which the services are furnished applies. Carriers must develop a list of covered services based on the State scope of practice.

Examples of the types of services that a CNS may furnish include services that traditionally have been reserved for physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition. Also, if authorized under the scope of his or her State license, a CNS may furnish services billed under all levels of evaluation and management codes and diagnostic tests if furnished in collaboration with a physician.

3. Incident To

If covered CNS services are furnished, services and supplies furnished incident to the services of the CNS may also be covered if they would have been covered when furnished incident to the services of an MD/DO as described in §60.

C. Application of Coverage Rules

1. Types of CNS Services

Examples of the types of services that CNS may provide are services that traditionally have been reserved for physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition. State law or regulation governing a CNS' scope of practice for his or her service area applies.

2. Services Otherwise Excluded From Coverage

A CNS' services are not covered if they are otherwise excluded from coverage even though a CNS may be authorized by State law to perform them. For example, the Medicare law excludes from coverage routine foot care and routine physical checkups and services that are not reasonable and necessary for diagnosis or treatment of an illness or injury or to improve the function of a malformed body member. Therefore, these services are precluded from coverage even though they may be within a CNS' scope of practice under State law.

See §60.2 for coverage of services performed by a CNS incident to the services of physicians.

D. Collaboration

Collaboration is a process in which a CNS works with one or more physicians (MD/DO) to deliver health care services within the scope of the CNS' professional expertise with medical direction and appropriate supervision as required by the law of the State in which the services are furnished. In the absence of State law governing collaboration, collaboration is to be evidenced by the CNS documenting his or her scope of practice and indicating the relationships that the CNS has with physicians to deal with issues outside the CNS' scope of practice.

The collaborating physician does not need to be present with the CNS when the services are furnished or to make an independent evaluation of each patient who is seen by the CNS.

E. Direct Billing and Payment

A CNS may bill directly and receive direct payment for their services.

F. Assignment Requirement

Assignment is required for the service to be covered.

220 - Coverage of Outpatient Rehabilitation Therapy Services (Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services) Under Medical Insurance

(Rev.63, Issued: 12-29-06, Effective: 01-01-07, Implementation: on or before 01-29-07)

A comprehensive knowledge of the policies that apply to therapy services cannot be obtained through manuals alone. The most definitive policies are Local Coverage Determinations found at the Medicare Coverage Database www.cms.hhs.gov/mcd.

A list of Medicare contractors is found at the CMS Web site. Specific questions about all Medicare policies should be addressed to the contractors through the contact information supplied on their Web sites. General Medicare questions may be addressed to the Medicare regional offices http://www.cms.hhs.gov/RegionalOffices/.

A. Definitions

The following defines terms used in this section and §230:

ACTIVE PARTICIPATION of the clinician in treatment means that the clinician personally furnishes in its entirety at least 1 billable service on at least one day of treatment.

ASSESSMENT is separate from evaluation, and is included in services or procedures, (it is not separately payable). The term assessment as used in Medicare manuals related to therapy services is distinguished from language in Current Procedural Terminology (CPT) codes that specify assessment, e.g., 97755, Assistive Technology Assessment, which may be payable). Assessments shall be provided only by clinicians, because assessment requires professional skill to gather data by observation and patient inquiry and may include limited objective testing and measurement to make clinical judgments regarding the patient's condition(s). Assessment determines, e.g., changes in the patient's status since the last visit/treatment day and whether the planned procedure or service should be modified. Based on these assessment data, the professional may make judgments about progress toward goals and/or determine that a more complete evaluation or re-evaluation (see definitions below) is indicated. Routine weekly assessments of expected progression in accordance with the plan are not payable as re-evaluations.

CERTIFICATION is the physician's/nonphysician practitioner's (NPP) approval of the plan of care. Certification requires a dated signature on the plan of care or some other document that indicates approval of the plan of care. A certification interval is 30 calendar days or 1 month, whichever is longer.

The CLINICIAN is a term used in this manual and in Pub 100-04, chapter 5, section 10 or section 20, to refer to only a physician, nonphysician practitioner or a therapist (but not to an assistant, aide or any other personnel) providing a service within their scope of practice and consistent with state and local law. Clinicians make clinical judgments and are responsible for all services they are permitted to supervise. Services that require the skills of a therapist, may be appropriately furnished by clinicians, that is, by or under the supervision of qualified physicians/NPPs when their scope of practice, state and local laws allow it and their personal professional training is judged by Medicare contractors as sufficient to provide to the beneficiary skills equivalent to a therapist for that service.

COMPLEXITIES are complicating factors that may influence treatment, e.g., they may influence the type, frequency, intensity and/or duration of treatment. Complexities may be represented by diagnoses (ICD-9 codes), by patient factors such as age, severity, acuity, multiple conditions, and motivation, or by the patient's social circumstances such as the support of a significant other or the availability of transportation to therapy.

A DATE may be in any form (written, stamped or electronic). The date may be added to the record in any manner and at any time, as long as the dates are accurate. If they are different, refer to both the date a service was performed and the date the entry to the record was made. For example, if a physician certifies a plan and fails to date it, staff may add "Received Date" in writing or with a stamp. The received date is valid for certification/re-certification purposes. Also, if the physician faxes the referral, certification, or re-certification and forgets to date it, the date that prints out on the fax is valid. If services provided on one date are documented on another date, both dates should be documented.

The EPISODE of Outpatient Therapy – For the purposes of therapy policy, an outpatient therapy episode is defined as the period of time, in calendar days, from the first day the patient is under the care of the clinician (e.g., for evaluation or treatment) for the current condition(s) being treated by one therapy discipline (PT, or OT, or SLP) until the last date of service for that plan of care for that discipline.

During the episode, the beneficiary may be treated for more than one condition; including conditions with an onset after the episode has begun. For example, a beneficiary receiving PT for a hip fracture who, after the initial treatment session, develops low back pain would also be treated under a PT plan of care for rehabilitation of low back pain. That plan may be modified from the initial plan, or it may be a separate plan specific to the low back pain, but treatment for both conditions concurrently would be considered the same episode of PT treatment. If that same patient developed a swallowing problem during intubation for the hip surgery, the first day of treatment by the SLP would be a new episode of SLP care.

EVALUATION is a separately payable comprehensive service provided by a clinician, as defined above, that requires professional skills to make clinical judgments about conditions for which services are indicated based on objective measurements and subjective evaluations of patient performance and functional abilities. Evaluation is warranted e.g., for a new diagnosis or when a condition is treated in a new setting. These evaluative judgments are essential to development of the plan of care, including goals and the selection of interventions.

RE-EVALUATION provides additional objective information not included in other documentation. Re-evaluation is separately payable and is periodically indicated during an episode of care when the professional assessment of a clinician indicates a significant improvement or decline or change in the patient's condition or functional status that was not anticipated in the plan of care for that interval. Although some regulations and state practice acts require re-evaluation at specific intervals, for Medicare payment, re-evaluations must meet Medicare coverage guidelines. The decision to provide a re-evaluation shall be made by a clinician.

INTERVAL of treatment consists of 1 month or 30 calendar days whichever is more.

NONPHYSICIAN PRACTITIONERS (NPP) means physician assistants, clinical nurse specialists, and nurse practitioners, who may, if state and local laws permit it, and when appropriate rules are followed, provide, certify or supervise therapy services.

PHYSICIAN with respect to outpatient rehabilitation therapy services means a doctor of medicine, osteopathy (including an osteopathic practitioner), podiatric medicine, or optometry (for low vision rehabilitation only). Chiropractors and doctors of dental surgery or dental medicine are not considered physicians for therapy services and may neither refer patients for rehabilitation therapy services nor establish therapy plans of care.

PATIENT, client, resident, and beneficiary are terms used interchangeably to indicate enrolled recipients of Medicare covered services.

PROVIDERS of services are defined in §1861(u) of the Act, 42CFR400.202 and 42CFR485 Subpart H as participating hospitals, critical access hospitals (CAH), skilled nursing facilities (SNF), comprehensive outpatient rehabilitation facilities (CORF), home health agencies (HHA), hospices, participating clinics, rehabilitation agencies or outpatient rehabilitation facilities (ORF). Providers are also defined as public health agencies with agreements only to furnish outpatient therapy services, or community mental health centers with agreements only to furnish partial hospitalization services. To qualify as providers of services, these providers must meet certain conditions enumerated in the law and enter into an agreement with the Secretary in which they agree not to charge any beneficiary for covered services for which the program will pay and to refund any erroneous collections made. Note that the word PROVIDER in sections 220 and 230 is not used to mean a person who provides a service, but is used as in the statute to mean a facility or agency such as rehabilitation agency or home health agency.

QUALIFIED PROFESSIONAL means a physical therapist, occupational therapist, speech-language pathologist, physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to perform therapy services, and who also may appropriately perform therapy services under Medicare policies. Qualified professionals may also include physical therapist assistants (PTA) and occupational therapy assistants (OTA) when working under the supervision of a qualified therapist, within the scope of practice allowed by state law. Assistants are limited in the services they may provide (see section 230.1 and 230.2) and may not supervise others.

QUALIFIED PERSONNEL means staff (auxiliary personnel) who have been educated and trained as therapists and qualify to furnish therapy services only under direct supervision incident to a physician or NPP. See §230.5 of this manual. Qualified personnel may or may not be licensed as therapists but meet all of the requirements for therapists with the exception of licensure.

SIGNATURE means a legible identifier of any type (e.g., hand written, electronic, or signature stamp). Policies in CMS IOM Pub. 100-08, Medicare Program Integrity Manual, chapter 3, §3.4.1.1 (B) concerning signatures apply.

SUPERVISION LEVELS for outpatient rehabilitation therapy services are the same as those for diagnostic tests defined in 42CFR410.32. Depending on the setting, the levels include personal supervision (in the room), direct supervision (in the office suite), and general supervision (physician/NPP is available but not necessarily on the premises).

SUPPLIERS of therapy services include individual practitioners such as physicians, NPPs, physical therapists and occupational therapists who have Medicare provider numbers. Regulatory references on physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs) are at 42CFR410.60 (C)(1), 485.701-729, and 486.150-163. Speech-language pathologists are not suppliers because the Act

does not provide coverage of any speech-language pathology services furnished by a speech-language pathologist as an independent practitioner. (See §230.3.)

THERAPIST refers only to qualified physical therapists, occupational therapists and speech-language pathologists, as defined in §230. Qualifications that define therapists are in §§230.1, 230.2, and 230.3. Skills of a therapist are defined by the scope of practice for therapists in the state).

THERAPY (or outpatient rehabilitation services) includes only outpatient physical therapy, occupational therapy and speech-language pathology services paid using the Medicare Physician Fee Schedule or the same services when provided in hospitals that are exempt from the hospital Outpatient Prospective Payment System and paid on a reasonable cost basis, including Critical Access Hospitals.

Therapy services referred to in this manual are those skilled rehabilitative services provided according to the standards and conditions in CMS manuals, (e.g., in this chapter and in the Medicare Claims Processing Manual, CMS IOM Pub. 100-04, chapter 5), within their scope of practice by qualified professionals or qualified personnel, as defined in this section, represented by procedures found in the American Medical Association's "Current Procedural Terminology (CPT)." A list of CPT (HCPCS) codes is provided in CMS IOM Pub. 100-04, Chapter 5, §20, and in Local Coverage Determinations developed by contractors.

Unless modified by the words "maintenance" or "not", the term therapy refers to rehabilitative therapy services as described in §220.2(C).

TREATMENT DAY means a single calendar day on which treatment, evaluation or re-evaluation is provided. There could be multiple visits, treatment sessions/encounters on a treatment day.

VISITS OR TREATMENT SESSIONS begin at the time the patient enters the treatment area (of a building, office, or clinic) and continue until all services (e.g., activities, procedures, services) have been completed for that session and the patient leaves that area to participate in a non-therapy activity. It is likely that not all minutes in the visits/treatment sessions are billable (e.g., rest periods). There may be two treatment sessions in a day, for example, in the morning and afternoon. When there are two visits/ treatment sessions in a day, plans of care indicate treatment amount of twice a day.

B References

Paper Manuals. The following manuals, now outdated, were resources for the Internet Only Manuals.

- Part A Medicare Intermediary Manual, (Pub. 13)
- Part B Medicare Carrier Manual, (Pub. 14)
- Hospital Manual, (Pub. 10)

- Outpatient Physical Therapy/CORF Manual, (Pub. 9)

Regulation and Statute. The information in this section is based in part on the following current references:

- 42CFR refers to Title 42, Code of Federal Regulation (CFR).
- The Act refers to the Social Security Act.

Internet Only Manuals. Current Policies that concern providers and suppliers of therapy services are located in many places throughout CMS Manuals. Sites that may be of interest include:

- Pub.100-01 GENERAL INFORMATION, ELIGIBILITY, AND ENTITLEMENT,
    - Chapter 1- General Overview

      10.1 - Hospital Insurance (Part A) for Inpatient Hospital, Hospice and SNF Services - A Brief Description

      10.2 - Posthospital Home Health Services

      10.3 - Supplementary Medical Insurance (Part B) - A Brief Description

      20.2 - Discrimination Prohibited

- Pub. 100-02, MEDICARE BENEFIT POLICY MANUAL
    - Ch 6 - Hospital Services Covered Under Part B

      10 - Medical and Other Health Services Furnished to Inpatients of Participating Hospitals

      20 - Outpatient Hospital Services

      20.2 - Distinguishing Outpatient Hospital Services Provided Outside the Hospital

      20.4.1 - Coverage of Outpatient Therapeutic Services

      70 - Outpatient Hospital Psychiatric Services
    - Ch 8 - Coverage of Extended Care (SNF) Services Under Hospital Insurance

      30.4. - Direct Skilled Rehabilitation Services to Patients

      40 - Physician Certification and Recertification

      50.3 - Physical, Speech, and Occupational Therapy Furnished by the Skilled Nursing Facility or by Others Under Arrangements with the Facility and Under Its Supervision

      70.3 - Inpatient Physical Therapy, Occupational Therapy, and Speech Pathology Services

- Pub. 100-03 MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL

  - Part 1

    20.10 - Cardiac Rehabilitation Programs

    30.1 - Biofeedback Therapy

    30.1.1 - Biofeedback Therapy for the Treatment of Urinary Incontinence

    50.1 – Speech Generating Devices

    50.2 - Electronic Speech Aids

    50.4 - Tracheostomy Speaking Valve

  - Part 2

    150.2 - Osteogenic Stimulator

    150.4 - Neuromuscular Electrical Stimulator (NMES) in the Treatment of Disuse Atrophy

    160.3 - Assessing Patient's Suitability for Electrical Nerve Stimulation

    160.7 - Electrical Nerve Stimulators

    160.11 - Osteogenic Stimulation

    160.12 - Neuromuscular Electrical Stimulation (NMES)

    160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)

    160.17 - L-Dopa

  - Part 3

    170.1 - Institutional and Home Care Patient Education Programs

    170.2 - Melodic Intonation Therapy

    170.3 - Speech Pathology Services for the Treatment of Dysphagia

    180 - Nutrition

  - Part 4

    230.8 - Non-implantable Pelvic Flood Electrical Stimulator

    240.7 - Postural Drainage Procedures and Pulmonary Exercises

    270.1 -Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds

    270.4 - Treatment of Decubitus Ulcers

    280.3 - Specially Sized Wheelchairs

    280.4 - Seat Lift

    280.5 - Safety Roller

    280.9 - Power Operated Vehicles That May Be Used as Wheelchairs

    280.13 - Transcutaneous Electrical Nerve Stimulators (TENS)

290.1 - Home Health Visits to A Blind Diabetic

- Pub. 100-08 PROGRAM INTEGRITY MANUAL
  - Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

    3.4.1.1 - Documentation Specifications for Areas Selected for Prepayment or Postpayment MR

    3.4.1.1.1 Exception From the Uniform Dollar Limitation ("Therapy Cap")
  - Chapter 13 - Local Coverage Determinations

    13.5.1 - Reasonable and Necessary Provisions in LCDs

Specific Therapy Policies**.** Sections 220 and 230 of this chapter describe the standards and conditions that apply generally to outpatient rehabilitation therapy services. Specific policies may differ by setting. Other policies concerning therapy services are found in other manuals. When a therapy service policy is specific to a setting, it takes precedence over these general outpatient policies. For special rules on:

- CORFs - See chapter 12 of this manual and also Pub. 100-04, chapter 5;
- SNF - See chapter 8 of this manual and also Pub. 100-04, chapter 6, for SNF claims/billing;
- HHA - See chapter 7 of this manual, and Pub. 100-04, chapter 10;
- GROUP THERAPY AND STUDENTS - See Pub. 100-02, chapter 15, §230;
- ARRANGEMENTS - Pub. 100-01, chapter 5, §10.3;
- COVERAGE is described in the Medicare Program Integrity Manual, Pub. 100-08, chapter 13, §13.5.1; and
- THERAPY CAPS - See Pub. 100-04, chapter 5, §10.2, for a complete description of this financial limitation.

C General

Therapy services are a covered benefit in §§1861(g), 1861(p), and 1861(ll) of the Act. Therapy services may also be provided incident to the services of a physician/NPP under §§1861(s)(2) and 1862(a)(20) of the Act.

Covered therapy services are furnished by providers, by others under arrangements with and under the supervision of providers, or furnished by suppliers (e.g., physicians, NPP, enrolled therapists), who meet the requirements in Medicare manuals for therapy services.

Where a prospective payment system (PPS) applies, therapy services are paid when services conform to the requirements of that PPS. For example, see Pub. 100-04 for a description of applicable Inpatient Hospital Part B and Outpatient PPS rules. Reimbursement for therapy provided to Part A inpatients of hospitals or residents of SNFs in covered stays is included in the respective PPS rates.

Payment for therapy provided by an HHA under a plan of treatment is included in the home health PPS rate. Therapy may be billed by an HHA on bill type 34x if there are no home health services billed under a home health plan of care at the same time (e.g., the patient is not homebound), and there is a valid therapy plan of treatment.
In addition to the requirements described in this chapter, the services must be furnished in accordance with health and safety requirements set forth in regulations at 42CFR484, and 42CFR485.

220.1 - Conditions of Coverage and Payment for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR424.24

Refer to §230.4 for physical therapist/occupational therapist in private practice rules.

Coverage rules for specific services are in Pub. 100-03, the Medicare National Coverage Determinations Manual.

Other payment rules are found in Pub. 100-04, chapter 5.

Since the outpatient therapy benefit under Part B provides coverage only of therapy services, payment can be made only for those services that constitute therapy. In cases where there is doubt about whether a service is therapy, the contractor's local coverage determination (LCD) shall prevail.

In order for a service to be covered, it must have a benefit category in the statute, it must not be excluded and it must be reasonable and necessary. Therapy services are a benefit under §1861 of the Act. Consult Pub. 100-08, chapter 13, §13.5.1 for full descriptions of a reasonable and necessary service.

Outpatient therapy services furnished to a beneficiary by a provider or supplier are payable only when furnished in accordance with certain conditions. The following conditions of coverage apply. The requirements noted (*) are also conditions of payment in 42CFR424.24(c) and according to the Act §1835 (a)(2)(D) are the three conditions that must be certified:

- (i) such services are or were required because the individual needed therapy services* (see §220.1.3); and

- (ii) a plan for furnishing such services has been established by a physician/NPP or by the therapist providing such services and is periodically reviewed by a physician/NPP* (see §220.1.2); and

- (iii) such services are or were furnished while the individual is or was under the care of a physician* (see §220.1.1); and

- Services must be furnished on an outpatient basis. (See §220.1.4)

- All of the conditions are met when a physician/NPP certifies an outpatient plan of care for therapy. Certification is required for coverage and payment of a therapy claim. Each of these conditions is discussed separately in the sections that follow.

220.1.1 - Outpatient Therapy Must be Under the Care of a Physician/Nonphysician Practitioners (NPP) (Orders/Referrals and Need for Care)

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

An order (sometimes called a referral) for therapy service, if it is documented in the medical record, provides evidence of both the need for care and that the patient is under the care of a physician. However, the certification requirements are met when the physician certifies the plan of care. If the signed order includes a plan of care (see essential requirements of plan in §220.1.2), no further certification of the plan is required. Payment is dependent on the certification of the plan of care rather than the order, but the use of an order is prudent to determine that a physician is involved in care and available to certify the plan.

(The CORF services benefit does not recognize an NPP for orders and certification.)

220.1.2 - Plans of Care for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services

(Rev. 60, Issued: 11-09-06; Effective: 12-09-06; Implementation: 12-09-06)

Reference: 42CFR 410.61

A. Establishing the plan (See §220.1.3 for certifying the plan.)

The services must relate directly and specifically to a written treatment plan as described in this chapter. The plan, (also known as a plan of care or plan of treatment) must be established before treatment is begun. The plan is established when it is developed (e.g., written or dictated).

The signature and professional identity (e.g., MD, OTR/L) of the person who established the plan, and the date it was established must be recorded with the plan. Establishing the plan, which is described below, is not the same as certifying the plan, which is described in §§220.1.1 and 220.1.3

Outpatient therapy services shall be furnished under a plan established by:

- A physician/NPP (consultation with the treating physical therapist, occupational therapist, or speech-language pathologist is recommended. Only a physician may establish a plan of care in a CORF);
- The physical therapist who will provide the physical therapy services;
- The occupational therapist who will provide the occupational therapy services; or
- The speech-language pathologist who will provide the speech-language pathology services.

The plan may be entered into the patient's therapy record either by the person who established the plan or by the provider's or supplier's staff when they make a written record of that person's oral orders before treatment is begun.

Treatment under a Plan. The evaluation and treatment may occur and are both billable either on the same day or at subsequent visits. It is appropriate that treatment begins when a plan is established.

Therapy may be initiated by qualified professionals or qualified personnel based on a dictated plan. Treatment may begin before the plan is committed to writing only if the treatment is performed or supervised by the same clinician who establishes the plan. Payment for services provided before a plan is established may be denied.

Two Plans. It is acceptable to treat under two separate plans of care when different physician's/NPP's refer a patient for different conditions. It is also acceptable to combine the plans of care into one plan covering both conditions if one or the other referring physician/NPP is willing to certify the plan for both conditions. The Treatment Notes continue to require timed code treatment minutes and total treatment time and need not be separated by plan. Progress Reports should be combined if it is possible to make clear that the goals for each plan are addressed. Separate Progress Reports referencing each plan of care may also be written, at the discretion of the treating clinician, or at the request of the certifying physician/NPP, but shall not be required by contractors.

B. Contents of Plan (See §220.1.3 for certifying the plan.)

The plan of care shall contain, at minimum, the following information as required by regulation (42CFR424.24 and 410.61) (See §220.3 for further documentation requirements):

- Diagnoses;
- Long term treatment goals; and
- Type, amount, duration and frequency of therapy services.

The plan of care shall be consistent with the related evaluation, which may be attached and is considered incorporated into the plan.

Long term treatment goals should be developed for the entire episode of care and not only for the services provided under a plan for one interval of care.

The type of treatment may be PT, OT, or SLP, or, where appropriate, the type may be a description of a specific treatment or intervention. (For example, where there is a single evaluation service, but the type is not specified, the type is assumed to be consistent with the therapy discipline (PT, OT, SLP) ordered, or of the therapist who provided the evaluation.) Where a physician/NPP establishes a plan, the plan must specify the type (PT, OT, SLP) of therapy planned.

There shall be different plans of care for each type of therapy discipline. When more than one discipline is treating a patient, each must establish a diagnosis, goals, etc. independently. However, the form of the plan and the number of plans incorporated into one document are not limited as long as the required information is present and related to each discipline separately. For example, a physical therapist may not provide services under an occupational therapist plan of care. However, both may be treating the patient for the same condition at different times in the same day for goals consistent with their own scope of practice.

The amount of treatment refers to the number of times in a day the type of treatment will be provided. Where amount is not specified, one treatment session a day is assumed.

The frequency refers to the number of times in a week the type of treatment is provided. Where frequency is not specified, one treatment is assumed. If a scheduled holiday occurs on a treatment day that is part of the plan, it is appropriate to omit that treatment day unless the clinician who is responsible for writing Progress Reports determines that a brief, temporary pause in the delivery of therapy services would adversely affect the patient's condition.

The duration is the number of weeks, or the number of treatment sessions, for THIS PLAN of care.

The above policy describes the minimum requirements for payment. It is anticipated that clinicians may choose to make their plans more specific, in accordance with good practice. For example, they may include these optional elements: short term goals, goals and duration for the current episode of care, specific treatment interventions, procedures, modalities or techniques and the amount of each.

C. Changes to the Therapy Plan

Changes are made in writing in the patient's record and signed by one of the following professionals responsible for the patient's care:

- The physician/NPP;
- The physical therapist (in the case of physical therapy);
- The speech-language pathologist (in the case of speech-language pathology services);
- The occupational therapist (in the case of occupational therapy services; or
- The registered professional nurse or physician/NPP on the staff of the facility pursuant to the oral orders of the physician/NPP or therapist.

While the physician/NPP may change a plan of treatment established by the therapist providing such services, the therapist may not significantly alter a plan of treatment established or certified by a physician/NPP without their documented written or verbal approval [See §220.1.3(C)]. A change in long-term goals, (for example if a new condition was to be treated) would be a significant change. An insignificant alteration in the plan would be a decrease in the frequency or duration due to the patient's illness, or a modification of short-term goals to adjust for improvements made toward the same long-term goals. If a patient has achieved a goal and/or has had no response to a treatment that is part of the plan, the therapist may delete a specific intervention from the plan of care prior to physician/ NPP approval. This shall be reported to the physician/NPP responsible for the patient's treatment prior to the next certification.

Procedures (e.g., neuromuscular reeducation) and modalities (e.g., ultrasound) are not goals, but are the means by which long and short term goals are obtained. Changes to procedures and modalities do not require physician signature when they represent adjustments to the plan that result from a normal progression in the patient's disease or condition. Only when the patient's condition changes significantly, making revision of long term goals necessary, is a physician's/NPP's signature required on the change, (long term goal changes may be accompanied by changes to procedures and modalities).

220.1.3 - Certification and Recertification of Need for Treatment and Therapy Plans of Care

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR424.24(c)

See specific certification rules for CORF in this manual, chapter 12, §30(E) and in Pub. 100-01, chapter 4, §20 for hospital services.

A. Method and Disposition of Certifications

Certification requires a dated signature on the plan of care or some other document that indicates approval of the plan of care. It is not appropriate for a physician/NPP to certify a plan of care if the patient was not under the care of some physician/NPP at the time of the treatment or if the patient did not need the treatment. Since delayed certification is allowed, the date the certification is signed is important only to determine if it is timely or delayed. The certification must relate to treatment during the interval on the claim.

Unless there is reason to believe the plan was not signed appropriately, or it is not timely, no further evidence that the patient was under the care of a physician/NPP and that the patient needed the care is required.

The format of all certifications and recertifications and the method by which they are obtained is determined by the individual facility and/or practitioner. Acceptable documentation of certification may be, for example, a physician's progress note, a physician/NPP order, or a plan of care that is signed and dated during the interval of treatment by a physician/NPP, and indicates the physician/NPP is aware that therapy service is or was in progress and the physician/NPP makes no record of disagreement with the plan when there is evidence the plan was sent (e.g., to the office) or is available in the record (e.g., of the institution that employs the physician/NPP) for the physician/NPP to review.

The certification should be retained in the clinical record and available if requested by the contractor.

B. Initial Certification of Plan

The physician's/NPP's certification of the plan for the first 30 days of treatment (with or without an order) satisfies all of the certification requirements noted above in §220.1 for the first interval of 30 calendar days or 1 month of treatment.

Timing of Initial Certification. The provider or supplier (e.g., facility, physician/NPP, or therapist) should obtain certification as soon as possible after the plan of care is established, unless the requirements of delayed certification are met. "As soon as possible" means that the physician/NPP shall certify the plan as soon as it is obtained, or before the end of the first interval beginning at the initial therapy treatment. Since payment may be denied if a physician does not certify the plan, the therapist should forward the plan to the physician as soon as it is established. Evidence of diligence in providing the plan to the physician may be considered by the contractor during review in the event of a delayed certification.

Timely certification of the first interval of treatment is met when physician/NPP certification of the plan for the first interval of treatment is documented, by signature or verbal order, and dated before the end of the interval. If the order to certify is verbal, it must be followed within 14 days by a signature to be timely. A dated notation of the order to certify the plan should be made in the patient's medical record.

C. Review of Plan and Recertification

Reference: 42CFR424.24(c), 1861(r)

Payment and coverage conditions require that the plan must be reviewed, dated and signed by a physician/NPP every 30 days to complete the certification requirements in 42CFR 410.61(e), unless delayed certification requirements are met. When therapy

services are continued for longer than 1 month, the physician/NPP who is responsible for the patient's care at that time should review and certify the plan for each interval of therapy. It is not required that the same physician/NPP order, certify and/or recertify the plans.

Recertifications that document the need for continued therapy in subsequent intervals should be signed before or during the subsequent intervals of treatment (when they are timely) or later, when they are delayed. Subsequent recertifications should be completed before or during the next interval, unless they are delayed.

Physician/NPP options for Certification. A physician/NPP may certify or recertify a plan for less than 30 days of treatment, if the physician/NPP determines it is appropriate. This direction should be included in an order preceding the treatment (preferably), or in the plan of care.

Physicians/NPPs may require that the patient make a visit for an examination if, in the professional's judgment, the visit is needed prior to certifying the plan. Physicians/NPPs should indicate their requirement for visits, preferably on an order preceding the treatment, or on the plan of care. Physicians/NPPs should not sign a certification if they require a visit and a visit was not made. However, Medicare does not require a visit unless the National Coverage Determination (NCD) for a particular treatment requires it (e.g., see Pub. 100-03, §270.1 - Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds).

Restrictions on Certification. Certifications and recertifications by doctors of podiatric medicine must be consistent with the scope of the professional services provided by a doctor of podiatric medicine as authorized by applicable state law. Optometrists may order and certify only low vision services. Chiropractors may not certify or recertify plans of care for therapy services.

D. Delayed Certification

References: §1835(a) of the Act
42CFR424.11(d)(3)

Certifications are required for each 30 day interval of treatment and are timely when the certification occurs before or during the interval. Certification and recertification requirements shall be deemed satisfied where, at any later date, a physician/NPP makes a certification accompanied by a reason for the delay. Certifications are acceptable without justification for 30 days after they are due. Delayed certification should include one or more certifications or recertifications on a single signed and dated document.

Delayed certifications should include any evidence the provider or supplier considers necessary to justify the delay. For example, a certification may be delayed because the physician did not sign it, or the original was lost. In the case of a long delayed certification (over 6 months), the provider or supplier may choose to submit with the

delayed certification some other documentation (e.g., an order, progress notes, telephone contact, requests for certification or signed statement of a physician/NPP) indicating need for care and that the patient was under the care of a physician at the time of the treatment. Such documentation may be requested by the contractor for delayed certifications if it is required for review.

It is not intended that needed therapy be stopped or denied when certification is delayed. The delayed certification of otherwise covered services should be accepted unless the contractor has reason to believe that there was no physician involved in the patient's care, or treatment did not meet the patient's need (and therefore, the certification was signed inappropriately).

EXAMPLE: Payment should be denied if there is a certification signed 2 years after treatment by a physician/NPP who has/had no knowledge of the patient when the medical record also shows no order, note, physician/NPP attended meeting, correspondence with a physician/NPP, documentation of discussion of the plan with a physician/NPP, documentation of sending the plan to any physician/NPP, or other indication that there was a physician/NPP involved in the case.

EXAMPLE: Payment should not be denied, even when certified 2 years after treatment, when there is evidence that a physician approved needed treatment, such as an order, documentation of therapist/physician/NPP discussion of the plan, chart notes, meeting notes, requests for certification, or certifications for intervals before or after the service in question.

E. Denials Due to Certification

Denial for payment that is based on absence of certification is a technical denial, which means a statutory requirement has not been met. Certification is a statutory requirement in SSA 1835(a)(2)- ('periodic review" of the plan).

For example, if a patient is treated and the provider/supplier cannot produce (on contractor request) a plan of care (timely or delayed) for the billed treatment dates certified by a physician/NPP, then that service might be denied for lack of the required certification. If an appropriate certification is later produced, the denial shall be overturned.

In the case of a service furnished under a provider agreement as described in 42CFR489.21, the provider is precluded from charging the beneficiary for services denied as a result of missing certification.

However, if the service is provided by a supplier (in the office of the physician/NPP, or therapist) a technical denial due to absence of a certification results in beneficiary liability. For that reason, it is recommended that the patient be made aware of the need for certification and the consequences of its absence.

A technical denial decision may be reopened by the contractor or reversed on appeal as appropriate, if delayed certification is later produced.

220.1.4 - Requirement That Services Be Furnished on an Outpatient Basis

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR410.60

Therapy services are payable under the Physician Fee Schedule when furnished by 1.) a provider to its outpatients in the patient's home; 2.) a provider to patients who come to the facility's outpatient department; 3.) a provider to inpatients of other institutions, or 4.) a supplier to patients in the office or in the patient's home. (CORF rules differ on providing therapy at home.)

Coverage includes therapy services furnished by participating hospitals and SNFs to their inpatients who have exhausted Part A inpatient benefits or who are otherwise not eligible for Part A benefits. Providers of therapy services that have inpatient facilities, other than participating hospitals and SNFs, may not furnish covered therapy services to their own inpatients. However, since the inpatients of one institution may be considered the outpatients of another institution, all providers of therapy services may furnish such services to inpatients of another health facility.

A certified distinct part of an institution is considered to be a separate institution from a nonparticipating part of the institution. Consequently, the certified distinct part may render covered therapy services to the inpatients of the noncertified part of the institution or to outpatients. The certified part must bill the intermediary under Part B.

Therapy services are payable when furnished in the home at the same physician fee schedule payments as in other outpatient settings. Additional expenses incurred by providers due to travel to a person who is not homebound will not be covered.

Under the Medicare law, there is no authority to require a provider to furnish a type of service. Therefore, a hospital or SNF may furnish therapy to its inpatients without having to set up facilities and procedures for furnishing those services to its outpatients. However, if the provider chooses to furnish a particular service, it may not charge any individual or other person for items or services for which the individual is entitled to have payment made under the program because it is bound by its agreement with Medicare. Thus, whenever a hospital or SNF furnishes outpatient therapy to a Medicare beneficiary (either directly or under arrangements with others) it must bill the program under Part B and may charge the patient only for the applicable deductible and coinsurance.

220.2 - Reasonable and Necessary Outpatient Rehabilitation Therapy Services

(Rev.63, Issued: 12-29-06, Effective: 01-01-07, Implementation: on or before 01-29-07)

References: Pub. 100-08, chapter 13, §13.5.1,
42CFR410.59,
42CFR410.60

A. General

To be covered, services must be skilled therapy services as described in this chapter and be rendered under the conditions specified. Services provided by professionals or personnel who do not meet the qualification standards, and services by qualified people that are not appropriate to the setting or conditions are unskilled services. Unskilled services are palliative procedures that are repetitive or reinforce previously learned skills, or maintain function after a maintenance program has been developed.

Services which do not meet the requirements for covered therapy services in Medicare manuals are not payable using codes and descriptions for therapy services. For example, services related to activities for the general good and welfare of patients, e.g., general exercises to promote overall fitness and flexibility and activities to provide diversion or general motivation, do not constitute therapy services for Medicare purposes. Also, services not provided under a therapy plan of care, or are provided by staff who are not qualified or appropriately supervised, are not covered or payable therapy services.

Examples of coverage policies that apply to all outpatient therapy claims are in this chapter, in Pub. 100-04, chapter 5, and Pub. 100-08, chapter 13. Some policies in other manuals are repeated here for emphasis and clarification. Further details on documenting reasonable and necessary services are found in section 220.3 of this chapter.

B. Reasonable and Necessary

To be considered reasonable and necessary the following conditions must each be met. (This is a representative list of required conditions and does not fully describe reasonable and necessary services. See the remainder of this section and associated information in section 230.):

- The services shall be considered under accepted standards of medical practice to be a specific and effective treatment for the patient's condition. Acceptable practices for therapy services are found in:
    - Medicare manuals (such as this manual and Publications 100-03 and 100-04),
    - Contractors Local Coverage Determinations (LCDs and NCDs are available on the Medicare Coverage Database: http://www.cms.hhs.gov/mcd, and
    - Guidelines and literature of the professions of physical therapy, occupational therapy and speech-language pathology.

- The services shall be of such a level of complexity and sophistication or the condition of the patient shall be such that the services required can be safely and effectively performed only by a therapist, or in the case of physical therapy and occupational therapy by or under the supervision of a therapist. Services that do not require the performance or supervision of a therapist are not skilled and are not considered reasonable or necessary therapy services, even if they are performed or supervised by a qualified professional.

- If the contractor determines the services furnished were of a type that could have been safely and effectively performed only by or under the supervision of such a qualified professional, it shall presume that such services were properly supervised when required. However, this presumption is rebuttable, and, if in the course of processing claims it finds that services are not being furnished under proper supervision, it shall deny the claim and bring this matter to the attention of the Division of Survey and Certification of the Regional Office.

- While a beneficiary's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a beneficiary's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by nonskilled personnel. See item C for descriptions of skilled (rehabilitative) services.

- There must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time, or the services must be necessary for the establishment of a safe and effective maintenance program required in connection with a specific disease state. In the case of a progressive degenerative disease, service may be intermittently necessary to determine the need for assistive equipment and/or establish a program to maximize function (see item D for descriptions of maintenance services); and

- The amount, frequency, and duration of the services must be reasonable under accepted standards of practice. The contractor shall consult local professionals or the state or national therapy associations in the development of any utilization guidelines.

NOTE: Claims for therapy services denied because they are not considered reasonable and necessary are excluded by §1862(a)(1) of the Act and are thus subject to consideration under the waiver of liability provision in §1879 of the Act.

C. Rehabilitative Therapy

Description of Rehabilitative Therapy. The concept of rehabilitative therapy includes recovery or improvement in function and, when possible, restoration to a previous level of health and well-being. Therefore, evaluation, re-evaluation and assessment

documented in the Progress Report should describe objective measurements which, when compared, show improvements in function, or decrease in severity, or rationalization for an optimistic outlook to justify continued treatment.

Covered therapy services shall be rehabilitative therapy services unless they meet the criteria for maintenance therapy requiring the skills of a therapist described below. Rehabilitative therapy services are skilled procedures that may include but are not limited to:

Evaluations; reevaluations

Establishment of treatment goals specific to the patient's disability or dysfunction and designed to specifically address each problem identified in the evaluation;

Design of a plan of care addressing the patient's disorder, including establishment of procedures to obtain goals, determining the frequency and intensity of treatment;

Continued assessment and analysis during implementation of the services at regular intervals;

Instruction leading to establishment of compensatory skills;

Selection of devices to replace or augment a function (e.g., for use as an alternative communication system and short-term training on use of the device or system); and

Patient and family training to augment rehabilitative treatment or establish a maintenance program. Education of staff and family should be ongoing through treatment and instructions may have to be modified intermittently if the patient's status changes.

Skilled Therapy. Rehabilitative therapy occurs when the skills of a therapist, (See definition of therapist in section 220 of this chapter) are necessary to safely and effectively furnish a recognized therapy service whose goal is improvement of an impairment or functional limitation. (See also section 220.3 of this chapter for documenting skilled therapy.)

Skilled therapy may be needed, and improvement in a patient's condition may occur, even where a chronic or terminal condition exists. For example, a terminally ill patient may begin to exhibit self-care, mobility, and/or safety dependence requiring skilled therapy services. The fact that full or partial recovery is not possible does not necessarily mean that skilled therapy is not needed to improve the patient's condition. In the case of a progressive degenerative disease, for example, service may be intermittently necessary to determine the need for assistive equipment and establish a program to maximize

function. The deciding factors are always whether the services are considered reasonable, effective treatments for the patient's condition and require the skills of a therapist, or whether they can be safely and effectively carried out by nonskilled personnel without the supervision of qualified professionals.

Services that can be safely and effectively furnished by nonskilled personnel or by PTAs or OTAs without the supervision of therapists are not rehabilitative therapy services. If at any point in the treatment of an illness it is determined that the treatment is not rehabilitative, or does not legitimately require the services of a qualified professional for management of a maintenance program as described below, the services will no longer be considered reasonable and necessary. Services that are not reasonable or necessary should be excluded from coverage under §1862(a)(1) of the Act.

Potential for Improvement Due to Treatment. If an individual's expected rehabilitation potential would be insignificant in relation to the extent and duration of physical therapy services required to achieve such potential, therapy would not be covered because it is not considered rehabilitative or reasonable and necessary.

Improvement is evidenced by successive objective measurements whenever possible (see objective measurement instruments for evaluation in the §220.3.C of this chapter).

Therapy is not required to effect improvement or restoration of function where a patient suffers a transient and easily reversible loss or reduction of function (e.g., temporary weakness which may follow a brief period of bed rest following abdominal surgery) which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Therapy furnished in such situations is not considered reasonable and necessary for the treatment of the individual's illness or injury and the services are not covered. (See exceptions for maintenance in §220.2D of this manual).

D. Maintenance Programs

During the last visits for rehabilitative treatment, the clinician may develop a maintenance program. The goals of a maintenance program would be, for example, to maintain functional status or to prevent decline in function. The specialized skill, knowledge and judgment of a therapist would be required, and services are covered, to design or establish the plan, assure patient safety, train the patient, family members and/or unskilled personnel and make infrequent but periodic reevaluations of the plan.

The services of a qualified professional are not necessary to carry out a maintenance program, and are not covered under ordinary circumstances. The patient may perform such a program independently or with the assistance of unskilled personnel or family members.

Where a maintenance program is not established until after the rehabilitative therapy program has been completed (and the skills of a therapist are not necessary) development of a maintenance program would not be considered reasonable and necessary for the

treatment of the patient's condition. It would be excluded from coverage under §1862(a)(1) of the Act unless the patient's safety was at risk (see below).

EXAMPLE: A Parkinson patient who has been under a rehabilitative physical therapy program may require the services of a therapist during the last week or two of treatment to determine what type of exercises will contribute the most to maintain the patient's present functional level following cessation of treatment. In such situations, the design of a maintenance program appropriate to the capacity and tolerance of the patient by the qualified therapist, the instruction of the patient or family members in carrying out the program, and such infrequent reevaluations as may be required would constitute covered therapy because of the need for the skills of a qualified professional.

Evaluation and Maintenance Plan without Rehabilitative Treatment. After the initial evaluation of the extent of the disorder, illness, or injury, if the treating qualified professional determines the potential for rehabilitation is insignificant, an appropriate maintenance program may be established prior to discharge. Since the skills of a therapist are required for the development of the maintenance program and training the patient or caregivers, this service is covered.
EXAMPLE: The skills of a qualified speech-language pathologist may be covered to develop a maintenance program for a patient with multiple sclerosis, for services intended to prevent or minimize deterioration in communication ability caused by the medical condition, when the patient's current medical condition does not yet justify the need for the skilled services of a speech-language pathologist. Evaluation, development of the program and training the family or support personnel would require the skills of a therapist and would be covered. The skills of a therapist are not required and services are not covered to carry out the program.

Skilled Maintenance Therapy for Safety. If the services required to maintain function involve the use of complex and sophisticated therapy procedures, the judgment and skill of a therapist may be necessary for the safe and effective delivery of such services. When the patient's safety is at risk, those reasonable and necessary services shall be covered, even if the skills of a therapist are not ordinarily needed to carry out the activities performed as part of the maintenance program.

Example. Where there is an unhealed, unstable fracture, which requires regular exercise to maintain function until the fracture heals, the skills of a therapist would be needed to ensure that the fractured extremity is maintained in proper position and alignment during maintenance range of motion exercises.

220.3 - Documentation Requirements for Therapy Services

(Rev.63, Issued: 12-29-06, Effective: 01-01-07, Implementation: on or before 01-29-07)

A. General

Therapy services shall be payable when the medical record and the information on the claim form consistently and accurately report covered therapy services. Documentation must be legible, relevant and sufficient to justify the services billed. In general, services must be covered therapy services provided according to the requirements in Medicare manuals. Medicare requires that the services billed be supported by documentation that justifies payment. Documentation must comply with all legal/regulatory requirements applicable to Medicare claims.

The documentation guidelines in sections 220 and 230 of this chapter identify the minimal expectations of documentation by providers or suppliers or beneficiaries submitting claims for payment of therapy services to the Medicare program. State or local laws and policies, or the policies of the profession, the practice, or the facility may be more stringent. Additional documentation not required by Medicare is encouraged when it conforms to state or local law or to professional guidelines of the American Physical Therapy Association, the American Occupational Therapy Association, or the American Speech-Language Hearing Association. It is encouraged but not required that narratives that specifically justify the medical necessity of services be included in order to support approval when those services are reviewed. (See also section 220.2-Reasonable and Necessary Outpatient Rehabilitation Therapy Services)

Contractors shall consider the entire record when reviewing claims for medical necessity so that the absence of an individual item of documentation does not negate the medical necessity of a service when the documentation as a whole indicates the service is necessary. Services are medically necessary if the documentation indicates they meet the requirements for medical necessity including that they are skilled, rehabilitative services, provided by clinicians (or qualified professionals when appropriate) with the approval of a physician/NPP, safe, and effective (i.e., progress indicates that the care is effective in rehabilitation of function).

B. Documentation Required

List of required documentation. These types of documentation of therapy services are expected to be submitted in response to any requests for documentation, unless the contractor requests otherwise. The timelines are minimum requirements for Medicare payment. Document as often as the clinician's judgment dictates but no less than the frequency required in Medicare policy:

- Evaluation /and Plan of Care (may be one or two documents). Include the initial evaluation and any re-evaluations relevant to the episode being reviewed;

- Certification (physician/NPP approval of the plan) and recertifications when records are requested after the certification/recertification is due. See definitions in section 220 and certification policy in section 220.1.3 of this chapter. Certification of the plan is required for payment made after the certification interval.

- Progress Reports when records are requested after the reports are due. (See definitions in section 220 and descriptions in 220.3 D);

- Treatment Notes for each treatment day (may also serve as Progress Reports when required information is included in the notes); and

- A separate justification statement may be included either as a separate document or within the other documents if the provider/supplier wishes to assure the contractor understands their reasoning for services that are more extensive than is typical for the condition treated. A separate statement is not required if the record justifies treatment without further explanation.

Limits on Requirements. Contractors shall not require more specific documentation unless other Medicare manual policies require it. Contractors may request further information to be included in these documents concerning specific cases under review when that information is relevant, but not submitted with records.

Dictated Documentation. For Medicare purposes, dictated therapy documentation is considered completed on the day it was dictated. The qualified professional may edit and electronically sign the documentation at a later date.

Dates for Documentation. The date the documentation was made is important only to establish the date of the initial the plan of care because therapy cannot begin until the plan is established unless treatment is performed or supervised by the same clinician who establishes the plan. However, contractors may require that treatment notes and progress reports be entered into the record within 1 week of the last date to which the Progress Report or Treatment Note refers. For example, if treatment began on the first of the month at a frequency of twice a week, a Progress Report would be required at the end of the month. Contractors may require that the Progress Report that describes that month of treatment be dated not more than 1 week after the end of the month described in the report.

Document Information to Meet Requirements. In documenting records, clinicians must be familiar with the requirements for covered and payable outpatient therapy services as described in the manuals. For example, the records should justify:

- The patient is under the care of a physician/NPP;

Physician/NPP care shall be documented by physician/NPP certification (approval) of the plan of care; and

Although not required, other evidence of physician/NPP involvement in the patient's care may include, for example: order/referral, conference, team meeting notes,

- Services require the skills of a therapist.

Services must not only be provided by the qualified professional or qualified personnel, but they must require, for example, the expertise, knowledge, clinical judgment, decision making and abilities of a therapist that assistants, qualified personnel, caretakers or the patient cannot provide independently. A clinician may not merely supervise, but must apply the skills of a therapist by actively participating in the treatment of the patient during each Progress Report Period. In addition, a therapist's skills may be documented, for example, by the clinician's descriptions of their skilled treatment, the changes made to the treatment due to a clinician's assessment of the patient's needs on a particular treatment day or changes due to progress the clinician judged sufficient to modify the treatment toward the next more complex or difficult task.

A therapist's skill may also be required for safety reasons, if an unstable fracture requires the skill of a therapist to do an activity that might otherwise be done independently by the patient at home. Or the skill of a therapist might be required for a patient learning compensatory swallowing techniques to perform cervical auscultation and identify changes in voice and breathing that might signal aspiration. After the patient is judged safe for independent use of these compensatory techniques, the skill of a therapist is not required to feed the patient, or check what was consumed.

- Services are of appropriate type, frequency, intensity and duration for the individual needs of the patient.

Documentation should establish the variables that influence the patient's condition, especially those factors that influence the clinician's decision to provide more services than are typical for the individual's condition.

Clinicians and contractors shall determine typical services using published professional literature and professional guidelines. The fact that services are typically billed is not necessarily evidence that the services are typically appropriate. Services that exceed those typically billed should be carefully documented to justify their necessity, but are payable if the individual patient benefits from medically necessary services. Also, some services or episodes of treatment should be less than those typically billed, when the individual patient reaches goals sooner than is typical.

Documentation should establish through objective measurements that the patient is making progress toward goals. Note that regression and plateaus can happen during treatment. It is recommended that the reasons for lack of progress be noted and the justification for continued treatment be documented if treatment continues after regression or plateaus.

Needs of the Patient. When a service is reasonable and necessary, the patient also needs the services. Contractors determine the patient's needs through knowledge of the individual patient's condition, and any complexities that impact that condition, as described in documentation (usually in the evaluation, re-evaluation, and Progress Report). Factors that contribute to need vary, but in general they relate to such factors as the patient's diagnoses, complicating factors, age, severity, time since onset/acuity, self-efficacy/motivation, cognitive ability, prognosis, and/or medical, psychological and social stability. Patients who need therapy generally respond to therapy, so changes in objective and sometimes to subjective measures of improvement also help establish the need for services. The use of scientific evidence, obtained from professional literature, and sequential measurements of the patient's condition during treatment is encouraged to support the potential for continued improvement that may justify the patients need for therapy.

C. Evaluation/Re-Evaluation and Plan of Care

The initial evaluation, or the plan of care including an evaluation, should document the necessity for a course of therapy through objective findings and subjective patient self-reporting. Utilize the guidelines of the American Physical Therapy Association, the American Occupational Therapy Association, or the American Speech-Language and Hearing Association as guidelines, and not as policy. Only a clinician may perform an initial examination, evaluation, re-evaluation and assessment or establish a diagnosis or a plan of care. A clinician may include, as part of the evaluation or re-evaluation, objective measurements or observations made by a PTA or OTA within their scope of practice, but the clinician must actively and personally participate in the evaluation or re-evaluation. The clinician may not merely summarize the objective findings of others or make judgments drawn from the measurements and/or observations of others.

Documentation of the evaluation should list the conditions and complexities and, where it is not obvious, describe the impact of the conditions and complexities on the prognosis and/or the plan for treatment such that it is clear to the contractor who may review the record that the services planned are appropriate for the individual.

Evaluation shall include:

- A diagnosis (where allowed by State and local law) and description of the specific problem(s) to be evaluated and/or treated. The diagnosis should be specific and as relevant to the problem to be treated as possible. In many cases, both a medical diagnosis (obtained from a physician/NPP) and an impairment based treatment diagnosis related to treatment are relevant. The treatment diagnosis may or may not be identified by the therapist, depending on their scope of practice. Where a diagnosis is not allowed, use a condition description similar to the appropriate ICD-9 code. For example the medical diagnosis made by the physician is CVA; however, the treatment diagnosis or condition description for PT may be abnormality of gait, for OT, it may be hemiparesis, and for SLP, it may be dysphagia. For PT and OT, be sure to include the body part evaluated.

Include all conditions and complexities that may impact the treatment. A description might include, for example, the premorbid function, date of onset, and current function;

- **Results of one of the following four measurement instruments are recommended, but not required:**

National Outcomes Measurement System (NOMS) by the American Speech-Language Hearing Association

Patient Inquiry by Focus On Therapeutic Outcomes, Inc. (FOTO)

Activity Measure – Post Acute Care (AM-PAC)

OPTIMAL by Cedaron through the American Physical Therapy Association

- **If results of one of the four instruments above is not recorded, the record shall contain instead the following information indicated by asterisks (*) and should contain (but is not required to contain) all of the following, as applicable**. Since published research supports its impact on the need for treatment, information in the following indented bullets may also be included with the results of the above four instruments in the evaluation report at the clinician's discretion. This information may be incorporated into a test instrument or separately reported within the required documentation. If it changes, update this information in the re-evaluation, and/or Treatment Notes, and/or Progress Reports, and/or in a separate record. When it is provided, contractors shall take this documented information into account to determine whether services are reasonable and necessary.

Documentation supporting illness severity or complexity including, e.g.,

  - Identification of other health services concurrently being provided for this condition (e.g., physician, PT, OT, SLP, chiropractic, nurse, respiratory therapy, social services, psychology, nutritional/dietetic services, radiation therapy, chemotherapy, etc.), and/ or

  - Identification of durable medical equipment needed for this condition, and/or

  - Identification of the number of medications the beneficiary is talking (and type if known); and/or

- If complicating factors (complexities) affect treatment, describe why or how. For example: Cardiac dysrhythmia is not a condition for which a therapist would directly treat a patient, but in some patients such dysrhythmias may so directly and significantly affect the pace of progress in treatment for other conditions as to require an exception to caps for necessary services. Documentation should indicate how the progress was affected by the complexity. Or, the severity of the patient's condition as reported on a functional measurement tool may be so great as to suggest extended treatment is anticipated; and/or

- Generalized or multiple conditions. The beneficiary has, in addition to the primary condition being treated, another disease or condition being treated, or generalized musculoskeletal conditions, or conditions affecting multiple sites and these conditions will directly and significantly impact the rate of recovery; and/or.

- Mental or cognitive disorder. The beneficiary has a mental or cognitive disorder in addition to the condition being treated that will directly and significantly impact the rate of recovery; and/or.

- Identification of factors that impact severity including e.g., age, time since onset, cause of the condition, stability of symptoms, how typical/atypical are the symptoms of the diagnosed condition, availability of an intervention/treatment known to be effective, predictability of progress.

Documentation supporting medical care prior to the current episode, if any, (or document none) including, e.g.,

- Record of discharge from a Part A qualifying inpatient, SNF, or home health episode within 30 days of the onset of this outpatient therapy episode, or

- Identification of whether beneficiary was treated for this same condition previously by the same therapy discipline (regardless of where prior services were furnished; and

- Record of a previous episode of therapy treatment from the same or different therapy discipline in the past year.

Documentation required to indicate beneficiary health related to quality of life, specifically,

- The beneficiary's response to the following question of self-related health: "At the present time, would you say that your health is excellent, very good, fair, or poor?" If the beneficiary is unable to respond, indicate why; and

Documentation required to indicate beneficiary social support including, specifically,

- Where does the beneficiary live (or intend to live) at the conclusion of this outpatient therapy episode? (e.g., private home, private apartment, rented room, group home, board and care apartment, assisted living, SNF), and

- Who does beneficiary live with (or intend to live with) at the conclusion of this outpatient therapy episode? (e.g., lives alone, spouse/significant other, child/children, other relative, un related person(s), personal care attendant), and

- Does the beneficiary require this outpatient therapy plan of care in order to return to a premorbid (or reside in a new) living environment, and

- Does the beneficiary require this outpatient therapy plan of care in order to reduce Activities of Daily Living (ADL) or Instrumental Activities of Daily Living or (IADL) assistance to a premorbid level or to reside in a new level of living environment (document prior level of independence and current assistance needs); and

*Documentation required to indicate objective, measurable beneficiary physical function including, e.g.

- Functional assessment individual item and summary scores (and comparisons to prior assessment scores) from commercially available therapy outcomes instruments other than those listed above; or

- Functional assessment scores (and comparisons to prior assessment scores) from tests and measurements validated in the professional literature that are appropriate for the condition/function being measured; or

- Other measurable progress towards identified goals for functioning in the home environment at the conclusion of this therapy episode of care.

- Clinician's clinical judgments or subjective impressions that describe the current functional status of the condition being evaluated, when they provide further information to supplement measurement tools; and

- A determination that treatment is not needed, or, if treatment is needed a prognosis for return to premorbid condition or maximum expected condition with expected time frame and a plan of care.

NOTE: When the Evaluation Serves as the Plan of Care. When an evaluation is the only service provided by a provider/supplier in an episode of treatment, the evaluation serves as the plan of care if it contains a diagnosis, or in states where a therapist may not diagnose, a description of the condition from which a diagnosis may be determined by the referring physician/NPP. The goal, frequency, intensity and duration of treatment are implied in the diagnosis and one-time service. The referral/order of a physician/NPP is the certification that the evaluation is needed and the patient is under the care of a physician. Therefore, when evaluation is the only service, a referral/order and evaluation are the only required documentation. If the patient presented for evaluation without a referral or order and does not require treatment, a physician referral/order or certification of the evaluation is required for payment of the evaluation. A referral/order dated after the evaluation shall be interpreted as certification of the plan to evaluate the patient.

The time spent in evaluation shall not also be billed as treatment time. Evaluation minutes are untimed and are part of the total treatment minutes, but minutes of evaluation shall not be included in the minutes for timed codes reported in the treatment notes.

Re-evaluations shall be included in the documentation sent to contractors when a re-evaluation has been performed. See the definition in section 220. Re-evaluations are usually focused on the current treatment and might not be as extensive as initial evaluations. Continuous assessment of the patient's progress is a component of ongoing therapy services and is not payable as a re-evaluation. A re-evaluation is not a routine, recurring service but is focused on evaluation of progress toward current goals, making a professional judgment about continued care, modifying goals and/or treatment or terminating services. A formal re-evaluation is covered only if the documentation supports the need for further tests and measurements after the initial evaluation. Indications for a re-evaluation include new clinical findings, a significant change in the patient's condition, or failure to respond to the therapeutic interventions outlined in the plan of care.

A re-evaluation may be appropriate prior to planned discharge for the purposes of determining whether goals have been met, or for the use of the physician or the treatment setting at which treatment will be continued.

A re-evaluation is focused on evaluation of progress toward current goals and making a professional judgment about continued care, modifying goals and/or treatment or terminating services. Reevaluation requires the same professional skills as evaluation. The minutes for re-evaluation are documented in the same manner as the minutes for

evaluation. Current Procedural Terminology does not define a re-evaluation code for speech-language pathology; use the evaluation code.

Plan of Care. See section 220.1.2 for requirements of the plan. The evaluation and plan may be reported in two separate documents or a single combined document.

D. Progress Report

The Progress Report provides justification for the medical necessity of treatment.

Contractors shall determine the necessity of services based on the delivery of services as directed in the plan and as documented in the Treatment Notes and Progress Report. For Medicare payment purposes, information required in Progress Reports shall be written by a clinician that is, either the physician/NPP who provides or supervises the services, or by the therapist who provides the services and supervises an assistant. It is not required that the referring or supervising physician/NPP sign the Progress Reports written by a PT, OT or SLP.

Timing. The minimum Progress Report Period shall be at least once every 10 treatment days or at least once during each certification interval, whichever is less. The beginning of the first reporting period is the first day of the episode of treatment regardless of whether the service provided on that day is an evaluation, re-evaluation or treatment. Regardless of the date on which the report is actually written (and dated), the end of the Progress Report Period is either a date chosen by the clinician, the 10^{th} treatment day, or the last day of the certification interval, whichever is shorter. The next treatment day begins the next reporting period. The Progress Report Period requirements are complete when both the elements of the Progress Report and the clinician's active participation in treatment have been documented.

For example, for a patient evaluated on Monday, October 1 and being treated five times a week, on weekdays: On October 5, (before it is required), the clinician may choose to write a Progress Report for the last week's treatment (from October 1 to October 5). October 5 ends the reporting period and the next treatment on Monday, October 8 begins the next reporting period. If the clinician does not choose to write a report for the next week, the next report is required to cover October 8 through October 19, which would be 10 treatment days.

Absences. Holidays, sick days or other patient absences may fall within the Progress Report Period. Days on which a patient does not encounter qualified professional or qualified personnel for treatment, evaluation or re-evaluation do not count as treatment days. However, absences do not affect the requirement for a Progress Report at least once during each certification interval. If the patient is absent unexpectedly at the end of the reporting period, when the clinician has not yet provided the required active participation during that reporting period, a Progress Report is still required, but without the clinician's active participation in treatment, the requirements of the Progress Report Period are incomplete.

Delayed Reports. If the clinician has not written a Progress Report before the end of the Progress Reporting Period, it shall be written within 7calendar days of the end of the reporting period. If the clinician did not participate actively in treatment during the Progress Report Period, documentation of the delayed active participation shall be entered in the Treatment Note as soon as possible. The Treatment Note shall explain the reason for the clinician's missed active participation. Also, the Treatment Note shall document the clinician's guidance to the assistant or qualified personnel to justify that the skills of a therapist were required during the reporting period. It is not necessary to include in this Treatment Note any information already recorded in prior Treatment Notes or Progress Reports.

The contractor shall make a clinical judgment whether continued treatment by assistants or qualified personnel is reasonable and necessary when the clinician has not actively participated in treatment for longer than one reporting period. Judgment shall be based on the individual case and documentation of the application of the clinician's skills to guide the assistant or qualified personnel during and after the reporting period.

Early Reports. Often, Progress Reports are written weekly, or even daily, at the discretion of the clinician. Clinicians are encouraged, but not required to write Progress Reports more frequently than the minimum required in order to allow anyone who reviews the records to easily determine that the services provided are appropriate, covered and payable.

Elements of Progress Reports may be written in the Treatment Notes if the provider/supplier or clinician prefers. If each element required in a Progress Report is included in the Treatment Notes at least once during the Progress Report Period, then a separate Progress Report is not required. Also, elements of the Progress Report may be incorporated into a revised Plan of Care. Although the Progress Report written by a therapist does not require a physician/NPP signature when written as a stand-alone document, the Plan of Care accompanied by the Progress Report shall be re-certified by a physician/NPP.

Progress Reports for Services Billed Incident to a Physician's Service. The policy for incident to services requires, for example, the physician's initial service, direct supervision of therapy services, and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment (See section 60.1B of this chapter. Also, see the billing requirements for services incident to a physician in Pub. 100-04, chapter 26, Items 17, 19, 24, and 31.) Therefore, supervision and reporting requirements for supervising physician/NPPs supervising staff are the same as those for PTs and OTs supervising PTAs and OTAs with certain exceptions noted below.

When a therapy service is provided by a therapist, supervised by a physician/NPP and billed incident to the services of the physician/NPP, the Progress Report shall be written and signed by the therapist who provides the services.

When the services incident to a physician are provided by qualified personnel who are not therapists, the ordering or supervising physician/NPP must personally provide at least one treatment session during each Progress Report Period and sign the Progress Report.

Documenting Clinician Participation in Treatment in the Progress Report. Verification of the clinician's required participation in treatment during the Progress Report Period shall be documented by the clinician's signature on the Treatment Note and/or on the Progress Report. When unexpected discontinuation of treatment occurs, contractors shall not require a clinician's participation in treatment for the incomplete reporting period.

The Discharge Note is required for each episode of treatment. The Discharge Note shall be a Progress Report written by a clinician, and shall cover the reporting period from the last Progress Report to the date of discharge. In the case of a discharge unanticipated in the plan or previous Progress Report, the clinician may base any judgments required to write the report on the Treatment Notes and verbal reports of the assistant or qualified personnel. In the case of a discharge anticipated within 3 treatment days of the Progress Report, the clinician may provide objective goals which, when met, will authorize the assistant or qualified personnel to discharge the patient. In that case, the clinician should verify that the services provided prior to discharge continued to require the skills of a therapist, and services were provided or supervised by a clinician. The Discharge Note shall include all treatment provided since the last Progress Report and indicate that the therapist reviewed the notes and agrees to the discharge.

At the discretion of the clinician, the discharge note may include additional information; for example, it may summarize the entire episode of treatment, or justify services that may have extended beyond those usually expected for the patient's condition. Clinicians should consider the discharge note the last opportunity to justify the medical necessity of the entire treatment episode in case the record is reviewed. The record should be reviewed and organized so that the required documentation is ready for presentation to the contractor if requested.

Assistant's Participation in the Progress Report

Physical Therapist Assistants or Occupational Therapy Assistants may write elements of the Progress Report dated between clinician reports. Reports written by assistants are not complete Progress Reports. The clinician must write a Progress Report during each Progress Report Period regardless of whether the assistant writes other reports. However, reports written by assistants are part of the record and need not be copied into the clinicians report. Progress Reports written by assistants supplement the reports of clinicians and shall include:

- Date of the beginning and end of the reporting period that this report refers to;

- Date that the report was written (not required to be within the reporting period);

- Signature, and professional identification, or for dictated documentation, the identification of the qualified professional who wrote the report and the date on which it was dictated;

- Objective reports of the patient's subjective statements, if they are relevant. For example, "Patient reports pain after 20 repetitions". Or, "The patient was not feeling well on 11/05/06 and refused to complete the treatment session." ; and

- Objective measurements (preferred) or description of changes in status relative to each goal currently being addressed in treatment, if they occur. Note that assistants may not make clinical judgments about why progress was or was not made, but may report the progress objectively. For example: "increasing strength" is not an objective measurement, but "patient ambulates 15 feet with maximum assistance" is objective.

Descriptions shall make identifiable reference to the goals in the current plan of care. Since only long term goals are required in the plan of care, the Progress Report may be used to add, change or delete short term goals. Assistants may change goals only under the direction of a clinician. When short term goal changes are dictated to an assistant or to qualified personnel, report the change, clinician's name, and date. Clinicians verify these changes by cosignatures on the report or in the clinician's Progress Report. (See section 220.1.2(C) to modify the plan for changes in long term goals).

The evaluation and plan of care are considered incorporated into the Progress Report, and information in them is not required to be repeated in the report. For example, if a time interval for the treatment is not specifically stated, it is assumed that the goals refer to the plan of care active for the current Progress Report Period. If a body part is not specifically noted, it is assumed the treatment is consistent with the evaluation and plan of care.

Any consistent method of identifying the goals may be used. Preferably, the long term goals may be numbered (1, 2, 3,) and the short term goals that relate to the long term goals may be numbered and lettered 1.A, 1.B, etc. The identifier of a goal on the plan of care may not be changed during the episode of care to which the plan refers. A clinician, an assistant on the order of a therapist or qualified personnel on the order of a physician/NPP shall add new goals with new identifiers or letters. Omit reference to a goal after a clinician has reported it to be met, and that clinician's signature verifies the change.

<u>Content of Clinician (Therapist, Physician/NPP) Progress Reports</u>

In addition to the requirements above for notes written by assistants, the Progress Report of a clinician shall also include:

- Assessment of improvement, extent of progress (or lack thereof) toward each goal;

- Plans for continuing treatment, reference to additional evaluation results, and/or treatment plan revisions should be documented in the clinician's Progress Report; and

- Changes to long or short term goals, discharge or an updated plan of care that is sent to the physician/NPP for certification of the next interval of treatment.

A re-evaluation should not be required before every Progress Report routinely, but may be appropriate when assessment suggests changes not anticipated in the original plan of care.

Care must be taken to assure that documentation justifies the necessity of the services provided during the reporting period, particularly when reports are written at the minimum frequency. Justification for treatment must include, for example, objective evidence or a clinically supportable statement of expectation that:

- The patient's condition has the potential to improve or is improving in response to therapy;

- Maximum improvement is yet to be attained; and

- There is an expectation that the anticipated improvement is attainable in a reasonable and generally predictable period of time.

Objective evidence consists of standardized patient assessment instruments, outcome measurements tools or measurable assessments of functional outcome. Use of objective measures at the beginning of treatment, during and/or after treatment is recommended to quantify progress and support justifications for continued treatment. Such tools are not required, but their use will enhance the justification for needed therapy.

Example: The Plan states diagnosis is 787.2- Dysphagia secondary to other late effects of CVA. Patient is on a restricted diet and wants to drink thick liquids. Therapy is planned 3X week, 45 minute sessions for 6 weeks. Long term goal is to consume a mechanical soft diet with thin liquids without complications such as aspiration pneumonia. Short Term Goal 1: Patient will improve rate of laryngeal elevation/timing of closure by using the super-supraglottic swallow on saliva swallows without cues on 90% of trials. Goal 2: Patient will compensate for reduced laryngeal elevation by controlling bolus size to ½ teaspoon without cues 100%. The Progress Report for 1/3/06 to 1/29/06 states: 1. Improved to 80% of trials; 2. Achieved. Comments: Highly motivated; spouse assists with practicing, compliant with current restrictions. New Goal: "5. Patient will implement above strategies to swallow a sip of water without coughing for 5 consecutive trials. Mary Johns, CCC-SLP, 1/29/06." Note the provider is billing 92526 three times a week, consistent with the plan; progress is documented; skilled treatment is documented.

E. Treatment Note

The purpose of these notes is simply to create a record of all treatments and skilled interventions that are provided and to record the time of the services in order to justify the use of billing codes on the claim. Documentation is required for every treatment day, and every therapy service. The format shall not be dictated by contractors and may vary depending on the practice of the responsible clinician and/or the clinical setting.

The Treatment Note is not required to document the medical necessity or appropriateness of the ongoing therapy services. Descriptions of skilled interventions should be included in the plan or the Progress Reports and are allowed, but not required daily. Non-skilled interventions need not be recorded in the Treatment Notes as they are not billable. However, notation of non-skilled treatment or report of activities performed by the patient or non-skilled staff may be reported voluntarily as additional information if they are relevant and not billed. Specifics such as number of repetitions of an exercise and other details included in the plan of care need not be repeated in the Treatment Notes unless they are changed from the plan.

Documentation of each Treatment shall include the following required elements:

- Date of treatment; and

- Identification of each specific intervention/modality provided and billed, for both timed and untimed codes, in language that can be compared with the billing on the claim to verify correct coding. Record each service provided that is represented by a timed code, regardless of whether or not it is billed, because the unbilled timed services may impact the billing; and

- Total timed code treatment minutes and total treatment time in minutes. Total treatment time includes the minutes for timed code treatment and untimed code treatment. Total treatment time does not include time for services that are not billable (e.g., rest periods). For Medicare purposes, it is not required that unbilled services that are not part of the total treatment minutes be recorded, although they may be included voluntarily to provide an accurate description of the treatment, show consistency with the plan, or comply with state or local policies. The amount of time for each specific intervention/modality provided to the patient may also be recorded voluntarily, but contractors shall not require it, as it is indicated in the billing. The billing and the total timed code treatment minutes must be consistent. See CMS IOM, Pub. 100-04, chapter 5, section 20.2 for description of billing timed codes; and

- Signature and professional identification of the qualified professional who furnished or supervised the services and a list of each person who contributed to that treatment (i.e., the signature of Kathleen Smith, PTA, with notation of the help of Judy Jones, PT, supervisor, when permitted by state and local law). The signature and identification of the supervisor need not be on each Treatment Note, unless the supervisor

actively participated in the treatment, but the supervisor's identification must be clear in the Plan of Care, or Progress Report. When the treatment is supervised without active participation by the supervisor, the supervisor is not required to cosign the Treatment Note written by a qualified professional. When a supervisor is absent, the presence of a similarly qualified supervisor on that day is sufficient documentation and it is not required that the substitute supervisor sign or be identified in the documentation. Since a clinician must sign the Progress Report, the name and professional identification of the supervisor shall be included in the Progress Report.

If a treatment is added or changed under the direction of a clinician during the treatment days between the interval Progress Reports, the change must be recorded and justified on the medical record, either in the Treatment note or the Progress Report, as determined by the policies of the provider/supplier. New exercises added or changes made to the exercise program help justify that the services are skilled. For example: The original plan was for therapeutic activities, gait training and neuromuscular re-education. "On Feb. 1 clinician added electrical stim. to address shoulder pain."

Documentation of each Treatment may also include the following optional elements to be mentioned only if the qualified professional recording the note determines they are appropriate and relevant. If these are not recorded daily, any relevant information should be included in the progress report.

- Patient self-report;
- Adverse reaction to intervention;
- Communication/consultation with other providers (e.g., supervising clinician, attending physician, nurse, another therapist, etc.);
- Significant, unusual or unexpected changes in clinical status;
- Equipment provided; and/or
- Any additional relevant information the qualified professional finds appropriate.

See CMS IOM Pub. 100-04, chapter 5, section 20.2 for instructions on how to count minutes. It is important that the total number of timed treatment minutes support the billing of units on the claim, and that the total treatment time reflects services billed as untimed codes.

230 - Practice of Physical Therapy, Occupational Therapy, and Speech-Language Pathology

(Rev.63, Issued: 12-29-06, Effective: 01-01-07, Implementation: on or before 01-29-07)

A. Group Therapy Services. Contractors pay for outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services provided simultaneously to two or more individuals by a practitioner as group therapy services (97150). The individuals can be, but need not be performing the same activity. The physician or therapist involved in group therapy services must be in constant attendance, but one-on-one patient contact is not required.

B. Therapy Students

1. General

Only the services of the therapist can be billed and paid under Medicare Part B. The services performed by a student are not reimbursed even if provided under "line of sight" supervision of the therapist; however, the presence of the student "in the room" does not make the service unbillable. Pay for the direct (one-to-one) patient contact services of the physician or therapist provided to Medicare Part B patients. Group therapy services performed by a therapist or physician may be billed when a student is also present "in the room".

EXAMPLES:

Therapists may bill and be paid for the provision of services in the following scenarios:

- The qualified practitioner is present and in the room for the entire session. The student participates in the delivery of services when the qualified practitioner is directing the service, making the skilled judgment, and is responsible for the assessment and treatment.

- The qualified practitioner is present in the room guiding the student in service delivery when the therapy student and the therapy assistant student are participating in the provision of services, and the practitioner is not engaged in treating another patient or doing other tasks at the same time.

- The qualified practitioner is responsible for the services and as such, signs all documentation. (A student may, of course, also sign but it is not necessary since the Part B payment is for the clinician's service, not for the student's services).

2. Therapy Assistants as Clinical Instructors

Physical therapist assistants and occupational therapy assistants are not precluded from serving as clinical instructors for therapy students, while providing services within their scope of work and performed under the direction and supervision of a licensed physical or occupational therapist to a Medicare beneficiary.

3. Services Provided Under Part A and Part B

The payment methodologies for Part A and B therapy services rendered by a student are different. Under the MPFS (Medicare Part B), Medicare pays for services provided by physicians and practitioners that are specifically authorized by statute. Students do not meet the definition of practitioners under Medicare Part B. Under SNF PPS, payments are based upon the case mix or Resource Utilization Group (RUG) category that describes the patient. In the rehabilitation groups, the number of therapy minutes delivered to the patient determines the RUG category. Payment levels for each category are based upon the costs of caring for patients in each group rather than providing specific payment for each therapy service as is done in Medicare Part B.

230.1 - Practice of Physical Therapy

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

A. General

Physical therapy services are those services provided within the scope of practice of physical therapists and necessary for the diagnosis and treatment of impairments, functional limitations, disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.)

B. Qualified Physical Therapist Defined

Reference: 42CFR484.4

A qualified physical therapist for program coverage purposes is a person who is licensed as a physical therapist by the state in which he or she is practicing and meets one of the following requirements:

- Has graduated from a physical therapy curriculum approved by (1) the American Physical Therapy Association, or by (2) the Committee on Allied Health Education and Accreditation of the American Medical Association, or (3) Council on Medical Education of the American Medical Association, and the American Physical Therapy Association; or
- Prior to January 1, 1966, (1) was admitted to membership by the American Physical Therapy Association, or (2) was admitted to registration by the American Registry of Physical Therapists, or (3) has graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education; or
- Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination conducted, approved or sponsored by the Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking qualification as a physical therapist after December 31, 1977; or
- Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

- If trained outside the United States, (1) was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy, (2) meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

C. Services of Physical Therapy Support Personnel

Reference: 42CFR 484.4

A physical therapist assistant (PTA) is a person who is licensed as a physical therapist assistant, if applicable, by the State in which practicing, and

- Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or
- Has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a PTA after December 31, 1977.

The services of PTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising physical therapist. PTAs may not provide evaluation services, make clinical judgments or decisions or take responsibility for the service. They act at the direction and under the supervision of the treating physical therapist and in accordance with state laws.

A physical therapist must supervise PTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for PTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation agencies, and public health agencies, 42CFR485.713 indicates that when a PTA provides services, either on or off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of a PTA shall not be billed as services incident to a physician/NPP's service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., theraband, hand putty, electrodes) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the physical therapist, and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130.

Services provided by aides, even if under the supervision of a therapist, are not therapy services in the outpatient setting and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D. Application of Medicare Guidelines to PT Services

This subsection will be used in the future to illustrate the application of the above guidelines to some of the physical therapy modalities and procedures utilized in the treatment of patients.

230.2 - Practice of Occupational Therapy

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

A. General

Occupational therapy services are those services provided within the scope of practice of occupational therapists and necessary for the diagnosis and treatment of impairments, functional disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.)

Occupational therapy is medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning. Such therapy may involve:

The evaluation, and reevaluation as required, of a patient's level of function by administering diagnostic and prognostic tests;

The selection and teaching of task-oriented therapeutic activities designed to restore physical function; e.g., use of woodworking activities on an inclined table to restore shoulder, elbow, and wrist range of motion lost as a result of burns;

The planning, implementing, and supervising of individualized therapeutic activity programs as part of an overall "active treatment" program for a patient with a diagnosed psychiatric illness; e.g., the use of sewing activities which require following a pattern to reduce confusion and restore reality orientation in a schizophrenic patient;

The planning and implementing of therapeutic tasks and activities to restore sensory-integrative function; e.g., providing motor and tactile activities to increase sensory input and improve response for a stroke patient with functional loss resulting in a distorted body image;

The teaching of compensatory technique to improve the level of independence in the activities of daily living, for example:

- Teaching a patient who has lost the use of an arm how to pare potatoes and chop vegetables with one hand;
- Teaching an upper extremity amputee how to functionally utilize a prosthesis;
- Teaching a stroke patient new techniques to enable the patient to perform feeding, dressing, and other activities as independently as possible; or
- Teaching a patient with a hip fracture/hip replacement techniques of standing tolerance and balance to enable the patient to perform such functional activities as dressing and homemaking tasks.

The designing, fabricating, and fitting of orthotics and self-help devices; e.g., making a hand splint for a patient with rheumatoid arthritis to maintain the hand in a functional position or constructing a device which would enable an individual to hold a utensil and feed independently; or

Vocational and prevocational assessment and training, subject to the limitations specified in item B below.

Only a qualified occupational therapist has the knowledge, training, and experience required to evaluate and, as necessary, reevaluate a patient's level of function, determine whether an occupational therapy program could reasonably be expected to improve, restore, or compensate for lost function and, where appropriate, recommend to the physician/NPP a plan of treatment.

B. Qualified Occupational Therapist Defined

Reference: 42CFR484.4

A qualified occupational therapist for program coverage purposes is an individual who meets one of the following requirements:

- Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education of the American Medical Association and the American Occupational Therapy Association;
- Is eligible for the National Registration Examination of the American Occupational Therapy Association; or
- Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

C. Services of Occupational Therapy Support Personnel

Reference: 42CFR 484.4

An occupational therapy assistant (OTA) is a person who:

- Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or
- Has 2 years of appropriate experience as an occupational therapy assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

The services of OTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising occupational therapist. OTAs may not provide evaluation services, make clinical judgments or

decisions or take responsibility for the service. They act at the direction and under the supervision of the treating occupational therapist and in accordance with state laws.

An occupational therapist must supervise OTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for OTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation agencies, and public health agencies, 42CFR485.713 indicates that when an OTA provides services, either on or off the organization's premises, those services are supervised by a qualified occupational therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of an OTA shall not be billed as services incident to a physician/NPP's service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., looms, ceramic tiles, or leather) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the occupational therapist and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130 of this manual.

Services provided by aides, even if under the supervision of a therapist, are not therapy services in the outpatient setting and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D. Application of Medicare Guidelines to Occupational Therapy Services

Occupational therapy may be required for a patient with a specific diagnosed psychiatric illness. If such services are required, they are covered assuming the coverage criteria are met. However, where an individual's motivational needs are not related to a specific diagnosed psychiatric illness, the meeting of such needs does not usually require an individualized therapeutic program. Such needs can be met through general activity programs or the efforts of other professional personnel involved in the care of the patient. Patient motivation is an appropriate and inherent function of all health disciplines, which is interwoven with other functions performed by such personnel for the patient. Accordingly, since the special skills of an occupational therapist are not required, an occupational therapy program for individuals who do not have a specific diagnosed psychiatric illness is not to be considered reasonable and necessary for the treatment of an illness or injury. Services furnished under such a program are not covered.

Occupational therapy may include vocational and prevocational assessment and training. When services provided by an occupational therapist are related solely to specific employment opportunities, work skills, or work settings, they are not reasonable or necessary for the diagnosis or treatment of an illness or injury and are not covered. However, carriers and intermediaries exercise care in applying this exclusion, because the assessment of level of function and the teaching of compensatory techniques to improve the level of function, especially in activities of daily living, are services which

occupational therapists provide for both vocational and nonvocational purposes. For example, an assessment of sitting and standing tolerance might be nonvocational for a mother of young children or a retired individual living alone, but could also be a vocational test for a sales clerk. Training an amputee in the use of prosthesis for telephoning is necessary for everyday activities as well as for employment purposes. Major changes in life style may be mandatory for an individual with a substantial disability. The techniques of adjustment cannot be considered exclusively vocational or nonvocational.

230.3 - Practice of Speech-Language Pathology

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

A. General

Speech-language pathology services are those services provided within the scope of practice of speech-language pathologists and necessary for the diagnosis and treatment of speech and language disorders, which result in communication disabilities and for the diagnosis and treatment of swallowing disorders (dysphagia), regardless of the presence of a communication disability. (See Pub. 100-03, chapter 1, §170.3)

B. Qualified Speech-Language Pathologist Defined

A qualified speech-language pathologist for program coverage purposes meets one of the following requirements:

- The education and experience requirements for a Certificate of Clinical Competence in (speech-language pathology or audiology) granted by the American Speech-Language Hearing Association; or
- Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Speech-language pathologists may not enroll and submit claims directly to Medicare. The services of speech-language pathologists may be billed by providers such as rehabilitation agencies, HHAs, CORFs, hospices, outpatient departments of hospitals, and suppliers such as physicians, NPPs, physical and occupational therapists in private practice.

C. Services of Speech-Language Pathology Support Personnel

Services of speech-language pathology assistants are not recognized for Medicare coverage. Services provided by speech-language pathology assistants, even if they are licensed to provide services in their states, will be considered unskilled services and denied as not reasonable and necessary if they are billed as therapy services.

Services provided by aides, even if under the supervision of a therapist, are not therapy services and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D. Application of Medicare Guidelines to Speech-Language Pathology Services

1. Evaluation Services

Speech-language pathology evaluation services are covered if they are reasonable and necessary and not excluded as routine screening by §1862(a)(7) of the Act. The speech-language pathologist employs a variety of formal and informal speech, language, and dysphagia assessment tests to ascertain the type, causal factor(s), and severity of the speech and language or swallowing disorders. Reevaluation of patients for whom speech, language and swallowing were previously contraindicated is covered only if the patient exhibits a change in medical condition. However, monthly reevaluations; e.g., a Western Aphasia Battery, for a patient undergoing a rehabilitative speech-language pathology program, are considered a part of the treatment session and shall not be covered as a separate evaluation for billing purposes. Although hearing screening by the speech-language pathologist may be part of an evaluation, it is not billable as a separate service.

2. Therapeutic Services

The following are examples of common medical disorders and resulting communication deficits, which may necessitate active rehabilitative therapy. This list is not all-inclusive:

Cerebrovascular disease such as cerebral vascular accidents presenting with dysphagia, aphasia/dysphasia, apraxia, and dysarthria;

Neurological disease such as Parkinsonism or Multiple Sclerosis with dysarthria, dysphagia, inadequate respiratory volume/control, or voice disorder; or

Laryngeal carcinoma requiring laryngectomy resulting in aphonia.

3. Aural Rehabilitation

Aural rehabilitation may be covered and medically necessary when it has been determined by a speech-language pathologist in collaboration with an audiologist that the beneficiary's current amplification options (hearing aid, other amplification device or cochlear implant) will not sufficiently meet the patient's functional communication needs.

Assessment for the need for aural rehabilitation may be done by a speech language pathologist and includes evaluation of comprehension and production of language in oral, signed or written modalities, speech and voice production, listening skills, speech reading, communications strategies, and the impact of the hearing loss on the patient/client and family.

Aural rehabilitation consists of treatment that focuses on comprehension, and production of language in oral, signed or written modalities; speech and voice production, auditory training, speech reading, multimodal (e.g., visual, auditory-visual, and tactile) training, communication strategies, education and counseling. In determining the necessity for treatment, the beneficiary's performance in both clinical and natural environment should be considered.

4. Dysphagia

Dysphagia, or difficulty in swallowing, can cause food to enter the airway, resulting in coughing, choking, pulmonary problems, aspiration or inadequate nutrition and hydration with resultant weight loss, failure to thrive, pneumonia and death. It is most often due to complex neurological and/or structural impairments including head and neck trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer,

dementias, and encephalopathies. For these reasons, it is important that only qualified professionals with specific training and experience in this disorder provide evaluation and treatment.

The speech-language pathologist performs clinical and instrumental assessments and analyzes and integrates the diagnostic information to determine candidacy for intervention as well as appropriate compensations and rehabilitative therapy techniques. The equipment that is used in the examination may be fixed, mobile or portable. Professional guidelines recommend that the service be provided in a team setting with a physician/NPP who provides supervision of the radiological examination and interpretation of medical conditions revealed in it.

Swallowing assessment and rehabilitation are highly specialized services. The professional rendering care must have education, experience and demonstrated competencies. Competencies include but are not limited to: identifying abnormal upper aerodigestive tract structure and function; conducting an oral, pharyngeal, laryngeal and respiratory function examination as it relates to the functional assessment of swallowing; recommending methods of oral intake and risk precautions; and developing a treatment plan employing appropriate compensations and therapy techniques.

230.4 - Services Furnished by a Physical or Occupational Therapist in Private Practice

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

A. General

In order to qualify to bill Medicare directly as a therapist, each individual must be enrolled as a private practitioner and employed in one of the following practice types: an unincorporated solo practice, unincorporated partnership, unincorporated group practice, physician/NPP group or groups that are not professional corporations, if allowed by state and local law. Physician/NPP group practices may employ physical therapists in private practice (PTPP) and/or occupational therapists in private practice (OTPP) if state and local law permits this employee relationship.

For purposes of this provision, a physician/NPP group practice is defined as one or more physicians/NPPs enrolled with Medicare who may bill as one entity. For further details on issues concerning enrollment, see the provider enrollment Web site at www.cms.hhs.gov/providers/enrollment.

Private practice also includes therapists who are practicing therapy as employees of another supplier, of a professional corporation or other incorporated therapy practice. Private practice does not include individuals when they are working as employees of an institutional provider.

Services should be furnished in the therapist's or group's office or in the patient's home. The office is defined as the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in the practice at that location. If services are furnished in a private practice office space, that space shall be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. For

example, a therapist in private practice may furnish aquatic therapy in a community center pool. As required in other settings (such as rehabilitation agencies and CORFs), the practice would have to rent or lease the pool for those hours, and the use of the pool during that time would have to be restricted to the therapist's patients, in order to recognize the pool as part of the therapist's own practice office during those hours. Therapists in private practice must be approved as meeting certain requirements, but do not execute a formal provider agreement with the Secretary.

If therapists who have their own Medicare Personal Identification number (PIN) or National Provider Identifier (NPI) are employed by therapist groups, physician/NPP groups, or groups that are not professional organizations, the requirement that therapy space be owned, leased, or rented may be satisfied by the group that employs the therapist. Each physical or occupational therapist employed by a group should enroll as a PT or OT in private practice.

When therapists with a Medicare PIN/NPI provide services in the physician's/NPP's office in which they are employed, and bill using their PIN/NPI for each therapy service, then the direct supervision requirement for PTAs and OTAs apply.

When the PT or OT who has a Medicare PIN/ NPI is employed in a physician's/NPP's office the services are ordinarily billed as services of the PT or OT, with the PT or OT identified on the claim as the supplier of services. However, services of the PT or OT who has a Medicare PIN/NPI may also be billed by the physician/NPP as services incident to the physician's/NPP's service. (See §230.5 for rules related to PTA and OTA services incident to a physician.) In that case, the physician/NPP is the supplier of service, the Unique Provider Identification Number (UPIN) or NPI of the physician/NPP (ordering or supervising, as indicated) is reported on the claim with the service and all the rules for incident to services (§230.5) must be followed.

B. Private Practice Defined

Reference: **Federal Register** November, 1998, pages 58863-58869; 42CFR 410.38(b)

The carrier considers a therapist to be in private practice if the therapist maintains office space at his or her own expense and furnishes services only in that space or the patient's home. Or, a therapist is employed by another supplier and furnishes services in facilities provided at the expense of that supplier.

The therapist need not be in full-time private practice but must be engaged in private practice on a regular basis; i.e., the therapist is recognized as a private practitioner and for that purpose has access to the necessary equipment to provide an adequate program of therapy.

The physical or occupational therapy services must be provided either by or under the direct supervision of the therapist in private practice. Each physical or occupational therapist in a practice should be enrolled as a Medicare provider. If a physical or occupational therapist is not enrolled, the services of that therapist must be directly supervised by an enrolled physical or occupational therapist. Direct supervision requires that the supervising private practice therapist be present in the office suite at the time the service is performed. These direct supervision requirements apply only in the private practice setting and only for physical therapists and occupational therapists and their

assistants. In other outpatient settings, supervision rules differ. The services of support personnel must be included in the therapist's bill. The supporting personnel, including other therapists, must be W-2 or 1099 employees of the therapist in private practice or other qualified employer.

Coverage of outpatient physical therapy and occupational therapy under Part B includes the services of a qualified therapist in private practice when furnished in the therapist's office or the beneficiary's home. For this purpose, "home" includes an institution that is used as a home, but not a hospital, CAH or SNF, (**Federal Register** Nov. 2, 1998, pg 58869). Place of Service (POS) includes:

- 03/School, only if residential,
- 04/Homeless Shelter,
- 12/Home, other than a facility that is a private residence,
- 14/Group Home,
- 33/Custodial Care Facility.

C. Assignment

Reference: Nov. 2, 1998 **Federal Register**, pg. 58863

See also Pub. 100-04 chapter 1, §30.2.

When physicians, NPPs, PTPPs or OTPPs obtain provider numbers, they have the option of accepting assignment (participating) or not accepting assignment (nonparticipating). In contrast, providers, such as outpatient hospitals, SNFs, rehabilitation agencies, and CORFs, do not have the option. For these providers, assignment is mandatory.

If physicians/NPPs, PTPPs or OTPPs accept assignment (are participating), they must accept the Medicare Physician Fee Schedule amount as payment. Medicare pays 80% and the patient is responsible for 20%. In contrast, if they do not accept assignment, Medicare will only pay 95% of the fee schedule amount. However, when these services are not furnished on an assignment-related basis, the limiting charge applies. (See §1848(g)(2)(c) of the Act.)

NOTE: Services furnished by a therapist in the therapist's office under arrangements with hospitals in rural communities and public health agencies (or services provided in the beneficiary's home under arrangements with a provider of outpatient physical or occupational therapy services) are not covered under this provision. See section 230.6.

230.5 - Physical Therapy, Occupational Therapy and Speech-Language Pathology Services Provided Incident to the Services of Physicians and Non-Physician Practitioners (NPP)

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

References: §1861(s)(2)(A) of the Act

42 CFR 410.10(b)

42 CFR 410.26

Pub. 100-02, ch. 15, §60.

The Benefit. Therapy services have their own benefit under §1861 of the Social Security Act and shall be covered when provided according to the standards and conditions of the benefit described in Medicare manuals. The statute 1862(a)(20) requires that payment be made for a therapy service billed by a physician/NPP only if the service meets the standards and conditions--other than licensing--that would apply to a therapist. (For example, see coverage requirements in Pub. 100-08, chapter 13, §13.5.1(C), Pub. 100-04, chapter 5, and also the requirements of this manual, §220 and §230.

Incident to a Therapist. There is no coverage for services provided incident to the services of a therapist. Although PTAs and OTAs work under the supervision of a therapist and their services may be billed by the therapist, their services are covered under the benefit for therapy services and not by the benefit for services incident to a physician/NPP. The services furnished by PTAs and OTAs are not incident to the therapist's service.

Qualifications of Auxiliary Personnel. Therapy services appropriately billed incident to a physician's/NPP's service shall be subject to the same requirements as therapy services that would be furnished by a physical therapist, occupational therapist or speech-language pathologist in any other outpatient setting with one exception. When therapy services are performed incident to a physician's/NPP's service, the qualified personnel who perform the service do not need to have a license to practice therapy, unless it is required by state law. The qualified personnel must meet all the other requirements except licensure. Qualifications for therapists are found in 42CFR484.4 and in section 230.1, 230.2, and 230.3 of this manual. In effect, these rules require that the person who furnishes the service to the patient must, at least, be a graduate of a program of training for one of the therapy services as described above. Regardless of any state licensing that allows other health professionals to provide therapy services, Medicare is authorized to pay only for services provided by those trained specifically in physical therapy, occupational therapy or speech-language pathology. That means that the services of athletic trainers, massage therapists, recreation therapists, kinesiotherapists, low vision specialists or any other profession may not be billed as therapy services.

The services of PTAs and OTAs also may not be billed incident to a physician's/NPP's service. However, if a PT and PTA (or an OT and OTA) are both employed in a physician's office, the services of the PTA, when directly supervised by the PT or the services of the OTA, when directly supervised by the OT may be billed by the physician group as PT or OT services using the PIN/NPI of the enrolled PT (or OT). (See Section 230.4 for private practice rules on billing services performed in a physician's office.) If the PT or OT is not enrolled, Medicare shall not pay for the services of a PTA or OTA billed incident to the physician's service, because they do not meet the qualification standards in 42CFR484.4.

Therapy services provided and billed incident to the services of a physician/NPP also must meet all incident-to requirements in this manual in chapter 15, §60. Where the policies have different requirements, the more stringent requirement shall be met.

For example, when therapy services are billed as incident to a physician/NPP services, the requirement for direct supervision by the physician/NPP and other incident to

requirements must be met, even though the service is provided by a licensed therapist who may perform the services unsupervised in other settings.

The mandatory assignment provision does not apply to therapy services furnished by a physician/NPP or "incident to" a physician's/NPP's service. However, when these services are not furnished on an assignment-related basis; the limiting charge applies.

For emphasis, following are some of the standards that apply to therapy services billed incident-to the services of a physician/NPP in the physician's/NPP's office or the beneficiary's residence.

A. Therapy services provided to the beneficiary must be covered and payable outpatient rehabilitation services as described, for example, in this section as well as Pub. 100-08, chapter 13, §13.5.1.

B. Therapy services must be provided by, or under the direct supervision of a physician (a doctor of medicine or osteopathy) or NPP who is legally authorized to practice therapy services by the state in which he or she performs such function or action. Direct supervision requirements are the same as in 42CFR410.32(b)(3). The supervisor must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician/NPP must be present in the same room in the office where the service is performed.

C. The services must be of a level of complexity that require that they be performed by a therapist or under the direct supervision of the therapist, physician/NPP who is licensed to perform them. Services that do not require the performance or supervision of the therapist, physician/NPP, are not considered reasonable or necessary therapy services even if they are performed or supervised by a physician/NPP or other qualified professional.

D. Services must be furnished under a plan of treatment as in §220.1.2 of this chapter. The services provided must relate directly to the physician/NPP service to which it is incident.

230.6 - Therapy Services Furnished Under Arrangements With Providers and Clinics

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

References: See also Pub. 100-01, chapter 5, §10.3.

A. General

For rules regarding services provided under arrangement, see Pub. 100-01, chapter 5, §10.3.

A provider may have others furnish outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services through arrangements under which

receipt of payment by the provider for the services discharges the liability of the beneficiary or any other person to pay for the service.

However, it is not intended that the provider merely serve as a billing mechanism for the other party. For such services to be covered the provider must assume professional responsibility for the services.

The provider's professional supervision over the services requires application of many of the same controls that are applied to services furnished by salaried employees. The provider must:

- Accept the patient for treatment in accordance with its admission policies;
- Maintain a complete and timely clinical record on the patient which includes diagnosis, medical history, orders, and progress notes relating to all services received;
- Maintain liaison with the attending physician/NPP with regard to the progress of the patient and to assure that the required plan of treatment is periodically reviewed by the physician/NPP;
- Secure from the physician/NPP the required certifications and recertifications; and
- Ensure that the medical necessity of such service is reviewed on a sample basis by the agency's staff or an outside review group.

In addition, when a provider provides outpatient services under an arrangement with others, such services must be furnished in accordance with the terms of a written contract, which provides for retention by the provider of responsibility for and control and supervision of such services. The terms of the contract should include at least the following:

- Provide that the therapy services are to be furnished in accordance with the plan of care established according to Medicare policies for therapy plans of care in section 220.1.2 of this chapter;
- Specify the geographical areas in which the services are to be furnished;
- Provide that contracted personnel and services meet the same requirements as those which would be applicable if the personnel and services were furnished directly by the provider;
- Provide that the therapist will participate in conferences required to coordinate the care of an individual patient;
- Provide for the preparation of treatment records, with progress notes and observations, and for the prompt incorporation of such into the clinical records of the clinic;
- Specify the financial arrangements. The contracting organization or individual may not bill the patient or the health insurance program; and
- Specify the period of time the contract is to be in effect and the manner of termination or renewal.

B. Special Rules for Hospitals

- A hospital may bill Medicare for outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services that it furnishes to its outpatients either directly or under arrangements in the hospital's outpatient department. If a hospital furnishes medically necessary therapy services in its outpatient department to individuals who are registered as its outpatients, those services must be billed directly by the hospital using bill type 13X or 85X for critical access hospitals. Note that services provided to residents of a Medicare-certified SNF may not be billed by the hospital as services to its outpatients.
- When a hospital sends its therapists to the home of an individual who is registered as an outpatient of the hospital but who is unable, for medical reasons, to come to the hospital to receive medically necessary therapy services, the services must meet the requirements applicable to outpatient hospital therapy services, as set forth in the regulations and applicable Medicare manuals. The hospital may bill for those services directly using bill type 13X or 85X for critical access hospitals.
- If a hospital sends its therapists to provide therapy services to individuals who are registered as its outpatients and who are residing in the non-certified part of a SNF, or in another residential setting (e.g., a group home, assisted living facility or domiciliary care home), the hospital may bill for the services as hospital outpatient services if the services meet the requirements applicable to outpatient hospital therapy services, as set forth in the regulations and applicable Medicare manuals.
- A hospital may make an arrangement with another entity such as an Outpatient Rehab Facility (Rehabilitation Agency) or a private practice, to provide therapy services to individuals who are registered as outpatients of the hospital. These services must meet the requirements applicable to services furnished under arrangements and the requirements applicable to the outpatient hospital therapy services as set forth in the regulations and applicable Medicare manuals. The hospital uses bill type 13X or 85X for critical access hospitals to bill for the services that another entity furnishes under arrangement to its outpatients.
- Where the provider is a public health agency or a hospital in a rural community, it may enter into arrangements to have outpatient physical therapy services furnished in the private office of a qualified physical therapist if the agency or hospital does not have the capacity to provide on its premises all of the modalities of treatment, tests, and measurements that are included in an adequate outpatient physical therapy program and the services and modalities which the public health agency or hospital cannot provide on its premises are not available on an outpatient basis in another accessible certified facility.
- In certain settings and under certain circumstances, hospitals may not bill Medicare for therapy services as services of the hospital:

- If a hospital sends its therapists to provide therapy services to patients of another hospital, including a patient at an inpatient rehabilitation facility or a long term care facility, the services must be furnished under arrangements made with the hospital sending the therapists by the hospital having the patients and billed as hospital services by the facility whose patients are treated. These services would be subject to existing hospital bundling rules and would be paid under the payment method applicable to the hospital at which the individuals are patients.
- A hospital may not send its therapists to provide therapy services to individuals who are receiving services from an HHA under a home health plan of care and bill for the therapy services as hospital outpatient services. For patients under a home health plan of care, payment for therapy services (unless provided by physicians/NPPs) is included or bundled into Medicare's episodic payment to the HHA, and those services must be billed by the HHA under the HHA consolidated billing rules. For patients receiving HHA services under an HHA plan of care, therapy services must be furnished directly or under arrangements made by the HHA, and only the HHA may bill for those services.

- If a hospital sends its therapists to provide services under arrangements made by a SNF to residents of the Medicare-certified part of a SNF, SNF consolidated billing rules apply. For arrangements specific to SNF Part A, see Pub. 100-04, chapter 6, §10.4. This means that therapy services furnished to SNF residents in the Medicare-certified part of a SNF cannot be billed by any entity other than the SNF. Therefore, a hospital may not bill Medicare for PT/OT/SLP services furnished to residents of a Medicare-certified part of a SNF by its therapists as services of the hospital.

NOTE: If the SNF resident is in a covered Part A stay, the therapy services would be included in the SNF's global PPS per diem payment for the covered Part A stay itself. If the resident is in a noncovered stay (Part A benefits exhausted, no prior qualifying hospital stay, etc.), but remains in the Medicare-certified part of a SNF, the SNF would submit the Part B therapy bill to its fiscal intermediary.

SNF Setting	**Applicable Rules**	
Medicare Part A or B	**Consolidated Billing Rules Apply?**	**Hospital May Bill For Outpatient Services?**

Part A (Medicare Covered / PPS) Resident in Medicare-certified part of a SNF	Yes	No
Medicare Part B Resident in Medicare-certified part of a SNF	Yes	No
Medicare Part B Not a Resident in Medicare-certified part of a SNF	No	Yes

- A hospital may not send therapy staff to provide therapy services in non-residential health care settings and bill for the services as if they were provided at the hospital, even if the hospital owns the other facility or entity. Examples of such non-residential settings include CORFs, rehabilitation agencies, ORFs and offices of physicians/NPPs or other practitioners, such as physical therapists. For example, services furnished to patients of a CORF must be billed as CORF services and not as outpatient hospital services. Even if a CORF contracts with a hospital to furnish services to CORF patients, the hospital may not bill Medicare for the services as hospital outpatient services. However, the CORF could have the hospital furnish services to its patients under arrangements, in which case the CORF would bill for the services.

Psychiatric hospitals are treated the same as other hospitals for the purpose of therapy billing.

240 - Chiropractic Services - General

(Rev. 1, 10-01-03)

B3-2250, B3-4118

The term "physician" under Part B includes a chiropractor who meets the specified qualifying requirements set forth in §30.5 but only for treatment by means of manual manipulation of the spine to correct a subluxation.

Effective for claims with dates of services on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation.

Implementation of the chiropractic benefit requires an appreciation of the differences between chiropractic theory and experience and traditional medicine due to fundamental differences regarding etiology and theories of the pathogenesis of disease. Judgments about the reasonableness of chiropractic treatment must be based on the application of chiropractic principles. So that Medicare beneficiaries receive equitable adjudication of claims based on such principles and are not deprived of the benefits intended by the law, carriers may use chiropractic consultation in carrier review of Medicare chiropractic claims.

Payment is based on the physician fee schedule and made to the beneficiary or, on assignment, to the chiropractor.

A. Verification of Chiropractor's Qualifications

Carriers must establish a reference file of chiropractors eligible for payment as physicians under the criteria in §30.1. They pay only chiropractors on file. Information needed to establish such files is furnished by the CMS RO.

The RO is notified by the appropriate State agency which chiropractors are licensed and whether each meets the national uniform standards.

240.1 - Coverage of Chiropractic Services

(Rev. 1, 10-01-03)

B3-2251

240.1.1 - Manual Manipulation

(Rev. 1, 10-01-03)

B3-2251.1

Coverage of chiropractic service is specifically limited to treatment by means of manual manipulation, i.e., by use of the hands. Additionally, manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

No other diagnostic or therapeutic service furnished by a chiropractor or under the chiropractor's order is covered. This means that if a chiropractor orders, takes, or interprets an x-ray, or any other diagnostic test, the x-ray or other diagnostic test, can be used for claims processing purposes, but Medicare coverage and payment are not available for those services. This prohibition does not affect the coverage of x-rays or other diagnostic tests furnished by other practitioners under the program. For example, an x-ray or any diagnostic test taken for the purpose of determining or demonstrating the existence of a subluxation of the spine is a diagnostic x-ray test covered under §1861(s)(3) of the Act if ordered, taken, and interpreted by a physician who is a doctor of medicine or osteopathy.

Manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

Effective for claims with dates of service on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation. However, an x-ray may be used for this purpose if the chiropractor so chooses.

The word "correction" may be used in lieu of "treatment." Also, a number of different terms composed of the following words may be used to describe manual manipulation as defined above:

- Spine or spinal adjustment by manual means;
- Spine or spinal manipulation;

- Manual adjustment; and
- Vertebral manipulation or adjustment.

In any case in which the term(s) used to describe the service performed suggests that it may not have been treatment by means of manual manipulation, the carrier analyst refers the claim for professional review and interpretation.

240.1.2 - Subluxation May Be Demonstrated by X-Ray or Physician's Exam

(Rev. 1, 10-01-03)

B3-2251.2

Subluxation is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact.

A subluxation may be demonstrated by an x-ray or by physical examination, as described below.

1. Demonstrated by X-Ray

An x-ray may be used to document subluxation. The x-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment. Unless more specific x-ray evidence is warranted, an x-ray is considered reasonably proximate if it was taken no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment. In certain cases of chronic subluxation (e.g., scoliosis), an older x-ray may be accepted provided the beneficiary's health record indicates the condition has existed longer than 12 months and there is a reasonable basis for concluding that the condition is permanent. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

2. Demonstrated by Physical Examination

Evaluation of musculoskeletal/nervous system to identify:

Pain/tenderness evaluated in terms of location, quality, and intensity;

Asymmetry/misalignment identified on a sectional or segmental level;

Range of motion abnormality (changes in active, passive, and accessory joint movements resulting in an increase or a decrease of sectional or segmental mobility); and

Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament.

To demonstrate a subluxation based on physical examination, two of the four criteria mentioned under "physical examination" are required, one of which must be asymmetry/misalignment or range of motion abnormality.

The history recorded in the patient record should include the following:

Symptoms causing patient to seek treatment;

Family history if relevant;

Past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history);

Mechanism of trauma;

Quality and character of symptoms/problem;

Onset, duration, intensity, frequency, location and radiation of symptoms;

Aggravating or relieving factors; and

Prior interventions, treatments, medications, secondary complaints.

A. Documentation Requirements: Initial Visit

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History as stated above.
2. Description of the present illness including:

    Mechanism of trauma;

    Quality and character of symptoms/problem;

    Onset, duration, intensity, frequency, location, and radiation of symptoms;

    Aggravating or relieving factors;

    Prior interventions, treatments, medications, secondary complaints; and

    Symptoms causing patient to seek treatment.

These symptoms must bear a direct relationship to the level of subluxation. The symptoms should refer to the spine (spondyle or vertebral), muscle (myo), bone (osseo or osteo), rib (costo or costal) and joint (arthro) and be reported as pain (algia), inflammation (itis), or as signs such as swelling, spasticity, etc. Vertebral pinching of spinal nerves may cause headaches, arm, shoulder, and hand problems as well as leg and foot pains and numbness. Rib and rib/chest pains are also recognized symptoms, but in general other symptoms must relate to the spine as such. The subluxation must be causal, i.e., the symptoms must be related to the level of the subluxation that has been cited. A statement on a claim that there is "pain" is insufficient. The location of pain must be described and whether the particular vertebra listed is capable of producing pain in the area determined.

3. Evaluation of musculoskeletal/nervous system through physical examination.

4. Diagnosis: The primary diagnosis must be subluxation, including the level of subluxation, either so stated or identified by a term descriptive of subluxation. Such terms may refer either to the condition of the spinal joint involved or to the direction of position assumed by the particular bone named.

5. Treatment Plan: The treatment plan should include the following:

    Recommended level of care (duration and frequency of visits);

Specific treatment goals; and

Objective measures to evaluate treatment effectiveness.

6. Date of the initial treatment.

B. Documentation Requirements: Subsequent Visits

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History

   Review of chief complaint;

   Changes since last visit;

   System review if relevant.

2. Physical exam

   Exam of area of spine involved in diagnosis;

   Assessment of change in patient condition since last visit;

   Evaluation of treatment effectiveness.

3. Documentation of treatment given on day of visit.

240.1.3 - Necessity for Treatment

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam, as described above.

Most spinal joint problems fall into the following categories:

- Acute subluxation-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical exam as specified above. The result of chiropractic manipulation is expected to be an improvement in, or arrest of progression, of the patient's condition.
- Chronic subluxation-A patient's condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered.

For Medicare purposes, a chiropractor **must** place an AT modifier on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However the presence of the AT modifier may not in all instances indicate that the service is

reasonable and necessary. As always, contractors may deny if appropriate after medical review.

A. Maintenance Therapy

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied. Chiropractors who give or receive from beneficiaries an ABN shall follow the instructions in Pub. 100-04, Medicare Claims Processing Manual, chapter 23, section 20.9.1.1 and include a GA (or in rare instances a GZ) modifier on the claim.

B. Contraindications

Dynamic thrust is the therapeutic force or maneuver delivered by the physician during manipulation in the anatomic region of involvement. A relative contraindication is a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. The following are **relative contraindications** to dynamic thrust:

Articular hyper mobility and circumstances where the stability of the joint is uncertain;

Severe demineralization of bone;

Benign bone tumors (spine);

Bleeding disorders and anticoagulant therapy; and

Radiculopathy with progressive neurological signs.

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis;

Acute fractures and dislocations or healed fractures and dislocations with signs of instability;

An unstable os odontoideum;

Malignancies that involve the vertebral column;

Infection of bones or joints of the vertebral column;

Signs and symptoms of myelopathy or cauda equina syndrome;

For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and

A significant major artery aneurysm near the proposed manipulation.

240.1.4 – Location of Subluxation

(Rev. 1, 10-01-03)

B3-2251.4

The precise level of the subluxation must be specified by the chiropractor to substantiate a claim for manipulation of the spine. This designation is made in relation to the part of the spine in which the subluxation is identified:

Area of Spine	Names of Vertebrae	Number of Vertebrae	Short Form or Other Name
Neck	Occiput	7	Occ, CO
	Cervical		C1 thru C7
	Atlas		C1
	Axis		C2
Back	Dorsal or	12	D1 thru D12
	Thoracic		T1 thru T12
	Costovertebral		R1 thru R12
	Costotransverse		R1 thru R12
Low Back	Lumbar	5	L1 thru L5
Pelvis	IIii, r and 1		I, Si
Sacral	Sacrum, Coccyx		S, SC

In addition to the vertebrae and pelvic bones listed, the Ilii (R and L) are included with the sacrum as an area where a condition may occur which would be appropriate for chiropractic manipulative treatment.

There are two ways in which the level of the subluxation may be specified.

The exact bones may be listed, for example: C5, C6, etc.

The area may suffice if it implies only certain bones such as: Occipito-atlantal (occiput and C1 (atlas)), lumbo-sacral (L5 and Sacrum), sacro-iliac (sacrum and ilium).

Following are some common examples of acceptable descriptive terms for the nature of the abnormalities:

Off-centered

Misalignment

Malpositioning

Spacing - abnormal, altered, decreased, increased

Incomplete dislocation

Rotation

Listhesis - antero, postero, retro, lateral, spondylo

Motion - limited, lost, restricted, flexion, extension, hyper mobility, hypomotility, aberrant

Other terms may be used. If they are understood clearly to refer to bone or joint space or position (or motion) changes of vertebral elements, they are acceptable.

240.1.5 - Treatment Parameters

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2251.5

The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time. Acute subluxation (e.g., strains or sprains) problems may require as many as three months of treatment but some require very little treatment. In the first several days, treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.

Chronic spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already "set" and fibrotic tissue has developed. This condition may require a longer treatment time, but not with higher frequency.

Some chiropractors have been identified as using an "intensive care" concept of treatment. Under this approach multiple daily visits (as many as four or five in a single day) are given in the office or clinic and so-called room or ward fees are charged since the patient is confined to bed usually for the day. The room or ward fees are not covered and reimbursement under Medicare will be limited to not more than one treatment per day.

250 - Medical and Other Health Services Furnished to Inpatients of Hospitals and Skilled Nursing Facilities

(Rev. 1, 10-01-03)

B3-2255

There are several services which, when provided to a hospital or SNF inpatient, are covered under Part B, even though the patient has Part A coverage for the hospital or SNF stay. Those services are:

Physicians' services (including the services of residents and interns in unapproved teaching programs);

Physician assistant services, furnished after December 31,1990;

Certified nurse-midwife services, as described in §180, furnished after December 31, 1990; and

Qualified clinical psychologist services, as defined in §160, furnished after December 31, 1990;

Screening mammography services;

Screening pap smears and pelvic exams;

Screening glaucoma services;

Influenza, pneumococcal pneumonia, and hepatitis B vaccines and their administrations;

Colorectal screening;

Bone mass measurements;

Diabetes self-management; and

Prostate screening;

Because of the bundling requirement described in paragraph B, pneumococcal and hepatitis B vaccine services must be provided directly or arranged for by the hospital in order to be covered when furnished to a hospital inpatient. The other services listed are not subject to bundling but, because they are excluded from the statutory definition of inpatient hospital services, may be covered only under Part B.

Payment may be made under Part B for the medical and other health services enumerated in paragraph C, but only where no payment can be made for such services under Part A. For example, payment may be made under Part B for the services in question where the beneficiary is an inpatient of a hospital or skilled nursing facility (SNF) and has exhausted his or her allowed days of inpatient coverage under Part A (or has elected not to use his or her lifetime reserve days). In the case of an inpatient of a SNF, Part B payment may be made if the patient is receiving Part A benefits for most of his or her care but the participating SNF does not furnish the services to its inpatients either directly or under arrangements (i.e., does not bill for services furnished to its inpatients by other suppliers).

A. Conditions for Part A Payment

In hospitals (including hospitals under the prospective payment system (PPS)) and SNFs, Part B payment may be made for the services listed in paragraph C if the services are reasonable and necessary and if:

No Part A payment is made at all for the hospital or SNF stay because of patient exhaustion of benefit days before admission;

The admission was disapproved as not reasonable and necessary and limitation of liability payment was not made;

The patient was not otherwise eligible for or entitled to coverage under Part A (see the Medicare Benefit Policy Manual, Chapter 16, “General Exclusions From Coverage,” §180); or

In the case of a hospital paid under the PPS, no Part A day outlier payment is made (for discharges before October 1997) for one or more outlier days due to patient exhaustion of benefit days after admission but before the case's arrival at outlier status or because outlier days are otherwise not covered and waiver of liability payment is not made. (Outlier days are days for which extra payment is made under PPS for long stay cases.)

Part B payment may be made for the medical and other health services listed in paragraph C when they are reasonable and necessary and furnished at any time during the stay if no Part A payment is made. However, if only day outlier payment is denied under Part A, Part B payment may be made for only the services furnished on the denied outlier days.

In non-PPS hospitals and in SNFs, Part B payment may be made for the indicated covered services delivered on any day for which Part A payment is denied (i.e., because of patient exhaustion of benefit days, the patient or services received were not at the hospital level or SNF level of care, or the patient was not otherwise eligible for or entitled to payment under Part A).

B. Bundling of Services to Hospital Inpatients

In the case of a hospital inpatient, the services described in paragraph C are covered only if they are furnished by the hospital directly, or by another entity under arrangements made by the hospital. Only the hospital is allowed to bill for the services, and the bills must be submitted to the intermediary rather than to the carrier.

Certain services are exempt from the bundling requirement and may be billed directly to the carrier even when furnished to a hospital inpatient. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §170.)

C. Covered Part B Services When Part A Coverage is Not Available

The medical and other services covered under Part B when furnished to patients of hospitals and SNFs include the following:

Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests;

X-ray, radium, and radioactive isotope therapy including materials and services of technicians;

Surgical dressings, splints, casts, and other devices used for reduction of fractures and dislocations;

Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices;

Leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes, including adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient's physical condition;

Outpatient physical therapy, outpatient occupational therapy, and outpatient speech-language pathology services; and

Ambulance services.

260 - Ambulatory Surgical Center Services

(Rev. 1, 10-01-03)

B3-2265

Facility services furnished by ambulatory surgical centers (ASCs) in connection with certain surgical procedures are covered under Part B. To receive coverage of and payment for its services under this provision, a facility must be certified as meeting the requirements for an ASC and enter into a written agreement with CMS. Medicare periodically updates the list of covered procedures and related payment amounts through release of regulations and Program Memoranda. The ASC must accept Medicare's payment for such procedures as payment in full with respect to those services defined as ASC facility services.

Where services are performed in an ASC, the physician and others who perform covered services may also be paid for his/her professional services; however, the "professional" rate is then adjusted since the ASC incurs the facility costs.

260.1 - Definition of Ambulatory Surgical Center (ASC)

(Rev. 1, 10-01-03)

B3-2265.1

An ASC for purposes of this benefit is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients. It enters into an agreement with CMS to do so. An ASC is either independent (i.e., not a part of a provider of services or any other facility), or operated by a hospital (i.e., under the common ownership, licensure, or control of a hospital). If the hospital based surgery center is certified as an ASC it is considered and ASC and is subject to rules for ASCs. If a hospital based surgery center is not certified as an ASC it continues under the program as part of the hospital. In this case the applicable outpatient payment rules apply. This may be OPPS, for most hospitals, or may be provisions for hospitals excluded from OPPS. See the Medicare Claims Processing Manual, Chapter 4, for billing and payment requirements for hospital outpatient services.

260.2 - Ambulatory Surgical Center Services

(Rev. 1, 10-01-03)

B3-2265.2

The ASC facility services are services furnished in an ASC in connection with a covered surgical procedure that are otherwise covered if furnished on an inpatient or outpatient basis in a hospital in connection with that procedure. Not included in the definition of facility services are medical and other health services, even though furnished within the ASC, which are covered under other portions of the Medicare program, or not furnished in connection with covered surgical procedures. This distinction between covered ASC facility services and services which are not covered ASC facility services is important, since the facility payment rate includes only the covered ASC facility services. Services

which are not covered ASC facility services such as physicians' services and prosthetic devices other than intraocular lenses (IOLs), may be covered and billable under other Medicare provisions.

Since there is no uniformity among ASCs as to what items and services they include in their facility fee or charge, the Medicare definition of covered facility services is both inclusive and exclusive. The regulations specify what are and are not facility services. Facility services are items and services furnished in connection with listed covered procedures, which are covered if furnished in a hospital operating suite or hospital outpatient department in connection with such procedures. These do not include physicians' services, or medical and other health services for which payment may be made under other Medicare provisions (e.g., services of an independent laboratory located on the same site as the ASC).

Examples of covered ASC facility services include:

Nursing Services, Services of Technical Personnel, and Other Related Services - These include all services in connection with covered procedures furnished by nurses and technical personnel who are employees of the ASC. In addition to the nursing staff, this category includes orderlies, technical personnel, and others involved in patient care;

Use by the Patient of the ASC's Facilities - This category includes operating and recovery rooms, patient preparation areas, waiting rooms, and other areas used by the patient or offered for use by the patient's relatives in connection with surgical services; and

Drugs, Biologicals, Surgical Dressings, Supplies, Splints, Casts, Appliances, and Equipment - This category includes all supplies and equipment commonly furnished by the ASC in connection with surgical procedures. See below for certain exceptions. Drugs and biologicals are limited to those that cannot be self-administered. (See §60.)

Coverage policy for surgical dressings is similar to that followed under Part B. Under Part B, coverage for surgical dressings is limited to primary dressings; i.e., therapeutic and protective coverings applied directly to lesions on the skin or on openings to the skin required as the result of surgical procedures. (Items such as Ace bandages, elastic stockings and support hose, Spence boots and other foot coverings, leotards, knee supports, surgical leggings, gauntlets, and pressure garments for the arms and hands are generally used as secondary coverings and therefore are not covered as surgical dressings.) Surgical dressings usually are applied first by a physician and are covered as "incident to" a physician's service in a physician's office setting. In the ASC setting, such dressings are included in the facility's services.

However, others may reapply surgical dressings later, including the patient or a member of the patient's family. When the patient on a physician's order obtains surgical dressings from a supplier, e.g., a drugstore, the surgical dressing is covered under Part B. The same policy applies in the case of dressings obtained by the patient on a physician's order following surgery in an ASC; the dressings are covered and paid as a Part B service by the local Part B carrier, included in the definition of facility services.

Similarly, “other supplies, splints, and casts” include only those furnished by the ASC at the time of the surgery. Additional covered supplies and materials furnished later are generally furnished as “incident to” a physician’s service, not as an ASC facility service. The term “supplies” includes those required for both the patient and ASC personnel, e.g., gowns, masks, drapes, hoses, and scalpels, whether disposable or reusable.

Diagnostic or Therapeutic Items and Services

These are items and services furnished by ASC staff in connection with covered surgical procedures. With respect to diagnostic tests, many ASCs perform simple tests just before surgery, primarily urinalysis and blood hemoglobin or hematocrit, which are generally included in their facility charges. To the extent that such simple tests are included in the ASC’s facility charges, they are considered facility services. However, under the Medicare program, diagnostic tests are not covered in laboratories independent of a physician’s office, rural health clinic, or hospital unless the laboratories meet the regulatory requirements for the conditions for coverage of services of independent laboratories. (See 42 CFR 405.1310.) Therefore, diagnostic tests performed by the ASC other than those generally included in the facility’s charge are not covered under Part B as such and are not be billed to the carrier as diagnostic tests. If the ASC has its laboratory certified as meeting the regulatory conditions, then the laboratory itself bills the carrier (or the beneficiary) for the tests performed.

The ASC may make arrangements with an independent laboratory or other laboratory, such as a hospital laboratory, to perform diagnostic tests it requires prior to surgery. In general, however, the necessary laboratory tests are done outside the ASC prior to scheduling of surgery, since the test results often determine whether the beneficiary should even have the surgery done on an outpatient basis in the first place.

Administrative, Recordkeeping, and Housekeeping Items and Services

These include the general administrative functions necessary to run the facility e.g., scheduling, cleaning, utilities, and rent.

Blood, Blood Plasma, Platelets, etc., Except Those to Which Blood Deductible Applies

While covered procedures are limited to those not expected to result in extensive loss of blood, in some cases, blood or blood products are required. Usually the blood deductible results in no expenses for blood or blood products being included under this provision. However, where there is a need for blood or blood products beyond the deductible, they are considered ASC facility services and no separate charge is permitted to the beneficiary or the program.

Materials for Anesthesia

These include the anesthetic itself, and any materials, whether disposable or reusable, necessary for its administration.

Intraocular Lenses (IOLs)

Effective for services furnished on or after March 12, 1990, ASC facility services include intraocular lenses approved by the Food and Drug Administration (FDA) for insertion during or subsequent to cataract surgery.

FDA has classified IOLs into the following four categories, any of which are included:

Anterior chamber angle fixation lenses;

Iris fixation lenses;

Irido-capsular fixation lenses; and

Posterior chamber lenses.

While FDA has approved many IOLs, it still considers some IOLs investigational. The fact that they are covered under Medicare is an exception to the general policy not to cover experimental or investigational items or services. The exception is made because the Congress, recognizing the widespread use of IOLs, directed the FDA to study them without interfering with availability to patients.

The carrier is not concerned with whether a given item or service is an ASC facility service, unless the ASC makes a separate charge for it. In such a case, the carrier determines whether the item or service falls into the categories described in the following section. If it determines the item or service does fall into one of those categories, it makes payment following the applicable rules for such items and services found elsewhere in this chapter. If the item or service does not fall into one of the categories described, the carrier denies the claim.

260.3 - Services Furnished in ASCs Which are Not ASC Facility Services

(Rev. 1, 10-01-03)

B3-2265.3

A single payment is made to an ASC that encompasses all “facility services” furnished by the ASC in connection with a covered procedure. However, a number of items and services covered under Medicare may be furnished in an ASC which are not considered facility services, and which the ASC payment does not include. These non-ASC services are covered and paid for under the applicable provisions of Part B. In addition, the ASC may be part of a medical complex that includes other entities, such as an independent laboratory, supplier of durable medical equipment, or a physician’s office, which are covered as separate entities under Part B. In general, an item or service separately covered under Medicare is not considered an ASC service. Examples of services payable in addition to ASC services are found in §260.4.

260.4 - Coverage of Services in ASCs, Which are Not ASC Services

(Rev. 1, 10-01-03)

B3-2265.4

Physicians’ Services

This category includes most covered services performed in ASCs, which are not considered ASC facility services. Physicians' services were covered before coverage of ASC services, and the ASC amendment did not change this. Consequently, physicians who perform covered services in ASCs receive payment under the existing Part B system. Physicians' services include the services of anesthesiologists administering or supervising the administration of anesthesia to ASC patients and the patients' recovery from the anesthesia. The term physicians' services also includes any routine pre- or post-operative services, such as office visits, consultations, diagnostic tests, removal of stitches, changing of dressings, and other services which are defined in the set "global" fee for a given surgical procedure (CPT code). The carrier applies the same criteria, limits and understandings to physicians' services for procedures done in the ASC that were applied to the procedures done by the same physicians on an inpatient hospital basis.

The Sale, Lease, or Rental of Durable Medical Equipment (DME) to ASC Patients for Use in Their Homes

If the ASC furnished items of DME to patients, it must have a DME supplier number, and it is treated as a DME supplier, as described in §§110. While an ASC is not a "provider of services" under Medicare, the carrier considers it a "supplier of services" for purposes of the second paragraph of §110. All the rules and conditions ordinarily applicable to DME are applicable where ASCs furnish such items.

Prosthetic Devices

Prosthetic devices, other than intraocular lenses (IOLs), whether implanted, inserted, or otherwise applied by covered surgical procedures, are covered, but are not included in the ASC facility payment amount. However, §4063(b) of P.L. 100-203 amended §1833 (i)(2)(A) of the Act to mandate that payment for an intraocular lens (IOL) inserted during or subsequent to cataract surgery in an ASC be included in the facility payment rate. This bundling of the payment for an IOL with the facility fee is effective for services furnished on or after March 12, 1990. More information on coverage of prosthetic devices may be found in §120. Further information on the coverage of IOLs may be found in §260.2.

Ambulance Services

If the ASC furnishes ambulance services, they are covered as ambulance services pursuant to the terms and conditions of the Medicare Benefit Policy Manual, Chapter 10, "Ambulance Services," §§10.

Leg, Arm, Back, and Neck Braces

These items of equipment, like prosthetic devices, are covered under Part B, but are not included in the ASC facility payment amount. Coverage of these items is described in §130.

Artificial Legs, Arms, and Eyes

Like prosthetic devices and braces, this equipment is not considered part of an ASC facility service and so is not included in the ASC facility payment rate. Information regarding the coverage of these items is set out in §130.

Services of Independent Laboratory

As noted in §260.2, only a very limited number and type of diagnostic tests are considered ASC facility services and included in the ASC facility payment rate. In most cases, diagnostic tests performed directly by an ASC are not considered ASC facility services and are not covered under Medicare because §1861(s) of the statute limits coverage of diagnostic tests in facilities other than physicians' offices, rural health clinics, or hospitals to facilities that meet the statutory definition of an independent laboratory. (See §§80.1 for a description of independent laboratories and covered services.) Accordingly, if an ASC wishes to provide laboratory services directly, it has its laboratory certified as an independent laboratory for the services to be covered. Otherwise, the ASC makes arrangements with a covered laboratory or laboratories for laboratory services, as provided in 42 CFR 416.49. If the ASC has a certified independent laboratory, the laboratory itself bills the carrier, pursuant to §§80.

260.5 - List of Covered Ambulatory Surgical Center Procedures

(Rev. 1, 10-01-03)

B3-2266

The law ties coverage of ambulatory surgical center (ASC) services under Part B to specified surgical procedures, which are contained in a list revised and published periodically by CMS. Groupings and related prices are also published periodically. These are published in the Federal Register and on the CMS Web site.

260.5.1 - Nature and Applicability of ASC List

(Rev. 1, 10-01-03)

B3-2266.1

With respect to facility services, the carrier makes payment for a procedure performed in an independent facility on a Medicare beneficiary only if the procedure is on the list. (The payment is the ASC facility services amount, subject to wage index adjustment and applicable deductible and coinsurance.) If a procedure is not on the list, the carrier makes no payment for ASC facility services. This policy applies to all facilities with an agreement with CMS to be covered as ASCs, both independent facilities and those hospital-affiliated ambulatory surgical centers which choose to be covered as ASCs and enter into the ASC agreement.

The list of covered procedures merely indicates procedures, which are covered and paid for if performed in the ASC setting. It does not require these procedures to be performed in such settings, nor is any out-of-the-ordinary justification or special review required if listed procedures are performed on a hospital inpatient basis. The choice of operating site remains a matter for the professional judgment of the patient's physician. Also, all the general coverage rules regarding the medical necessity of a particular procedure for a particular patient are applicable to ASC services in the same manner as all other covered services.

260.5.2 - Nomenclature and Organization of the List

(Rev. 1, 10-01-03)

B3-2266.2

The listed procedures are all considered “surgical procedures” for coverage purposes under the ASC provision, regardless of the specific use to which the procedure is put. For example, many of the “oscopy” procedures listed - bronchoscopy, laryngoscopy, etc., may be employed for either diagnostic or therapeutic purposes, or both at the same time, such as when the “oscopy” permits both detection and removal of a polyp. Those procedures are considered “surgical procedures” within the context of the ASC provision. Also, surgical procedures are commonly thought of as those involving an incision of some type, whether done with a scalpel or (more recently) a laser, followed by removal or repair of an organ or other tissue. In recent years, the development of fiber optics technology, together with new surgical instruments utilizing that technology, has resulted in surgical procedures that, while invasive and manipulative, do not require incisions. Instead, the procedures are performed without an incision through various body openings. Those procedures, some of which include the “oscopy” procedures mentioned above, are also considered surgical procedures for purposes of the ASC provision, and several are included in the list of covered procedures.

260.5.3 - Rebundling of CPT Codes

(Rev. 1, 10-01-03)

B3-2266.3

Instructions regarding the Correct Coding Initiative apply to coverage of ASC facility services.

270 - Telehealth Services

(Rev. 31, Issued: 04-01-05; Effective: 01-01-05; Implementation: 05-02-05)

Background

Section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) - Revision of Medicare Reimbursement for Telehealth Services amended §1834 of the Act to provide for an expansion of Medicare payment for telehealth services.

Effective October 1, 2001, coverage and payment for Medicare telehealth includes consultation, office visits, individual psychotherapy, and pharmacologic management delivered via a telecommunications system. Eligible geographic areas include rural health professional shortage areas and counties not classified as a metropolitan statistical area (MSA). Additionally, Federal telemedicine demonstration projects as of December 31, 2000, may serve as the originating site regardless of geographic location.

An interactive telecommunications system is required as a condition of payment; however, BIPA does allow the use of asynchronous “store and forward” technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. BIPA does not require that a practitioner present the patient for interactive telehealth services.

With regard to payment amount, BIPA specified that payment for the professional service performed by the distant site practitioner (i.e., where the expert physician or practitioner

is physically located at time of telemedicine encounter) is equal to what would have been paid without the use of telemedicine. Distant site practitioners include only a physician as described in §1861(r) of the Act and a medical practitioner as described in §1842(b)(18)(C) of the Act. BIPA also expanded payment under Medicare to include a $20 originating site facility fee (location of beneficiary).

Previously, the Balanced Budget Act of 1997 (BBA) limited the scope of Medicare telehealth coverage to consultation services and the implementing regulation prohibited the use of an asynchronous 'store and forward' telecommunications system. The BBA of 1997 also required the professional fee to be shared between the referring and consulting practitioners, and prohibited Medicare payment for facility fees and line charges associated with the telemedicine encounter.

The BIPA required that Medicare Part B (Supplementary Medical Insurance) pay for this expansion of telehealth services beginning with services furnished on October 1, 2001.

Time limit for teleconsultation provision.

The teleconsultation provision as authorized by §4206 (a) and (b) of the BBA of 1997 and implemented in 42 CFR 410.78 and 414.65 applies only to teleconsultations provided on or after January 1, 1999, and before October 1, 2001.

270.1 - Eligibility Criteria

(Rev. 1, 10-01-03)

Furnished by CMS

Beneficiaries are eligible for telehealth services **only** if they are presented from an originating site located either in a rural HPSA or in a county outside of a MSA.

Entities participating in a Federal telemedicine demonstration project that were approved by or were receiving funding from the Secretary of Health and Human Services as of December 31, 2000, qualify as originating sites regardless of geographic location. Such entities are not required to be in a rural HPSA or non-MSA.

An originating site is the location of an eligible Medicare beneficiary at the time the service being furnished via telecommunications system occurs. Originating sites authorized by law are listed below.

The office of a physician or practitioner.

A hospital.

A critical access hospital.

A rural health clinic.

A federally qualified health center.

270.2 – List of Medicare Telehealth Services

(Rev. 53, Issued: 07-07-06; Effective: 01-01-06; Implementation: 08-07-06)

Furnished by CMS

The use of a telecommunications system may substitute for a face-to-face, “hands on” encounter for consultations, office visits, individual psychotherapy, pharmacologic management, psychiatric diagnostic interview examination, end stage renal disease related services, and individual medical nutrition therapy. These services and corresponding current procedure terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes are listed below.

Consultations (CPT codes 99241 - 99275) (Effective October 1, 2001 – December 31, 2005).

Consultations (CPT codes 99241 – 99255) (Effective January 1, 2006).

Office or other outpatient visits (CPT codes 99201 - 99215).

Individual psychotherapy (CPT codes 90804 - 90809).

Pharmacologic management (CPT code 90862).

Psychiatric diagnostic interview examination (CPT code 90801) (Effective March 1, 2003).

End stage renal disease related services (HCPCS codes G0308, G0309, G0311, G0312, G0314, G0315, G0317, and G0318). (Effective January 1, 2005).

Individual Medical Nutrition Therapy (HCPCS codes G0270, 97802, and 97803) (Effective January 1, 2006).

270.3 – Conditions of Payment

(Rev. 1, 10-01-03)

Furnished by CMS

For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit.

Exception to the Interactive Telecommunications Requirement

In the case of Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telemedicine when asynchronous “store and forward technology,” in single or multimedia formats, is used as a substitute for an interactive telecommunications system. The originating site and distant site practitioner must be included within the definition of the demonstration program.

For the purposes of this instruction, store and forward means the asynchronous transmission of medical information to be reviewed at a later time by a physician or practitioner at the distant site. A patient’s medical information may include but not limited to, video clips, still images, x-rays, MRIs, EKGs and EEGs, laboratory results, audio clips, and text. The physician or practitioner at the distant site reviews the case without the patient being present. Store and forward substitutes for an interactive encounter with the patient present; the patient is not present in real-time.

NOTE: Asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients' condition and adequate for rendering or confirming a diagnosis or a treatment plan. Dermatological photographs, e.g., photographs of a skin lesion, may be considered to meet the requirement of a single media format under this instruction.

Telepresenters: A medical professional is not required to present the beneficiary to the physician or practitioner at the distant site unless medically necessary. The decision of medical necessity will be made by the physician or practitioner located at the distant site.

270.4 – Payment – Physician/Practitioner at a Distant Site

(Rev. 43, Issued: 12-23-05; Effective: 01-01-06; Implementation: 04-03-06)

Furnished by CMS

The term "distant site" means the site where the physician or practitioner providing the professional service is located at the time the service is provided via a telecommunications system.

The payment amount for the professional service provided via a telecommunications system by the physician or practitioner at the distant site is equal to the current fee schedule amount for the service provided. Payment for telehealth services (see §270.2) should be made at the same amount as when these services are furnished without the use of a telecommunications system. For Medicare payment to occur, the service must be within a practitioner's scope of practice under State law. The beneficiary is responsible for any unmet deductible amount and applicable coinsurance.

Medicare Practitioners Who May Receive Payment at the Distant Site (i.e., at a Site Other Than Where a Beneficiary Is)

As a condition of Medicare Part B payment for telehealth services, the physician or practitioner at the distant site must be licensed to provide the service under State law. When the physician or practitioner at the distant site is licensed under State law to provide a covered telehealth service (see §270.2) then he or she may bill for and receive payment for this service when delivered via a telecommunications system.

Medicare practitioners who may bill for a covered telehealth service are listed below (subject to State law):

Physician;

Nurse practitioner;

Physician assistant;

Nurse midwife;

Clinical nurse specialist;

Clinical psychologist;

Clinical social worker; and

Registered dietitian or nutrition professional.

* Clinical psychologists and clinical social workers cannot bill for psychotherapy services that include medical evaluation and management services under Medicare. These practitioners may not bill or receive payment for the following CPT codes: 90805, 90807, and 90809.

270.4.1 – Payment for ESRD-Related Services as a Telehealth Service

(Rev. 31, Issued: 04-01-05; Effective: 01-01-05; Implementation: 05-02-05)

The ESRD-related services included in the monthly capitation payment (MCP) with 2 or 3 visits per month and ESRD-related services with 4 or more visits per month may be paid as Medicare telehealth services. However, at least 1 visit must be furnished face-to-face "hands on" to examine the vascular access site by a physician, clinical nurse specialist, nurse practitioner, or physicians assistant. An interactive audio and video telecommunications system may be used for providing additional visits required under the 2-to-3 visit MCP and the 4-or-more visit MCP. The medical record must indicate that at least one of the visits was furnished face-to-face "hands on" by a physician, clinical nurse specialist, nurse practitioner, or physician assistant.

The MCP physician, for example, the physician or practitioner who is responsible for the complete monthly assessment of the patient and establishes the patient's plan of care, may use other physicians and practitioners to furnish ESRD-related visits through an interactive audio and video telecommunications system. The non-MCP physician or practitioner must have a relationship with the billing physician or practitioner such as a partner, employees of the same group practice or an employee of the MCP physician, for example, the non MCP physician or practitioner is either a W-2 employee or 1099 independent contractor. However, the physician or practitioner who is responsible for the complete monthly assessment and establishes the ESRD beneficiary's plan of care should bill for the MCP in any given month.

Clinical Criteria

The visit including a clinical examination of the vascular access site must be conducted face-to-face "hands on" by a physician, clinical nurse specialist, nurse practitioner or physician's assistant. For additional visits, the physician or practitioner at the distant site is required, at a minimum, to use an interactive audio and video telecommunications system that allows the physician or practitioner to provide medical management services for a maintenance dialysis beneficiary. For example, an ESRD-related visit conducted via telecommunications system must permit the physician or practitioner at the distant site to perform an assessment of whether the dialysis is working effectively and whether the patient is tolerating the procedure well (physiologically and psychologically). During this assessment, the physician or practitioner at the distant site must be able to determine whether alteration in any aspect of the beneficiary's prescription is indicated, due to such changes as the estimate of the patient's dry weight.

Clarification on originating sites

Medicare telehealth originating sites only include a physician's or practitioner's office, hospital, critical access hospital, rural health clinic, or Federally-qualified health center. ESRD facilities are not originating sites (dialysis facilities are not defined in the law as an originate site). ESRD-related visits may be furnished through an interactive

telecommunications system (other than the required visit to examine the vascular access site) when the beneficiary is located in an originating site as defined in §270.1, including a physician's satellite office within a dialysis center.

270.5 - Originating Site Facility Fee Payment Methodology

(Rev. 1, 10-01-03)

Furnished by CMS

The term originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous, store and forward telecommunications technologies, an originating site is only a Federal telemedicine demonstration program conducted in Alaska or Hawaii.

For telehealth services (see §270.2) furnished from October 1, 2001, through December 31, 2002, the originating site fee is the lesser of $20 or the actual charge. For services furnished on or after January 1 of each subsequent year, the Medicare Economic Index (MEI) will update the facility fee for the originating site annually.

For telehealth services furnished from October 1, 2001, through December 31, 2002, the payment amount to the originating site is the lesser of 80 percent of the actual charge or the originating site facility fee of $20. The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance. The originating site facility fee payment methodology for each type of facility is clarified below:

When the originating site is a hospital outpatient department, payment for the originating site facility fee must be made as described above and not under the outpatient prospective payment system. Payment is not based on current fee schedules or other payment methodologies.

For hospital inpatients, payment for the originating site facility fee must be made outside the diagnostic related group (DRG) payment since this is a Part B benefit, similar to other services paid separately from the DRG payment.

When the originating site is a critical access hospital, contractors make payment separately from the cost-based reimbursement methodology.

The originating site facility fee for telehealth services is not a Federally qualified health center (FQHC) and rural health clinic (RHC) service. When an FQHC or RHC serves as the originating site, the originating site facility fee must be paid separately from the center or clinic all-inclusive rate.

When the originating site is a physician's or practitioner's office, the payment amount, in accordance with the law, is the lesser of 80 percent of the actual charge or originating site facility fee regardless of geographic location. The geographic cost index (GPCI) should not be applied to the originating site facility fee. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the physician fee schedule.

270.5.1 Originating Site Facility Fee Payment (ESRD-Related Services)

(Rev. 31, Issued: 04-01-05; Effective: 01-01-05; Implementation: 05-02-05)

With regard to ESRD-related services included in the MCP, the originating site facility fee payment may be made for each visit furnished through an interactive telecommunications system. When the physician or practitioner at the distant site furnishes an ESRD-related patient visit(s) included in the MCP through an interactive telecommunications system, the originating site facility may bill for a telehealth facility fee.

EXAMPLE: A 70 year old ESRD beneficiary receives 2 ESRD-related visits through an interactive telecommunications system and the required face-to-face visit (to examine the vascular access site) during the month of November. In this scenario the originating site should bill for two originating site facility fees as described by HCPCS code Q3014 and the MCP physician at the distant site should bill for ESRD-related services with 2 to 3 visits as a telehealth service, e.g., G3018 "GT".

For more information on telehealth claims processing see Pub. 100-04, chapter 12, section 190 (Medicare telehealth claims processing).

280 – Preventive and Screening Services

(Rev. 48, Issued: 03-24-06; Effective: 01-01-06; Implementation: 04-03-06)

See section 50.4.4.2 for coverage requirements for PPV, hepatitis B vaccine, and Influenza Virus Vaccine.

See Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," for coverage requirements for the following:

- §40 for screening pelvic examinations,
- §50 for prostate cancer screening test and procedures, and,
- §70.4 for glaucoma screening.

280.1 – Glaucoma Screening

(Rev. 48, Issued: 03-24-06; Effective: 01-01-06; Implementation: 04-03-06)

A. Conditions of Coverage

The regulations implementing the Benefits Improvements and Protection Act of 2000, §102, provide for annual coverage for glaucoma screening for beneficiaries in the following high risk categories:

- Individuals with diabetes mellitus;
- Individuals with a family history of glaucoma; or
- African-Americans age 50 and over.

In addition, beginning with dates of service on or after January 1, 2006, 42 CFR 410.23(a)(2), revised, the definition of an eligible beneficiary in a high-risk category is expanded to include:

- Hispanic-Americans age 65 and over.

Medicare will pay for glaucoma screening examinations where they are furnished by or under the direct supervision in the office setting of an ophthalmologist or optometrist, who is legally authorized to perform the services under State law.

Screening for glaucoma is defined to include:

- A dilated eye examination with an intraocular pressure measurement; and
- A direct ophthalmoscopy examination, or a slit-lamp biomicroscopic examination.

Payment may be made for a glaucoma screening examination that is performed on an eligible beneficiary after at least 11 months have passed following the month in which the last covered glaucoma screening examination was performed.

The following HCPCS codes apply for glaucoma screening:

G0117 - Glaucoma screening for high-risk patients furnished by an optometrist or ophthalmologist; and

G0118 - Glaucoma screening for high-risk patients furnished under the direct supervision of an optometrist or ophthalmologist.

The type of service for the above G codes is: TOS Q.

For providers who bill intermediaries, applicable types of bill for screening glaucoma services are 13X, 22X, 23X, 71X, 73X, 75X, and 85X. The following revenue codes should be reported when billing for screening glaucoma services:

- Comprehensive outpatient rehabilitation facilities (CORFs), critical access hospitals (CAHs), skilled nursing facilities (SNFs), independent and provider-based RHCs and free standing and provider-based FQHCs bill for this service under revenue code 770. CAHs electing the optional method of payment for outpatient services report this service under revenue codes 96X, 97X, or 98X.
- Hospital outpatient departments bill for this service under any valid/appropriate revenue code. They are not required to report revenue code 770.

B. Calculating the Frequency

Once a beneficiary has received a covered glaucoma screening procedure, the beneficiary may receive another procedure after 11 full months have passed. To determine the 11-month period, start the count beginning with the month after the month in which the previous covered screening procedure was performed.

C. Diagnosis Coding Requirements

Providers bill glaucoma screening using screening (“V”) code V80.1 (Special Screening for Neurological, Eye, and Ear Diseases, Glaucoma). Claims submitted without a screening diagnosis code may be returned to the provider as unprocessable.

D. Payment Methodology

1. Carriers

Contractors pay for glaucoma screening based on the Medicare physician fee schedule. Deductible and coinsurance apply. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge (refer to the Medicare Claims Processing Manual, Chapter 12, "Physician/Non-physician Practitioners," for more information about the Medicare limiting charge).

2. Intermediaries

Payment is made for the facility expense as follows:

- Independent and provider-based RHC/free standing and provider-based FQHC - payment is made under the all inclusive rate for the screening glaucoma service based on the visit furnished to the RHC/FQHC patient;
- CAH - payment is made on a reasonable cost basis unless the CAH has elected the optional method of payment for outpatient services in which case, procedures outlined in the Medicare Claims Processing Manual, Chapter 3, §30.1.1, should be followed;
- CORF - payment is made under the Medicare physician fee schedule;
- Hospital outpatient department - payment is made under outpatient prospective payment system (OPPS);
- Hospital inpatient Part B - payment is made under OPPS;
- SNF outpatient - payment is made under the Medicare physician fee schedule (MPFS); and
- SNF inpatient Part B - payment is made under MPFS.

Deductible and coinsurance apply.

E. Special Billing Instructions for RHCs and FQHCs

Screening glaucoma services are considered RHC/FQHC services. RHCs and FQHCs bill the contractor under bill type 71X or 73X along with revenue code 770 and HCPCS codes G0117 or G0118 and RHC/FQHC revenue code 520 or 521 to report the related visit. Reporting of revenue code 770 and HCPCS codes G0117 and G0118 in addition to revenue code 520 or 521 is required for this service in order for CWF to perform frequency editing.

Payment should not be made for a screening glaucoma service unless the claim also contains a visit code for the service. Therefore, the contractor installs an edit in its system to assure payment is not made for revenue code 770 unless the claim also contains a visit revenue code (520 or 521).

280.2 - Colorectal Cancer Screening

(Rev. 1, 10-01-03)

B3-4180

280.2.1 - Covered Services and HCPCS Codes

See Business Requirements at http://cms.hhs.gov/manuals/pm_trans/R3BP.pdf

(Rev. 3, 12-19-03)

B3-4180.1

Medicare covers colorectal cancer screening test/procedures for the early detection of colorectal cancer for the HCPCS codes indicated.

A. Effective for Services Furnished On or After January 1, 1998:

G0107 - Colorectal cancer screening; fecal-Occult blood test, 1-3 simultaneous determinations;

G0104 - Colorectal cancer screening; flexible sigmoidoscopy;

G0105 - Colorectal cancer screening; colonoscopy on individual at high risk;

G0106 - Colorectal cancer screening barium enema; alternative to GO104, screening sigmoidoscopy;

G0120 - Colorectal cancer screening barium enema; alternative to GO105, screening sigmoidoscopy.

B. Effective for Services Furnished On or After July 1, 2001:

G0121 - Colorectal Cancer Screening; Colonoscopy on Individual Not Meeting Criteria for High Risk

C. Effective for Services Furnished On or After January 1, 2004:

G0328 - Colorectal cancer screening; fecal-occult blood test, immunoassay,

1-3 simultaneous determinations.

280.2.2 - Coverage Criteria

(Rev. 3, 12-19-03)

B3-4180.2

The following are the coverage criteria for these screenings:

A. Screening Fecal-Occult Blood Tests (FOBT) (Codes G0107 & G0328)

Effective for services furnished on or after January 1, 2004, one screening FOBT (code G0107 **or** G0328) is covered for beneficiaries who have attained age 50, at a frequency of once every 12 months (i.e., at least 11 months have passed following the month in which the last covered screening FOBT was done). Screening FOBT means: (1) a guaiac-based test for peroxidase activity in which the beneficiary completes it by taking samples from two different sites of three consecutive stools **or**, (2) a immunoassay (or immunochemical) test for antibody activity in which the beneficiary completes the test by taking the appropriate number of samples according to the specific manufacturer's instructions. This expanded coverage is in accordance with revised regulations at 42 CFR 410.37(a)(2) that includes " other tests determined by the Secretary through a national coverage determination." This screening requires a written order from the beneficiary's attending physician. (The term "attending physician" is defined to mean a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act) who is fully

knowledgeable about the beneficiary's medical condition, and who would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.)

B. Screening Flexible Sigmoidoscopies (code G0104)

For claims with dates of service on or after January 1, 2002, carriers pay for screening flexible sigmoidoscopies (Code G0104) for beneficiaries who have attained age 50 when these services were performed by a doctor of medicine or osteopathy, or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861(aa)(5) of the Act and in the Code of Federal Regulations at 42 CFR 410.74, 410.75, and 410.76) at the frequencies noted below. For claims with dates of service prior to January 1, 2002, pay for these services under the conditions noted only when they are performed by a doctor of medicine or osteopathy.

For services furnished from January 1, 1998, through June 30, 2001, inclusive

Once every 48 months (i.e., at least 47 months have passed following the month in which the last covered screening flexible sigmoidoscopy was done).

For services furnished on or after July 1, 2001

Once every 48 months as calculated above **unless** the beneficiary does not meet the criteria for high risk of developing colorectal cancer (refer to §280.2.3) **and** the beneficiary has had a screening colonoscopy (code G0121) within the preceding 10 years. If such a beneficiary has had a screening colonoscopy within the preceding 10 years, then he or she can have covered a screening flexible sigmoidoscopy only after at least 119 months have passed following the month that he/she received the screening colonoscopy (code G0121).

NOTE: If during the course of a screening flexible sigmoidoscopy a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a flexible sigmoidoscopy with biopsy or removal should be billed and paid rather than code G0104.

C. Screening Colonoscopies for Beneficiaries at High Risk of Developing Colorectal Cancer (Code G0105)

The carrier must pay for screening colonoscopies (code G0105) when performed by a doctor of medicine or osteopathy at a frequency of once every 24 months for beneficiaries at high risk for developing colorectal cancer (i.e., at least 23 months have passed following the month in which the last covered G0105 screening colonoscopy was performed). Refer to §280.2.3 for the criteria to use in determining whether or not an individual is at high risk for developing colorectal cancer.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal should be billed and paid rather than code G0105.

D. Screening Colonoscopies Performed on Individuals Not Meeting the Criteria for Being at High-Risk for Developing Colorectal Cancer (Code G0121)

Effective for services furnished on or after July 1, 2001, screening colonoscopies (code G0121) are covered when performed under the following conditions:

1. On individuals not meeting the criteria for being at high risk for developing colorectal cancer (refer to §280.2.3);
2. At a frequency of once every 10 years (i.e., at least 119 months have passed following the month in which the last covered G0121 screening colonoscopy was performed); and
3. If the individual would otherwise qualify to have covered a G0121 screening colonoscopy based on the above (see §§280.2.2.D.1 and 2) **but** has had a covered screening flexible sigmoidoscopy (code G0104), then the individual may have a covered G0121 screening colonoscopy only after at least 47 months have passed following the month in which the last covered G0104 flexible sigmoidoscopy was performed.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal should be billed and paid rather than code G0121.

E. Screening Barium Enema Examinations (codes G0106 and G0120)

Screening barium enema examinations are covered as an alternative to either a screening sigmoidoscopy (code G0104) or a screening colonoscopy (code G0105) examination. The same frequency parameters for screening sigmoidoscopies and screening colonoscopies above apply.

In the case of an individual aged 50 or over, payment may be made for a screening barium enema examination (code G0106) performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed. For example, the beneficiary received a screening barium enema examination as an alternative to a screening flexible sigmoidoscopy in January 1999. The count starts beginning February 1999. The beneficiary is eligible for another screening barium enema in January 2003.

In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination (code G0120) performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed. For example, a beneficiary at high risk for developing colorectal cancer received a screening barium enema examination (code G0120) as an alternative to a screening colonoscopy (code G0105) in January 2000. The count starts beginning February 2000. The beneficiary is eligible for another screening barium enema examination (code G0120) in January 2002.

The screening barium enema must be ordered in writing after a determination that the test is the appropriate screening test. Generally, it is expected that this will be a screening double contrast enema unless the individual is unable to withstand such an exam. This means that in the case of a particular individual, the attending physician must determine that the estimated screening potential for the barium enema is equal to or greater than the screening potential that has been estimated for a screening flexible sigmoidoscopy, or for

a screening colonoscopy, as appropriate, for the same individual. The screening single contrast barium enema also requires a written order from the beneficiary's attending physician in the same manner as described above for the screening double contrast barium enema examination.

280.2.3 - Determining Whether or Not the Beneficiary is at High Risk for Developing Colorectal Cancer

(Rev. 1, 10-01-03)

B3-4180.3

A. Characteristics of the High Risk Individual

An individual at high risk for developing colorectal cancer has one or more of the following:

A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;

A family history of familial adenomatous polyposis;

A family history of hereditary nonpolyposis colorectal cancer;

A personal history of colorectal cancer;

A personal history of adenomatous polyps;

Inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

B. Partial List of ICD-9-CM Codes Indicating High Risk

Listed below are some examples of diagnoses that meet the high risk criteria for colorectal cancer. This is not an all-inclusive list. There may be more instances of conditions which may be coded and could be at the medical directors' discretion.

- **Personal History**
  - V10.05 - Personal history of malignant neoplasm of large intestine
  - V10.06 - Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus
- **Chronic Digestive Disease Condition**
  - 555.0 - Regional enteritis of small intestine
  - 555.1 - Regional enteritis of large intestine
  - 555.2 - Regional enteritis of small intestine with large intestine
  - 555.9 - Regional enteritis of unspecified site
  - 556.0 - Ulcerative (chronic) enterocolitis
  - 556.1 - Ulcerative (chronic) ileocolitis
  - 556.2 - Ulcerative (chronic) proctitis
  - 556.3 - Ulcerative (chronic) proctosigmoiditis

- 556.8 - Other ulcerative colitis
- 556.9 - Ulcerative colitis, unspecified (nonspecific PDX on the MCE)

- **Inflammatory Bowel**
  - 558.2 - Toxic gastroenteritis and colitis
  - 558.9 - Other and unspecified noninfectious gastroenteritis and colitis

280.2.4 - Determining Frequency Standards

(Rev. 1, 10-01-03)

B3-4180.4

To determine the 11, 23, 47, and 119-month periods, the count starts beginning with the month after the month in which a previous test/procedure was performed.

EXAMPLE: The beneficiary received a fecal-occult blood test in January 2000. The carrier starts its count beginning with February 2000. The beneficiary is eligible to receive another blood test in January 2001 (the month after 11 full months have passed).

280.2.5 - Noncovered Services

(Rev. 1, 10-01-03)

B3-4180.5

The following noncovered HCPCS codes are used to allow claims to be billed and denied for beneficiaries who need a Medicare denial for other insurance purposes for the dates of service indicated:

A. From January 1, 1998 Through June 30, 2001, Inclusive

Code G0121 (colorectal cancer screening; colonoscopy on an individual not meeting criteria for high risk) should be used when this procedure is performed on a beneficiary who does NOT meet the criteria for high risk. This service should be denied as noncovered because it fails to meet the requirements of the benefit for these dates of service. The beneficiary is liable for payment. Note that this code is a covered service for dates of service on or after July 1, 2001.

B. On or After January 1, 1998

Code G0122 (colorectal cancer screening; barium enema) should be used when a screening barium enema is performed NOT as an alternative to either a screening colonoscopy (code G0105) or a screening flexible sigmoidoscopy (code G0104). This service should be denied as noncovered because it fails to meet the requirements of the benefit. The beneficiary is liable for payment.

280.3 - Screening Mammography

(Rev. 1, 10-01-03)

A3-3660.10, B3-4601.1

Section 4163 of the Omnibus Budget Reconciliation Act of 1990 added §1834(c) of the Act to provide for Part B coverage of mammography screening performed on or after

January 1, 1991. The term “screening mammography” means a radiologic procedure provided to an asymptomatic woman for the purpose of early detection of breast cancer and includes a physician’s interpretation of the results of the procedure. Unlike diagnostic mammographies, there do not need to be signs, symptoms, or history of breast disease in order for the exam to be covered.

A doctor’s prescription or referral is not necessary for the procedure to be covered. Payment may be made for a screening mammography furnished to a woman at her direct request, and based on a woman’s age and statutory frequency parameter.

Section 4101 of the Balanced Budget Act (BBA) of 1997 provides for annual screening mammographies for women over 39 and waives the Part B deductible. Coverage applies as follows:

Age	**Screening Period**
Less than 35 years old	No payment may be made for a screening mammography performed on a woman under 35 years of age.
35-39	(Baseline). Pay for only one screening mammography performed on a woman between her 35th and 40th birthday.
Over age 39	For a woman over 39, pay for a screening mammography performed after 11 full months have passed following the month in which the last screening mammography was performed.

To determine the 11-month period, intermediaries and carriers start counting beginning with the month after the month in which a previous screening mammography was performed.

EXAMPLE: If Mrs. Smith received a screening mammography examination in January 1998, begin counting the next month (February 1998) until 11 months have elapsed. Payment can be made for another screening mammography in January 1999.

See the Medicare Claims Processing Manual, Chapter 18, “Preventive and Screening Services,” §30, for billing and payment instructions.

280.4 - Screening Pap Smears

(Rev. 1, 10-01-03)

A3-3628.1, B3-4603.1

Effective, January 1, 1998, §4102 of the Balanced Budget Act (BBA) of 1997 (P.L. 105-33) amended §1861(nn) of the Act (42 USC 1395X(nn)) to include coverage every three years for a screening Pap smear or more frequent coverage for women:

1. At high risk for cervical or vaginal cancer; or

2. Of childbearing age who have had a Pap smear during any of the preceding three years indicating the presence of cervical or vaginal cancer or other abnormality.

Effective July 1, 2001, the Consolidated Appropriations Act of 2001 (P.L. 106-554) modifies §1861(nn) to provide Medicare coverage for biennial screening Pap smears. Specifications for frequency limitations are defined below.

For claims with dates of service from January 1, 1998, through June 30, 2001, screening Pap smears are covered when ordered and collected by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or other authorized practitioner (e.g., a certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist, who is authorized under State law to perform the examination) under one of the following conditions.

The beneficiary has not had a screening Pap smear test during the preceding three years (i.e., 35 months have passed following the month that the woman had the last covered Pap smear ICD-9-CM code V76.2 is used to indicate special screening for malignant neoplasm, cervix); or

There is evidence (on the basis of her medical history or other findings) that she is of childbearing age and has had an examination that indicated the presence of cervical or vaginal cancer or other abnormalities during any of the preceding three years; and at least 11 months have passed following the month that the last covered Pap smear was performed; or

She is at high risk of developing cervical or vaginal cancer ICD-9-CM code V15.89, other specified personal history presenting hazards to health) and at least 11 months have passed following the month that the last covered screening Pap smear was performed. The high risk factors for cervical and vaginal cancer are:

Cervical Cancer High Risk Factors

Early onset of sexual activity (under 16 years of age);

Multiple sexual partners (five or more in a lifetime);

History of a sexually transmitted disease (including HIV infection); and

Fewer than three negative or any Pap smears within the previous seven years.

Vaginal Cancer High Risk Factors

The DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy

The term “woman of childbearing age” means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner, to be of childbearing age, based on her medical history or other findings. Payment is not made for a screening Pap smear for women at high risk or who qualify for coverage under the childbearing provision more frequently than once every 11 months after the month that the last screening Pap smear covered by Medicare was performed.

B. For Claims with Dates of Service on or After July 1, 2001

When the beneficiary does not qualify for a more frequently performed screening Pap smear as noted in items 1 and 2 above, contractors pay for the screening Pap smear only after at least 23 months have passed following the month during which the beneficiary

received her last covered screening Pap smear. All other coverage and payment requirements remain the same.

See the Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," for billing procedures.

290 - Foot Care

(Rev. 1, 10-01-03)

A3-3158, B3-2323, HO-260.9, B3-4120.1

A. Treatment of Subluxation of Foot

Subluxations of the foot are defined as partial dislocations or displacements of joint surfaces, tendons ligaments, or muscles of the foot. Surgical or nonsurgical treatments undertaken for the sole purpose of correcting a subluxated structure in the foot as an isolated entity are not covered.

However, medical or surgical treatment of subluxation of the ankle joint (talo-crural joint) is covered. In addition, reasonable and necessary medical or surgical services, diagnosis, or treatment for medical conditions that have resulted from or are associated with partial displacement of structures is covered. For example, if a patient has osteoarthritis that has resulted in a partial displacement of joints in the foot, and the primary treatment is for the osteoarthritis, coverage is provided.

B. Exclusions from Coverage

The following foot care services are generally excluded from coverage under both Part A and Part B. (See §290.F and §290.G for instructions on applying foot care exclusions.)

1. Treatment of Flat Foot

The term "flat foot" is defined as a condition in which one or more arches of the foot have flattened out. Services or devices directed toward the care or correction of such conditions, including the prescription of supportive devices, are not covered.

2. Routine Foot Care

Except as provided above, routine foot care is excluded from coverage. Services that normally are considered routine and not covered by Medicare include the following:

- The cutting or removal of corns and calluses;
- The trimming, cutting, clipping, or debriding of nails; and
- Other hygienic and preventive maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

3. Supportive Devices for Feet

Orthopedic shoes and other supportive devices for the feet generally are not covered. However, this exclusion does not apply to such a shoe if it is an integral part of a leg

brace, and its expense is included as part of the cost of the brace. Also, this exclusion does not apply to therapeutic shoes furnished to diabetics.

C. Exceptions to Routine Foot Care Exclusion

1. Necessary and Integral Part of Otherwise Covered Services

In certain circumstances, services ordinarily considered to be routine may be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of ulcers, wounds, or infections.

2. Treatment of Warts on Foot

The treatment of warts (including plantar warts) on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body.

3. Presence of Systemic Condition

The presence of a systemic condition such as metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and, therefore, excluded from coverage). Accordingly, foot care that would otherwise be considered routine may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet. (See subsection A.)

In these instances, certain foot care procedures that otherwise are considered routine (e.g., cutting or removing corns and calluses, or trimming, cutting, clipping, or debriding nails) may pose a hazard when performed by a nonprofessional person on patients with such systemic conditions. (See §290.G for procedural instructions.)

4. Mycotic Nails

In the absence of a systemic condition, treatment of mycotic nails may be covered.

The treatment of mycotic nails for an ambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient has marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

The treatment of mycotic nails for a nonambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

For the purpose of these requirements, documentation means any written information that is required by the carrier in order for services to be covered. Thus, the information submitted with claims must be substantiated by information found in the patient's medical record. Any information, including that contained in a form letter, used for documentation purposes is subject to carrier verification in order to ensure that the information adequately justifies coverage of the treatment of mycotic nails.

D. Systemic Conditions That Might Justify Coverage

Although not intended as a comprehensive list, the following metabolic, neurologic, and peripheral vascular diseases (with synonyms in parentheses) most commonly represent the underlying conditions that might justify coverage for routine foot care.

Diabetes mellitus *

Arteriosclerosis obliterans (A.S.O., arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)

Buerger's disease (thromboangiitis obliterans)

Chronic thrombophlebitis *

Peripheral neuropathies involving the feet -

Associated with malnutrition and vitamin deficiency *

- Malnutrition (general, pellagra)
- Alcoholism
- Malabsorption (celiac disease, tropical sprue)
- Pernicious anemia

Associated with carcinoma *

Associated with diabetes mellitus *

Associated with drugs and toxins *

Associated with multiple sclerosis *

Associated with uremia (chronic renal disease) *

Associated with traumatic injury

Associated with leprosy or neurosyphilis

Associated with hereditary disorders

- Hereditary sensory radicular neuropathy
- Angiokeratoma corporis diffusum (Fabry's)
- Amyloid neuropathy

When the patient's condition is one of those designated by an asterisk (*), routine procedures are covered only if the patient is under the active care of a doctor of medicine or osteopathy who documents the condition.

E. Supportive Devices for Feet

Orthopedic shoes and other supportive devices for the feet generally are not covered. However, this exclusion does not apply to such a shoe if it is an integral part of a leg brace, and its expense is included as part of the cost of the brace. Also, this exclusion does not apply to therapeutic shoes furnished to diabetics.

F. Presumption of Coverage

In evaluating whether the routine services can be reimbursed, a presumption of coverage may be made where the evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement. For purposes of applying this presumption the following findings are pertinent:

Class A Findings

Nontraumatic amputation of foot or integral skeletal portion thereof.

Class B Findings

Absent posterior tibial pulse;

Advanced trophic changes as: hair growth (decrease or absence) nail changes (thickening) pigmentary changes (discoloration) skin texture (thin, shiny) skin color (rubor or redness) (Three required); and

Absent dorsalis pedis pulse.

Class C Findings

Claudication;

Temperature changes (e.g., cold feet);

Edema;

Paresthesias (abnormal spontaneous sensations in the feet); and

Burning.

The presumption of coverage may be applied when the physician rendering the routine foot care has identified:

1. A Class A finding;
2. Two of the Class B findings; or
3. One Class B and two Class C findings.

Cases evidencing findings falling short of these alternatives may involve podiatric treatment that may constitute covered care and should be reviewed by the intermediary's medical staff and developed as necessary.

For purposes of applying the coverage presumption where the routine services have been rendered by a podiatrist, the contractor may deem the active care requirement met if the claim or other evidence available discloses that the patient has seen an M.D. or D.O. for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type services. The intermediary may also accept the podiatrist's statement that the diagnosing and treating M.D. or D.O. also concurs with the podiatrist's findings as to the severity of the peripheral involvement indicated.

Services ordinarily considered routine might also be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of diabetic ulcers, wounds, and infections.

G. Application of Foot Care Exclusions to Physician's Services

The exclusion of foot care is determined by the nature of the service. Thus, payment for an excluded service should be denied whether performed by a podiatrist, osteopath, or a doctor of medicine, and without regard to the difficulty or complexity of the procedure.

When an itemized bill shows both covered services and noncovered services not integrally related to the covered service, the portion of charges attributable to the noncovered services should be denied. (For example, if an itemized bill shows surgery for an ingrown toenail and also removal of calluses not necessary for the performance of toe surgery, any additional charge attributable to removal of the calluses should be denied.)

In reviewing claims involving foot care, the carrier should be alert to the following exceptional situations:

1. Payment may be made for incidental noncovered services performed as a necessary and integral part of, and secondary to, a covered procedure. For example, if trimming of toenails is required for application of a cast to a fractured foot, the carrier need not allocate and deny a portion of the charge for the trimming of the nails. However, a separately itemized charge for such excluded service should be disallowed. When the primary procedure is covered the administration of anesthesia necessary for the performance of such procedure is also covered.
2. Payment may be made for **initial** diagnostic services performed in connection with a specific symptom or complaint if it seems likely that its treatment would be covered even though the resulting diagnosis may be one requiring only noncovered care.

The name of the M.D. or D.O. who diagnosed the complicating condition must be submitted with the claim. In those cases, where active care is required, the approximate date the beneficiary was last seen by such physician must also be indicated.

NOTE: Section 939 of P.L. 96-499 removed "warts" from the routine foot care exclusion effective July 1, 1981.

Relatively few claims for routine-type care are anticipated considering the severity of conditions contemplated as the basis for this exception. Claims for this type of foot care should not be paid in the absence of convincing evidence that nonprofessional performance of the service would have been hazardous for the beneficiary because of an underlying systemic disease. The mere statement of a diagnosis such as those mentioned in §D above does not of itself indicate the severity of the condition. Where development is indicated to verify diagnosis and/or severity the carrier should follow existing claims processing practices which may include review of carrier's history and medical consultation as well as physician contacts.

The rules in §290.F concerning presumption of coverage also apply.

Codes and policies for routine foot care and supportive devices for the feet are not exclusively for the use of podiatrists. These codes must be used to report foot care services regardless of the specialty of the physician who furnishes the services. Carriers must instruct physicians to use the most appropriate code available when billing for routine foot care.

300 - Diabetes Self-Management Training Services

(Rev. 13, 05-13-04)

Section 4105 of the Balanced Budget Act of 1997 permits Medicare coverage of diabetes self-management training (DSMT) services when these services are furnished by a certified provider who meets certain quality standards. This program is intended to educate beneficiaries in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the skills for self-management.

Diabetes self-management training services may be covered by Medicare only if the treating physician or treating qualified nonphysician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed. The referring physician or qualified nonphysician practitioner must maintain the plan of care in the beneficiary's medical record and documentation substantiating the need for training on an individual basis when group training is typically covered, if so ordered. The order must also include a statement signed by the physician that the service is needed as well as the following:

- The number of initial or follow-up hours ordered (the physician can order less than 10 hours of training);
- The topics to be covered in training (initial training hours can be used for the full initial training program or specific areas such as nutrition or insulin training); and
- A determination that the beneficiary should receive individual or group training.

The provider of the service must maintain documentation in file that includes the original order from the physician and any special conditions noted by the physician.

When the training under the order is changed, the training order/referral must be signed by the physician or qualified nonphysician practitioner treating the beneficiary and maintained in the beneficiary's file in the DSMT's program records.

NOTE: All entities billing for DSMT under the fee-for-service payment system or other payment systems, facilities, federally qualified health centers (FQHCs), End-Stage Renal Disease (ESRD), rural health clinics (RHCs) or managed care organizations must meet all national coverage requirements.

300.1 - Beneficiaries Eligible for Coverage and Definition of Diabetes

(Rev. 13, 05-13-04)

Medicare Part B covers 10 hours of initial training for a beneficiary who has been diagnosed with diabetes.

Diabetes is diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria;

- a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions;

- a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or

- a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Documentation that the beneficiary is diabetic is maintained in the beneficiary's medical record.

Beneficiaries are eligible to receive follow-up training each calendar year following the year in which they have been certified as requiring initial training or they may receive follow-up training when ordered even if Medicare does not have documentation that initial training has been received. In that instance, contractors shall not deny the follow-up service even though there is no initial training recorded.

300.2 - Certified Providers

(Rev. 13, 05-13-04)

PM AB -02-151, B-01-40

A designated certified provider bills for DSMT provided by an accredited DSMT program. Certified providers must submit a copy of their accreditation certificate to the contractor. The statute states that a "certified provider" is a physician or other individual or entity designated by the Secretary that, in addition to providing outpatient self-management training services, provides other items and services for which payment may be made under title XVIII, and meets certain quality standards. The CMS is designating all providers and suppliers that bill Medicare for other individual services such as hospital outpatient departments, renal dialysis facilities, physicians and durable medical equipment suppliers as certified. All suppliers/providers who may bill for other Medicare services or items and who represent a DSMT program that is accredited as meeting quality standards can bill and receive payment for the entire DSMT program. Registered dietitians are eligible to bill on behalf of an entire DSMT program on or after January 1, 2002, as long as the provider has obtained a Medicare provider number. A dietitian may not be the sole provider of the DSMT service.

The CMS will not reimburse services on a fee-for-service basis rendered to a beneficiary if they are:

- An inpatient in a hospital or skilled nursing facility (SNF);
- In hospice care;
- A resident in a nursing home; or
- An outpatient in a rural health clinic (RHC) or (FQHC)

NOTE: While separate payment is not made for this service to RHCs or FQHCs, the service is covered but is considered included in the encounter rate.

All DSMT programs must be accredited as meeting quality standards by a CMS approved national accreditation organization. Currently, CMS recognizes the American Diabetes Association and the Indian Health Service as approved national accreditation organizations. Programs without accreditation by a CMS-approved national accreditation organization are not covered. Certified providers may be asked to submit updated accreditation documents at any time or to submit outcome data to an organization designated by CMS.

Enrollment of DMEPOS Suppliers

The DMEPOS suppliers are reimbursed for diabetes training through local carriers. In order to file claims for DSMT, a DMEPOS supplier must be enrolled in the Medicare program with the National Supplier Clearinghouse (NSC). The supplier must also meet the quality standards of a CMS-approved national accreditation organization as stated above. DMEPOS suppliers must obtain a provider number from the local carrier in order to bill for DSMT.

The carrier requires a completed Form CMS-855, along with an accreditation certificate as part of the provider application process. After it has been determined that the quality standards are met, a billing number is assigned to the supplier. Once a supplier has received a provider identification (PIN) number, the supplier can begin receiving reimbursement for this service.

Carriers should contact the National Supplier Clearinghouse (NSC) according to the instruction in Pub 100-08, the Medicare Program Integrity Manual, Chapter 10, "Healthcare Provider/Supplier Enrollment," to verify an applicant is currently enrolled and eligible to receive direct payment from the Medicare program.

The applicant is assigned specialty 87.

Any DMEPOS supplier that has its billing privileges deactivated or revoked by the NSC will also have the billing number deactivated by the carrier.

300.3 - Coding Frequency of Training

(Rev. 13, 05-13-04)

A. Coding

The following HCPCS codes are used for DSMT:

- G0108 - Diabetes outpatient self-management training services, individual, per 30 minutes.
- G0109 - Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes.

The type of service for these codes is 1.

B. Initial Training

Medicare will cover initial training that meets the following conditions:

- Is furnished to a beneficiary who has not previously received initial or follow-up training under HCPCS G0108 or G0109.

- Is furnished within a continuous 12-month period.
- Does not exceed a total of 10 hours for the initial training. The 10 hours of training can be done in any combination of 1/2 hour increments. They can be spread over the 12-month period or less.
- With the exception of 1 hour of individual training, training is usually furnished in a group setting who need not all be Medicare beneficiaries.
- The one hour of individual training may be used for any part of the training including insulin training.
- Is furnished in increments of no less than one-half hour.

C. Individual Training

Medicare covers training on an individual basis for a Medicare beneficiary under any of the following conditions:

- No group session is available within two months of the date the training is ordered;
- The beneficiary's physician (or qualified nonphysician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing or language limitations or other such special conditions as identified by the treating physician or non-physician practitioner, that will hinder effective participation in a group training session; or
- The physician orders additional insulin training.
- The need for individual training must be identified by the physician or non-physician practitioner in the referral.

NOTE: If individual training has been provided to a Medicare beneficiary and subsequently the carrier or intermediary determines that training should have been provided in a group, down-coding the reimbursement from individual to the group level and provider education would be the appropriate actions instead of denying the service as billed.

D. Follow-Up Training

After receiving the initial training, Medicare covers follow-up training that meets the following conditions:

- Consists of no more than two hours individual or group training for a beneficiary each year;
- Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries;
- Is furnished any time in a calendar year following a year in which the beneficiary completes the initial training (e.g., beneficiary completes initial

training in November 2003 therefore the beneficiary is entitled to 2 hours of follow-up training beginning in January of 2004);

- Is furnished in increments of no less than one-half hour; and

- The physician (or qualified nonphysician practitioner) treating the beneficiary must document in the beneficiary's medical record that the beneficiary is a diabetic.

300.4 - Payment for DSMT

(Rev. 13, 05-13-04)

PM AB -02-151, B-01-40

Payment to providers for outpatient diabetes self-management training is based on rates established under the Medicare Physician Fee Schedule.

- Payment may only be made to any provider that bills Medicare for other individual Medicare Services;

- Payment may be made only for training sessions actually attended by the beneficiary and documented on attendance sheets;

- Other conditions for fee-for-service payment. The beneficiary must meet the following conditions if the provider is billing for initial training:

  ° The beneficiary has not previously received initial or follow-up training for which Medicare payment was made under this benefit;

  ° The beneficiary is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home; or

  ° The beneficiary is not receiving services as an outpatient in an RHC or FQHC.

300.4.1 – Incident-To Provision

(Rev. 13, 05-13-04)

The "incident to" requirements of section 1861(s)(2)(A) of the Social Security Act do not apply to DSMT services. Section 1861 (s)(2)(S) of the Act authorizes DSMT in a stand alone provision. DSMT services are covered only if the physician or qualified non-physician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed and refers the patient to the DSMT program. The referral must be done under a comprehensive plan of care related to the beneficiary's diabetic condition. Training may be furnished by a physician, individual, or entity that meets the following conditions:

- Furnishes other services for which direct Medicare payment may be made;

- May properly receive Medicare payment under 42CFR 424.73 or 424.80 which set forth prohibitions on assignment and reassignment of claims;

- Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under 42CFR 410.142 to meet one of the sets of quality standards described in 42 CFR 410.144; and

- Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at CFR 410.146.

    - Any certified providers or suppliers that provide other individual items or services under Medicare that meet CMS's quality standards and meet the conditions for CMS approval pursuant to 42 CFR 410.145, may receive reimbursement for diabetes training. Entities are more likely than individuals to bill for DSMT services. These certified providers must be currently receiving payment for other Medicare services.

300.5 - Bill Processing Requirements

(Rev. 13, 05-13-04)

See chapter 25 of the Medicare Claims Processing Manual, for instructions for intermediaries, hospitals, and outpatient facilities.

See chapter 26 of the Medicare Claims Processing Manual, for instructions for carriers and physicians intermediaries, hospitals, and outpatient facilities.

Billing is to the "certified provider's" regular intermediary or carrier, i.e., there are no specialty contractors for this service. (See §300.2 above for definition of "certified provider" in this instance.

300.5.1 - Special Claims Processing Instructions for FIs

(Rev. 24, Issued: 10-29-04, Effective: 01-01-05, Implementation: 01-03-05)

- Coding and Payment Requirements

  The provider bills for DSMT on Form CMS-1450 or its electronic equivalent. The cost of the service is billed under revenue code 942 in FL 42 "Revenue Code." The provider will report HCPCS codes G0108 or G0109 in FL 44 "HCPCS/Rates." The definition of the HCPCS code used should be entered in FL 43 "Description."

- Applicable Bill Types

  The appropriate bill types are 12x, 22x, 13x, 34x (can be billed if service is outside of the treatment plan), 72x, 74x, 75x, 83x and 85x.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R63BP	12/29/2006	Outpatient Therapy Cap Exceptions Process for Calendar Year (CY) 2007	01/29/2007	5478
R62BP	12/22/2006	Private Contracting-Definition of Physician/Practitioner	04/02/2007	5426
R60BP	11/09/2006	Outpatient Therapy Cap Clarification	01/02/2007	5271
R55BP	09/29/2006	Psychological and Neuropsychological Tests	12/28/2006	5204
R53BP	07/07/2006	Medicare Telehealth Services Update	08/07/2006	5122
R52BP	06/30/2006	Therapy Caps Exception Process	03/13/2006	4364
R51BP	06/23/2006	Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests; Clinical Psychologist Services	09/21/2006	4400
R48BP	03/24/2006	Expansion of Glaucoma Screening Services	04/03/2006	4365
R47BP	02/15/2006	Therapy Caps Exception Process	03/13/2006	4364
R46BP	02/13/2006	Therapy Caps Exception Process	03/13/2006	4364
R43BP	12/23/2005	List of Medicare Telehealth Services	04/03/2006	4204
R37BP	08/12/2005	Conforming Changes for Change Request 3648 to Pub. 100-02	09/12/2005	3912
R36BP	06/24/2005	Pub. 100-02, Chapter 15, Sections 220 and 230 Therapy Services	06/06/2005	3648
R34BP	05/06/2005	Pub. 100-02, Chapter 15, Sections 220 and 230 Therapy Services	06/06/2005	3648
R31BP	04/01/2005	List of Medicare Telehealth Services	05/02/2005	3747
R30BP	02/18/2005	Policy for Repair and Replacement of Durable Medical Equipment (DME)	N/A	3693
R24BP	10/29/2004	Revision of Section 300.5.1, Chapter 15 of the Medicare Benefit Policy Manual to include 22x TOB as an applicable TOB for Diabetes Self-Management Training	01/03/2005	3531

Rev #	Issue Date	Subject	Impl Date	CR#
R63BP	12/29/2006	Outpatient Therapy Cap Exceptions Process for Calendar Year (CY) 2007	01/29/2007	5478
R23BP	10/08/2004	Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full Replacement of CR 3063	10/04/2004	3449
R18BP	09/03/2004	Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full Replacement of CR 3063	10/04/2004	3449
R17BP	06/18/2004	Providing Information for Incident to Services.	10/04/2004	3242
R13BP	05/28/2004	Diabetes Self Management Training Services	06/28/2004	3185
R12BP	05/28/2004	Chiropractor's Services	10/04/2004	3063
R09BP	04/23/2004	Arrangements for Physical, Occupational, and Speech Language Pathology Services (PT, OT, SLP)	05/24/2004	3134
R06BP	01/23/2004	Intravenous Immune Globulin	04/05/2004	3059
R05BP	01/09/2004	Coverage of Outpatient Physical Therapy, Occupational Therapy and Speech-Language Pathology Services Under Medical Insurance	03/15/2004	2859 & 2779
R04BP	01/02/2004	Dentists, podiatrists, and optometrists are added to the definition/list of physicians who may opt out of Medicare	02/02/2004	3016
R03BP	12/19/2003	Coverage of iFOBT	01/05/2004	2996
R01BP	10/01/2003	Introduction to the Benefit Policy Manual	N/A	N/A

Medicare Financial Management Manual

Chapter 7 - Internal Control Requirements

Table of Contents

(Rev. 132, 10-05-07)

Transmittals for Chapter 7

10 - Introduction

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

This chapter provides guidelines and policies to the Medicare contractors to enable them to strengthen their internal control procedures. The CMS contracts with companies to administer the Medicare program under the Social Security Act *and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)*. The Medicare contractors shall administer the Medicare program efficiently and economically to achieve the program objectives. Internal control is a major part of managing an organization. Internal control also serves as the first line of defense in safeguarding assets and preventing and detecting errors and fraud. In short, internal control helps government program managers achieve desired results through effective stewardship of public resources.

10.1 - Authority

(Rev. 95, Issued: 04-28-06; Effective/Implementation Dates: 05-30-06)

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) establishes internal control requirements that shall be met by CMS. For CMS to meet the requirements of FMFIA, Medicare contractors shall demonstrate that they comply with the FMFIA guidelines.

10.1.1 - Federal Managers' Financial Integrity Act of 1982 (FMFIA)

(Rev. 66, Issued: 03-04-05, Effective: 10-01-04, Implementation: 04-04-05)

The act requires that internal accounting and administrative controls of each executive agency be established in accordance with the standards prescribed by the Comptroller General. Under FMFIA, the Office of Management and Budget (OMB) establishes guidelines for agencies to evaluate their systems of internal accounting and administrative control to determine such systems' compliance with the standards established by the Comptroller General.

Under the prescribed standards of the FMFIA, agencies must provide reasonable assurance to the President and Congress on an annual basis that: (1) Obligations and costs are in compliance with applicable law; (2) Funds, property, and other assets are safeguarded against waste, loss, unauthorized use, or misappropriation; and (3) Revenues and expenditures applicable to agency operations are properly recorded and accounted for to permit the preparation of accounts, reliable financial and statistical reports, and to maintain accountability over the assets.

10.1.2 - FMFIA and the CMS Medicare Contractor Contract

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The CMS contract with its Medicare contractors includes an article titled FMFIA. In this article, the Medicare contractor agrees to cooperate with CMS in the development of procedures permitting CMS to comply with FMFIA and other related standards

prescribed by the Comptroller General of the United States. Under various provisions of the Social Security Act, *and the Medicare Prescription Drug, Improvement Modernization Act of 2003 (MMA),* Medicare contractors *shall* be evaluated by CMS on administrative service performance. The CMS evaluates Medicare contractor's performance by various internal and external reviews.

To further sensitize the Medicare contractors as to the importance of FMFIA compliance, CMS requires the Medicare contractors to annually provide assurance that internal controls are in place and to identify and correct any areas of weakness in their operations. The vehicle used by the Medicare contractors to provide this assurance is the Certification Package for Internal Controls (CPIC). The CPIC includes a self-certification representation that the Medicare contractor's internal controls are in compliance with FMFIA expectations, that the Medicare contractor recognizes the importance of internal controls, and the Medicare contractor has provided required documentation in the package.

10.1.3 - Chief Financial Officers Act of 1990 (CFO)

(Rev. 66, Issued: 03-04-05, Effective: 10-01-04, Implementation: 04-04-05)

The CFO Act of 1990 established a leadership structure, provided for long range planning, required audited financial statements, and strengthened accountability reporting. The aim of the CFO Act is to improve financial management systems and information. The CFO Act also requires the development and maintenance of agency financial management systems that comply with: applicable accounting principles, standards, and requirements; internal control standards; and requirements of OMB, the Department of the Treasury, and others.

10.1.4 - OMB Circular A-123

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

OMB Circular A-123, Management's Responsibility for Internal Control, December 21, 2004, provides specific requirements for assessing and reporting on internal controls. *The* Circular requires Federal agencies to prepare a separate assurance statement on the effectiveness of internal control over financial reporting. The Circular is issued under the authority of FMFIA and provides additional guidance. The Circular emphasizes that internal control should benefit rather than encumber management, and should make sense for each agency's operating structure and environment.

10.1.5 - GAO Standards for Internal Controls in the Federal Government

(Rev. 66, Issued: 03-04-05, Effective: 10-01-04, Implementation: 04-04-05)

The FMFIA requires the Government Accountability Office (GAO) to issue standards for internal control in government. GAO's "Standards for Internal Controls in the Federal Government" were updated in November 1999. The standards provide the overall framework for establishing and maintaining internal control and for identifying and

addressing major performance and management challenges as well as areas of greatest risk of fraud, waste, abuse, and mismanagement. These are the internal control standards that CMS and its Medicare contractors must follow.

10.2 - GAO Standards in the Federal Government
(Rev. 7, 08-30-02)

10.2.1 - Definition and Objectives
(Rev. 7, 08-30-02)

Internal controls are the checks and balances that ensure that operational objectives are carried out as planned in the most effective and efficient manner possible. We should not look upon these controls as separate specialized systems, but as integral parts of each system that management uses to accomplish the objectives of the Medicare program. In this regard Internal Controls are not just financial tools that safeguard assets, but are tools that are of vital importance to day-to-day programmatic and administrative operations as well. Internal control should be the first thought in CMS's oversight process. That is, can we be sure that there are adequate internal controls in place and operating effectively for the process we are evaluating?

Internal controls are an integral part of an organization's management to provide reasonable assurance that the following objectives are being achieved:

- Effectiveness and efficiency of operations;
- Reliability of financial reporting; and
- Compliance with applicable laws and regulations

Internal control also serves as the first line of defense in safeguarding assets and preventing and detecting errors and fraud. In short, internal control, which is synonymous with management control, helps program managers achieve desired results through effective stewardship of resources.

10.2.2 - Fundamental Concepts
(Rev. 66, Issued: 03-04-05, Effective: 10-01-04, Implementation: 04-04-05)

Three fundamental concepts provide the underlying framework for designing and applying the internal control standards.

A. A continuous built-in component of operations

Internal control includes measures and practices that are used to mitigate risks and exposures that could potentially prevent an organization from achieving its goals and objectives. Internal control is not one event or circumstance, but a series of actions that permeate an organization's activities. These actions are pervasive and are inherent in the

way management runs the organization. Internal controls involve an organization-wide commitment that defines and implements a continuous process of assessing, monitoring, and tracking activities and risks, through an integrated and effective communication mechanism.

B. Are effected by people

An organization's management directs internal control, which is carried out by the people within that organization. Management's commitment to establish strong internal control affects the organization's practices. Management sets goals and policies, provides resources, and monitors and evaluates the performance of the organization. The organization's internal control environment is established by these policies and is controlled by available resources. Although internal control begins with this established environment, the employees make it work and must be adequately trained. It is the manner in which the entire organization embraces the internal control that affects their accountability and operational results.

C. Provide reasonable assurance, not absolute assurance

Reasonable assurance indicates that an internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance regarding achievement of an entity's objectives, and further indicates that the likelihood of achievement of these objectives is affected by limitations inherent in all internal control systems.

Examples of limitations are:

a. Judgment - the effectiveness of controls will be limited by decisions made by human judgment under pressures to conduct business based on information at hand;

b. Breakdowns - even well designed internal controls can break down. Employees sometimes misunderstand instructions or simply make mistakes. Errors may also result from new technology and the complexity of computerized information systems;

c. Management Override - high-level personnel may be able to override prescribed policies and procedures for personal gain or advantage. This should not be confused with management intervention, which represents management actions to depart from prescribed policies and procedures for legitimate purposes;

d. Collusion - control systems can be circumvented by employee collusion. Individuals acting collectively can alter financial data or other management information in a manner that cannot be identified by control systems.

10.2.3 - Standards for Internal Control

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Internal control consists of five interrelated standards. The GAO "Standards for Internal Control in the Federal Government" describes these five standards:

A. Control environment;

B. Risk assessment;

C. Control activities;

D. Information and communication; and

E. Monitoring.

Each of these internal control standards plays an important role in the overall control environment of an organization. These standards define the minimum level of quality acceptable for internal control in government and provide the basis against which the internal control is to be evaluated.

While each internal control standard is an integral part of the management process and plays a specific role, it is the combination of these standards that establishes internal control in an organization. The control environment provides the discipline and atmosphere in which the organization conducts its activities and carr*ies* out its control responsibilities. It also serves as the foundation for the other standards. Within this environment, management conducts risk assessments to assess potential affect of internal and external risks in achieving the organization's objectives. Control activities are implemented to help ensure that management directives are carried out as planned. Relevant information is captured and communicated in a timely and effective manner throughout the organization on an ongoing basis. The organization's operations are continuously monitored as an integral part of the organization's performance evaluation.

10.2.3.1 - Control Environment

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Management and employees should establish and maintain an environment throughout the organization that sets a positive and supportive attitude toward internal control and conscientious management.

The control environment of an organization sets the tone of an organization, influencing the *internal* control consciousness of its people. It is the foundation for all other standards of internal control, providing discipline and structure. Control environment factors include the integrity, ethical values, and competence of the organization's people; management's philosophy and operating style; and the way management assigns authority and responsibility and organizes and develops its human resources.

10.2.3.2 - Risk Assessment

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Every organization faces a variety of risks from external and internal sources that must be assessed. A precondition to risk assessment is establishment of control objectives, linked at different levels and internally consistent.

Risk assessment is the identification and analysis of relevant risks to the achievement of established objectives. A key factor in the consideration of an internal control structure is the importance and risk associated with a program and its associated cost effectiveness. When determining whether a particular control objective should be established, the risk of failure and the potential affect must be considered along with the cost of establishing the control.

10.2.3.3 - Control Activities

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The control activities help ensure that management's directives are carried out. The control activities should be effective and efficient in accomplishing the organization's control objectives.

Control activities are the written activities used to support policies and procedures that help ensure management directives are carried out. Also see *s*ection 20.3, Policies and Procedures. They help ensure that necessary actions are taken to address potential risks that may affect the organization's objectives. Control activities occur throughout the organization, at all levels and in all functions. They include a range of activities as diverse as approvals, authorizations, verifications, reconciliation, performance reviews, security of assets, and segregation of duties. For examples of Non-Information Systems and Information Systems control activities, see GAO – Internal Control Management and Evaluation Tool at: www.gao.gov/new.items/d011008g.pdf.

10.2.3.4 - Information and Communication

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Information should be recorded and communicated to management and others within the entity who need it and in a form and within a time frame that enables them to carry out their internal control and other responsibilities.

Pertinent information *shall* be identified, captured, and communicated in a form and time frame that enables *employees* to carry out their responsibilities. Information systems produce reports containing operational, financial, and compliance related information that make it possible to control the organization. Information systems deal not only with internally generated data, but also information about external events, activities and conditions necessary for informed decision making and external reporting. Effective communication also must occur in a broader sense, flowing down, across, and up the

organizational structure. All personnel must receive a clear message from top management that control responsibilities must be taken seriously. They must understand their own role in the internal control system, as well as how individual activities relate to the work of others. They must have a means of communicating significant information *throughout the organization*. The organization must also effectively communicate with external parties, such as customers, suppliers, state officials, and legislators.

10.2.3.5 - Monitoring

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Internal control monitoring should assess the quality of performance over time and ensure that the findings of audits and other reviews are promptly resolved.

Internal control systems need to be monitored. Monitoring is a process that assesses the quality of the system's performance over time. Internal control should generally be designed to assure that ongoing monitoring occurs in the course of normal operations. This is accomplished through ongoing monitoring activities, separate evaluations, or a combination of the two. Ongoing monitoring includes regular management and supervisory activities, and other actions *(such as periodic reviews, reconciliations, or comparison of data)* personnel take in performing their duties. The scope and frequency of separate evaluations will depend primarily on an assessment of risks and the effectiveness of ongoing monitoring procedures.

20 - Medicare Contractor Internal Control Review Process

(Rev. 7, 08-30-02)

20.1 - Risk Assessment

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Risk assessment identifies areas that should be reviewed to determine which components of an organization's operation present the highest probability of waste, loss, or misappropriation. The risk assessment process is the identification, measurement, prioritization and mitigation of risks. This process is intended to provide the Medicare contractors with:

- Direction for what areas should get priority attention from management due to the nature, sensitivity and importance of the area's operations;
- A preliminary judgment from managers about the adequacy of existing internal control policies and procedures to minimize or detect problems; and
- An early indication of where potential internal control weaknesses exist that should be corrected.

The CMS requires Medicare contractors to perform an annual risk assessment, to identify the most critical areas and areas of greatest risk to be subjected to a review. Operational

managers with knowledge and experience in their particular business area shall perform risk assessments. Outside sources can assist with this process, but should not be solely relied upon (e.g., Internal Audit departments, Statement on Auditing Standards Number 70 (SAS 70) audit, etc.).

When performing your yearly risk assessment, you are to consider all results from final reports issued during the fiscal year from internal and external reviews including GAO, OIG, CFO audit, Contractor Performance Evaluation (CPE), CPIC and 1522 reviews and results of your own or CMS-sponsored SAS 70 audits. Any of these findings could impact your risk assessment and preparation of your certification statement. Your risk assessment process shall provide sufficient documentation to fully explain the reasoning behind and the planned testing methodology for each selected area.

The Medicare contractor shall submit a description of the risk assessment process to CMS as an attachment with the annual CPIC and maintain sufficient documentation to support the risk assessment process. Examples of sufficient documentation are meeting agendas, meeting notes or minutes, and emails. The documentation should be readily available for CMS review.

Below are the elements to include in the description or methodology of your risk assessment process:

- Who - List who is involved and state their roles and responsibilities.
- Where - List the geographical location(s) for which the certification applies. For multi-site contractors, review and explain the roles for all sites, i.e., do they do their own risk assessment and control objective testing.
- What – Describe the risk factors and the risk assessment process.
- When - List when the risk assessment process was completed.
- Why – Prioritize control objectives based upon their level of risk while ensuring high risk areas are reviewed in accordance with the scoring criteria guidelines in section 20.1.
- How – Describe the scoring methodology and provide a description and definition for each risk and exposure factor. Include specific value ranges used in your scoring methodology.

The Medicare contractor is encouraged to exceed the risk assessment approach provided below based on its unique operations. The risk assessment process shall at a minimum include the following and shall be submitted as part of the CPIC package:

Step 1 - Segment Operations

Segment the Medicare contractor's operation into common operational areas of activity that can be evaluated. List the primary components of the unit with consideration to the business purpose, objectives, or goals of the auditable unit. Limit the list to the primary activities designed to achieve the goals and objectives of the auditable unit. Include the CMS control objectives applicable to each auditable unit.

Step 2 - Prioritize Risk and Exposure Factors

Identify the primary risks and exposure factors that could jeopardize the achievement of the goals and objectives of the unit as well as the organization's ability to achieve the objectives of reliable financial reporting, safeguarding of assets, and compliance with budget, laws, regulations and instructions. Risk and exposure factors can arise due to both internal and external circumstances. Document the definitions and methodology of the risk and exposure factors used in the risk assessment process.

Step 3 – Create a Matrix to Illustrate the Prioritization of Risk and Exposure Factors

Create a matrix listing on the left axis by operational areas of activity (see step 1 above). The top axis should list all the risk and exposure factors of concern and determine the weight each column should have. Some columns may weigh more than other columns. Develop a scoring methodology and provide a description and definitions of this methodology used for each risk or exposure factor. This methodology can use an absolute ranking or relative risk identification. Absolute ranking would assign predefined quantifiable measures such as dollars, volume, or some other factor in ranges that would equate to a ranking score such as high, medium or low. Relative risk ranking involves identifying the risk and exposure factors into natural clusters by definition and assigning values to these clusters. Include a legend with the score ranges representing high-risk, medium-risk, and low-risk on the risk matrix.

Assign a score to each cell based on the methodology predetermined. Retain notes to support scoring of key risk factors such as "prior audits" and factors that are scored very high or very low. This will assist CMS in evaluating the reasonableness of your risk assessment results. Total the scores for each line item (control objective). The higher scores for each line item will prioritize the risk areas for consideration to be reviewed to support the CPIC. If a high risk control objective is included in a current year Type II SAS 70 audit, *you may* rely on the SAS 70 testing and document this as the rationale for excluding it from testing.

The CMS considers system security to be a critical risk area. Therefore, contractors shall include control objective A.1 in your CPIC each year. All Medicare contractors are required to certify their system security compliance. Contractors shall verify that a system's security features meet CMS' Core Security Requirements as defined by the Business Partners Systems Security Manual (BPSSM). Medicare contractors should write a few paragraphs to self-certify that their organization has successfully completed all required security activities including the security self-assessment of their Medicare IT systems and associated software in accordance with the terms of their Medicare

Agreement/Contract. See section 3.3 of the BPSSM, which can be found at www.cms.hhs.gov/it/security for more details. Also, include the results of the testing of A.1 in the Executive Summary. See section 30.3.

20.1.1- Risk Analysis Chart

(Rev. 117, Issued: 02-13-07; Effective: 01-01-07; Implementation: 01-29-07)

This chart is provided to assist Medicare contractors in selecting the high-risk activities within their organization.

HIGH RISK FACTORS	MEDIUM RISK FACTORS	LOW RISK FACTORS
❖ Recent audit findings showing material weaknesses related to internal control processes.	❖ Potential program weaknesses related to violation of privacy issues.	❖ Areas where CAPs have already been implemented.
❖ Areas affected by significant changes in laws, regulations, special requirements or instructions.	❖ Areas with high visibility.	❖ Areas with low visibility; routine program operations.
❖ Areas where policies and procedures regarding internal control over financial reporting are not well documented.	❖ Areas where due dates are often not met or responses to correspondence are late.	❖ Areas where workers are meeting routine program operations and performance targets and attitudes and staff motivations are high.
❖ Areas of significant financial vulnerabilities (e. g., new accounting or regulatory guidelines).	❖ Areas with consistent complaints or inquiry.	❖ Areas that undergo frequent financial audits/ reviews by external parties (e.g., CFO, SAS 70, CPIC, etc.).
❖ Areas where guidelines have varied interpretations and/or areas being restructured. ❖ Areas with new contract activities.	❖ Areas where recent policy changes were implemented. ❖ Areas with reorganization activities.	❖ Areas that managers perform periodic reviews to ensure that work assignments are performed consistently, and accurately.
❖ Areas where objectives of the corporate mission could be in jeopardy if not properly implemented.	❖ Areas where there is a breakdown in communication with corporate, regional, state or satellite offices, etc.	❖ Work activities are being phased out.
❖ Areas lacking performance measures or monitoring.	❖ Areas with new or problematic performance measures.	❖ Areas with established and validated performance measures.

Scoring Criteria Guidelines:

High: If an activity has two or more high risk rating factors, review annually.

Medium: If an activity has two or more medium risk factors, review biannually.

Low: Low activities can be reviewed within a 5-year timeframe or at manager's discretion that should be balanced with costs and resources.

20.2 - Internal Control Objectives

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Internal control objectives are established to identify risk and vulnerabilities. Control objectives may be set for an entity as a whole, or be targeted to specific activities within the entity. Generally, objectives fall into three categories:

1. Operations - relating to effective and efficient use of the organization's resources.

2. Financial Reporting-- relating to preparation of reliable financial statements.

3. Compliance - relating to the organization's compliance with applicable laws and regulations.

An acceptable internal control system can be expected to provide reasonable assurance of achieving objectives relating to the reliability of operations, financial reporting and compliance. Achievement of those objectives depends on how activities within the organization's control are performed.

Section 50 lists the minimum set of control objectives. The Medicare contractor may add to the CMS control objective list. For the respective operational areas selected for review in Step 2 of the Risk Assessment discussion, cross-reference the high risk operational areas to CMS' or the Medicare contractor's unique control objectives on a work sheet. Some control objectives will apply to more than one operational area selected for review. The control objectives identified in this step shall be validated by documentation of the control activities (see section 10.2.3.3) used as well as testing (see section 20.4) that supports the control objectives.

Reminder: Excessive control is costly and counterproductive. Too little control presents undue risk. There should be a conscious effort made to achieve an appropriate balance.

20.2.1 – Medicare Control Objectives

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The complete list of control objectives is in section 50. If you completed your risk assessment prior to issuance of the current year CMS control objectives, you should ensure that any new or revised control objectives are assessed and the risk matrix is updated. In addition, you should create or update the control activities supporting any new or revised control objectives as appropriate (see section 10.2.3.3).

20.3 – Policies and Procedures

(Rev. 95, Issued: 04-28-06; Effective/Implementation Dates: 05-30-06)

Policies and procedures are a set of established guidelines or rules for conducting the affairs of a business. Good policies:

- Are written in clear, concise, and simple language. They are updated as necessary, signed and dated.
- Address what the guideline or rule is; not how to implement the guideline or rule.
- Are readily available and properly communicated to staff.

Procedures are a set of steps in a plan intended to influence and determine decisions and actions. Good procedures are tied to policies and:

- Are written in clear, concise, and simple language.
- Are tied to the policy.
- Are developed and implemented with the user in mind.
- Are readily available and properly communicated to staff.

Medicare contractors shall have written policies and procedures to achieve their control objectives. These policies and procedures shall be updated in a timely manner to reflect changes in CMS instructions or your internal operations.

Medicare contractors shall demonstrate and document that its policies and procedures are actually being used as designed and are effectively and efficiently meeting the control objective, as described in section 50. Evaluation and testing of the effectiveness of controls are important in determining if the major areas of risk have been properly mitigated.

An example of a policy is, "an agency shall establish physical control to secure and safeguard vulnerable assets". The specific control activities, or procedures, which support this policy may include: all doors to the facility have locks, the locks only have one key, all keys are held by security guards, security guards are stationed at every door.

20.4 - Testing Methods

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Testing the policies and procedures involves ensuring that the documented policies and procedures are actually being used as designed and are effective to meet a control objective. Evaluating and testing the effectiveness of policies and procedures is important to determine if the major areas of risks have been properly mitigated and provide reasonable assurance that the control objective is met.

Testing and evaluating the policies and procedures consists of five steps:

Step 1: Select the policies or procedures to be tested

It is both impractical and unnecessary to test all policies and procedures. The policies and procedures to be tested are those that primarily contribute to the achievement of the control objectives. A policy or procedure may be eliminated from testing when it does not meet the control objective to be tested due to being poorly designed, unnecessary or duplicative, or not performed in a timely manner. However, if this justification is invoked, other policies and procedures should be tested to validate meeting the control objective. Another justification for testing elimination is due to the cost of testing the policy or procedure exceeds the value of the control objective to be tested. If a policy or procedure is eliminated from testing, the reasoning should be documented.

Step 2: Select test methods

Once the policies and procedures to be tested are determined, test methods shall be determined. A combination of tests can be used depending on risk or type of activity. The following methods can be used to test the policies and procedures:

1. Document Analysis: a test method used to determine if the policies and procedures are effective by reviewing existing records, completed forms, or other documentation.

2. Observations: a test method used to determine if the policies and procedures are working by watching the performance of that control objective. Observation is often used when the reviewer wants to test how the control objective works for an entire cycle for the function or activity. In this case, the observer watches the performance of all of the steps and observes all involved personnel. For example, a reviewer may observe what happens to a check from the time it is received to the time it is entered into the log and secured in the office safe. A reviewer would record who took which steps, and which controls were used.

3. Interviews: a test method used to determine if the policy or procedure is working by eliciting information from the personnel who perform the control objective. Interviews should be used to supplement document analyses and/or observations. Interviews can provide valuable information about the operation of controls under many different situations.

Step 3: Determine how much testing is needed

The next sub-step is to determine the extent of the testing efforts. In most cases, it is unrealistic to observe each policy and procedure or to review 100 percent of all records. Instead, policies and procedures are tested by observing a selected number of controls performed or by reviewing a portion of the existing records. This selection process is

called sampling. A representative sample provides confidence that the findings are not by chance by taking into account the factors of breadth and size.

1. Breadth: Breadth of the sample assures that the testing covers all bases and is a representative cross section of the universe being tested. This will provide confidence that the sample will lead to a conclusion about the situation as a whole.

2. Size: Size is the number of items sampled. The size should be large enough to allow a conclusion that the findings have not happened by chance and provide confidence in the conclusion. The size of the sample should not be so large that testing becomes too costly. When selecting the size of the sample consider:

    a. Experience: Reducing the size of the sample when controls have operated satisfactorily in the past and no major changes have occurred.

    b. Margin of Error: Increase the size of the sample when only a small margin of error is acceptable.

    c. Importance: Increase the size of the sample when an important resource is at stake.

    d. Type: Increase the size of the sample when the control to be tested requires judgment calls. Decrease the size of the sample when the control is routine.

Step 4: Plan data collection

The sampling plan gives an idea of the *"who, where, what, when, why, and how"* (see section 20.1) aspect of the tests to be conducted. A data collection plan can be used to determine how the test results will be recorded. The accurate recording of test results is an extremely important part of the test documentation. Planning data collection prior to beginning the testing can be very helpful to ensure the information collected will provide conclusive data from which to evaluate the controls.

Step 5: Conduct the tests

The final step of testing and evaluating controls consists of actually effectuating the testing protocol and documenting the results.

At the conclusion of the testing, the results are analyzed and evaluated. Evaluating involves reviewing the information collected and making an overall judgment on the adequacy of the internal control system as a whole. Deficient areas are to be categorized into *Control Deficiencies,* Reportable Conditions, *Significant Deficiencies, and* Material Weaknesses and should be considered for inclusion in the CPIC submission (see section 30.6).

20.5 - Documentation and Working Papers
(Rev. 117, Issued: 02-13-07; Effective: 01-01-07; Implementation: 01-29-07)

The Medicare contractor shall document through its working papers the process it employed to support its internal control certification. This documentation shall include working papers so that a CMS reviewer can conclude that the Risk Assessment process as described in section 20.1 follows or exceeds these guidelines, and that the Control Activities (section 10.2.3.3) identified to support the high risk control objectives selected for review are current and clearly stated. Finally, the CPIC documentation shall demonstrate how the Testing Methods employed comply with the general parameters as described in section 20.4 for the purpose of Control Activity validation.

Working papers contain evidence accumulated throughout the review to support the work performed, the results of the review, including findings made, the judgment and/or conclusion of the reviewers. They are the records kept by the reviewer of the procedures applied, the tests performed, the information obtained, and the pertinent judgment and/or conclusions reached in the review process. Examples of working papers are review programs, analyses, memoranda, letters of confirmation and representation, abstracts of documents, and schedules or commentaries prepared or obtained by the reviewer. Working papers may be in the form of data stored on tapes, film, or other media.

General Content of Working papers - Working papers should ordinarily include documentation showing that:

- The work has been adequately planned and supervised.
- The review evidence obtained, the reviewing procedures applied, and the testing performed has provided sufficient, competent evidential matter to support the reviewer's judgments and/or conclusions.

Format of Working Papers - Working paper requirements should ensure that the working papers follow certain standards. As a whole, a good set of working papers should contain the following:

- The objectives, scope, methodology, and the results of the review.
- Proper support for findings, judgments and/or conclusions, and to document the nature and scope of the work conducted.
- Sufficient information so that supplementary oral explanations are not required.
- Adequate indexing and cross-referencing, and summaries and lead schedules, as appropriate.
- Date and signature by the preparer and reviewer.

- Evidence of supervisory review of the work.

1. Proper heading should be given to the basic content of the working papers.

30 - Certification Package for Internal Controls (CPIC)
(Rev. 7, 08-30-02)

30.1 – CPIC Requirements
(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The Medicare contractor self-certification process provides CMS with assurance that contractors are in compliance with the FMFIA, OMB Circular A-123, and CFO Act of 1990 by incorporating internal control standards into their operations. The Medicare contractor self-certification process supports the audit of CMS' financial statements by the Office of Inspector General (OIG) and the CMS Administrator's FMFIA assurance statement.

This compliance is achieved by *an annual* self-certification statement and has been known as a CPIC. Through these self-certification statements, CMS has required each Medicare contractor to provide assurances that internal controls are in place and to identify and correct any areas of weakness in its operations. Medicare contractors are expected to evaluate the effectiveness of their operations against CMS' control objectives discussed above. The control objectives represent the minimum expectations for contractor performance in the area of internal controls.

Medicare contractors shall have written policies and procedures regarding their overall CPIC process and the preparation of the annual CPIC submission. They shall also have written policies and procedures that discuss the handling of potential internal control deficiencies identified by employees and managers in the course of their daily operations. This should include the process for reporting issues upward through the appropriate levels of management, tracking them to completion of any necessary corrective actions, and considering them for inclusion in the CPIC submission.

The CPIC represents a summary of your internal control environment for the period *October 1* through *June 30* (the CPIC period), as certified by your organization. It shall include an explicit conclusion as to whether the internal controls over financial reporting are effective (see section 30.1.1). All material weaknesses that were identified during this period shall be included in the CPIC submission. You should consider the results of final reports issued from internal and external audits and reviews, such as GAO and OIG audits as well as CFO Act audits, consultant reviews, management control reviews, CPE reviews, SAS 70 audits, and other similar activities. These findings should be *classified* as *control deficiencies*, reportable conditions, *significant deficiencies, or material weaknesses* based upon the definitions provided in section 30.6. Medicare contractors shall submit an update for the period July 1 through *September 30* to report subsequently identified material weaknesses. The update shall be no more than a one page summary of

the material weakness*(es)* and the proposed corrective action. A CAP shall be completed in accordance to the guidelines shown at section 40.1. If no additional material weaknesses have been identified, submit the following: "No material weaknesses have been identified during the period July 1 through September 30; therefore no additional material weaknesses have been reported". Send the update report from the VP or CFO email box to internalcontrols@cms.hhs.gov *within five business days after September 30*.

Electronic CPIC reports *shall* be received by CMS *within fifteen business days after June 30*. The Medicare contractor is not required to submit a hard copy report if it has the capability to insert electronic signatures. Where applicable, the CPIC hard copy report *shall* be post marked *within fifteen business days after June 30.*

The CPIC shall include:

- A Certification Statement (including an assurance statement on the effectiveness of internal controls over financial reporting as of June 30);
- An Executive Summary;
- A description of your risk assessment process. This should include a matrix to illustrate the prioritization of risk and exposure factors and a narrative or flowchart that outlines the risk assessment process (see section 20.1 for more details regarding the risk assessment), and
- A CPIC Report of Material Weaknesses.

NOTE: A hardcopy of the CPIC package is not required, if the Medicare contractor has electronic signature capability. If electronic signature capability is not available, please send the hardcopies to:

Chief Financial Officer
Office of Financial Management
Attn: Accounting Management Group, N3-11-17
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

An electronic version of all documents (*including updates*) submitted as part of your CPIC submission shall be sent to CMS at internalcontrols@cms.hhs.gov as Microsoft Excel or Word files. Electronic copies shall also be sent to your Associate Regional Administrator for Financial Management *and Fee for Service Operations*, CFO/SAS 70 Coordinator, Consortium Contractor Management Officer (CCMO) and/or the Project Officer of the Medicare Administrative Contractor (MAC). The file names for all electronic files submitted, as part of your CPIC package should begin with the three or four letter abbreviation assigned to each Medicare contractor in section 40.3.

Additionally, in the subject line of your email submission, you shall include the corporate name of the entity submitting the CPIC.

Maintain the appropriate and necessary documents to support any assertions and conclusions made during the self-assessment process. In your working papers, you are required to document the respective policies and procedures for each control objective reviewed. These policies and procedures should be in writing, be updated to reflect any changes in operations, and be operating effectively and efficiently within your organization.

The supporting documentation and rationale for your certification statement, whether prepared internally or by an external organization, shall be available for review and copying by CMS and its authorized representatives.

30.1.1 - OMB Circular A-123 and Internal Control Over Financial Reporting

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Medicare contractors shall use the five steps below to assess the effectiveness of its internal control over financial reporting. Documentation shall occur within each of the basic steps, whether documenting the assessment methodology during the planning phase or documenting key processes and test results during the evaluation and testing steps.

1) Plan and Scope the Evaluation

During this phase, the Medicare contractor shall leverage existing internal and external audits/reviews being performed (SAS 70, CPIC, 912 Evaluations, Federal Information Security Management (FISMA), Contractor Performance Evaluations (CPE), etc.) when conducting its assessment of internal control over financial reporting. Management shall consider the results of these audits/reviews in order to identify gaps between current control activities and the documentation of them. The control objectives of A, F, G, I, J, K, and L shall be considered if applicable.

If a Medicare contractor has a SAS 70 audit in the current or past two fiscal years, it shall be used as a basis for the statement of assurance combined with other audits and reviews as appropriate. The Medicare contractor shall conduct additional testing for Circular A-123 as deemed necessary. For example, if the SAS 70 audit report was unqualified (no findings in Section I (Opinion Letter)), then the Medicare contractor is not required to conduct additional testing. If Section I of the prior year's SAS 70 audit report is qualified (one or more findings that have not been corrected and validated), then the Medicare contractor shall conduct additional testing on the findings identified in Section I and the exceptions identified in Section III. (See SAS 70 Reliance Examples chart). If other audits and reviews contradict the SAS 70 audit, then that contradiction shall be addressed via testing if the issue has not already been corrected and validated.

2) Document Controls and Evaluate Design of Controls

This step begins with the documentation and evaluation of entity-level controls. Consideration must be given to the five standards of internal control (control environment, risk assessment, control activities, information and communication, and monitoring) (see section 10.2.3 – Standards for Internal Control) that can have a pervasive effect on the risk of error or fraud, and will aid in determining the nature and extent of internal control testing that may be required at the transaction or process level. The GAO issued an internal control evaluation tool (www.gao.gov/new.items/d011008g.pdf) to assess the effectiveness of internal control and identify important aspects of control in need of improvement. This tool shall be used in conducting your assessment.

At the process level, documentation shall be prepared in the form of a cycle memo*(s)* that demonstrates an understanding, from beginning to end, of the underlying processes and document flows involved in each major transaction cycle. Identify the key control activities that are relied upon to assure the relevant financial statement assertions are met. For each key control activity, state: (a) the frequency of performance; (b) the specific steps performed; (c) how exceptions are resolved; and (d) how the performance of the control activity and related results/disposition are documented. For ineffective or partially effective key control activities, *indicate the following in the documentation:* (a) the identified vulnerability caused by the ineffective process, including a specific statement of risk and impact; (b) any existing mitigating/compensating controls that address the identified vulnerability; and (c) a corrective action plan to address the problem if not done so by the mitigating/compensating controls.

Key financial reporting cycle memos would include financial reporting, accounts receivable, accounts payable, and claims expense. Documentation of the controls will provide the foundation for subsequent work and will facilitate the review and evaluation of key controls. *Note: Medicare contractors may combine related cycles (e.g., accounts payable and claims expense).*

3) Test Operating Effectiveness

Testing of the operation of key controls shall be performed and documented *(refer to "Plan and Scope the Evaluation" (see above) as to testing applicability),* to determine whether the control is operating effectively, partially effectively, or not effectively. Testing shall address both manual and *automated* controls. Ideally, testing should be performed throughout the year. The results of testing completed prior to June 30th will form the basis of the June 30th assurance statement. As testing continues into the fourth quarter, the results of that testing, along with any items corrected since the June 30th assurance statement will be considered in the September 30th assurance statement update.

4) Identify and Correct Deficiencies

If design or operating deficiencies are noted, the potential impact of control gaps or deficiencies on financial reporting shall be discussed with management. The magnitude

or significance of the deficiency will determine if it should be categorized as a control deficiency, *a significant deficiency,* or a material weakness *(see section 30.6).*

Corrective action plans (CAPs) shall be created and implemented to remediate identified deficiencies (see section 40).

5) Report on Internal Controls

The culmination of the Medicare contractor's assessment will be the assurance statement regarding its internal control over financial reporting. The statement will be one of three types:

1) Unqualified Statement of Assurance

Each Medicare contractor shall submit, as part of the CPIC report, an assurance statement for internal controls over financial reporting stating:

> "… (Medicare contractor) has effective internal controls over financial reporting in compliance with OMB Circular A-123."

Note: For example, if the SAS 70 audit (augmented by internal reviews, if necessary) did not result in any findings or material weaknesses, then an unqualified statement of assurance would be applicable.

2) Qualified Statement of Assurance

Each Medicare contractor shall submit, as part of the CPIC report, an assurance statement for internal controls over financial reporting stating:

> "…(Medicare contractor) has effective internal controls over financial reporting in compliance with OMB Circular A-123, except for the material weakness(es) identified in the attached Report of Material Weaknesses."

Note: For example, if a SAS 70 audit and internal reviews in the current year disclosed either findings or a material weakness, then a qualified statement of assurance (see above) or a statement of no assurance (see below) would be issued, depending on the pervasiveness of the findings or material weakness. The results of work performed in other control-related activities may also be used to support your assertion as to the effectiveness of internal controls.

3) Statement of No Assurance

Each Medicare contractor shall submit, as part of the CPIC report, an assurance statement for internal controls over financial reporting stating:

"…(Medicare contractor) is unable to provide assurance that its internal control over financial reporting was operating effectively due to the material weakness(es) identified in the attached Report of Material Weaknesses."

or

"…(Medicare contractor) did not fully implement the requirements included in OMB Circular A-123 and therefore cannot provide assurance that its internal control over financial reporting was operating effectively."

This chart is provided to assist Medicare contractors in determining when to conduct testing.

SAS 70 Reliance Examples

Scenario	Prior Fiscal Year 2	Prior Fiscal Year 1	Current Fiscal Year	Additional Testing Required or Not Required*
1	No SAS 70	No SAS 70	Unqualified	Not Required
2	No SAS 70	Unqualified	No SAS 70	Not Required
3	Unqualified	No SAS 70	No SAS 70	Not Required
4	Qualified	Unqualified	No SAS 70	Not Required
5	No SAS 70	No SAS 70	Qualified	Not Required
6	No SAS 70	Qualified	No SAS 70 and the Findings are Corrected and Validated by CMS (CAP Closure Letter Received)	Not Required
7	Unqualified	Qualified	No SAS 70 and the Findings are Corrected and Validated by CMS (CAP Closure Letter Received)	Not Required
8	Qualified	No SAS 70 and the Findings are Corrected and Validated by CMS (CAP Closure Letter Received)	No SAS 70	Not Required
9	Unqualified	Qualified	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	Required
10	No SAS 70	Qualified	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	Required
11	Qualified	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	Required

SAS 70 Unqualified Report - No Findings in Section I

SAS 70 Qualified Report - 1 or More Findings in Section I

*Note: Assumes other subsequent audits and reviews do not contradict the SAS 70 or contradictions have been corrected and validated.

30.2 - Certification Statement

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Provide a certification statement to CMS pertaining to your internal controls. Listed below is a generic certification statement. This statement should be included as part of your CPIC. The statement is to be signed jointly by your Medicare CFO and Vice President (VP) for Medicare *or the equivalent Senior Executive responsible for Medicare*. The CPIC is due *within fifteen business days after June 30* and shall cover the period from *October 1* through *June 30.* An updated assurance statement for the period *July 1* through *September 30* is due to CMS *within five business days after September 30*. Your certification statement should follow this outline:

Chief Financial Officer
Office of Financial Management
Attn: Accounting Management Group, N3-11-17
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Chief Financial Officer:

As *the* (Medicare Chief Financial Officer and Vice President for Medicare) of (contractor name), we are writing to provide certification of reasonable assurance for the period *October 1* through *June 30* that (contractor name) internal controls are in compliance with the Federal Managers' Financial Integrity Act (FMFIA) and Chief Financial Officers (CFO) Act by incorporating internal control standards into our operations. We are also providing an unqualified [or qualified] statement of assurance that (contractor name) has effective internal controls over financial reporting in compliance with revised OMB Circular A-123 [except for the material weaknesses identified in the attached Report of Material Weaknesses].

We are cognizant of the importance of internal controls. We have taken the necessary actions to assure that an evaluation of the system of internal controls and the inherent risks have been conducted and documented in a conscientious and thorough manner. Accordingly, we have included an assessment and testing of the programmatic, administrative, and financial controls for the Medicare program operations.

In the enclosures to this letter, we have provided an executive summary that identifies a list of the minimum requirements. See section 30.3 Executive Summary for the list of minimum requirements to be provided in your CPIC.

If material weaknesses have been identified, use the following language: "Material weaknesses have been reported to you and the appropriate regional office. The respective Corrective Action Plans have been forwarded to your office." If no material weaknesses were identified, use the following language: "No material weaknesses have been identified during our review*;* therefore no material weaknesses have been reported."

We have included a description of our risk assessment analysis and our CPIC Report of Material Weaknesses. This letter and attachments summarize the results of our review.

We also understand that officials from the Centers for Medicare & Medicaid Services, Office of Inspector General, Government Accountability Office, or any other appropriate Government agency have authority to request and review the working papers from our evaluation.

Sincerely,

(Medicare Chief Financial Officer Signature)

(Vice President for Medicare Signature)

30.3 - Executive Summary

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

An executive summary shall be included in your CPIC, and at a minimum provide:

A. The contractor identification numbers;

B. The geographical locations for which the certification applies;

C. A list of the control objectives selected for internal review;

D. The specific time period during which each of the reviews were conducted;

E. The name and title of the person(s) who conducted the review;

F. The location and custodian of the working papers for the review;

G. The name, telephone number, and email address of a contact person who can explain the risk assessment process, the certification review, the results, and the status of any corrective action plans;

H. The total number of material weaknesses reported in the CPIC Report of Material Weaknesses;

I. The total number of *control deficiencies,* reportable conditions *and significant deficiencies* reported in the CPIC Report of *Internal Control Deficiencies;* and

J. A list of all other internal and external reviews conducted during the CPIC reporting period. The list should include the type of review, who conducted the

review, dates conducted, functional areas reviewed, and the number of findings in each area. (Do not include the certification reviews already listed in 'C' above.)

30.4 - CPIC- Report of Material Weaknesses

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The CPIC Report of Material Weaknesses shall include all *initial* material weaknesses identified *during the CPIC period* and not yet corrected and approved by a CAP closing letter. This report shall be updated as new findings are identified. It shall be prepared as a spreadsheet and include the following columns of information:

1. CMS Finding Number. The Medicare contractor shall use the CMS finding number assigned in the final audit report for all external findings. Assign a CMS finding number *(see section 40.3)* to all internally-identified material weaknesses. This shall be done as soon as the determination is made that the finding is a material weakness. Note: Information related to each material weakness should be on only one row of the spreadsheet; the "wrap text" function in Excel should be *used*.

2. *C*ontrol *O*bjective *I*mpacted (*see* section 50). Each material weakness shall have at least one control objective associated with it. However, a material weakness could have more than one control objective associated with it. If more than one control objective is impacted by the material weakness, the finding shall be listed only once with multiple control objectives listed with it. *P*rioritize the control objectives impacted by each finding and limit them to no more than five.

3. Summary of the material weakness.

4. Corrective action plan (CAP).

5. CAP target completion date.

6. Actual completion date for the CAP (if completed).

7. Date the material weakness was identified.

8. Date the initial CAP was submitted to CMS as instructed in section 30.7.

9. Original source of the finding. If the original source is a Contractor Performance Evaluation review, you shall include the report date and site location of the review. If the original source is *your* CPIC, identify the material weakness as either FMFIA or financial reporting (FR). See section 30.6.

EXAMPLE REPORT OF MATERIAL WEAKNESSES
Medicare Contractor XYZ
CPIC Report of Material Weaknesses
Reporting Period *FY XXXX*

(1) CMS Finding Number	(2) Control Objective (s) Impacted	(3) Summary of the Material Weakness	(4) Corrective Action Plan (CAP)	(5) CAP Target Completion Date	(6) Actual Completion Date	(7) Date Material Weakness Identified	(8) Date Initial CAP Submitted to CMS	(9) Original Source of Finding
XYZ-*08*-C-001	J.4	One individual opens Medicare checks and records them in the cash receipts log. This indicates inadequate separation of duties for this process.	Duties of opening mail and logging in cash receipts are being assigned to separate individuals.	*03/15/2008*	*03/15/2008*	*02/03/2008*	*02/27/2008*	Internal Review
XYZ-*08*-C-002	J.3	There is no integrated general ledger accounting system to adequately track all Medicare financial data	The services of a consulting firm have been obtained to develop an integrated general ledger system for reporting Medicare financial data.	*04/30/2008*		*02/20/2008*	*02/27/2008*	Internal Review
XYZ-*08*-S-001	A.1	No Entity Wide Security Plan	Create an entity Wide Security Plan	*6/30/2008*		*03/01/2008*	*03/10/2008*	SAS 70 Audit

30.5 - CPIC- Report of *Internal Control Deficiencies*

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The CPIC Report of Internal Control *Deficiencies shall include control deficiencies, reportable conditions, and significant deficiencies. The CPIC report of Internal Control Deficiencies shall* not be submitted as part of the annual CPIC submission. However, you are required to report in the Executive Summary the number of *control deficiencies*, reportable conditions, *and significant deficiencies* identified during the period covered by the CPIC. The CPIC Report of Internal *Control Deficiencies* should be prepared as a spreadsheet and include the following columns of information:

1. The original source of the finding.

2. *The type of control deficiency (control deficiency, reportable condition, or significant deficiency).*

3. *Whether it is a design deficiency or operating deficiency.*

4. The control objective numbers impacted (from section 50).

5. *The corrective action plan.*

6. A summary of the *control deficiency,* reportable condition*, and significant deficiencies* including when the condition was observed and if a corrective action plan was implemented (or the status if not corrected).

Each *control deficiency*, reportable condition, *and significant deficiency shall* be listed and the total number of *control deficiencies,* reportable conditions, *and significant deficiencies shall* be included *in the report.* The Medicare contractors are required to prepare and maintain this report internally and update this report as new *control deficiencies* are identified. It *shall* be available for review by CMS central and/or regional office staff. When *control deficiencies* are identified, evaluate internal corrective actions for each of the *deficiencies* and correct each problem. While you are required to document, track, and correct problems identified as *control deficiencies*, reportable conditions, *and significant deficiencies (and material weaknesses)*, no CAP is required to be submitted to CMS *for control deficiencies or reportable conditions (see section 40).*

30.6 - Definitions of Reportable Conditions and Material Weaknesses

Definitions of *Control Deficiency,* Reportable Condition*, Significant Deficiency*, *and* Material Weakness

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

These terms are defined as follows:

CONTROL DEFICIENCY:

A control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis.

REPORTABLE CONDITION:

FMFIA overall – A control deficiency, or combination of control deficiencies, that in management's judgment, should be communicated because they represent significant weaknesses in the design or operation of internal control that could adversely affect the organization's ability to meet its internal control objectives.

SIGNIFICANT DEFICIENCY:

Financial Reporting – *A control deficiency, or combination of control deficiencies, that adversely affects the entity's ability to initiate, authorize, record, process, or report financial data reliably in accordance with generally accepted accounting principles such that there is "more than remote" (i.e., at least reasonably possible) likelihood that a misstatement of the entity's financial statements that is more than inconsequential will not be prevented or detected.*

MATERIAL WEAKNESS:

FMFIA overall – Reportable condition in which the Medicare contractor's CFO and VP of Medicare determine to be significant enough to report outside of the Medicare contractor.

Financial reporting – *Significant deficiency,* or combination of significant deficienc*ies*, that results in "more than remote" (*i.e., at least reasonably possible)* likelihood that a material misstatement of the financial statements will not be prevented or detected.

30.7 - Material Weaknesses Identified during the Reporting Period

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The evaluation of your internal control environment should be an ongoing process throughout the fiscal year. It should not be a once-a-year event, which occurs prior to submission of your annual CPIC. The identification and reporting of material weaknesses should not wait until the end of the CPIC reporting period. During the reporting period, if material weaknesses are identified, send an electronic Initial CAP report within 45 days of identifying the problem, via E-mail, to CAPS@cms.hhs.gov and internalcontrols@cms.hhs.gov. (See section 40.4). Within that same time frame you are required to provide written notification, to your Associate Regional Administrator for Financial Management *and Fee for Service Operations.*

40 - Corrective Action Plans

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The CMS conducts various financial management and electronic data processing (EDP) audit*s*/reviews performed by the OIG, GAO, independent CPA firms, and the CMS central office (CO) and regional office (RO) staff to provide reasonable assurance that Medicare contractors have developed and implemented internal controls. The results of these audits/reviews indicate whether the contractors' internal controls are operating as designed. Correcting these deficiencies is essential to improving financial management and internal control. Therefore, audit resolution remains a top priority at CMS.

The CMS has established policies and procedures to ensure that the Medicare contractors have appropriate CAPs for addressing findings identified through the following:

1. CFO financial or electronic data processing (EDP) audits related to annual CFO Financial Statement audits, which may include network vulnerability assessment/security testing (NVA/ST);

2. SAS 70 audits;

3. CPICs;

4. Accounts receivable (AR) Agreed Upon Procedures (AUP) reviews;

5. Health & Human Services (HHS), OIG Information Technology (IT) Controls Assessments;

6. Financial reviews conducted by the GAO;

7. CMS' 1522 workgroup reviews;

8. CMS' CPIC reviews; and

9. OMB Circular A-123 assessments.

Administrative cost audits, provider audits conducted by the OIG, Medicare contractor initiated systems security annual compliance audits, and system penetration tests are excluded from these procedures. *The word "finding" includes control deficiency, reportable condition, significant deficiency, and material weakness. For SAS 70 audits, CAPs to be submitted to CMS are required for findings noted in the opinion letter only (section I), not those reported in section III of the SAS 70 Report. For OMB Circular A-123 assessments, CAPs to be submitted to CMS are required for significant deficiency and material weakness findings.*

40.1 - Submission, Review, and Approval of Corrective Action Plans

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Upon completion of any of the audit*s*/reviews noted in section 40, with the exception of *the* CPIC, the Medicare contractor will receive a final report from the auditors/*reviewers*

noting all findings identified during their audit/review. Within 45 calendar days of the date of the report, the Medicare contractor is required to submit an initial CAP report, using the Initial CAP report format from section 40.5. For SAS 70 and the AR AUP reports, initial CAPS are due within 45 calendar days of the electronic receipt date of the final report since these reports are dated with the final day of fieldwork, not the date of issuance.

The initial CAP report shall address newly identified and reported findings that have been assigned a finding number either by the auditor (*e.g.,* SAS 70 audit) or by the Medicare contractor (i.e., CPIC). The CAP *shall* summarize the procedures that have been or will be implemented to correct the finding. Upon receipt of the initial CAP reports, the Internal Control Team will send the reports to the appropriate CMS business owner for review of the CAP. Business owners may either approve the CAP as submitted, or may request additional information to be included in the CAP. All business owner comments shall be provided to the Medicare contractors before the due date of the next quarterly CAP report. Responses to the CMS business owner comments on the initial CAPs shall be included in the next Quarterly CAP Report due after the date of receipt of the comments.

After an initial CAP has been submitted, the CAP shall be merged onto the Quarterly CAP using the report format in section 40.6. This report will contain all findings and CAPs previously submitted to CMS and provide updates to the actions taken to resolve the findings. If there has been no change in a specific CAP since the submission of the previous CAP report, note the date along with a comment of "no change" in the Update/Status column of that CAP.

The quarterly updates will also be reviewed; however, CMS will not respond to the quarterly updates unless the CAP indicates that the Medicare contractor is not making adequate progress on implementing the CAP or has made significant changes to target completion dates.

The Quarterly CAP report is due within 30 days following the end of each quarter. Therefore, all electronic and hardcopy CAP reports should be received by CMS on or before January 30, April 30, July 30, and October 30 annually. The Quarterly CAP report should address all open findings, as well as continue to report information on all findings reported as completed by the Medicare contractors until CMS sends the Medicare contractor a closeout letter indicating which findings are officially closed. After the Medicare contractor receives the closeout letter, the CAP shall be removed from the Quarterly CAP report.

Submit Initial and Quarterly CAP reports electronically to: CAPS@cms.hhs.gov. Medicare contractors are required to furnish an electronic copy of the CAP report*s* to their CMS Associate Regional Administrator for Financial Management and *Fee for Service Operations,* CCMO, and the designated Regional Office CFO/SAS 70 coordinator.

NOTE: If the electronic copy of the Initial and Quarterly CAP reports has the VP of Medicare Operations electronic signature or is sent from the VP of Medicare Operations email or the CFO's email, then a hardcopy is not required to be sent to CMS. Otherwise, a hardcopy is required.

Medicare contractors shall maintain and have available for review backup documentation to support implementation of each CAP. This will facilitate the validation of CAPS by CMS or its agents.

40.2 - Corrective Action Plan (CAP) Reports

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The Initial or Quarterly CAP report shall include the data explained below using the format provided in section 40.4 and section 40.5. Findings should be grouped by type of review (i.e. CFO, SAS 70, AR AUP, CPIC, etc.). Definitions of CAP report data fields:

CMS finding number - The finding number assigned by the auditor/reviewer (or assigned by the Medicare contractor if it is a CPIC material weakness) and noted in final reports to identify and track contractor findings. See section 40.3, for the *finding* number methodology *used* by the auditors.

Repeat CMS Finding Numbers – If a finding is repeated or duplicated in subsequent years or reported in more than one type of review, provide all other CMS finding numbers for that issue. Repeat finding numbers listed for a particular finding shall be an identical issue, not a related or similar issue and have been identified as a repeat by the auditors in their audit report.

Findings with a repeat finding number shall only be listed once on the CAP report. The CMS finding number column will be populated with the primary finding number. The primary finding number is the finding number that was identified first. If in subsequent audit/reviews, the same finding is identified by the auditors, the auditors will assign a finding number applicable to the type of audit/review being conducted, and also note in the audit report that it is a repeat finding of a prior audit. The auditor should also note the repeat finding number so that the findings can be easily linked.

Control objective(s) impacted - Required only for SAS 70 findings and CPIC material weaknesses. This represents the control objective number(s) impacted by an identified finding. More than one control objective may be impacted for each finding but you need to prioritize and limit the control objectives impacted to no more than five.

Finding/material weakness - A detailed description of the finding as identified by the auditor/reviewer in their final report or the material weakness as reported in the CPIC.

Responsible individual name – The name of an individual that can provide information on the resolution of the CAP, and is responsible for ensuring that the finding is resolved.

Responsible individual email - The email address of an individual that can provide information on the resolution of the CAP, and is responsible for ensuring that the finding is resolved.

Responsible individual phone number, is the phone number of an individual that can provide information on the resolution of the CAP and is responsible for ensuring that the finding is resolved.

Corrective action procedure(s) - The detailed actions that the Medicare contractor will take or has taken to resolve the finding. If the procedures have more than one step, all steps shall be included in one cell. Additionally, if the steps have multiple target and actual completion dates, include these in the Update/status of CAP column.

Target completion date - The date the contractor expects the final step of the corrective action procedure to be fully implemented.

Actual completion date - The date all steps of the corrective action procedure are *considered by the contractor* to be complete and the contractor has resolved the finding.

Update/status of CAP - Subsequent actions taken by the Medicare contractor to implement the initial CAP. If there are more than five control objectives impacted, add them to this field. If there has been no change in a specific CAP since the previous report, simply list the current date along with a comment of "no change" in the Update/Status of CAP column.

40.3 - CMS Finding Numbers

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The CMS Finding Numbers should be assigned using the following instructions. Each section of digits should be separated by a dash.

A. The first three, four, or five digits are letters, which identify the name of the contractor. Each contractor is assigned a unique set of letters listed below.

B. The second two digits are the last two numbers of the year of the review.

C. The next one digit is a letter to identify the type of review.

Choose one from the following list:

- *A - 123 non-IT self-assessment*
- C - CPIC (your annual self certification package);
- E - CFO EDP audit;

- F - CFO Financial audit;
- G - GAO review (financial reviews);
- *I – A-123 IT (EDP) self-assessment;*
- M - CMS' CPIC reviews;
- N - SAS 70 Novation;
- O - OIG review HHS/OIG/IT controls assessment;
- P - CMS' 1522 reviews;
- R - AR AUP review;
- S - SAS 70 audit; and
- V - CFO related NVA/ST

D. The last three digits are three numbers assigned sequentially to each finding *type* beginning with 001.

Contractor Abbreviations

Cahaba Government Benefit Administrators (d.b.a. Alabama BCBS)	CAH
Chisholm Administrative Services (d.b.a. BCBS Oklahoma)	CAS
CIGNA Health Care	CIG
CIGNA Health Care, Durable Medical Equipment (DME) MAC	*CIGD*
Cooperativa de Seguros de Vida de Puerto Rico	COP
First Coast Service Options, Inc.	FCSO
Blue Cross and Blue Shield of Georgia, Inc.	GEO
Group Health Incorporated	GHI
Healthnow New York, Inc.	HLN
Highmark Medicare Services	HMS
Mutual of Omaha Insurance Company	MUT
Blue Cross and Blue Shield of Nebraska	NEB
National Government Services, Inc.	*NGS*
National Government Services, Inc. DME MAC	*NGSD*
National Heritage Insurance Company	NHIC
National Heritage Insurance Company, DME MAC	NHICD
Noridian Mutual Insurance Company, A/B MAC	NOR

Noridian Mutual Insurance Company, DME MAC	NORD
Palmetto Government Benefits Administrators (d.b.a. Blue Cross and Blue Shield of South Carolina*)*	PGBA
Pinnacle Business Solutions, Inc. (d.b.a. Arkansas BC/BS)	PBSI
Riverbend Government Benefits Administrator (d.b.a. Blue Cross and Blue Shield of Tennessee)	RGBA
TrailBlazer Health Enterprises, LLC	THE
Triple S, Inc.	SSS
TriSpan Health Services (d.b.a. as BCBS Mississippi)	TRI
Wheatlands Administrative Services, Inc.	WAS
Wisconsin Physicians Service Insurance Corporation	WPS
Chickasaw Nation Industries, Inc. *(Medicare Secondary Payer Recovery Contractor)*	CNI
Retiree Drug Subsidy (ViPS) (Part D Contractor)	RDSV

40.4 - Initial CAP Report

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

All initial CAPs shall be reported on the Initial CAP Report. After this initial submission, CAPs shall be merged onto the Quarterly CAP report. All CAPs, for the reviews noted in section 40, shall be consolidated onto one Quarterly CAP Report. However, if you have findings for an affiliated data center or system maintainer, these findings shall be reported on a separate CAP report, and not with reported contractor findings. Specifically, if the three or four letter abbreviation listed in section 40.3 is not the same for all findings, a separate CAP report is required for each set of findings associated with that abbreviation code.

The contractor shall use the Initial CAP Report, as an Excel spreadsheet and add their data following the steps below. The format of the spreadsheet should not be altered. Additionally, this electronic file should be labeled Initial CAP Report, should be identified using the contractor abbreviations found in section 40.3, and should include the submission date. For example, Wheatlands Administrative Services, Inc. (WAS) would name this file "WAS Initial CAP Report 10/30/06.xls".

The initial CAP Report format will be distributed by and can be obtained from: CAPS@cms.hhs.gov.

40.5 - Quarterly CAP Report

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The contractor shall use the Quarterly CAP Report, as an Excel spreadsheet and add their data accordingly, without making changes to the format. Additionally, this electronic file shall be labeled Quarterly CAP Report, should be identified using the contractor

abbreviations found in section 40.3, and shall include the submission date. For example, Wheatlands Administrative Services, Inc. (WAS) would name this file "WAS Quarterly CAP Report 10/30/06.xls".

The Quarterly CAP Report format will be distributed by and can be obtained from: CAPS@cms.hhs.gov.

40.6 – Entering Data into the Initial or Quarterly CAP Report

(Rev. 117, Issued: 02-13-07; Effective: 01-01-07; Implementation: 01-29-07)

Overview

The CMS spreadsheet application form assists the contractors to enter data quickly and easily into the CAP report. The application features drop down lists, reducing the amount of manually entered data, and has the ability to detect errors as each data element of information is entered. It also provides specific help features to assist in correcting detected errors.

Launching the Spreadsheet Application

Locate the file and double click on it to start Microsoft Excel and load the spreadsheet application. Or manually open Excel and use the 'File' – Open menu command to select and open the file, which also loads the spreadsheet application.

When opening the file, a Dialogue Box pops up. You shall click on Enable Macros. This will allow the spreadsheet to function properly and provide assistance in entering data and check for errors.

Entering Data

The first ten rows of the Initial or Quarterly CAP report are considered to be the header of the spreadsheet and contain eight data elements (rows 2 through 9). The data elements are Contractor Name, Contractor Number, Date of Submission, Contact Person Name, Contact Person Email, Contact Person Phone Number, and Vice President (VP) for Medicare Operations Name, and VP for Medicare Operations Signature.

Header data elements:

Contractor Name – Position your cursor in cell B2 of the spreadsheet. A dialogue box will appear. Click on the [arrow] on the right side of the CMS Contractor Name dialogue box to invoke the Pull Down Menu of contractor names. Select the appropriate name. After the name is selected, the cursor will automatically move to the next field: Contactor Number.

Contractor Number – Enter your contractor number(s). The number cannot exceed 5 digits and if less than 5 digits are entered, leading zeros will automatically be entered. If

more than 1 contractor number is entered, separate the numbers with a comma (,). Maintainers and Data Centers are not required to enter a contractor number, thus this field shall be left blank. A flyover help box is provided to ensure the proper format is followed.

Date of Submission – Enter the date in the format of mm/dd/yyyy that the CAP report will be submitted to CMS. A flyover help box is provided to ensure the proper format is followed.

Contact Person's Name – Enter the first and last name of the person that may be contacted regarding any questions on the submission of the CAP report.

Contact Person's Email– Enter the email address of the contact person. The email address shall be properly formatted with a '@' sign.

Contact Person's Phone # - Enter the contact person's phone number (i.e., 410-786-5555, ext.123456). The phone number may have an extension of up to 6 digits. A flyover help box is provided to ensure that the proper format is followed.

VP for Medicare Operations Name – Enter the first and last name of the Vice President of Medicare Operations.

VP for Medicare Operations Signature – Insert electronic signature if capable.

NOTE: If incomplete information is entered or is not entered in the proper format, an error message will be displayed after each data entry indicating that the information is invalid. The application will not allow you to continue until all errors in the header are corrected. Also, you may use the function 7 (F7) key to enable spell check.

Row 11 provides the name of each column in the Detail section of the spreadsheet. The cells in this row may not be changed.

Proceed to cell A12 to begin to enter data in the Detail section of the spreadsheet.

To enter data, click the Edit Data button in the header section.

A dialogue box containing the 'CMS CAP Data Input' form will appear to allow information to be entered in the appropriate data fields. See Figure 1. All edits shall be performed in this input form. Edits performed directly into a cell when not in this form cannot be saved.

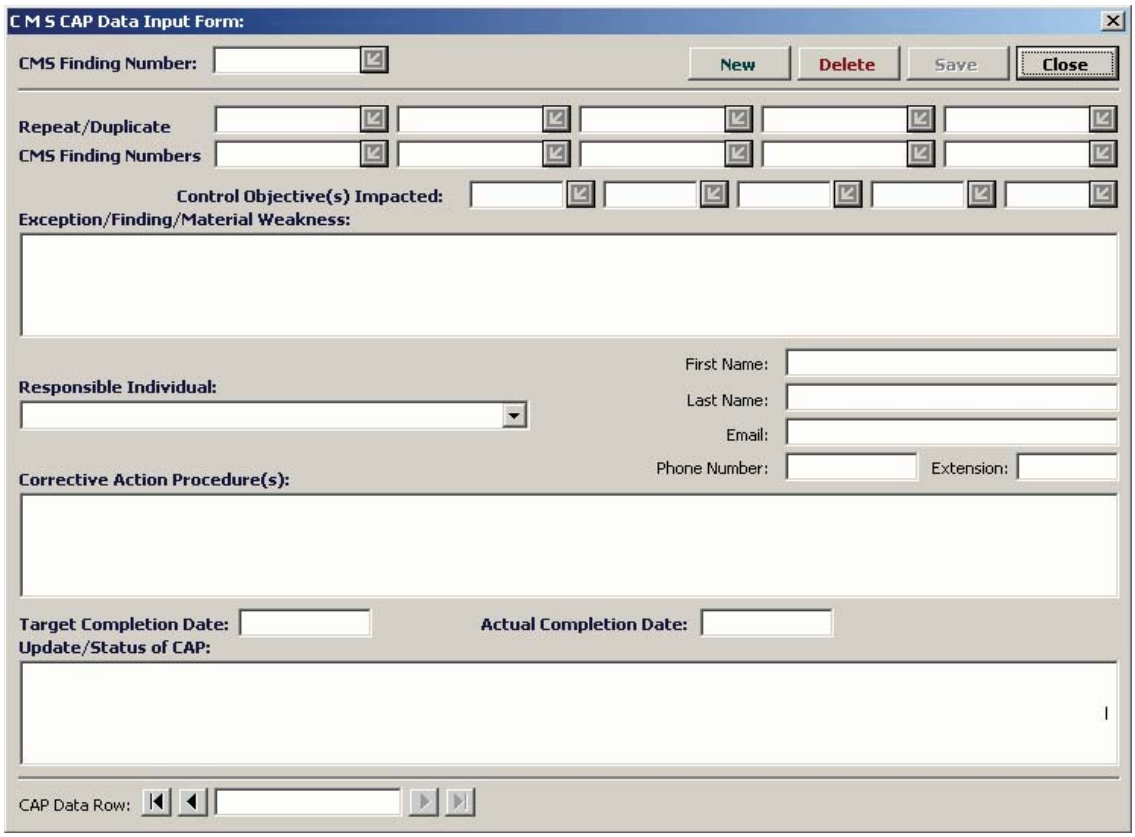

Figure 1: CMS CAP Data Input Form

Click on the [arrow] to the right of the CMS finding number to open the next dialogue box containing the components of the CMS finding number. All components are required.

CMS Finding Number components:

Contractor abbreviation – The abbreviation will automatically be populated based on the Contractor Name entered in row 2 of the Header and as a result, will be grayed out. In order to change the abbreviation, the Contractor Name will have to be changed in the Header.

NOTE: Since the contractor abbreviation will always link to the contractor name, Initial and Quarterly CAP reports can no longer combine findings that originated at your contractor location, your data center and/or those applicable to your maintainer system in one report. Separate reports using the spreadsheet application form shall be completed for contractor, data center, and maintainer findings.

Year of Review – Enter the last 2 digits of the applicable fiscal year (FY) that the review was conducted.

Type of Review – Press on the [arrow] on the right side of the Type of Review dialogue box to invoke the Pull Down Menu of review types. Select the review applicable to the reported finding.

Sequential Numbering of Finding – Press on the up or down [arrows] to the right side of the Sequential Numbering of Finding dialogue box to enter the finding number as reported by the auditors in their final report.

When all components have been entered, click on the Save & Close button. Press the Clear button to delete entered data if corrections are necessary. After corrections are completed, click on the Save & Close button.

Use the tab key or the mouse pointer to move to the next box, which is the Repeat/Duplicate Finding Number. If appropriate, press on the first [arrow] on the right side of the Repeat/Duplicate Finding Number to open the next dialogue box containing the components of the first Repeat/Duplicate Finding Number. Press subsequent [arrows] to enter additional repeat findings. The application allows a total of ten repeat/duplicate finding numbers to be entered.

When all components of the Repeat/Duplicate Finding Number have been entered, click on the Save & Close button. Press the Clear button to delete entered data if corrections are necessary. After corrections are completed, click on the Save & Close button.

Use the tab key or the mouse pointer to move to the next cell, which is the Control Objective(s) Impacted. If the Type of Review entered in CMS Finding Number dialogue box was either C for CPIC submissions, N for Novation SAS 70 audits, or S for SAS 70 audits, this field will be activated and control objectives need to be entered. All other Types of Reviews/audits will disable this field and as a result, will be grayed out.

Press on the [arrow] on the right side of the Control Objective(s) Impacted dialogue box to open the Control Objectives Impacted selection box. Based on the FY entered as part of the CMS Finding Number, the Control Objective Impacted selection screen will provide a Pull Down Menu of the control objectives effective in that FY. Select the appropriate control objective from the list.

After each control objective has been entered, click on the Save & Close button. Press the Clear button to delete entered data if corrections are necessary. After corrections are completed, click on the Save & Close button. Repeat outlined steps until all applicable control objectives have been entered. The application allows a maximum of five control objectives to be entered. If more than 5 control objectives are impacted for a given finding, add the additional control objectives impacted to the Update/Status of CAP portion of the spreadsheet.

NOTE: If more than one control objective has been entered and deletions are necessary, you shall click the Clear button and delete the objectives in the reverse order of entry. For example, the last control objective entered shall be the first control objective deleted.

Use the tab key or the mouse pointer to move to the next cell, which is the Exception/Finding/Material Weakness box in the Data Input Form. Enter text exactly as it appears in the auditor's final report. Do not paraphrase. This field is limited to 1024 characters. Any additional information will be truncated. This is a required field.

Continue to use the tab key or the mouse pointer to move to the next few cells, which provide information on the Responsible Individual of the finding. Enter the first and last name of the Responsible Individual, their email address which shall be properly formatted with the '@' sign, and their phone number in the format of xxx-xxx-xxxx and shall not include parenthesis (i.e. 410-786-5555, ext.123456). The phone number may have an extension of up to 6 digits. Only one name, email address and phone number may be entered. These are required fields.

After the information is first entered into the individual fields, the information will be merged and displayed in a drop down list under the Responsible Individual title on the left of the screen. This information can then be used for subsequent CAPs without reentering the details.

The next box contains the Corrective Action Procedures. Enter the procedures that have or will be implemented to address the finding. This field is limited to 1024 characters. Any additional information will be truncated. This is a required field.

Press the tab key or the mouse pointer to the Target Completion Date entry area. Enter the date that the finding is expected to be resolved using the format mm/dd/yyyy. This is a required field that shall be completed for all findings and only allows one date with no text. If a finding is considered to be 'global', enter 02/22/2222. This date will act as an indicator to CMS that the finding is global and assist in easily identifying all findings.

Enter an Actual Completion Date using the format mm/dd/yyyy to indicate when the CAP was implemented. This field shall include only one date with no text. If the CAP has not been completed, leave this field blank.

The last field is the Update/Status field. Use this field to provide updates to corrective action procedures or to indicate that no changes have been made since the last reporting cycle. If a notation is made indicating that a CAP is complete, you shall ensure that an Actual Completion Date has been provided. This field is limited to 1024 characters. Any additional information will be truncated. This is a required field for the Quarterly CAP report.

Once you have filled in all the data fields, press the Save button on the top right hand corner. If you have failed to properly enter data in any of the fields, an error message should have already been displayed to indicate the fields where invalid data was entered. Therefore, all errors should have been corrected prior to saving the information.

Once the information is saved, which is indicated by the Save button being grayed out, you may either press the Close button or the New button. If you press the Close button,

you will be returned to the spreadsheet application form. The data entered into the Data Input Form will now appear in the Excel spreadsheet. However, you may press the New button to remain in the Data Input Form and continue to enter additional findings.

NOTE: We recommend that entries be saved after completing the Data Input Form for each finding to prevent the loss of any data.

Editing Existing CAP Data

On the bottom left of the CMS CAP Data Input Form, there is a control bar (CAP Data Row) that lets you scroll through the completed rows while remaining in the Data Input Form. By clicking on the left or right arrows, you can scroll through the entries and make any changes that are needed. Remember, you shall press the Save button after any changes are made.

The application does not allow you to edit any data unless you are in the Data Input Form. If you try to manually enter or edit any information directly in the spreadsheet, the changes will not save because the data is protected. If changes are needed to existing data, position the cursor in any field in the row where the change is needed and click on the Edit Data button in the Data Input Form.

Saving Files

To save the completed spreadsheet application form, press the Save As button at the top of the form. This button automatically creates a file name that incorporates user and date information that allows for easy tracking of spreadsheets and their different versions.

The format for the file includes: Contractor Abbreviation, Report Name and Date (i.e. AHS Quarterly CAP Report 123101.xls). Please do not change the recommended file name that the application creates.

50 – List of Medicare Control Objectives

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Control Number	Control Objective: Controls provide reasonable assurance that…
A	**Information Systems**
A.1	An entity-wide security program has been documented, approved and monitored by management in accordance with the CMS Business Partners Systems Security Manual (BPSSM) and includes requirements to assess security risks periodically, establish a security management structure and clearly assign security responsibilities, implement effective security-related personnel policies, monitor the security program's effectiveness and ensure

security officer training and employee security awareness.

A.2 Security related personnel policies are implemented that include performance of background investigations and contacting references, include confidentiality agreements with employees (regular, contractual and temporary) and include termination and transfer procedures that require exit interviews, return of property, such as keys and ID cards, notification to security management of terminations, removal of access to systems and escorting of terminated employees out of the facility.

A.3 Information resources are classified (risk-ranked) according to their criticality/sensitivity and are periodically formally reviewed.

A.4 Access to significant computerized applications (such as claims processing), accounting systems, systems software, and Medicare data are appropriately authorized, documented and monitored and includes approval by resource owners, procedures to control emergency and temporary access and procedures to share and properly dispose of data.

A.5 Security policies and procedures include controls to ensure the security of platform configurations and to ensure proper patch management of operating systems.

A.6 Physical access by all employees, including visitors, to Medicare facilities, data centers and systems is appropriately authorized, documented, and access violations are monitored and investigated.

A.7 Medicare application and related systems software development and maintenance activities are authorized, documented, tested, and approved. Application level controls must ensure completeness, accuracy, and authorization.

A.8 A System Development Life Cycle methodology is documented and in use and includes planning for and costs for security requirements in systems.

A.9 Change management policies and procedures exist that include documented testing and approval of changes for regular and emergency changes and restrictions on the use of public domain and personal software.

A.10 Access to program libraries is properly restricted and movement of programs among libraries is controlled.

A.11 Adequate segregation of duties exists between various functions within Medicare operations and is supported by appropriately

authorized and documented policies.

A.12 Activities of employees should be controlled via formal operating procedures that include monitoring of employee activities by management with documentation maintained to provide evidence of management's monitoring and review process.

A.13 A regular risk assessment of the criticality and sensitivity of computer operations, including all network components, IT platforms and critical applications has been established and updated annually. The assessment includes identification of threats, known system vulnerabilities, system flaws, or weaknesses that could be exploited by threat sources.

A.14 A centralized risk management focal point for IT risk assessment has been established that includes promotion awareness programs, processes and procedures to mitigate risks and monitoring processes to assess the effectiveness of risk mitigation programs.

A.15 A risk assessment and systems security plan has been documented, approved, and monitored by management in accordance with the CMS Risk Assessment and Systems Security Plan Methodologies.

A.16 Regularly scheduled processes required to support the Medicare Contractor's continuity of operations (data, facilities or equipment) are performed.

A.17 A corrective action management process is in place that includes planning, implementing, evaluating, and fully documenting remedial action addressing findings noted from all security audits and reviews of IT systems, components and operations.

A.18 Management has processes to monitor systems and the network for unusual activity, and/or intrusion attempts.

A.19 Management procedures are in place to ensure proper action in response to unusual activity, intrusion attempts and actual intrusions.

A.20 Management processes and procedures include reporting of intrusions attempts and intrusions in accordance with the Federal Information Security Management Act (FISMA).

B Claims Processing

B.1 The Medicare claims processing system tracks each claim from

receipt to final resolution.

B.2 The system checks each claim, adjustment, and any other transaction for validity and, in accordance with CMS instructions, rejects such claims, adjustment, or other transaction failing such validity check. (Maintainer Only)

B.3 The system generates an audit trail with respect to each claim, adjustment, or other related transaction. Such audit trail shall include the results of each applicable claim edit. (Maintainer Only)

B.4 Each claim is adjudicated in accordance with CMS instructions.

B.5 Claims are reopened in accordance with CMS guidelines and readjudicated in accordance with CMS instructions.

B.6 Claim payment amounts are calculated in accordance with CMS instruction. Fee schedules are properly received, logged, and changed in the system and monitored, and applied in accordance with CMS instructions. Reasonable costs and reasonable charges are received, logged, and changed in the system, monitored, and applied in accordance with CMS instructions.

B.7 The system shall identify and deny duplicate claims in accordance with CMS instructions. (Maintainer Only)

B.8 Claims are properly aged from the actual receipt date to the actual date of payment in compliance with CMS instructions.

B.9 The system shall detect apparent fraudulent or abusive practices in accordance with CMS instructions. Personnel are trained to detect fraudulent and abusive practices and, in accordance with CMS instructions, to deter such practices. Any such apparent fraudulent or abusive practices as are identified are documented and reported in accordance with CMS instructions. (Maintainer Only)

C Appeals

C.1 Medicare Part A and Part B redeterminations are processed based on CMS instructions, appropriately logged and completed within legislatively mandated time frames and tracked to meet CMS guidelines. Part B claims processed by Fiscal Intermediaries (FIs) *and Medicare Administrative Contractors (MACs)* follow the Part B appeals process redeterminations

C.2 Medicare Part B redeterminations *are processed* based on CMS instructions, appropriately logged and completed within

	legislatively mandated time frames and tracked to meet CMS guidelines.
C.3	Qualified Independent Contractor (QIC) request for cases are handled in compliance with CMS time frames.
C.4	Effectuations are processed as directed by CMS guidelines.
C.5	Contractor communications are clear and in compliance with CMS' instructions to include specific communications such as acknowledgement letters, decision letters, and information on additional appeal rights, etc.
D	**Beneficiary/Provider Services**
D.1	Personally identifiable health information, which is used and disclosed in accordance with the Privacy Act, is handled properly. (Internet Only Manual (IOM) Chapter 2-20.1.8-Beneficiary Customer Service).
D.2	Beneficiary and Provider written inquiries are retained and handled accurately, appropriately, and in a timely manner. (IOM Chapter 2-20.2 – Written Inquiries).
D.3	Telephone inquiries are answered timely, accurately, and appropriately. (IOM Chapter 2-20.1 Telephone Inquiries).
E	***Complementary Credits***
E.1	*Contractors shall report complementary credits received from the Coordination of Benefits Contractor (COBC) for Coordination of Benefits Agreement (COBA) crossover claims in the proper fiscal year on their Interim Expenditure Reports (IERs). The credit is applied properly on the IER report when it is reported in the fiscal year in which the claims being reimbursed were originally crossed to the COBC.*
E.2	*Contractors shall properly report their COBC accrual amounts on their monthly IER reports. These accruals shall be reported in the proper fiscal year (based on when the claims were crossed to the COBC), and shall be adjusted downward based upon (1) the details of the COBC Detailed Error Report; and (2) the information contained on the contractor's remittance advice that accompanies each reimbursement for crossover claims.*
F	**Medical Review (MR) -- If MR work has been transitioned to the Program Safeguard Contractors (PSCs) and you are no**

longer responsible for this function; do not include it in your CPIC submission.

F.1 *Contractor shall utilize the Progressive Corrective Action (PCA) process, in accordance with the Program Integrity Manual (PIM) and CMS instructions, to drive medical review (MR) activity (i.e., data analysis, claims review, local policy development).*

F.2 Contractor shall use the PIM and Budget Performance Request (BPR) guidelines, data analysis and prior year MR results, applicable Strategy Analysis findings, and Comprehensive Error Rate Testing (CERT) results to develop and update the MR strategy document. The MR Strategy document shall address site-specific problems, prioritization of problems, funding, and workload and shall be targeted toward the goal of reducing the paid claims and provider compliance error rate. All work performed by the MR unit shall be identified in the MR Strategy and targeted based on the contractor's prioritized problem list.

F.3 Contractor shall perform data analysis continuously throughout the fiscal year (FY) to identify potential problems such as aberrant billing submissions, potential areas of over utilization, and changes in patterns of care over time. Data from a variety of sources must be used for data analysis. [Examples of data sources could include: CMS and other national sources, contractor's internal *databases,* specialty data analysis contractors (e.g., Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC)) and PSCs, Medicare contractors with similar geographic or size qualities, Office of Inspector General (OIG) reports, Government Accountability Office (GAO) reports, enrollment data, fraud alerts, and other available sources.]

F.4 Contractors shall develop, revise, and maintain local policies as based on data analysis findings and as outlined in their MR Strategy. Local policies must be in the appropriate format (see www.cms.hhs.gov/coverage) in accordance with PIM guidelines.

F.5 Contractor shall ensure that effective MR edits are developed and implemented as a result of data analysis findings. The effectiveness of each MR edit shall be analyzed and measured by tracking the denial rate, appeals reversal rate, dollar return on the cost of operationalizing the edit, and billing behavior correction. MR edits shall be modified, or deleted when they are determined to no longer be effective.

F.6 Contractor shall budget and perform the MR workloads throughout

the FY as established in the MR strategy. Contractor *shall* report workload volume and associated costs, calculated in accordance with the approved cost allocation plan, accurately and timely in the monthly MR Interim Expenditure Reports (IERs). Variances between budgeted and actual *workload* volume (10 percent or greater) and costs (5 percent or greater) shall be adequately addressed by ensuring appropriate strategy revisions and budget adjustments are made and submitted to the RO in accordance with PIM instructions. *Please note that a variance analysis may not be required for NOBA/IER if variance amount is <$5,000.*

F.7 The MR unit shall effectively collaborate with Provider Outreach and Education (POE) by referring educational needs that will address existing program vulnerabilities and emerging problems identified during the MR process conducted throughout the fiscal year.

F.8 Contractor shall be capable of identifying the status of each individual claim subjected to medical review at any time (and all claims must be processed timely for closure in accordance with PIM instructions.)

F.9 Contractor shall effectively comply with all of the MR requirements of the Joint Operating Agreement (JOA) with the PSCs.

F.10 Contractor shall implement and utilize a Provider Tracking System (PTS) to track all informational provider contacts made by medical review and all educational referrals submitted to POE.

F.11 Contractor shall ensure that there is adequate internal networking and sharing of information, and appropriate collaborative actions are taken as a result, between Medical Review and other business functions such as Benefit Integrity/PSC, Appeals, Audits, POE, and inquiries.

F.12 Contractor shall apply quality assurance processes to all elements of the MR Strategy and to all aspects of program management, data analysis, edit effectiveness, problem identification, and claim adjudication.

G Medicare Secondary Payer (MSP)

G.1 Internal quality controls are established and maintained that ensure timely and accurate processing of secondary claims submitted, including paper MSP claims, with a primary payer's explanation of benefits (EOB) or remittance advice (RA). This includes utilization

of the MSPPAY module, resolving all MSP edits (including 6800 codes*), creation of "I"** records and resolving suspended claims. Contractor internal systems used to process MSP claims are updated via the Common Working File (CWF) automatic notice in an automated fashion.

*6800 edit codes can be located at: http://www.cms.hhs.gov/manuals/downloads/msp105c06.pdf at Publication # 100-05 (Medicare Secondary Payer Manual) in Chapter 6 (Medicare Secondary Payer CWF Processes).
** "I" records are located at: http://www.cms.hhs.gov/manuals/downloads/msp105c05.pdf

G.2 Audit trails for MSP recoveries (receivables) are maintained. This should also include the contractor's ability to create a complete audit trail if cases are housed or maintained electronically. An audit trail should contain detail to support all accounting transactions as a result of establishing, reconciling and resolving a receivable. For example, an audit trail should establish the identification and creation of the debt through to its resolution including the source of the receivable, reason(s) for adjustment(s), referral to Treasury, and collection of the debt. All correspondence specific to a case should be accessible and in date order.

G.3 Contractors have processes and procedures in place to ensure compliance with all CMS instructions and directives relating to Phase III (MSP Investigations) of the Coordination of Benefits Contracts. This includes transmitting appropriate, timely and complete Electronic Correspondence Referral System (ECRS)*, CWF Assistance Requests and ECRS MSP inquiries as a result of the receipt of a phone call, correspondence, claim or unsolicited check/voluntary refund. All references must be maintained in an area accessible to MSP staff and must be available for CMS review.

*The ECRS user guide is located at: www.cms.hhs.gov/manuals/downloads/msp105c5_att1.pdf at Publication #100-05 Medicare Secondary Payer Manual in Chapter 5 Contractor Prepayment Processing Requirements.

G.4 Contractors have processes in place to identify and track all incoming correspondence to ensure Budget and Performance Requirements *(Title XVIII contractors)/Statement of Work (Medicare Administrative Contractors)* task priority compliance and timely response and acknowledgement. These tracking mechanisms should include the ability to track ECRS submissions when awaiting a particular response/status from COBC, or if your

	ECRS submission may warrant further actions after COBC development/investigation (e.g., claims adjustments).
G.5	*Contractors shall have quality assurance measures in place to ensure the accuracy of the implementation of any CMS directive. Contractors shall also provide evidence that the results from quality assurance checks are documented to identify errors and that training venues are implemented to prevent the reoccurrence of these errors.*
H	**Administrative**
H.1	All employees comply with applicable laws and regulations, a code of ethics and conflict of interest standards. Education and training programs are in place to ensure that employees understand their responsibilities.
H.2	Procurements are awarded and administered in accordance with the Medicare Agreement/Contract, CMS regulations, CMS general instructions and the Federal Acquisition Regulation.
H.3	Incoming and outgoing mail shall be properly handled in accordance with published time frames, security guidelines, and in the most cost effective and efficient manner.
H.4	Medicare management structure provides for efficient contract performance and is consistent with business practices.
H.5	Records shall be retained according to guidelines established by CMS and other Federal agencies.
H.6	Internal controls provide reasonable assurance that certain regularly scheduled processes required to support the Medicare contractor's continuity of operations in the event of a catastrophic loss of relevant, distinguishable Medicare business unit facilities are performed as scheduled.
I	**Provider Audit**
I.1	Interim, tentative and PIP payments to Medicare providers are established, monitored and adjusted, if necessary, in a timely and accurate manner in accordance with CMS general instructions and provider payment files are updated in a timely and accurate manner. Adjustments to interim payments shall be made to *en*sure that payments approximate final program liability within established ranges. Payment records are adequately protected.

I.2	Information received by the contractor from CMS or obtained from other sources regarding new providers, change of ownership for an existing provider, termination of a provider, or a change of intermediary are identified, recorded, and processed in System Tracking for Audit and *R*eimbursement (STAR) in a timely and accurate manner and reflected in subsequent audit activities.
1.3	Provider Cost Reports are properly submitted and accepted in accordance with CMS' general instructions. Appropriate program policies and instructions are followed in situations where the provider did not file a cost report. Cost report submission information is timely and properly forwarded to the proper CMS Systems.
I.4	Desk review procedures and work performed are documented and are sufficient to obtain an accurate review of the submitted cost report. Documentation is established and maintained to identify situations requiring a limited desk review or a full desk review.
I.5	Notices of Program Reimbursement (NPR) are issued accurately and timely to providers and include all related documentation (e.g. an audit adjustment report, copy of the final settled cost report).
I.6	Inputs to mandated systems regarding provider audit, settlement, and reimbursement performance *(STAR)* are complete, accurate and in compliance with program instructions. Documentation supporting reports and inputs shall be maintained.
I.7	The contractor's cost report reopening process is conducted in accordance with CMS regulations and program policy.
I.8	Provider appeals (including both the Provider Reimbursement Review Board (PRRB) and Intermediary Appeals) are handled appropriately. Jurisdictional questions are addressed and PRRB timeframes for submission are observed.
I.9	The contractor's Provider Statistical and Reimbursement Report (PSRR) system is operated in accordance with CMS manuals and instructions. Related reports are distributed to providers in accordance with CMS manuals and instructions.
I.10	An internal quality control process has been established and is functioning in accordance with CMS instructions to ensure that audit work performed on providers' cost reports is accurate, meets CMS quality standards, and results in program payments to providers which are in accordance with Medicare law, regulations and program instructions.

I.11	Cost reports are scoped and selected for audit or settled without audit based on audit plans that adhere to CMS guidelines and instructions.
I.12	The contractor's audit process is conducted in accordance with CMS manual instructions and timelines, i.e., timeframes for issuance of the engagement letter, documentation requests, pre-exit and exit conferences, and settlement of the audited cost report.
I.13	Communications of audit programs, desk review programs, CMS audit and reimbursement policies, and other audit related instructions are timely and accurately communicated to all appropriate audit staff.
I.14	The contractor's audit staff maintains its necessary knowledge and skills by completing continuing education and training (CET) required by CMS instructions, and documentation is maintained to support compliance by each staff member.
I.15	Supervisory reviews of the audit and settlement process are conducted and the policies and procedures for these reviews are communicated to all supervisors in accordance with CMS program instructions.
I.16	All cost reports where fraud is suspected shall be referred to the Payment Safeguard Contractor (PSC) Benefit Integrity Unit in accordance with CMS and contractor instructions.
I.17	The contractor has processes and procedures in place to document that supervisory reviews by provider audit department management were completed on all provider audit CAPs from the establishment of the CAPs to the implementation and validation of the CAPs.

J **Financial**

Transactions for Medicare accounts receivable, payables, expenses shall be recorded and reported timely and accurately, and financial reporting shall be completed in accordance with CMS standards, Federal Acquisition Regulation (FAR), Financial Accounting Standards Advisory Board, Cost Accounting Standards, and Generally Accepted Accounting Principles (GAAP). For the following control objectives, the review shall focus on the following areas:

- Cost Report Settlement Process;
- Contractor Financial Reports:

- Statement of Financial Position (CMS-H750A/B),
- Status of Accounts Receivable (CMS-751A/B),
- Status of Debt – Currently Not Collectible (CNC) (CMS –C751 A/B),
- Status of Medicare Secondary Payer Accounts Receivable (CMS-M751A/B),
- Status of Medicare Secondary Payer Debt-Currently Not Collectible (CMS-MC751A/B),
- Reconcile the accounts receivable balance and activity to the Provider Overpayment Reporting (POR) System and the Physician Supplier Overpayment Reporting (PSOR) system,
- HIGLAS-CMS Balance Sheets and Income Statements,
- HIGLAS-CMS Treasury Report on Receivables (TROR),
- HIGLAS-CMS CNC Eligibility,
- HIGLAS-CMS MSP Recovery GHP/Non-GHP Receivables,
- Reconcile the HIGLAS accounts receivable balance and activity to the following reports/registers:

    CMS Beginning Balance Report,

    CMS Transaction Register,

    CMS Applied Collection Register,

    CMS Adjustment Register,

    CMS AR Overpayments Report,

    CMS Interest and Late Charges,

    CMS AR Balance Detail,

    CMS Written-Off/CNC,

- Monthly Contractor Financial Report (CMS 1522) and

Contractor Draws on Letter of Credit (CMS 1521),

- Reconciliation of Cash Balances and Cash Receipts.
- HIGLAS-CMS Trial Balance and General Ledger,
- HIGLAS-CMS Cash Management Reports,
- HIGLAS-CMS Accounts Payable Reports.

J.1 Financial statements and reports should include all authorized transactions that occurred for the period reported.

J.2 Financial transactions are valid and approved by authorized personnel in accordance with management and CMS' policies.

J.3 Recorded and processed transactions are correctly classified, maintained, summarized and reconciled. In addition, transactions shall be properly supported.

J.4 Segregation of duties exists within the areas of disbursement and collection (i.e., there shall be separate authorization, record keeping, and custody).

J.5 All assets, including cash and accounts receivable should exist and be properly valued and demanded accounts receivable should be properly aged. Accounts receivable should be correctly recorded in the books/records of the contractor.

J.6 All liabilities, including accounts payables should exist and be properly valued. Accounts payable should be correctly recorded in the books/records of the contractor.

J.7 Contractor Financial Reports are accurate, signed/certified by authorized individuals and presented timely to CMS in accordance with Publication (Pub) 100-06 of the Medicare Financial Management Manual, Chapter 5, Financial Reporting, *s*ection 230.

J.8 Banking information relevant to Medicare processing is accurately stated and conforms to the tripartite agreement.

K Debt Referral (MSP and Non-MSP)

K.1 Procedures are documented and followed to identify a debt eligible for referral to Treasury for cross servicing and Treasury Offset Program (TOP) prior to the debt becoming 180 days delinquent. These procedures are written and available for review. *Debts eligible for referral and debts ineligible for referral are properly*

reported on the appropriate CMS Forms 751, Contractor Financial Reports, Status of Accounts Receivable, or the Treasury Report on Receivables and Debt Collection Activities Report. For MSP debt, see Internet Only Manual (IOM), Pub 100-05, MSP Manual, Chapter 7, Section 60. For Non-MSP debt, see IOM, Pub 100-06, Chapter 4, Section 70. For MSP and Non-MSP debt, see also Pub 100-06, Chapter 5.

K.2 Intent to Refer letters (IRLs) for eligible debt are sent in a timely manner in accordance with CMS instructions. Use the MSP and Non-MSP references in K.1 to provide the timeframes for each type of debt.

K.3 Responses to the IRL letter are handled timely according to CMS instructions.- Appropriate systems are updated to reflect any changes to the eligibility status of the debt *and these statuses are properly reported on the financial reporting forms outlined in K.1. Procedures are in place to handle undeliverable letters. Use the references in K.1.*

K.4 Eligible delinquent debt is input to the Debt Collection System (DCS) timely and accurately in accordance with CMS instructions. Use references in K.1.

K.5 Contractor initiated recalls, collections, and adjustments are entered to DCS as appropriate, when there is a change to a debt that has been referred for cross servicing, in accordance with CMS instructions. Procedures to update these debts in DCS are in place and are being followed. Use the references in K.1.

K.6 Contractor has procedures in place to ensure that the Collection/Refund Spreadsheets are completed in accordance with CMS instructions. Use the references in K.1.

K.7 Treasury Cross-Servicing Dispute Resolution forms are researched, resolved, and responded to Treasury timely in accordance with CMS instructions. See references in K.1. Procedures are in place and are being followed to respond to these disputes/inquiries, update the DCS, and properly report the status and balance of the debt in the financial reporting forms outlined in K.1.

L Non-MSP Debt Collection

L.1 Demand letters initiate the collection of a provider debt as well as inform the provider of the existence of the debt, their appeal rights with respect to the debt, and the ramifications if the debt is not paid

or an agreement is not reached within a specified time period. In addition to the content of the demand letter, the demand letter shall be issued, printed and mailed timely.

L.2 Extended Repayment Plans (ERPs) shall be analyzed for approval or denial. A supervisor, in accordance with CMS instructions, reviews all ERPs. This includes monitoring all approved ERPs, the complete financial analysis of the provider's application, and the referral to CMS when necessary.

L.3 Interest is applied correctly and timely in accordance with CMS instructions. When necessary, interest adjustments are calculated correctly and processed and applied in a timely manner.

L.4 Bankruptcy cases are handled in accordance with CMS instructions and instructions given by the Office of General Counsel (OGC). An audit trail of the overpayment shall exist before and after the bankruptcy filing to ensure that Medicare's best interest can be represented by OGC.

L.5 Provider debt is collected timely, completely, and accurately with an appropriate audit trail of all collection activity and attempts of collection activity. This audit trail supports the amount of the provider debt.

L.6 All appropriate entries to CMS' POR/PSOR (Refer to Joint Signature Memorandum 06233), HIGLAS and contractor internal systems are made timely and accurately and reconciled among the relevant CMS systems. Discrepancies are corrected and an audit trail is maintained.

L.7 Timely review and processing of all 838 Credit Balance Reports. Ensure that all reported credit balances are collected and properly processed in accordance with CMS instructions.

L.8 All overpayments, which meet the thresholds established in the Financial Management Manual, regardless of where they are determined, (Claims Processing, PSC/BI, Overpayments, Audit and Reimbursement…) are demanded and collection efforts are pursued. Medicare contractors are not responsible for the demand and collection efforts for the demand and collection efforts of overpayments identified through the Recovery Audit Contractor Demonstration.

L.9 For overpayments subject to the limitation on recoupment of *s*ection 935 of the Medicare Modernization Act (MMA), recoupment is stopped when, a valid and timely first level appeal

(redetermination) is received and when a valid and timely 2nd level appeal (Qualified Independent Contractor (QIC) reconsideration) is received. Section 935 directs CMS to stop recoupment of an overpayment where a provider or supplier has appealed to the QIC until the QIC reconsideration decision. This does not apply to Part A cost report overpayments. Interest continues to accrue.

M **Provider Enrollment**

M.1 Review the CMS 855 enrollment applications and take appropriate action in accordance with CMS guidelines in the Program Integrity Manual (PIM), Chapter 10.

M.2 Reassignments of benefits are made in accordance with *s*ection 30.2 of the Medicare Claims Processing Manual and *s*ection 7, Chapter 10 of the PIM.

M.3 Billing arrangements are in accordance with *s*ection 30.2 of Medicare Claims Processing Manual.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R132FM	10/05/2007	Chapter 7, Internal Control Requirements Update	11/05/2007	5701
R117FM	02/12/2007	Internal Control Requirements Update	01/29/2007	5429
R116FM	01/31/2007	Internal Control Requirements Update – Replaced by Transmittal 117	01/29/2007	5429
R112FM	12/29/2006	Internal Control Requirements Update- Replaced by Transmittal 116	01/29/2007	5429
R103FM	07/21/2006	Internal Control Requirements Update	07/24/2006	5234
R95FM	04/28/2006	Internal Control Requirements Update	05/30/2006	4334
R66FM	03/04/2005	Internal Control Requirements Update	04/04/2005	3655
R34FM	02/06/2004	Internal Control Requirements Update	03/08/2004	3006
R15FM	02/07/2003	Federal Managers' Financial Integrity Act	03/21/2003	2513
R11FM	09/27/2002	Corrective Action Plans	09/27/2002	2287
R07FM	08/30/2002	Initial Publication of Chapter	10/01/2002	2231

- Improper allocation of costs to related organizations that have been determined to be improper.

- Accounting manipulations.

4.2.2 - Program Safeguard Contractor *and Zone Program Integrity Contractor* Benefit Integrity Unit

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

The PSC *and the ZPIC* BI unit is responsible for preventing, detecting, and deterring Medicare fraud. The PSC *and the ZPIC* BI unit:

- Prevents fraud by identifying program vulnerabilities.

- Proactively identifies incidents of potential fraud that exist within its service area and takes appropriate action on each case.

- Investigates (determines the factual basis of) allegations of fraud made by beneficiaries, providers, CMS, OIG, and other sources.

- Explores all available sources of fraud leads in its jurisdiction, including the MFCU and its corporate anti-fraud unit.

- Initiates appropriate administrative actions to deny or to suspend payments that should not be made to providers where there is reliable evidence of fraud.

- Refers cases to the Office of the Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions (see PIM, chapter 4, §§4.18ff, 4.19ff, and 4.20ff).

- Refer any necessary provider and beneficiary outreach to the POE staff at the AC or MAC.

Initiates and maintains networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups.

The PSC *and the ZPIC* BI units are required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent billing practices.

The PSC *and the ZPIC* BI units shall pursue leads through data analysis (PSCs *and ZPICs* shall follow chapter 2, §2.3 for sources of data), the Internet, the Fraud Investigation Database (FID), news media, etc. Proactive (self-initiated) leads may be generated and/or identified by any internal, AC, or MAC component, not just the PSC *and ZPIC* BI units (e.g., claims processing, data analysis, audit and reimbursement, appeals, medical review, enrollment). For workload reporting purposes the PSC *and*

ZPIC shall only identify as proactive, those investigations and cases that the PSC *and the ZPIC* self-initiated and any proactive leads the PSC *and the ZPIC* pursues that were received from the AC or MAC that did not originate from a complaint.

The PSC *and the ZPIC* BI units shall take prompt action after scrutinizing billing practices, patterns, or trends that may indicate fraudulent billing, i.e., reviewing data for inexplicable aberrancies (other than the expected) and relating the aberrancies to specific providers, identifying "hit and run" providers, etc. PSC *and ZPIC* BI units shall meet periodically with staff from their respective internal components and PSCs *and ZPICs* shall also meet with AC and MAC staff to discuss any problems identified that may be a sign of potential fraud.

Fraud leads from any external source (e.g., law enforcement, CMS referrals, beneficiary complaints) are considered to be reactive and not proactive. However, taking ideas from external sources, such as non-restricted Fraud Alerts and using them to look for unidentified aberrancies within PSC *and ZPIC* data is proactive.

4.2.2.1 - Organizational Requirements

(Rev. 259, Issued: 06-13-08, Effective: 07-01-08, Implementation: 07-07-08)

Full PSCs are not required to separate their MR and BI units. However, all BI information shall be kept confidential and secure and shared with MR only on a need-to-know basis.

The PSC *and the ZPIC* BI unit managers shall have sufficient authority to guide BI activities. The managers shall be able to establish, control, evaluate, and revise fraud-detection procedures to ensure their compliance with Medicare requirements.

The PSC *and the ZPIC* BI unit manager shall prioritize work coming into the PSC *and the ZPIC* BI unit to ensure that investigations and cases with the greatest program impact/and or urgency are given the highest priority. Allegations or cases having the greatest program impact would include cases involving:

- Patient abuse or harm.
- Multi-state fraud.
- High dollar amounts of potential overpayment.
- Likelihood for an increase in the amount of fraud or enlargement of a pattern.
- The PSCs, *ZPICs,* ACs, and MACs shall give high priority to fraud complaints made by Medicare supplemental insurers. If a referral by a Medigap insurer includes investigatory findings indicating fraud stemming from site reviews, beneficiary interviews and/or medical record reviews, *ZPIC and* PSC BI units shall 1) conduct an

Medicare Learning Network
MLN Matters
CMS
Information for Medicare Fee-for-Service Health Care Professionals

News Flash - ***Effective March 1, 2008,*** Medicare fee-for-service 837P and CMS-1500 claims must include an NPI in the primary fields on the claim (i.e., the billing, pay-to, and rendering fields). You may continue to submit NPI/legacy pairs in these fields or submit only your NPI on the claim. You may not submit claims containing only a legacy identifier in the primary fields. Failure to submit an NPI in the primary fields will result in your claim being rejected or returned as unprocessable beginning March 1, 2008. Until further notice, you may continue to include legacy identifiers only for the secondary fields.

MLN Matters Number: SE0749

Related Change Request (CR) #: N/A

Related CR Release Date: N/A

Effective Date: N/A

Related CR Transmittal #: N/A

Implementation Date: N/A

Addressing Misinformation Regarding Chiropractic Services and Medicare

Provider Types Affected

Providers submitting claims to Medicare contractors (carriers, and/or Part A/Part B Medicare Administrative Contractors (A/B MACs)) for Chiropractic services provided to Medicare beneficiaries

Provider Action Needed

This special edition article is being provided by the Centers for Medicare & Medicaid Services (CMS) to correct misinformation in the chiropractic community relating to Medicare and its regulations as they relate to chiropractic services. This article is informational only and represents no changes to existing Medicare policy.

Background

In order to correct misinformation about Medicare and its regulations which exist in the chiropractic community, the American Chiropractic Association (ACA) works to check the validity of all claims and provide accurate information based on the Medicare manual system maintained by CMS, as well as information in regulatory

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

and statutory language. CMS is providing this special edition article which it hopes will clarify certain issues, around which there may be some confusion. The specific issues being addressed are:

MISINFORMATION #1: There is a 12 visit cap or limit for chiropractic services.

Correction: There are no caps/limits in Medicare for covered chiropractic care rendered by chiropractors who meet Medicare's licensure and other requirements as specified in the Medicare Benefit Policy Manual, Chapter 15, Section 30.5. (This manual is available at ***http://www.cms.hhs.gov/manuals/IOM/list.asp*** on the CMS website.)

There may be review screens (numbers of visits at which the Medicare carrier or A/B MAC may require a review of documentation), but caps/limits are not allowed.

The Social Security Act (Section 1862 (a)(1); see ***http://www.ssa.gov/OP_Home/ssact/title18/1862.htm*** on the Internet) provides that Medicare will only pay for items or services it determines to be "reasonable and necessary," and if those items or services can be shown to be "reasonable and necessary," then those items or services are covered and will be paid by Medicare.

MISINFORMATION #2: If you are a non-participating (non-par) provider, you do not have to worry about billing Medicare.

Correction: Being non-par does not mean you don't have to bill Medicare. All Medicare covered services must be billed to Medicare, or the provider could face penalties.

A non-par provider is actually a provider involved in the Medicare program who has enrolled to be a Medicare provider but chooses to receive payment in a different method and amount than Medicare providers classified as participating. The non-par provider may receive reimbursement for rendered services directly from their Medicare patients. They submit a bill to Medicare so the beneficiary may be reimbursed for the portion of the charges for which Medicare is responsible.

It is important to note that non-par providers may choose to accept assignment, therefore, the amount paid by the beneficiary must be reported in Item 29 of the CMS 1500 claim form. This ensures that the beneficiary is reimbursed (if applicable) prior to Medicare sending payment to the provider.

Whether or not a non-par provider chooses to accept assignment on all claims or on a claim-by-claim basis, their Medicare reimbursement is five percent less than

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a participating provider, as reflected in the annual Medicare Physician Fee Schedule.

You can find a copy of the Medicare Participating Provider Agreement at ***http://www.cms.hhs.gov/cmsforms/downloads/cms460.pdf*** on the CMS website. The form contains important information regarding the participation process and the annual opportunity you have to make or change your participation decision.

Additional information is available in the Medicare Benefit Policy Manual (Chapter 15; Covered Medical and Other Health Services) at ***http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf*** on the CMS website and the Medicare Claims Processing Manual (Chapter 12; Physician/Nonphysician Practitioners) at ***http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf*** on the CMS website.

MISINFORMATION #3: If you are a non-participating (non-par) provider, you will never be audited nor have claims reviewed, etc.

Correction: Any Medicare claim submitted can be audited/reviewed; the non-participating (non-par) or participating (par) status of the physician does not affect the possibility of this occurring. CMS audits/reviews are intended to protect Medicare trust funds and also to identify billing errors so providers and their billing staff can be alerted of errors and educated on how to avoid future errors. Correct coverage, reimbursement, and billing requirements are readily available to assist you in understanding Medicare requirements. This information is in Medicare manuals that are at ***http://www.cms.hhs.gov/Manuals/*** on the CMS website. In addition, an excellent way to stay informed about changes to Medicare billing and coverage requirements is to monitor MLN Matters articles, such as this one, which are available at ***http://www.cms.hhs.gov/MLNMattersArticles/*** on the same site.

MISINFORMATION #4: You can opt out of Medicare.

Correction: Opting out of Medicare is not an option for Doctors of Chiropractic. Note that opting out and being non-participating are not the same things. Chiropractors may decide to be participating or non-participating with regard to Medicare, but they may not opt out.

For further discussions of the Medicare "opt out" provision, see the Medicare Benefits Policy Manual (Chapter 15, Section 40; Definition of Physician/Practitioner) at ***http://www.cms.hhs.gov/manuals/downloads/bp102c15.pdf***

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on the CMS website.

MISINFORMATION #5: You should get an Advance Beneficiary Notification (ABN) signed once for each patient, and it will apply to all services, all visits.

Correction: The decision to deliver an **ABN must be based on a genuine reason to expect that Medicare will not pay for a particular service on a specific occasion** for that beneficiary due to lack of medical necessity for that service. The ABN then allows the beneficiary to make an informed decision about receiving and paying for the service. Should the beneficiary decide to receive the service, you must then submit a claim to Medicare even though you expect the beneficiary to pay and you expect that Medicare will deny the claim.

For further information, see the Medicare Claims Processing Manual (Chapter 30) at ***http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf*** and the Medicare Benefits Policy Manual (Chapter 15) at ***http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf*** on the CMS website. Also see "What Doctors Need to Know about the Advance Beneficiary Notice (ABN)" at ***http://www.cms.hhs.gov/MLNProducts/downloads/ABN_READERS.pdf*** on the CMS website.

MISINFORMATION #6: Maintenance care is not a covered service under Medicare.

Correction: Spinal manipulation is a covered service under Medicare, no matter which phase of care you may be in; however, maintenance care is not **medically reasonable and necessary and therefore not reimburseable by Medicare**. Acute, chronic, and maintenance adjustments are all "covered" services, but only acute and chronic services are considered active care and may, therefore, be reimbursable. Maintenance therapy is defined (per Chapter 15, Section 30.5.B. of the Medicare Benefits Policy Manual)) as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

See MM3449 (Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy) at ***http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3449.pdf*** on the CMS website. This article contains important information on completing claims and how to identify acute and chronic adjustments as opposed to maintenance

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adjustments. **The article also recommends you consider issuing an ABN to the Medicare beneficiary when you provide maintenance services**. Additional details are available in the Medicare Benefits Policy Manual, Chapter 15, Section 30.5 (Chiropractor's Services) at ***http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf*** on the CMS website.

MISINFORMATION #7: Non-par providers do not have the same documentation requirements as par providers.

Correction: Chiropractic care has documentation requirements to show medical necessity. The participating status of the provider is irrelevant to the documentation requirements.

Specific details regarding documentation are in the Medicare Benefit Policy Manual (Chapter 15, Sections 30.5 and 240) at ***http://www.cms.hhs.gov/manuals/downloads/bp102c15.pdf*** on the CMS website. Also, see the Medicare Claims Processing Manual (Chapter 12, Section 220) at ***http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf*** on the CMS website.

Additional Information

If you have any questions regarding chiropractic issues and Medicare, please contact your Medicare carrier or A/B MAC at their toll-free number, which may be found at ***http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip*** on the CMS website.

News Flash **- It's seasonal flu time again! If you have Medicare patients who haven't yet received their flu shot, you can help them reduce their risk of contracting the seasonal flu and potential complications by recommending an annual influenza and a one-time pneumococcal vaccination. Medicare provides coverage for flu and pneumococcal vaccines and their administration. – And don't forget to immunize yourself and your staff. Protect yourself, your patients, and your family and friends. Get Your Flu Shot – Not the Flu! Remember - Influenza vaccination is a covered Part B benefit but the influenza vaccine is NOT a Part D covered drug. Health care professionals and their staff can learn more about Medicare's coverage of adult immunizations and related provider education resources, by reviewing Special Edition *MLN Matters* article SE0748 at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0748.pdf* on the CMS website.**

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Improper Medicare Fee-For-Service Payments Report - November 2006 Report

Overview

Background

The Social Security Act established the Medicare program in 1965. Medicare currently covers health care needs of people aged 65 and over, the disabled, people with End Stage Renal Disease (ESRD), and certain others that elect to purchase Medicare coverage. Both Medicare costs and the number of Medicare beneficiaries has increased dramatically since 1965. In fiscal year (FY) 2005, more than 43 million beneficiaries were enrolled in the Medicare program, and the total Medicare benefit outlays (both Medicare Fee-for-Service (FFS) and managed care payments) was estimated at about $339.4 B (1). The Medicare budget represents almost 15% of the total federal budget.

CMS uses several types of contractors to prevent improper payments from being made for Medicare claims and admissions including Carriers, Durable Medical Equipment Regional Carriers (DMERCs), Fiscal Intermediaries (FIs), and Quality Improvement Organizations (QIOs).

The primary goal of each Carrier/DMERC/FI is to "Pay it Right" – that is, to pay the right amount to the right provider for covered and correctly coded services. Budget constraints limit the number of claim reviews these contractors can conduct; thus, they must choose carefully which claims to review. To improve provider compliance, Carriers/DMERCs/FIs must also determine how best to educate providers about Medicare rules and implement the most effective methods for accurately answering coverage and coding questions. As part of its Improper Payments Information Act (IPIA) compliance efforts, and to help all Medicare FFS contractors better focus review and education, CMS has established the Comprehensive Error Rate Testing (CERT) program and Hospital Payment Monitoring Program (HPMP) to randomly sample and review claims submitted to Medicare.

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History of Error Rate Production

The Department of Health and Human Services (DHHS), Office of Inspector General

(OIG) estimated the Medicare FFS error rate from 1996 through 2002. The OIG designed their sampling method to estimate a national Medicare FFS paid claims error rate. Due to the sample size – approximately 6,000 claims – the OIG was unable to produce error rates by contractor type, specific contractor, service type, or provider type. The confidence interval for the national paid claims error rates during these years was +/- 2.5%. Following recommendations from the OIG, CMS increased the sample size for the CERT program when production began on the Medicare FFS error rate for the November 2003 Report. The sample size for error rates concerning Carriers/DMERCs/FIs in this reporting period was 139,312 paid and denied claims. The sample size for error rates concerning QIOs for the reporting period was 40,982 discharges.

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Types of Error Rates Produced

To better measure the performance of the Carriers/DMERCs/FIs and to gain insight into the causes of errors, CMS decided to calculate not only a national Medicare FFS paid claims error rate but also a provider compliance error rate.

Paid Claims Error Rate

This rate is based on dollars paid after the Medicare contractor made its payment decision on the claim. This rate includes fully denied claims for Carriers/DMERCs/FIs/QIOs. The paid claims error rate is the percentage of total dollars that all Medicare FFS contractors erroneously paid or denied and is a good indicator of how claim errors in the Medicare FFS Program impact the trust fund. CMS calculated the gross rate by adding underpayments to overpayments and dividing that sum by total dollars paid.

Provider Compliance Error Rate

This rate is based on how the claims looked when they first arrived at the Carrier/DMERC – before the Carrier/DMERC applied any edits or conducted any reviews. The provider compliance error rate is a good indicator of how well the Carrier/DMERC is educating the provider community since it measures how well providers prepared claims for submission. CMS does not collect covered charge data from FIs; therefore, current FI data is insufficient for calculating a provider compliance error rate. This rate is not generated for QIOs.

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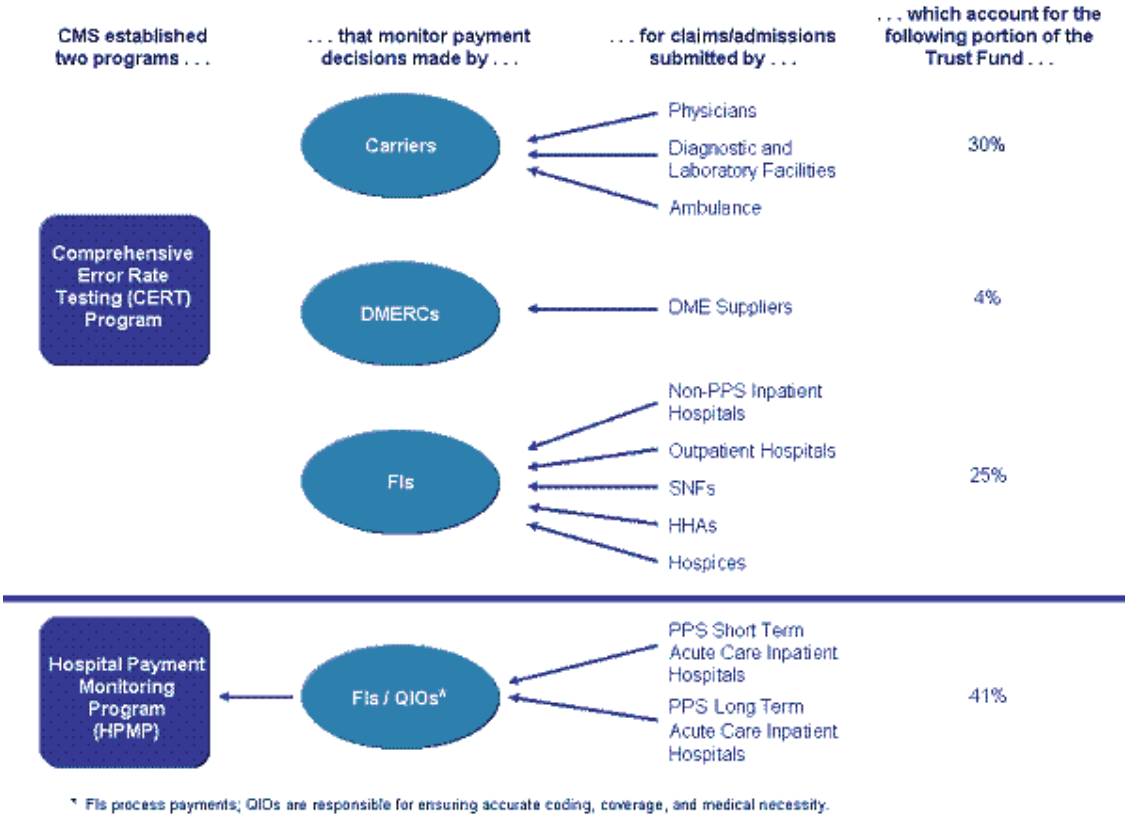
Two Measurement Programs: CERT and HPMP

CMS established two programs to monitor the accuracy of the Medicare FFS Program: the CERT program and HPMP. The main objective of these programs is to measure the degree to which CMS and its contractors are meeting the goal of *Paying It Right*. The HPMP monitors prospective payment system (PPS) short-term and long-term acute care inpatient hospital discharges. The CERT program monitors all other claims. The following figure (Figure 1) depicts the types of claims/admissions involved in each monitoring program.

Figure 1: Types of Claims/Admissions Reviewed By CERT and HPMP



The following table (Table 1) summarizes the data that is presented in this report.

Table 1: Error Rates Available in this Report

Monitoring Program	Type of Error Rate(s) Produced	Paid Claims Error Rate	Provider Compliance Error Rate
CERT + HPMP	Medicare FFS	✓	Not Produced
	Carrier/DMERC/FI	✓	✓
	Carrier-Specific	✓	✓
	DMERC-Specific	✓	✓
	FI-Specific	✓	Not Produced
	Type of Service	✓	✓

CERT	Type of Provider	✓	✓
HPMP	QIO Specific	✓	Not Produced
	Type of Service	✓	Not Produced
	Type of Provider	✓	Not Produced

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The CERT Program

CMS established the CERT program to monitor the accuracy of Medicare FFS payments made by Carriers/DMERCs/FIs. The main objective of the CERT program is to measure the degree to which CMS and Carriers/DMERCs/FIs are meeting the goal of "Paying it Right". See Appendix H for additional details about the sample used for this report.

Sampling and Medical Record Requests

For this report, the CERT Contractor randomly sampled 139,312 claims from Carriers/DMERCs/FIs. The CERT Contractor randomly selected about 187 claims each month from each Carrier/DMERC/FI. CERT designed this process to pull a blind, electronic sample of claims each day from all of the claims providers submitted that day.

The CERT Contractor requested the medical record associated with the sampled claim from the provider that submitted the claim. The CERT Contractor sent the initial request for medical records via letter. If the provider failed to respond to the initial request after 30 days, the CERT Contractor sent up to three subsequent letters in addition to follow-up phone calls to the provider.

In cases where the CERT Contractor received no documentation from the provider once 90 days had passed since the initial request, the CERT Contractor considered the case to be a no documentation claim and counted it as an error. The CERT Contractor considered any documentation received after the 90th day "late documentation." If the CERT Contractor received late documentation prior to the documentation cut-off date for this report, they reviewed the records and, if justified, revised the error in each rate throughout the report. If the CERT Contractor received late documentation after the cut-off date for this report, they attempted to complete the review process before the final production of the report. Claims that completed the review process were included in the report. Claims for which the CERT contractor received no documentation were counted as no documentation errors.

Review of Claims

Upon receipt of medical records, the CERT Contractor's clinicians conducted a review of the claims and submitted documentation to identify any improper payments. They checked the Common Working File to see if the person receiving the services was an eligible Medicare beneficiary, to see if the claim was a duplicate and to make sure that

no other insurer was responsible for paying the claim. When performing these reviews, the CERT contractor followed Medicare regulations, billing instructions, National Coverage Determinations (NCDs), coverage provisions in interpretive manuals, and the respective Carrier/DMERC/FI Local Coverage Determinations (LCDs), and articles.

Appeal of Claims

In the November 2003 reporting period, the CERT Contractor did not remove an error from the error rate if a provider appeal (using the normal appeals process) of a CERT initiated denial resulted in a reverse decision. In the November 2004 Report, the CERT Contractor implemented an appeals tracking system and began to back out overturned CERT initiated denials from the error rate; however, some contractors did not enter all the appeals information into the new tracking system before the cut-off date for the report. Therefore, CERT only backed out some of the determination reversals from the error rate in the November 2004 Report. As of the November 2005 report, all Carriers/DMERCs/FIs have the opportunity to ensure that all overturned appeals are entered into the appeals tracking system in sufficient time for production of the error rates.

Variation from the General Methodology

Readers should note that the CERT sample spans from April 2005 to March 2006 while CMS payment data is reported by calendar year. Therefore, the CERT program used payment data from calendar year 2005 to generate the projected improper payments in this report.

CERT also purposefully reduced the samples size for certain contractors during the last four months of sampling period. This reduction was performed because of an increase in percentage of claims that were reviewable versus those that were not. The resources required to review claims limit the number of claims that can be reviewed in the time allotted for the report. The reduction was necessary in order to stay within the budgeted sample size. Although this action led to claims being sampled at different levels within the sample period for some contractors, CERT analyzed the impact of this issue and determined that the standard estimation methodology did not need to be altered.

Naming Conventions

From time to time, a Carrier/DMERC/FI will choose to leave the Medicare program. When this occurs, CMS selects a replacement contractor to take over claims processing, error rate reduction efforts, etc. The *cutover date* is the term used to describe the date that the incoming contractor begins to receive and process claims while the outgoing contractor ceases operations. When preparing these improper payment reports, CMS has adopted a policy of listing the name of the contractor who processed claims from that jurisdiction for more than 6 months of the reporting period.

The following jurisdictions transitioned contractors during the reporting period:
Carefirst MD/DC to Highmark Medicare Services MD/DC
Medicare NW UT/OR/ID to Noridian UT/OR/ID
Regence UT to Noridian UT

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HPMP

The CMS established the HPMP to measure, monitor, and reduce the incidence of improper PPS acute care inpatient Medicare payments. FIs process these payments; QIOs are responsible for ensuring accurate coding, admission necessity, and coverage. HPMP operates through the QIO program as QIOs have responsibility for ascertaining the accuracy of these payments through the physician peer review process. QIOs work with acute care hospitals to identify and prevent payment errors.

Sampling
Each month a CMS contractor selected a random sample of paid short-term acute care inpatient claims for each state from a clinical data warehouse that mirrors the National Claims History (NCH) database. To allow time for hospital claims submission, HPMP sampled claims after the completion of three months from the month of discharge; claims are 97.5% complete at this time. Beginning with the November 2005 report, HPMP also sampled paid long-term acute care and FI-denied claims (both short-term and long-term). For long term acute care claims, a national random sample not stratified by state was selected monthly. Claims that had been denied at the FI were selected as a single, national random sample. The HPMP sampled a total of 40,982 claims from 52 states and jurisdictions (all 50 states plus Puerto Rico and Washington, D.C.).

Review of Claims
The CMS contractor that performed the sampling of PPS short-term acute care sample claims provided the sampled claims to the Clinical Data Abstraction Centers (CDACs) for screening. The CDACs validated Diagnosis Related Groups (DRGs), performing independent recoding and admission necessity screening based upon the information provided in the submitted record. Qualified coding specialists performed DRG coding validation. CDAC nurse reviewers performed admission necessity screening. Admission screening involved a detailed examination of each medical record using specific modules of the InterQual admission appropriateness criteria set. In addition, Maryland records were screened for length of stay (Maryland is the only waivered non-PPS state); Maryland length of stay errors are included under medically unnecessary services.

The CDACs did not follow-up with providers; the CDAC referred records that failed screening as well as those that were not received in a timely manner to the responsible QIO for case review. Under the case review process, records are again validated for coding and screened for admission necessity. Those records failing admission necessity screening are sent to peer physician review under which hospitals have further opportunity to supply documentation.

The long-term acute care sample was sent directly to QIOs and was not screened by the CDAC. Denied claims were handled only by the CDAC and were not sent to the QIOs.

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Weighting and Determining the Final Results

The error rates were weighted so that each Carrier/DMERC/FI/QIO contribution to the error rate was in proportion to its size (as measured by the percent of allowed charges for which they were responsible). The confidence interval is an expression of the numeric

range of values for which CMS is 95% certain that the mean values for the improper payment estimates will fall. As required by the IPIA, the CERT program has included an additional calculation of the 90% confidence interval for the national error rate calculation.

All national improper payment estimates from 1996 to present EXCLUDE coinsurance, deductibles and reductions to recover previous overpayments. When CMS began calculating the additional error rates for contractor-specific, service-type and provider-type in the November 2003 and November 2004 reports, these types INCLUDED coinsurance, deductibles and reductions. The CERT program was unable to exclude them from the improper payment amounts due to system limitations. CMS has since implemented new systems and revised methodology that has allowed for the EXCLUSION of coinsurance, deductibles and reductions from all improper payment amounts beginning with the November 2005 reporting period. As a result, the improper payment estimates from the November 2005 report and forward can not be compared to previously published estimates for contractor-specific, service-type, or provider-type calculations. However, since error rate estimates are unaffected, they can be compared across all reports.

Since error rates are calculated as the sum of overpayments and underpayments divided by the original dollars paid, estimated error rates >100% are possible. In particular, this situation can occur when very large underpayments are found among sampled records. The size of the associated confidence interval which represents the extent of variability should always be considered when evaluating estimated payment error rates.

Table 2: Summary of Inclusion vs. Exclusion

	National Rate	Contractor Specific	Service Type	Provider Type
1996 - 2002	**EXCLUDES** coinsurance, deductibles, and reductions	N/A	N/A	N/A
Nov 2003	**EXCLUDES** coinsurance, deductibles, and reductions	Carrier/DMERC/FI improper payment estimates **INCLUDE** coinsurance, deductibles, and reductions. QIO contractor-specific improper payment estimates **EXCLUDE** coinsurance, deductibles, and reductions.		
Nov 2004	**EXCLUDES** coinsurance, deductibles, and reductions	Carrier/DMERC/FI improper payment estimates **INCLUDE** coinsurance, deductibles, and reductions. QIO contractor-specific improper payment estimates **EXCLUDE** coinsurance, deductibles, and reductions.		
From Nov 2005 Forward	**EXCLUDES** coinsurance, deductibles, and reductions	Carrier/DMERC/FI/QIO improper payment estimates **EXCLUDE** coinsurance, deductibles, and reductions.		

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Outcome of Sampled Claims

In the CERT program, Carriers/DMERCs/FIs are notified of detected overpayments so that they can implement the necessary adjustments. Carriers/DMERCs/FIs are also notified of underpayments but they are not currently required to make payments to providers for underpayments identified in the CERT program. Carriers/DMERCs/FIs are encouraged to make payments to providers in underpayment cases identified by the CERT program. For more information about overpayments see Appendix F, for underpayments, see Appendix G. Sampled claims for which providers failed to submit

documentation were considered overpayments.

QIOs in the HPMP notified FIs of adjustments necessary due to overpayment and underpayment errors identified by the program. When a QIO determined that a DRG coding change was required, the FI was also informed of the appropriate DRG. In addition, the FI was informed when: a stay was found to be inappropriate, the requested medical records were not supplied, or insufficient documentation was provided. In each case, the stay was denied and was considered an overpayment. FIs were responsible for determining payment adjustments for claims found to be in error. The QIOs did not determine adjustment amounts nor did they implement payment adjustments.

Providers can appeal denials (including no documentation denials) following the normal appeal processes by submitting documentation supporting their claims. For the November 2003 Report, the CERT program did not consider the outcome of appeal determinations. However, beginning with the claims in the November 2004 Report, the CERT program considered the outcome of any appeal determinations that reversed the CERT program's decision when computing the error rates. The CERT program deducted $214.9 M in appeals reversals from the error rates contained in this report. Under the QIO case review process, hospitals have multiple opportunities to appeal a QIO decision. Cases are not included as payment errors for all HPMP calculations until all hospital case review appeals are complete. All known appeal determinations that reversed a QIO's decision are considered when computing error rates.

The CERT program identified $983,871 in actual overpayments and, as of the final cut-off date for this report, Carriers/DMERCs/FIs had collected $635,803 of those overpayments. The HPMP identified $14.5 M in overpayments and, as of the final cutoff date for this report, the FIs had processed $10.8 M in HPMP adjustments. CMS and its contractors will never collect a small proportion of the identified overpayments because:

- The responsible provider appealed the overpayment and the outcome of the appeal overturned the CERT decision.
- The provider has gone out of business.

However, for all other situations, the Carrier/DMERC/FI will continue their attempts to collect the overpayments.

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GPRA Goals

CMS aims to accomplish three error rate goals under the Government Performance and Results Act (GPRA).

1. Reduce the National Medicare FFS Paid Claims Error Rate.

- By November 2006, reduce the percent of improper payments under Medicare FFS to 5.1%.

  STATUS: This goal was met. The national paid claims error rate for the November 2006 reporting period was 4.4%. Because of the dramatic decrease

in the paid claims error rate, CMS has revised the goal for future years.

- By November 2007, reduce the percent of improper payments under Medicare FFS to 4.3%.
- By November 2008, reduce the percent of improper payments under Medicare FFS to 4.2%.
- By November 2009, reduce the percent of improper payments under Medicare FFS to 4.1%.

2. Reduce the Contractor-Specific Paid Claim Error Rate

- By November 2006, 50% of Medicare claims will be processed by contractors with an error rate less than or equal to the national error rate for November 2005.

  STATUS: This goal was met. During the November 2006 reporting period, 81% of the Medicare claims were processed by Carriers/DMERCs/FIs with a paid claim error rate less than or equal to the national error rate for November 2005 (5.2%).

- By November 2007, 75% of Medicare claims will be processed by contractors with an error rate less than or equal to the national error rate for November 2006.
- By November 2008, every Medicare claim will be processed by contractors with an error rate less than or equal to the national error rate for November 2007.

3. Decrease the Provider Compliance Error Rate

- In November 2006, decrease the Provider Compliance Error Rate 20% over the November 2005 level.

  STATUS: This goal was not met. Due to system limitations, CMS did not collect covered charge data from FIs during this reporting period. CMS was therefore unable to produce this rate for FIs during the November 2006 reporting period. The DMERC provider compliance error rate increased by 4% and the Carrier provider compliance error rate declined by 3% when compared to their 2005 levels.

- In November 2007, decrease the Provider Compliance Error Rate 20% over the November 2006 level.
- In November 2008, decrease the Provider Compliance Error Rate 20% over the November 2007 level.

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How Error Rates Will be Used

CMS will use the error rate findings described in this report to determine underlying reasons for claim errors and to adjust its action plans to improve compliance in payment, documentation, and provider billing practices. The tracking and reporting of error rates also helps CMS identify emerging trends and implement corrective actions designed to accurately manage all Medicare FFS contractors' performance. In addition,

the error rates will provide all Medicare FFS contractors with the guidance necessary to direct claim review activities, provider education efforts, and data analysis. Carriers/DMERCs/FIs also use the error rate findings to adjust their Error Rate Reduction Plans. CMS evaluates QIOs under their contract on payment error rates.

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1. 2006 CMS Statistics: U.S. Department of Health and Human Services, CMS pub. No 03455, October 2006

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Medicare
Program Integrity Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 12 **Date: SEPTEMBER 20, 2001**

CHANGE REQUEST 1143

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
12		1 2	

MANUALIZATION-EFFECTIVE DATE: Not Applicable

Chapter 12, FI, Carrier, DMERC and RHHI Interaction and Coordination with Program Safeguard Contractors (PSCs). This is a new chapter in the Program Integrity Manual.

Chapter 12, Section 1, Introduction: This Section provides background information regarding the workflow interaction between the PSCs and FIs, Carriers, DMERCs and RHHIs.

Chapter 12, Section 2, Program Safeguard Contractors for Corporate Integrity Agreements (PSC-CIA). This Section manualizes Transmittal AB-01-08, dated January 25, 2001, Change Request 1143.

These instructions should be implemented within your current operating budget.

NOTE: Red italicized font identifies new material.

Medicare Program Integrity Manual

Chapter 12 – FI, Carrier, DMERC and RHHI Interaction and Coordination with Program Safeguard Contractors (PSCs)

Table of Contents
(Rev. 12, 09-20-01)

1 – Introduction (Rev. 12, 09-20-01)

In the spring of 1999, HCFA (now CMS) began awarding Indefinite Delivery, Indefinite Quantity (IDIQ) contracts to Program Safeguard Contractors (PSCs) to perform program integrity and data analysis activities as defined in specific task orders. A PSC can perform one, some, all or any sub-set of the work associated with the following payment safeguard functions: medical review, cost report audit, data analysis, provider education, and fraud detection and prevention. Under the "umbrella" PSC contract, Request for Proposals (RFPs) for selected task orders are competed amongst the PSCs and awarded to one or more depending on the scope of each task order.

The purpose of this chapter is to inform you of the workflow process you are to follow for the PSC interaction and coordination with carriers, FIs, DMERCs, and RHHIs. We want to ensure timely and efficient coordination with the PSC to maximize the successful outcome of this program integrity initiative.

2 - Program Safeguard Contractors for Corporate Integrity Agreements (PSC-CIA) (Rev. 12, 09-20-01)

The PSC-CIA task order was awarded in November 1999 to Tri-Centurion, L.L.C. The PSC-CIA may perform on-site reviews of selected providers that are subject to CIAs to verify compliance efforts and confirm that the terms and conditions of the CIAs are being met. The PSC-CIA must also review a statistically valid random sample (SVRS) of claims submitted to Medicare by the providers and determine patterns or significant occurrences where claims are filed in contravention of applicable Medicare laws, regulations or policies.

Each year a selected number of CIAs are scheduled for review. The CIAs apply to providers serviced by various contractors. You may or may not be contacted, but if you are you may possibly be contacted more than once. To date, entities have entered into a CIA with the U.S. Department of Health and Human Services, Office of the Inspector General (OIG). CIAs are case-specific. Their terms are tailored to address the deficiencies that have been identified by the OIG with respect to providing and billing for health care services.

If a provider within your jurisdiction is on the list of CIAs to be reviewed, the regional office (RO) will ask that you identify a contact person at your site to coordinate any activities required by the PSC-CIA relating to the CIA compliance and billing reviews. Provide the name of the contact person to your RO benefit integrity representative. Depending upon the nature of the CIA, the PSC may need documents or other information on the following issues: reimbursement, medical review, benefit integrity, educational correspondence, coverage guidelines, provider files, and local medical review policies. No systems changes or special reports are required, only information fiscal intermediaries and carriers would have in the normal course of business. It is important for you to coordinate contacts with appropriate program integrity and program management staff.

You are responsible for coordinating appropriate follow-up actions that result from the compliance and billing reviews, such as provider overpayment or underpayment assessment and adjustment.

The Government Task Leader (GTL) or the Co-GTL will initially contact the appropriate RO to discuss the CIA workflow requirements. This will permit the RO to be aware of the coordination that will take place. The GTL or Co-GTL will then make the initial contact with your contact person regarding the PSC-CIA workflow process, necessary time lines and inform you when the PSC will contact you. The PSC will contact you and inform you of exactly what information it needs. You are to provide the information within fifteen (15) working days. If there is a problem supplying the information or a delay in giving the information, immediately contact the GTL or Co-GTL. Due to the confidential nature of the CIA, do not disclose any information about the CIA or your communication with the PSC-CIA at any time.

If there are any question or concerns, contact the GTL, John Martino at (215)-861-4177, E mail jmartino@cms.gov or the co-GTL, Maureen Savory at (410)-786-3077, E-mail msavory@cms.gov.

CMS Manual System

Pub. 100-02 Medicare Benefit Policy

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 12 **Date: MAY 28, 2004**

CHANGE REQUEST 3063

I. SUMMARY OF CHANGES: Manualizes definitions of chiropractic maintenance therapy and the reason for denials. Adds a requirement that the AT modifier be used in all cases where active/corrective chiropractic treatment is being performed. Explains that chiropractic claims billed without this modifier are considered maintenance therapy, and will be denied. Further explains that claims that exceed frequency limits must be billed without the AT modifier, that GA or GZ may be appropriate, and the claim will be denied. Deletes the paragraph in 15/240.1.5 about carrier development of parameters for an extension in course of treatment.

NEW/REVISED MATERIAL - EFFECTIVE DATE: October 1, 2004
***IMPLEMENTATION DATE:** October 4, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED –

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15/30/5/Chiropractor's Services
R	15/240/1/3/Necessity for Treatment
R	15/240/1/5 Treatment Parameters

***III. FUNDING:**

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-02	Transmittal: 12	Date: May 28, 2004	Change Request 3063

SUBJECT: New Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy

I. GENERAL INFORMATION

A. Background: Chapter 15, Section 30.5 of the Benefits Policy Manual states that chiropractic maintenance therapy is not medically reasonable or necessary and is not payable under the Medicare program.

The 2003 Improper Medicare FFS Payments report indicates that chiropractors have the highest Provider Compliance Error Rate in Medicare. The report indicates that chiropractors filed claims incorrectly almost a third of the time. In order to help chiropractors bill Medicare correctly, they need a way to indicate on each claim they submit, which claims are for active/corrective therapy and which are for maintenance therapy. A modifier ("AT") already exists for acute treatment.

B. Policy: For Medicare purposes, the AT modifier shall now be used only when chiropractors bill for active/corrective treatment. This CR:

1) Requires every chiropractic claim (those containing HCPCS code 98940, 98941, 98942) with a date of service on or after October 1, 2004, to include the Acute Treatment (AT) modifier if active/corrective treatment is being performed; or

2) No modifier if maintenance therapy is being performed. Contractors shall deny a chiropractic claim (containing HCPCS code 98940, 98941, 98942) with a date of service on or after October 1, 2004, that does not contain the AT modifier.

3) Every claim for chiropractic active/corrective treatment exceeding a contractor's frequency limit as published in an LCD, if any, should be billed without the AT (but with the GA or GZ modifier where applicable) and shall be reviewed and/or (auto)denied.

C. Provider Education: Carriers and Program Safeguard Contractors (PSCs) shall inform affected providers by posting to their Web sites the provider education article related to this instruction, which will be available at www.cms.hhs.gov/medlearn/matters, within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. If contractors have a listserv that targets affected providers, they shall use it to notify subscribers that information about "New Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy" is available on their Web site. Contractors are also encouraged, within available resources, to educate Chiropractors through seminars, conferences, etc. as they deem appropriate.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
3063.1	Effective for dates of service October 1, 2004 and later, carriers shall deny any chiropractic claim that lacks an AT modifier.	All carriers.
3063.2	Effective for dates of service October 1, 2004 and later, carriers, at their discretion, shall review and/or (auto)deny claims with an AT modifier if they have a published LMRP/LCD indicating an appropriate frequency for chiropractic services and said claim exceeds the limit.	All carriers.
3063.3	Effective immediately, each contractor shall educate chiropractors in their jurisdiction that beginning October 1, 2004, every claim for chiropractic active/corrective treatment must have the AT modifier and claims for maintenance therapy billed without the AT modifier.	All carriers.
3063.4	Effective immediately, each contractor shall educate chiropractors in their jurisdiction that beginning October 1, 2004, every claim for chiropractic active/corrective treatment exceeding the frequency limit, shall be billed without the AT (but with the GA or GZ where applicable) and will be autodenied.	All carriers.

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: October 1, 2004	**These instructions shall be**

Implementation Date: October 4, 2004 **Pre-Implementation Contact(s):** For medical review issues contact Dan Schwartz (dschwartz2@cms.hhs.gov), for CERT issues, Melanie Combs (mcombs@cms.hhs.gov, for policy issues, Terri Harris (tharris1@cms.hhs.gov). **Post-Implementation Contact(s):** Regional Office	**implemented within your current operating budget.**

CMS Manual System

Pub. 100-02 Medicare Benefit Policy

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 23 **Date: OCTOBER 8, 2004**

CHANGE REQUEST 3449

NOTE: Transmittal 18, CR 3449, dated September 3, 2004, is rescinded and replaced with Transmittal 23, CR 3449, dated October 8, 2004.

SUBJECT: Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full Replacement of CR 3063

I. SUMMARY OF CHANGES: Manualizes definitions of Chiropractic maintenance therapy and the reason for denials. Adds a requirement that the AT modifier be used in all cases where active/corrective treatment is being performed. Explains that chiropractic claims billed without this modifier are considered maintenance therapy and will be denied. Deletes the paragraph in 15/240.1.5 about carrier development of parameters for an extension in course of treatment.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: October 1, 2004
IMPLEMENTATION DATE: October 4, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15/30/5/Chiropractor's Services
R	15/240/1/3/Necessity for Treatment
R	15/240/1/5 Treatment Parameters

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Attachment - Business Requirements

Pub. 100-02	Transmittal: 23	Date: October 8, 2004	Change Request 3449

NOTE: Transmittal 18, CR 3449, dated September 3, 2004, is rescinded and replaced with Transmittal 23, CR 3449, dated October 8, 2004.

SUBJECT: Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full replacement of CR 3063.

I. GENERAL INFORMATION

A. Background: Chapter 15, Section 30.5 of the Benefits Policy Manual states that chiropractic maintenance therapy is not medically reasonable or necessary and is not payable under the Medicare program.

The 2003 Improper Medicare FFS Payments report indicates that chiropractors have the highest Provider Compliance Error Rate in Medicare. The report indicates that chiropractors filed claims incorrectly almost a third of the time. In order to help chiropractors bill Medicare correctly, they need a way to indicate on each claim they submit, which claims are for active/corrective therapy and which are for maintenance therapy. A modifier ("AT") already exists for acute treatment.

B. Policy: For Medicare purposes, the AT modifier shall now be used only when chiropractors bill for active/corrective treatment. This CR requires:

1) Every chiropractic claim (those containing HCPCS code 98940, 98941, 98942) with a date of service on or after October 1, 2004, to include the Acute Treatment (AT) modifier if active/corrective treatment is being performed; or

2) No modifier if maintenance therapy is being performed. Contractors shall deny a chiropractic claim (containing HCPCS code 98940, 98941, 98942) with a date of service on or after October 1, 2004, that does not contain the AT modifier.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Carriers and Program Safeguard Contractors (PSCs) who do medical review shall post this article, or a direct link to this article, on their website and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. In addition, contractors are encouraged, within available resources, to educate Chiropractors through seminars, conferences, etc. as they deem appropriate.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3449.1	Effective for dates of service October 1, 2004 and later, carriers shall deny any chiropractic claim that lacks an AT modifier.			X						
3449.2	Effective immediately, each contractor shall educate chiropractors in their jurisdiction that beginning October 1, 2004, every claim for chiropractic active/corrective treatment must have the AT modifier and claims for maintenance therapy must be billed without the AT modifier.			X						PSCs doing medical review

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: None

X-Ref Requirement #	Instructions

B. Design Considerations: None

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: None

D. Contractor Financial Reporting /Workload Impact: None

E. Dependencies: None

F. Testing Considerations: None

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: October 1, 2004 **Implementation Date:** October 4, 2004	**Medicare contractors shall implement these instructions within their current operating**

Pre-Implementation Contact(s): For medical review issues contact Dan Schwartz (dschwartz2@cms.hhs.gov), for CERT issues, Melanie Combs (mcombs@cms.hhs.gov, for policy issues, Terri Harris (tharris1@cms.hhs.gov). **Post-Implementation Contact(s):** Regional Office **Pre-Implementation Contact(s):** For medical review issues contact Dan Schwartz (dschwartz2@cms.hhs.gov), for CERT issues, Melanie Combs (mcombs@cms.hhs.gov, for policy issues, Terri Harris (tharris1@cms.hhs.gov). **Post-Implementation Contact(s):** Regional Office	**budgets.**

***Unless otherwise specified, the effective date is the date of service.**

30.5 - Chiropractor's Services

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2020.26

A chiropractor must be licensed or legally authorized to furnish chiropractic services by the State or jurisdiction in which the services are furnished. In addition, a licensed chiropractor must meet the following uniform minimum standards to be considered a physician for Medicare coverage. Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation provided such treatment is legal in the State where performed. All other services furnished or ordered by chiropractors are not covered.

If a chiropractor orders, takes, or interprets an x-ray or other diagnostic procedure to demonstrate a subluxation of the spine, the x-ray can be used for documentation. However, there is no coverage or payment for these services or for any other diagnostic or therapeutic service ordered or furnished by the chiropractor. For detailed information on using x-rays to determine subluxation, see §240.1.2.

In addition, in performing manual manipulation of the spine, some chiropractors use manual devices that are hand-held with the thrust of the force of the device being controlled manually. While such manual manipulation may be covered, there is no separate payment permitted for use of this device.

A - Uniform Minimum Standards

Prior to July 1, 1974

Chiropractors licensed or authorized to practice prior to July 1, 1974, and those individuals who commenced their studies in a chiropractic college before that date must meet all of the following three minimum standards to render payable services under the program:

- Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;
- Graduation from a college of chiropractic approved by the State's chiropractic examiners that included the completion of a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance covering adequate course of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing, and adjusting; and
- Passage of an examination prescribed by the State's chiropractic examiners covering the subjects listed above.

After June 30, 1974

Individuals commencing their studies in a chiropractic college after June 30, 1974, must meet all of the above three standards and all of the following additional requirements:

- Satisfactory completion of 2 years of pre-chiropractic study at the college level;
- Satisfactory completion of a 4-year course of 8 months each year (instead of a 3-year course of 6 months each year) at a college or school of chiropractic that includes not less than 4,000 hours in the scientific and chiropractic courses specified in the second bullet under "**Prior to July 1, 1974**" above, plus courses in the use and effect of x-ray and chiropractic analysis; and
- The practitioner must be over 21 years of age.

B - Maintenance Therapy

Under the Medicare program, Chiropractic maintenance therapy is not *considered to be medically reasonable or necessary, and is therefore not payable.* Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. *When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. For information on how to indicate on a claim a treatment is or is not maintenance, see §240.1.3.*

240.1.3 - Necessity for Treatment

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2251.3

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam, as described above.

Most spinal joint problems fall into the following categories:

- Acute subluxation-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical exam as specified above. The result of chiropractic manipulation is expected to be an improvement in, *or arrest of progression,* of the patient's condition.

- Chronic subluxation-A patient's condition is considered chronic when it is not expected to *significantly improve or be resolved with further treatment* (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, *without expectation of additional objective clinical improvements,* further manipulative treatment is considered maintenance therapy and is not covered.

*For Medicare purposes, a chiropractor **must** place an AT modifier on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However the presence of the AT modifier may not in all instances indicate that the service is reasonable and necessary. As always, contractors may deny if appropriate after medical review.*

A - Maintenance Therapy

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, *or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied. Chiropractors who give or receive from beneficiaries an ABN shall follow the*

instructions in Pub. 100-04, Medicare Claims Processing Manual, Chapter 23, section 20.9.1.1 and include a GA (or in rare instances a GZ) modifier on the claim.

B – Contraindications

Dynamic thrust is the therapeutic force or maneuver delivered by the physician during manipulation in the anatomic region of involvement. A relative contraindication is a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. The following are **relative contraindications** to dynamic thrust:

- Articular hyper mobility and circumstances where the stability of the joint is uncertain;
- Severe demineralization of bone;
- Benign bone tumors (spine);
- Bleeding disorders and anticoagulant therapy; and
- Radiculopathy with progressive neurological signs.

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

- Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis;
- Acute fractures and dislocations or healed fractures and dislocations with signs of instability;
- An unstable os odontoideum;
- Malignancies that involve the vertebral column;
- Infection of bones or joints of the vertebral column;
- Signs and symptoms of myelopathy or cauda equina syndrome;
- For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and
- A significant major artery aneurysm near the proposed manipulation.

240.1.5 - Treatment Parameters

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

B3-2251.5

The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time. Acute subluxation (e.g., strains or sprains) problems may require as many as three months of treatment but some require very little treatment. In the first several days, treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.

Chronic spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already “set” and fibrotic tissue has developed. This condition may require a longer treatment time, but not with higher frequency.

Some chiropractors have been identified as using an “intensive care” concept of treatment. Under this approach multiple daily visits (as many as four or five in a single day) are given in the office or clinic and so-called room or ward fees are charged since the patient is confined to bed usually for the day. The room or ward fees are not covered and reimbursement under Medicare will be limited to not more than one treatment per day.

CMS Manual System

Pub. 100-02 Medicare Benefit Policy

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 18 **Date: SEPTEMBER 3, 2004**

CHANGE REQUEST 3449

NOTE: Transmittal 12, CR 3063, dated May 28, 2004, is being rescinded and replaced with CR 3449.

SUBJECT: Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full Replacement of CR 3063

I. SUMMARY OF CHANGES: Manualizes definitions of Chiropractic maintenance therapy and the reason for denials. Adds a requirement that the AT modifier be used in all cases where active/corrective treatment is being performed. Explains that chiropractic claims billed without this modifier are considered maintenance therapy and will be denied. Deletes the paragraph in chapter 15, section 240.1.5 about carrier development of parameters for an extension in course of treatment. Revises language in CR 3063 to further explain that contractors that have Local Coverage Determinations (LCDs) with frequency limits shall instruct chiropractors that they may submit claims for services that exceed the frequency limits established within the LCD with or without the AT modifier depending on whether the chiropractor believes they have rendered active treatment or maintenance therapy, respectively, and that GA or GZ modifiers may be appropriate. Claims with or without an AT modifier will continue to be autodenied if the services exceed the frequency limits of reasonable and necessary services specified in the LCD. If contractors' LCDs do not specify frequencies that define the limit of reasonable and necessary care, contractors may deny if appropriate after medical review.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: October 1, 2004
IMPLEMENTATION DATE: October 4, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15/30.5/Chiropractor's Services
R	15/240.1.3/Necessity for Treatment
R	15/240.1.5/Treatment Parameters

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Attachment - Business Requirements

Pub. 100-02	Transmittal: 18	Date: September 3, 2004	Change Request 3449

NOTE: Transmittal 12, CR 3063, dated May 28, 2004, is being rescinded and replaced with CR 3449.

SUBJECT: Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full Replacement of CR 3063

I. GENERAL INFORMATION

A. Background: Chapter 15, section 30.5 of Pub. 100-02, Benefits Policy Manual states that chiropractic maintenance therapy is not medically reasonable or necessary and is not payable under the Medicare program.

The 2003 Improper Medicare FFS Payments report indicates that chiropractors have the highest Provider Compliance Error Rate in Medicare. The report indicates that chiropractors filed claims incorrectly almost a third of the time. In order to help chiropractors bill Medicare correctly, they need a way to indicate on each claim they submit, which claims are for active/corrective therapy and which are for maintenance therapy. A modifier ("AT") already exists for acute treatment.

B. Policy: For Medicare purposes, the AT modifier shall now be used only when chiropractors bill for active/corrective treatment. This CR requires:

1) Every chiropractic claim (those containing HCPCS code 98940, 98941, 98942) with a date of service on or after October 1, 2004, to include the Acute Treatment (AT) modifier if active/corrective treatment is being performed; or

2) No modifier if maintenance therapy is being performed. Contractors shall deny a chiropractic claim (containing HCPCS code 98940, 98941, 98942) with a date of service on or after October 1, 2004, that does not contain the AT modifier.

Every claim for chiropractic active/corrective treatment with or without the AT modifier (depending on whether the chiropractor believes they have rendered active treatment or maintenance therapy, respectively) will continue to be autodenied if the services exceed the frequency limits of reasonable and necessary services specified in the LCD. If contractors' LCDs do not specify frequencies that define the limit of reasonable and necessary care, contractors may deny if appropriate after medical review. For those services that exceed the frequency limits established within the LCD, chiropractors may wish to obtain an Advance Beneficiary Notice (ABN) from the beneficiary and also apply the GA or GZ modifier as appropriate.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Carriers and Program Safeguard Contractors (PSCs) who do medical review shall post this article, or a direct link to this article,

on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. In addition, contractors are encouraged, within available resources, to educate Chiropractors through seminars, conferences, etc. as they deem appropriate.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3449.1	Effective for dates of service October 1, 2004 and later, carriers shall deny any chiropractic claim that lacks an AT modifier.			X						
3449.2	Effective for dates of service October 1, 2004 and later, carriers shall autodeny claims with an AT modifier, by instituting a frequency edit if the claims exceed the frequency limits of reasonable and necessary services specified in an LCD.			X						
3449.3	Effective immediately, each contractor shall educate chiropractors in their jurisdiction that beginning October 1, 2004, every claim for chiropractic active/corrective treatment must have the AT modifier and claims for maintenance therapy must be billed without the AT modifier.			X						PSCs doing medical review

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3449.4	Effective immediately, each contractor shall educate chiropractors in their jurisdiction that beginning October 1, 2004, every claim for chiropractic active/corrective treatment with or without the AT modifier (depending on whether the chiropractor believes they have rendered active treatment or maintenance therapy, respectively) will continue to be autodenied if the services exceed the frequency limits of reasonable and necessary services specified in an LCD. If contractors' LCDs do not specify frequencies that define the limit of reasonable and necessary care, contractors may deny if appropriate after medical review. Also, for those services that exceed the frequency limits established within the LCD, chiropractors may wish to obtain an Advance Beneficiary Notice (ABN) from the beneficiary and also apply the GA or GZ modifier as appropriate.			X						PSCs doing medical review

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: None

X-Ref Requirement #	Instructions

B. Design Considerations: None

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: None

D. Contractor Financial Reporting /Workload Impact: None

E. Dependencies: None

F. Testing Considerations: None

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: October 1, 2004 **Implementation Date: October 4, 2004** **Pre-Implementation Contact(s):** For medical review issues contact Dan Schwartz (dschwartz2@cms.hhs.gov), for CERT issues, Melanie Combs (mcombs@cms.hhs.gov, for policy issues, Terri Harris (tharris1@cms.hhs.gov). **Post-Implementation Contact(s):** Regional Office	**Medicare contractors shall implement these instructions within their current operating budgets.**

***Unless otherwise specified, the effective date is the date of service.**

30.5 - Chiropractor's Services

(Rev. 18, Issued 09-03-04, Effective: 10-01-04, Implementation: 10-04-04)

A chiropractor must be licensed or legally authorized to furnish chiropractic services by the State or jurisdiction in which the services are furnished. In addition, a licensed chiropractor must meet the following uniform minimum standards to be considered a physician for Medicare coverage. Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation provided such treatment is legal in the State where performed. All other services furnished or ordered by chiropractors are not covered.

If a chiropractor orders, takes, or interprets an x-ray or other diagnostic procedure to demonstrate a subluxation of the spine, the x-ray can be used for documentation. However, there is no coverage or payment for these services or for any other diagnostic or therapeutic service ordered or furnished by the chiropractor. For detailed information on using x-rays to determine subluxation, see §240.1.2.

In addition, in performing manual manipulation of the spine, some chiropractors use manual devices that are hand-held with the thrust of the force of the device being controlled manually. While such manual manipulation may be covered, there is no separate payment permitted for use of this device.

A - Uniform Minimum Standards

Prior to July 1, 1974

Chiropractors licensed or authorized to practice prior to July 1, 1974, and those individuals who commenced their studies in a chiropractic college before that date must meet all of the following three minimum standards to render payable services under the program:

- Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

- Graduation from a college of chiropractic approved by the State's chiropractic examiners that included the completion of a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance covering adequate course of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing, and adjusting; and

- Passage of an examination prescribed by the State's chiropractic examiners covering the subjects listed above.

After June 30, 1974

Individuals commencing their studies in a chiropractic college after June 30, 1974, must meet all of the above three standards and all of the following additional requirements:

- Satisfactory completion of 2 years of pre-chiropractic study at the college level;

- Satisfactory completion of a 4-year course of 8 months each year (instead of a 3-year course of 6 months each year) at a college or school of chiropractic that includes not less than 4,000 hours in the scientific and chiropractic courses specified in the second bullet under "**Prior to July 1, 1974**" above, plus courses in the use and effect of x-ray and chiropractic analysis; and

- The practitioner must be over 21 years of age.

B - Maintenance Therapy

Under the Medicare program, chiropractic maintenance therapy is not *considered to be medically reasonable or necessary, and is therefore not payable.* Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. *When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. For information on how to indicate on a claim a treatment is or is not maintenance, see §240.1.3.*

240.1.3 - Necessity for Treatment

(Rev. 18, Issued 09-03-04, Effective: 10-01-04, Implementation: 10-04-04)

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam, as described above.

Most spinal joint problems fall into the following categories:

- Acute subluxation-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical exam as specified above. The result of chiropractic manipulation is expected to be an improvement in, *or arrest of progression,* of the patient's condition.

- Chronic subluxation-A patient's condition is considered chronic when it is not expected to *significantly improve or be resolved with further treatment* (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, *without expectation of additional objective clinical improvements,* further manipulative treatment is considered maintenance therapy and is not covered.

*For Medicare purposes, a chiropractor **must** place an AT modifier on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However the presence of the AT modifier may not in all instances indicate that the service is reasonable and necessary. Carriers may develop local coverage determinations (LCDs) that indicate an appropriate frequency of service for a given clinical indication. Contractors that have LCDs with frequency limits that define the limits of reasonable and necessary care shall instruct chiropractors that they may submit claims for services that exceed the frequency limits established within the LCD with or without the AT modifier depending on whether the chiropractor believes they have rendered active treatment or maintenance therapy, respectively. Claims with an AT modifier will continue to be autodenied if the services exceed the frequency limits of reasonable and necessary services specified in the LCD. If contractors' LCDs do not specify frequencies that define the limit of reasonable and necessary care, contractors may deny if appropriate after medical review.*

For those services that exceed the frequency limits established within the LCD chiropractors may wish to obtain an Advance Beneficiary Notice (ABN) from the beneficiary and also apply the GA or GZ modifier as appropriate.

A - Maintenance Therapy

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, *or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied. Chiropractors who give or receive from beneficiaries an ABN shall follow the instructions in Pub. 100-04, Medicare Claims Processing Manual, chapter 23, section 20.9.1.1 and include a GA (or in rare instances a GZ) modifier on the claim.*

B – Contraindications

Dynamic thrust is the therapeutic force or maneuver delivered by the physician during manipulation in the anatomic region of involvement. A relative contraindication is a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. The following are **relative contraindications** to dynamic thrust:

- Articular hypermobility and circumstances where the stability of the joint is uncertain;
- Severe demineralization of bone;
- Benign bone tumors (spine);
- Bleeding disorders and anticoagulant therapy; and
- Radiculopathy with progressive neurological signs.

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

- Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis;
- Acute fractures and dislocations or healed fractures and dislocations with signs of instability;
- An unstable os odontoideum;
- Malignancies that involve the vertebral column;
- Infection of bones or joints of the vertebral column;
- Signs and symptoms of myelopathy or cauda equina syndrome;
- For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and
- A significant major artery aneurysm near the proposed manipulation.

240.1.5 - Treatment Parameters

(Rev. 18, Issued 09-03-04, Effective: 10-01-04, Implementation: 10-04-04)

The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time. Acute subluxation (e.g., strains or sprains) problems may require as many as 3 months of treatment but some require very little treatment. In the first several days, treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.

Chronic spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already "set" and fibrotic tissue has developed. This condition may require a longer treatment time, but not with higher frequency.

Some chiropractors have been identified as using an "intensive care" concept of treatment. Under this approach multiple daily visits (as many as four or five in a single day) are given in the office or clinic and so-called room or ward fees are charged since the patient is confined to bed usually for the day. The room or ward fees are not covered and reimbursement under Medicare will be limited to not more than one treatment per day.

- Evidence of supervisory review of the work.

1. Proper heading should be given to the basic content of the working papers.

30 - Certification Package for Internal Controls (CPIC)
(Rev. 7, 08-30-02)

30.1 – CPIC Requirements
(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

The Medicare contractor self-certification process provides CMS with assurance that contractors are in compliance with the FMFIA, OMB Circular A-123, and CFO Act of 1990 by incorporating internal control standards into their operations. The Medicare contractor self-certification process supports the audit of CMS' financial statements by the Office of Inspector General (OIG) and the CMS Administrator's FMFIA assurance statement.

This compliance is achieved by *an annual* self-certification statement and has been known as a CPIC. Through these self-certification statements, CMS has required each Medicare contractor to provide assurances that internal controls are in place and to identify and correct any areas of weakness in its operations. Medicare contractors are expected to evaluate the effectiveness of their operations against CMS' control objectives discussed above. The control objectives represent the minimum expectations for contractor performance in the area of internal controls.

Medicare contractors shall have written policies and procedures regarding their overall CPIC process and the preparation of the annual CPIC submission. They shall also have written policies and procedures that discuss the handling of potential internal control deficiencies identified by employees and managers in the course of their daily operations. This should include the process for reporting issues upward through the appropriate levels of management, tracking them to completion of any necessary corrective actions, and considering them for inclusion in the CPIC submission.

The CPIC represents a summary of your internal control environment for the period *October 1* through *June 30* (the CPIC period), as certified by your organization. It shall include an explicit conclusion as to whether the internal controls over financial reporting are effective (see section 30.1.1). All material weaknesses that were identified during this period shall be included in the CPIC submission. You should consider the results of final reports issued from internal and external audits and reviews, such as GAO and OIG audits as well as CFO Act audits, consultant reviews, management control reviews, CPE reviews, SAS 70 audits, and other similar activities. These findings should be *classified* as *control deficiencies*, reportable conditions, *significant deficiencies, or material weaknesses* based upon the definitions provided in section 30.6. Medicare contractors shall submit an update for the period July 1 through *September 30* to report subsequently identified material weaknesses. The update shall be no more than a one page summary of

the material weakness*(es)* and the proposed corrective action. A CAP shall be completed in accordance to the guidelines shown at section 40.1. If no additional material weaknesses have been identified, submit the following: "No material weaknesses have been identified during the period July 1 through September 30; therefore no additional material weaknesses have been reported". Send the update report from the VP or CFO email box to internalcontrols@cms.hhs.gov *within five business days after September 30*.

Electronic CPIC reports *shall* be received by CMS *within fifteen business days after June 30*. The Medicare contractor is not required to submit a hard copy report if it has the capability to insert electronic signatures. Where applicable, the CPIC hard copy report *shall* be post marked *within fifteen business days after June 30.*

The CPIC shall include:

- A Certification Statement (including an assurance statement on the effectiveness of internal controls over financial reporting as of June 30);
- An Executive Summary;
- A description of your risk assessment process. This should include a matrix to illustrate the prioritization of risk and exposure factors and a narrative or flowchart that outlines the risk assessment process (see section 20.1 for more details regarding the risk assessment), and
- A CPIC Report of Material Weaknesses.

NOTE: A hardcopy of the CPIC package is not required, if the Medicare contractor has electronic signature capability. If electronic signature capability is not available, please send the hardcopies to:

Chief Financial Officer
Office of Financial Management
Attn: Accounting Management Group, N3-11-17
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

An electronic version of all documents (*including updates*) submitted as part of your CPIC submission shall be sent to CMS at internalcontrols@cms.hhs.gov as Microsoft Excel or Word files. Electronic copies shall also be sent to your Associate Regional Administrator for Financial Management *and Fee for Service Operations*, CFO/SAS 70 Coordinator, Consortium Contractor Management Officer (CCMO) and/or the Project Officer of the Medicare Administrative Contractor (MAC). The file names for all electronic files submitted, as part of your CPIC package should begin with the three or four letter abbreviation assigned to each Medicare contractor in section 40.3.

Additionally, in the subject line of your email submission, you shall include the corporate name of the entity submitting the CPIC.

Maintain the appropriate and necessary documents to support any assertions and conclusions made during the self-assessment process. In your working papers, you are required to document the respective policies and procedures for each control objective reviewed. These policies and procedures should be in writing, be updated to reflect any changes in operations, and be operating effectively and efficiently within your organization.

The supporting documentation and rationale for your certification statement, whether prepared internally or by an external organization, shall be available for review and copying by CMS and its authorized representatives.

30.1.1 - OMB Circular A-123 and Internal Control Over Financial Reporting

(Rev. 132, Issued: 10-05-07, Effective: 10-01-07, Implementation: 11-05-07)

Medicare contractors shall use the five steps below to assess the effectiveness of its internal control over financial reporting. Documentation shall occur within each of the basic steps, whether documenting the assessment methodology during the planning phase or documenting key processes and test results during the evaluation and testing steps.

1) Plan and Scope the Evaluation

During this phase, the Medicare contractor shall leverage existing internal and external audits/reviews being performed (SAS 70, CPIC, 912 Evaluations, Federal Information Security Management (FISMA), Contractor Performance Evaluations (CPE), etc.) when conducting its assessment of internal control over financial reporting. Management shall consider the results of these audits/reviews in order to identify gaps between current control activities and the documentation of them. The control objectives of A, F, G, I, J, K, and L shall be considered if applicable.

If a Medicare contractor has a SAS 70 audit in the current or past two fiscal years, it shall be used as a basis for the statement of assurance combined with other audits and reviews as appropriate. The Medicare contractor shall conduct additional testing for Circular A-123 as deemed necessary. For example, if the SAS 70 audit report was unqualified (no findings in Section I (Opinion Letter)), then the Medicare contractor is not required to conduct additional testing. If Section I of the prior year's SAS 70 audit report is qualified (one or more findings that have not been corrected and validated), then the Medicare contractor shall conduct additional testing on the findings identified in Section I and the exceptions identified in Section III. (See SAS 70 Reliance Examples chart). If other audits and reviews contradict the SAS 70 audit, then that contradiction shall be addressed via testing if the issue has not already been corrected and validated.

2) Document Controls and Evaluate Design of Controls

This step begins with the documentation and evaluation of entity-level controls. Consideration must be given to the five standards of internal control (control environment, risk assessment, control activities, information and communication, and monitoring) (see section 10.2.3 – Standards for Internal Control) that can have a pervasive effect on the risk of error or fraud, and will aid in determining the nature and extent of internal control testing that may be required at the transaction or process level. The GAO issued an internal control evaluation tool (www.gao.gov/new.items/d011008g.pdf) to assess the effectiveness of internal control and identify important aspects of control in need of improvement. This tool shall be used in conducting your assessment.

At the process level, documentation shall be prepared in the form of a cycle memo*(s)* that demonstrates an understanding, from beginning to end, of the underlying processes and document flows involved in each major transaction cycle. Identify the key control activities that are relied upon to assure the relevant financial statement assertions are met. For each key control activity, state: (a) the frequency of performance; (b) the specific steps performed; (c) how exceptions are resolved; and (d) how the performance of the control activity and related results/disposition are documented. For ineffective or partially effective key control activities, *indicate the following in the documentation:* (a) the identified vulnerability caused by the ineffective process, including a specific statement of risk and impact; (b) any existing mitigating/compensating controls that address the identified vulnerability; and (c) a corrective action plan to address the problem if not done so by the mitigating/compensating controls.

Key financial reporting cycle memos would include financial reporting, accounts receivable, accounts payable, and claims expense. Documentation of the controls will provide the foundation for subsequent work and will facilitate the review and evaluation of key controls. *Note: Medicare contractors may combine related cycles (e.g., accounts payable and claims expense).*

3) Test Operating Effectiveness

Testing of the operation of key controls shall be performed and documented *(refer to "Plan and Scope the Evaluation" (see above) as to testing applicability),* to determine whether the control is operating effectively, partially effectively, or not effectively. Testing shall address both manual and *automated* controls. Ideally, testing should be performed throughout the year. The results of testing completed prior to June 30th will form the basis of the June 30th assurance statement. As testing continues into the fourth quarter, the results of that testing, along with any items corrected since the June 30th assurance statement will be considered in the September 30th assurance statement update.

4) Identify and Correct Deficiencies

If design or operating deficiencies are noted, the potential impact of control gaps or deficiencies on financial reporting shall be discussed with management. The magnitude

or significance of the deficiency will determine if it should be categorized as a control deficiency, *a significant deficiency,* or a material weakness *(see section 30.6).*

Corrective action plans (CAPs) shall be created and implemented to remediate identified deficiencies (see section 40).

5) Report on Internal Controls

The culmination of the Medicare contractor's assessment will be the assurance statement regarding its internal control over financial reporting. The statement will be one of three types:

1) Unqualified Statement of Assurance

Each Medicare contractor shall submit, as part of the CPIC report, an assurance statement for internal controls over financial reporting stating:

> "… (Medicare contractor) has effective internal controls over financial reporting in compliance with OMB Circular A-123."

Note: For example, if the SAS 70 audit (augmented by internal reviews, if necessary) did not result in any findings or material weaknesses, then an unqualified statement of assurance would be applicable.

2) Qualified Statement of Assurance

Each Medicare contractor shall submit, as part of the CPIC report, an assurance statement for internal controls over financial reporting stating:

> "…(Medicare contractor) has effective internal controls over financial reporting in compliance with OMB Circular A-123, except for the material weakness(es) identified in the attached Report of Material Weaknesses."

Note: For example, if a SAS 70 audit and internal reviews in the current year disclosed either findings or a material weakness, then a qualified statement of assurance (see above) or a statement of no assurance (see below) would be issued, depending on the pervasiveness of the findings or material weakness. The results of work performed in other control-related activities may also be used to support your assertion as to the effectiveness of internal controls.

3) Statement of No Assurance

Each Medicare contractor shall submit, as part of the CPIC report, an assurance statement for internal controls over financial reporting stating:

"…(Medicare contractor) is unable to provide assurance that its internal control over financial reporting was operating effectively due to the material weakness(es) identified in the attached Report of Material Weaknesses."

or

"…(Medicare contractor) did not fully implement the requirements included in OMB Circular A-123 and therefore cannot provide assurance that its internal control over financial reporting was operating effectively."

This chart is provided to assist Medicare contractors in determining when to conduct testing.

SAS 70 Reliance Examples

Scenario	Prior Fiscal Year 2	Prior Fiscal Year 1	Current Fiscal Year	Additional Testing Required or Not Required*
1	No SAS 70	No SAS 70	Unqualified	Not Required
2	No SAS 70	Unqualified	No SAS 70	Not Required
3	Unqualified	No SAS 70	No SAS 70	Not Required
4	Qualified	Unqualified	No SAS 70	Not Required
5	No SAS 70	No SAS 70	Qualified	Not Required
6	No SAS 70	Qualified	No SAS 70 and the Findings are Corrected and Validated by CMS (CAP Closure Letter Received)	Not Required
7	Unqualified	Qualified	No SAS 70 and the Findings are Corrected and Validated by CMS (CAP Closure Letter Received)	Not Required
8	Qualified	No SAS 70 and the Findings are Corrected and Validated by CMS (CAP Closure Letter Received)	No SAS 70	Not Required
9	Unqualified	Qualified	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	Required
10	No SAS 70	Qualified	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	Required
11	Qualified	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	No SAS 70 and the Findings are NOT Corrected or Validated by CMS (No CAP Closure Letter)	Required

SAS 70 Unqualified Report - No Findings in Section I

SAS 70 Qualified Report - 1 or More Findings in Section I

*Note: Assumes other subsequent audits and reviews do not contradict the SAS 70 or contradictions have been corrected and validated.

Medicare
Program Integrity Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 12 **Date: SEPTEMBER 20, 2001**

CHANGE REQUEST 1143

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
12		1 2	

MANUALIZATION-EFFECTIVE DATE: Not Applicable

Chapter 12, FI, Carrier, DMERC and RHHI Interaction and Coordination with Program Safeguard Contractors (PSCs). This is a new chapter in the Program Integrity Manual.

Chapter 12, Section 1, Introduction: This Section provides background information regarding the workflow interaction between the PSCs and FIs, Carriers, DMERCs and RHHIs.

Chapter 12, Section 2, Program Safeguard Contractors for Corporate Integrity Agreements (PSC-CIA). This Section manualizes Transmittal AB-01-08, dated January 25, 2001, Change Request 1143.

These instructions should be implemented within your current operating budget.

NOTE: Red italicized font identifies new material.

Medicare Program Integrity Manual

Chapter 12 – FI, Carrier, DMERC and RHHI Interaction and Coordination with Program Safeguard Contractors (PSCs)

Table of Contents
(Rev. 12, 09-20-01)

1 – Introduction (Rev. 12, 09-20-01)

In the spring of 1999, HCFA (now CMS) began awarding Indefinite Delivery, Indefinite Quantity (IDIQ) contracts to Program Safeguard Contractors (PSCs) to perform program integrity and data analysis activities as defined in specific task orders. A PSC can perform one, some, all or any sub-set of the work associated with the following payment safeguard functions: medical review, cost report audit, data analysis, provider education, and fraud detection and prevention. Under the "umbrella" PSC contract, Request for Proposals (RFPs) for selected task orders are competed amongst the PSCs and awarded to one or more depending on the scope of each task order.

The purpose of this chapter is to inform you of the workflow process you are to follow for the PSC interaction and coordination with carriers, FIs, DMERCs, and RHHIs. We want to ensure timely and efficient coordination with the PSC to maximize the successful outcome of this program integrity initiative.

2 - Program Safeguard Contractors for Corporate Integrity Agreements (PSC-CIA) (Rev. 12, 09-20-01)

The PSC-CIA task order was awarded in November 1999 to Tri-Centurion, L.L.C. The PSC-CIA may perform on-site reviews of selected providers that are subject to CIAs to verify compliance efforts and confirm that the terms and conditions of the CIAs are being met. The PSC-CIA must also review a statistically valid random sample (SVRS) of claims submitted to Medicare by the providers and determine patterns or significant occurrences where claims are filed in contravention of applicable Medicare laws, regulations or policies.

Each year a selected number of CIAs are scheduled for review. The CIAs apply to providers serviced by various contractors. You may or may not be contacted, but if you are you may possibly be contacted more than once. To date, entities have entered into a CIA with the U.S. Department of Health and Human Services, Office of the Inspector General (OIG). CIAs are case-specific. Their terms are tailored to address the deficiencies that have been identified by the OIG with respect to providing and billing for health care services.

If a provider within your jurisdiction is on the list of CIAs to be reviewed, the regional office (RO) will ask that you identify a contact person at your site to coordinate any activities required by the PSC-CIA relating to the CIA compliance and billing reviews. Provide the name of the contact person to your RO benefit integrity representative. Depending upon the nature of the CIA, the PSC may need documents or other information on the following issues: reimbursement, medical review, benefit integrity, educational correspondence, coverage guidelines, provider files, and local medical review policies. No systems changes or special reports are required, only information fiscal intermediaries and carriers would have in the normal course of business. It is important for you to coordinate contacts with appropriate program integrity and program management staff.

You are responsible for coordinating appropriate follow-up actions that result from the compliance and billing reviews, such as provider overpayment or underpayment assessment and adjustment.

The Government Task Leader (GTL) or the Co-GTL will initially contact the appropriate RO to discuss the CIA workflow requirements. This will permit the RO to be aware of the coordination that will take place. The GTL or Co-GTL will then make the initial contact with your contact person regarding the PSC-CIA workflow process, necessary time lines and inform you when the PSC will contact you. The PSC will contact you and inform you of exactly what information it needs. You are to provide the information within fifteen (15) working days. If there is a problem supplying the information or a delay in giving the information, immediately contact the GTL or Co-GTL. Due to the confidential nature of the CIA, do not disclose any information about the CIA or your communication with the PSC-CIA at any time.

If there are any question or concerns, contact the GTL, John Martino at (215)-861-4177, E mail jmartino@cms.gov or the co-GTL, Maureen Savory at (410)-786-3077, E-mail msavory@cms.gov.

4.2.2 - Program Safeguard Contractor Benefit Integrity Unit

(Rev. 213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

The PSC BI unit is responsible for preventing, detecting, and deterring Medicare fraud. The PSC BI unit:

- Prevents fraud by identifying program vulnerabilities.

- Proactively identifies incidents of potential fraud that exist within its service area and takes appropriate action on each case.

- Investigates (determines the factual basis of) allegations of fraud made by beneficiaries, providers, CMS, OIG, and other sources.

- Explores all available sources of fraud leads in its jurisdiction, including the MFCU and its corporate anti-fraud unit.

- Initiates appropriate administrative actions to deny or to suspend payments that should not be made to providers where there is reliable evidence of fraud.

- Refers cases to the Office of the Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions (see PIM, chapter 4, §§4.18ff, 4.19ff, and 4.20ff).

- Refer any necessary provider and beneficiary outreach to the POE staff at the AC or MAC.

Initiates and maintains networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups.

The PSC BI units are required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent billing practices.

The PSC BI units shall pursue leads through data analysis (PSCs shall follow chapter 2, §2.3 for sources of data), the Internet, the Fraud Investigation Database (FID), news media, etc. Proactive (self-initiated) leads may be generated and/or identified by any internal PSC, AC, or MAC component, not just the PSC BI units (e.g., claims processing, data analysis, audit and reimbursement, appeals, medical review, enrollment). *For workload reporting purposes the PSC shall only identify as proactive, those investigations and cases that the PSC self-initiated and any proactive leads the PSC pursues that were received from the AC or MAC that did not originate from a complaint.*

The PSC BI units shall take prompt action after scrutinizing billing practices, patterns, or trends that may indicate fraudulent billing, i.e., reviewing data for inexplicable aberrancies (other than the expected) and relating the aberrancies to specific providers, identifying “hit and run” providers, etc. PSC BI units shall meet periodically with staff

from their respective internal components and PSCs shall also meet with AC and MAC staff to discuss any problems identified that may be a sign of potential fraud.

Fraud leads from any external source (e.g., law enforcement, CMS referrals, beneficiary complaints) are considered to be reactive and not proactive. However, taking ideas from external sources, such as non-restricted fraud alerts and using them to look for unidentified aberrancies within PSC data is proactive.

4.2.2.1 - Organizational Requirements

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

Full PSCs are not required to separate their MR and BI units. However, all BI information shall be kept confidential and secure and shared with MR only on a need-to-know basis.

The PSC BI unit managers shall have sufficient authority to guide BI activities. The managers shall be able to establish, control, evaluate, and revise fraud-detection procedures to ensure their compliance with Medicare requirements.

The PSC BI unit manager shall prioritize work coming into the PSC BI unit to ensure that investigations and cases with the greatest program impact/and or urgency are given the highest priority. Allegations or cases having the greatest program impact would include cases involving:

- Patient abuse or harm.
- Multi-state fraud.
- High dollar amounts of potential overpayment.
- Likelihood for an increase in the amount of fraud or enlargement of a pattern.

- The PSCs, ACs, and MACs shall give high priority to fraud complaints made by Medicare supplemental insurers. If a referral by a Medigap insurer includes investigatory findings indicating fraud stemming from site reviews, beneficiary interviews and/or medical record reviews, PSC BI units shall 1) conduct an immediate data run to determine possible Medicare losses, and 2) refer the case to the OIG.

- Law enforcement requests for assistance that involve responding to court-imposed deadlines.

- Law enforcement requests for assistance in ongoing investigations that involve national interagency (DHHS -DOJ) initiatives or projects.

4.2.2.2 - Liability of Program Safeguard Contractor Benefit Integrity Unit Employees

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

Under the terms of their contracts and proposed rule 42 CFR § 421.316(a), PSCs, their employees and professional consultants are protected from criminal or civil liability as a result of the activities they perform under their contracts as long as they use due care. If a PSC, or any of its employees or consultants are named as defendants in a lawsuit, CMS will determine, on a case-by-case basis, whether to request that the U.S. Attorney's office offer legal representation. If the U.S. Attorney's office does not provide legal representation, the PSC will be reimbursed for the reasonable cost of legal expenses it incurs in connection with defense of the lawsuit as long as funds are available and the expenses are otherwise allowable under the terms of the contract.

If a PSC is served with a complaint, it shall immediately contact its chief legal counsel and GTL. The PSC shall forward the complaint to the Department of Health and Human Services Office of the regional chief counsel (CMS regional attorney) who, in turn, will notify the U.S. Attorney. The HHS office and/or the GTL will notify the PSC whether legal representation will be sought from the U.S. Attorney prior to the deadline for filing an answer to the complaint.

4.2.2.3 – Anti-Fraud Training

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

All levels of PSC employees shall know the goals and techniques of fraud detection and control in general and as they relate to their own areas of responsibility (i.e., general orientation for new employees and highly technical sessions for BI unit staff and if applicable, medical review staff). All PSC BI unit staff shall be adequately qualified for the work of detecting and investigating situations of potential fraud.

CMS National Benefit Integrity Training

Each PSC BI unit shall send the appropriate representative(s) to CMS' national benefit integrity training each year it is provided.

4.2.2.3.1 - Training for Law Enforcement Organizations

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

The FBI agents and DOJ attorneys need to understand Medicare. PSC BI units shall conduct special training programs for them upon request. PSCs should also consider inviting appropriate DOJ, OIG, and FBI personnel to existing programs intended to orient employees to PSC operations, or to get briefings on specific cases or Medicare issues.

4.2.2.4 - Procedural Requirements

(Rev. 213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

Contractors shall provide written procedures for personnel in various contractor components (claims processing, MR, beneficiary services, POE, intermediary audit, etc.) to help identify potential fraud situations. Include provisions to ensure that personnel shall:

- Refer potential fraud cases promptly to the PSC BI unit.

- Forward complaints alleging fraud through the second-level screening staff to the PSC BI unit.

- Maintain confidentiality of referrals to the PSC.

- Forward to the PSC BI unit documentation of the details of telephone or personal contacts involving fraud issues discussed with providers or provider staff, and retain such information in individual provider files.

In addition, PSC BI units shall ensure the performance of the functions below and have written procedures for these functions:

- Keep educational/warning correspondence with providers and other fraud documentation concerning specific issues in individual provider files (refer to §4.2.2.4.2 for retention of this documentation), so that PSCs are able to retrieve such documentation easily.

- Maintain communication and information flowing between the PSC BI unit, and the DME PSC, AC, or MAC MR staff, and as appropriate, intermediary or MAC audit staffs.

- Communicate with the DME PSC, AC or MAC medical review staff on all findings of overutilization and coordinate with the AC or MAC provider outreach and education (POE) staff to determine what, if any, education has been provided before any BI investigation is pursued.

- Obtain and share information on health care fraud issues/fraud investigations among carriers, DME MACs, DMERCs fiscal intermediaries (including rural home health intermediaries (RHHIs)), A/B MACs, PSCs, CMS, and law enforcement.

- Serve as a reference point for law enforcement and other organizations and agencies to contact when they need help or information on Medicare fraud issues and do not know whom to contact.

- Coordinate and attend fraud-related meetings/conferences and inform all appropriate parties about these meetings/conferences. These meetings/conferences include, but are not limited to, health care task force meetings and conference calls.

- Distribute fraud alerts to the appropriate parties. Share PSC BI unit findings on fraud alerts with PSCs within the appropriate jurisdiction and CMS.

- Work with the Primary GTL, Associate GTL, and SME to develop and organize external programs and perform training as appropriate for law enforcement, ombudsmen, grantees (e.g., Harkin Grantees or Senior Medicare Patrol) and other CMS health care partners (e.g., AoA, State MFCU).

- Serve as a resource to CMS as necessary. For example, serve as a resource to CMS on the FID, including FID training.

- Help to develop fraud-related outreach materials (e.g., pamphlets, brochures, videos) in cooperation with beneficiary services and/or provider relations departments of the ACs and MACs, for use in their training. Submit written outreach material to the Primary GTL, Associate GTL, and SME for clearance.

- Assist in preparation and development of fraud-related articles for AC and MAC newsletters/bulletins. The PSC BI unit shall send CMS CO a copy of these newsletters/bulletins to the following address:

  Centers for Medicare & Medicaid Services (CMS)
  Re: Newsletter/Bulletin Articles
  Division of Benefit Integrity Management Operations
  Mail Stop C3-02-16
  7500 Security Boulevard
  Baltimore, Maryland 21244

- Provide resources and training for the development of internal and new hire fraud training.

- Take appropriate administrative action on cases not accepted by OIG or other investigative agencies. At a minimum, provide information for recovery of identified overpayments and other corrective actions discussed in PIM, chapter 3, §§8ff and 9ff.

- Subject to the requirements in PIM, chapter 4, §4.4.1, provide support to law enforcement agencies for investigation of potential fraud and abuse, including investigations for which an initial referral to law enforcement did not originate from the PSC BI unit.

- Properly prepare and document cases referred to OIG/OI; two copies of a summary report of investigation shall be included with each fraud referral made to the OIG. The referral format listed in PIM Exhibits 16.1 and 16.2 shall be followed, unless written guidance is provided by the applicable OIG/OI office and approved by the Primary GTL, Associate GTL, and SME. PSC BI units shall maintain files on the written guidance provided by the OIG/OI.

- Meet (in-person or telephone call) quarterly, or more frequently if necessary, with OIG agents to discuss pending or potential cases.

- Meet (in-person or telephone) *when needed* with DOJ to enhance coordination with them on current or pending cases.

- Furnish all available information upon request to OIG/OI with respect to excluded providers requesting reinStatement.

- Report to the Primary GTL, Associate GTL, and SME all cases that have been identified where a provider consistently fails to comply with the provisions of the assignment agreement.

- Maintain documentation on the number of investigations alleging fraud, the number of cases referred to OIG/OI (and the disposition of those cases), processing time of investigations, and types of violations referred to OIG (e.g., item or service not received, unbundling, waiver of co-payment).

- Conduct investigations (including procedures for reviewing questionable billing codes) and make beneficiary contacts (see PIM, chapter 4, §4.7.1 for details concerning investigations).

- Coordinate and communicate with the MR unit within your organization if a DME PSC, and coordinate and communicate with the MR units in the ACs and MACs if an A/B PSC to avoid duplication of work.

- Obtain approval from the Primary GTL, Associate GTL, and the OI field office before making an unannounced visit where fraud is suspected, and ensure that any other appropriate investigative agency is consulted with regard to the plan. PSC BI unit staff shall never engage in covert operations (e.g., undercover or surveillance activities). If OIG does not give approval, discuss this with the Primary GTL who will make the final decision.

- Obtain approval by e-mail, letter, or telephone call, and express any concerns (if a telephone call, follow up with a letter or e-mail) to the Primary GTL when the PSC BI unit is asked to accompany the OI or any other law enforcement agency going onsite to a provider for the purpose of gathering evidence in a fraud case (e.g., executing a search warrant). However, law enforcement must make clear the role of PSC BI unit personnel in the proposed onsite visit. The potential harm to the case and the safety of PSC BI unit personnel shall be thoroughly evaluated. PSC BI unit personnel shall properly identify themselves as PSC BI unit employees, and under no circumstances shall they represent themselves as law enforcement personnel or special agents. Lastly, under no circumstances shall PSC BI unit personnel accompany law enforcement in situations where their personal safety is in question.

The ACs and MACs ensure the performance of the functions below and have written procedures for these functions:

- Ensure no payments are made for items or services ordered, referred, or furnished by an individual or entity following the effective date of exclusion (see PIM, chapter 4, §4.19ff for exceptions).

- Ensure all instances where an excluded individual or entity that submits claims for which payment may not be made after the effective date of the exclusion are reported to the OIG (see PIM, chapter 4, §4.19ff).

Ensure no payments are made for an excluded individual or entity who is employed by a Medicare provider or supplier.

4.2.2.4.1 - Maintain Controlled Filing System and Documentation

(Rev. 176, Issued: 11-24-06, Effective: 12-26-06, Implementation: 12-26-06)

The PSC BI units shall maintain files on providers who have been the subject of complaints, prepayment flagging, PSC BI unit investigations, OIG/OI and/or DOJ investigations, U.S. Attorney prosecution, and any other civil, criminal, or administrative action for violations of the Medicare or Medicaid programs. The files shall contain documented warnings and educational contacts, the results of previous investigations, and copies of complaints resulting in investigations.

The PSC BI units shall set up a system for assigning and controlling numbers at the initiation of investigations, and shall ensure that:

- All incoming correspondence or other documentation associated with an investigation contains the same file number and is placed in a folder containing the original investigation material.

- Investigation files are adequately documented to provide an accurate and complete picture of the investigative effort.

- All contacts are clearly and appropriately documented.

- Each file contains the initial prioritization assigned and all updates.

- Each investigation file lists the name, organization, address, and telephone numbers of all persons with whom the PSC BI unit can discuss the investigation (including those working within the PSC).

It is important to establish and maintain histories and documentation on all fraud and abuse investigations and cases. PSC BI units shall conduct periodic reviews of the kinds of fraud detected over the past several months to identify any patterns of potential fraud

and abuse situations for particular providers. The PSC BI units shall ensure that all evidentiary documents are kept free of annotations, underlining, bracketing, or other emphasizing pencil, pen, or similar marks.

The PSC BI units shall establish an internal monitoring and investigation and case review system to ensure the adequacy and timeliness of fraud and abuse activities.

4.2.2.4.2- File/Document Retention
(Rev. 71, 04-09-04)

Files/documents shall be retained for 10 years. However, files/documents shall be retained indefinitely and shall not be destroyed if they relate to a current investigation or litigation/negotiation; ongoing Workers' Compensation set aside arrangements, or documents which prompt suspicions of fraud and abuse of overutilization of services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.

4.2.2.5 – Reserved for Future Use
(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.2.2.5.1 – Reserved for Future Use
(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.2.2.5.2 – Reserved for Future Use
(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.2.2.6 – Benefit Integrity Security Requirements
(Rev. 213, Issued: 06-29-07, Effective: 07-30-07, Implementation: 07-30-07)

To ensure a high level of security for the PSC BI function, the PSCs shall develop, implement, operate, and maintain security policies and procedures that meet and conform to the requirements of the Business Partners Security Manual (BPSSM) and the Core Security Requirements (CSR) and its operational appendices (A, B, C, and D). The BPSSM is located at:

http://www.cms.hhs.gov/manuals/downloads/117_systems_security.pdf and the CSR is at http://www.cms.hhs.gov/it/security. Further, the PSCs shall adequately inform and train all PSC employees to follow PSC security policies and procedures so the information the PSC obtains is confidential.

Note that data PSCs collect in the administration of PSC contracts belong to CMS. Thus, PSCs collect and use individually identifiable information on behalf of the Medicare program to routinely perform the business functions necessary for administration of the Medicare program, such as, medical review and program integrity activities to prevent

fraud and abuse. Consequently, any disclosure of individually identifiable information without prior consent from the individual to whom the information pertains, or without statutory or contract authority, requires CMS' prior approval.

This section discusses broad security requirements that PSCs shall follow. Most requirements listed below are in the BPSSM or CSRs and are included by reference. There are several exceptions. The first is requirement A (concerning PSC BI Unit Operations), which addresses several broad requirements; CMS has included requirement A here for emphasis and clarification. Two others are in requirement B (concerning sensitive information) and requirement G (concerning telephone security). Requirements B and G relate to security issues that are not systems related and are not in the BPSSM.

A. Program Safeguard Contractor Benefit Integrity Unit Operations

- The PSCs shall conduct their activities in areas not accessible to the general public.

- The PSC BI unit shall completely segregate itself from all other operations. Segregation shall include floor to ceiling walls and/or other measures described in CSR 2.2.6 that prevent unauthorized persons access to or inadvertent observation of sensitive and investigative information. The only exception to this requirement is that PSCs may co-locate PSC MR and PSC BI units in the same building and same office space. However, PS BI units shall keep all PSC BI unit information confidential and secure and shall share PSC BI unit information with PSC MR units only on need-to-know basis.

- Other requirements regarding PSC BI unit operations shall include sections 3.1, 3.1.2, 3.10.2, 4.1.1.2, 4.2, 4.2.5, and 4.2.6 of the BPSSM.

B. Handling and Physical Security of Sensitive and Investigative Material

See the BPSSM section 3.8 for definitions of sensitive and investigative material.

In addition, the PSCs shall follow the requirements provided below:

- Establish a policy that employees shall discuss specific allegations of fraud only within the context of their professional duties and only with those who have a valid need-to-know. This may include:

    - Appropriate CMS personnel,

    - Staff from the PSC, AC, or MAC medical review and/or benefit integrity unit staff,

    - PSC, AC, or MAC audit unit staff,

    - PSC, AC, or MAC data analysis staff,

- PSC, AC, or MAC senior management, or

- PSC, AC, or MAC corporate counsel.

- The CSRs require that:

  - The following workstation security requirements are specified and implemented: (1) what workstation functions can be performed, (2) the manner in which those functions are to be performed, (3) and the physical attributes of the surrounding of a specific workstation or class of workstation that can access CMS sensitive information. CMS requires that for PSCs all the local workstations as well as the workstations used at home comply with these requirements.

  - If PSC employees are authorized to work at home on sensitive data, they are required to observe the same security practices that they observe at the office. These should address such items as viruses, VPNs, and protection of sensitive data as printed documents.

  - Users are prohibited from installing desktop modems.

  - The connection of portable computing or portable network devices on the CMS claims processing network is restricted to approved devices only. Removable hard drives and/or a FIPS-approved method of cryptography shall be employed to protect information residing on portable and mobile information systems.

  - For alternate work site equipment controls, (1) only CMS Business Partner owned computers and software are used to process, access, and store sensitive information; (2) a specific room or area that has the appropriate space and facilities is used; (3) means are available to facilitate communication with their managers or other members of the Business Partner Security staff in case of security problems; (4) locking file cabinets or desk drawers; (5) "locking hardware" to secure IT equipment to larger objects such as desks or tables; and (6) smaller Business Partner-owned equipment is locked in a storage cabinet or desk when not in use. If wireless networks are used at alternate work sites, wireless base stations are placed away from outside walls to minimize transmission of data outside of the building.

Alternate work sites are those areas where employees, subcontractors, consultants, auditors, etc. perform work associated duties. The most common alternate work site is an employee's home. However, there may be other alternate work sites such as training centers, specialized work areas, processing centers, etc.

- Ensure the mailroom, general correspondence, and telephone inquiries procedures maintain confidentiality whenever the PSC receives correspondence, telephone calls, or other communication alleging fraud. Further, all internal written operating procedures shall clearly State security procedures.

- Direct mailroom staff not to open PSC BI unit mail in the mailroom, unless the PSC has requested the mailroom do so for safety and health precautions. Alternately, if mailroom staff opens PSC BI unit mail, mailroom staff shall not read the contents.

- For mail processing sites separate from the PSC, the PSCs shall minimize the handling of PSC BI unit mail by multiple parties before delivery to the PSC BI unit.

- The PSCs shall mark mail to CO or another PSC, "personal and confidential," and address it to a specific person.

- Where more specialized instructions do not prohibit PSC BI unit employees, PSC BI employees may retain sensitive and investigative materials at their desks, in office work baskets, and at other points in the office during the course of the normal work day. Regardless of other requirements, the employee shall restrict access to sensitive and investigative materials, and PSC staff shall not leave such material unattended.

- PSC staff shall safeguard all sensitive or investigative material when in transit.

- The PSC BI units shall maintain a controlled filing system (see PIM, chapter 4, §4.2.2.4.1).

C. Designation of a Security Officer

The Security Officer shall take such action as is necessary to correct breaches of the security standards and to prevent recurrence of the breaches. In addition, the Security Officer shall document the action taken and maintain that documentation for at least seven years. Actions shall include:

- Within one hour of discovering a security incident, clearly and accurately report the incident following BPSSM requirements for reporting of security incidents. For purposes of this requirement, a security incident is the same as the definition in section 3.6, Incident Reporting and Response, of the BPSSM.

- Specifically, the report shall address the following where appropriate:

    - Types of information about beneficiaries shall at a minimum address whether the compromised information includes name, address, HICN, and date of birth.

    - Types of information about providers shall at a minimum address if the compromised information includes name, address, and provider ID.

    - Whether law enforcement is investigating any of the providers with compromised information, and

    - Police reports.

Stop Inappropriate Payments for Chiropractic Treatments

Current Law: In 1972, section 273 of the Social Security Amendments (P.L. 92-603) expanded the definition of "physician" under Medicare Part B to include chiropractors. Currently, the only Medicare reimbursable chiropractic treatment is manual manipulation of the spine to correct a subluxation. Effective January 1, 2000, the Balanced Budget Act of 1997 required that subluxations be demonstrated by an x-ray or physical examination. In addition to these specific provisions, sections 1862(a)(1)(A) and 1988(e) of the Social Security Act require that all services billed to Medicare, including chiropractic manipulations, be medically necessary and supported by documentation.

Proposal (✓*Procedural*): CMS should ensure that chiropractic services comply with Medicare coverage criteria and require that its carriers educate chiropractors on Medicare Carriers Manual requirements for supporting documentation.

Reason for Action: Sixty-seven percent of chiropractic services provided to Medicare beneficiaries in 2001 did not meet Medicare coverage criteria and documentation requirements, potentially costing the program and its beneficiaries approximately $285 million. Specifically, we found that the majority of inappropriately paid services were maintenance treatments ($186 million unallowed payments).

Savings (in Millions):

FY 1	FY 2	FY 3	FY 4	FY 5
$285	TBD	TBD	TBD	TBD

Status: CMS agreed with our findings and recommendations. CMS has clarified its chiropractic coverage criteria and indicated that most carriers are taking steps to reduce chiropractic error rates, including targeted educational efforts and service specific medical reviews. In addition, as of October 1, 2004, CMS has required that chiropractors use the AT modifier to indicate that a service is not maintenance; only claims to which the modifier is attached are payable.

Reports:

OEI-06-97-00480 (final report, 9/98)
OEI-04-97-00490 (final report, 11/98)
OEI-09-02-00530 (final report, 5/05)

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Findings

National Medicare FFS Error Rate

The national paid claims error rate in the Medicare FFS program for this reporting period is 3.9% (which equates to $10.8 B). The 95% confidence interval for Medicare FFS program paid claims error rate was 3.7% - 4.1%. The 90% confidence interval (required to be reported by IPIA) was 3.8% - 4.1%.

Table 3a summarizes the overpayments, underpayments, improper payments, and error rates by contractor type.

Table 3a: Error Rates and Projected Improper Payments by Contractor Type

Sort This Table

Type of Contractor	Total Dollars Paid	Overpayments		Underpayments		(Overpayments + Underpayments)	
		Payment	Rate	Payment	Rate	Improper Payments	Error Rates
Carrier	$74.9B	$3.4B	4.5%	$0.2B	0.2%	$3.6B	4.8%
DMERC	$9.9B	$1.0B	10.2%	$0.0B	0.0%	$1.0B	10.3%
FI	$89.4B	$1.2B	1.3%	$0.1B	0.2%	$1.3B	1.5%
QIOs	$102.0B	$4.3B	4.2%	$0.7B	0.7%	$4.9B	4.8%
All Medicare FFS	**$276.2B**	**$9.8B**	**3.6%**	**$1.0B**	**0.4%**	**$10.8B**	**3.9%**

(2)

Table 3b summarizes the overpayments and underpayments, improper payments and error rates by year.

Table 3b: National Error Rates by Year

Year	Total Dollars Paid	Overpayments		Underpayments		Overpayments + Underpayments	
		Payment	Rate	Payment	Rate	Improper Payments	Rate
1996	$168.1 B	$23.5B	14.0%	$0.3 B	0.2%	$23.8 B	14.2%
1997	$177.9 B	$20.6B	11.6%	$0.3 B	0.2%	$20.9 B	11.8%
1998	$177.0 B	$13.8B	7.8%	$1.2 B	0.6%	$14.9 B	8.4%
1999	$168.9 B	$14.0B	8.3%	$0.5 B	0.3%	$14.5 B	8.6%
2000	$174.6 B	$14.1B	8.1%	$2.3 B	1.3%	$16.4 B	9.4%
2001	$191.3 B	$14.4B	7.5%	$2.4 B	1.3%	$16.8 B	8.8%
2002	$212.8 B	$15.2B	7.1%	$1.9 B	0.9%	$17.1 B	8.0%
2003	$199.1 B	$20.5B	10.3%	$0.9 B	0.5%	$12.7 B	6.4%
2004	$213.5 B	$20.8B	9.7%	$0.9 B	0.4%	$21.7 B	10.1%
2005	$234.1 B	$11.2 B	4.8%	$0.9 B	0.4%	$12.1 B	5.2%
2006	$246.8 B	$9.8 B	4.0%	$1.0 B	0.4%	$10.8 B	4.4%
2007	$276.2 B	$9.8 B	3.6%	$1.0 B	0.4%	$10.8 B	3.9%

(3)

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Paid Claims Error Rate by Error Type

Table 3c summarizes the percent of the total dollars improperly allowed by error category for this and previous reports.

Table 3c: Summary of Error Rates by Category

Type Of Error	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
	Net	Net	Net	Net	Net	Net	Net	Net	Gross	Gross	Gross	Gross
No Documentation Errors	1.9%	2.1%	0.4%	0.6%	1.2%	0.8%	0.5%	5.4%	3.1%	0.7%	0.6%	0.6%
Insufficient Documentation Errors	4.5%	2.9%	0.8%	2.6%	1.3%	1.9%	1.3%	2.5%	4.1%	1.1%	0.6%	0.4%
Medically Unnecessary Errors	5.1%	4.2%	3.9%	2.6%	2.9%	2.7%	3.6%	1.1%	1.6%	1.6%	1.4%	1.3%
Incorrect Coding Errors	1.2%	1.7%	1.3%	1.3%	1.0%	1.1%	0.9%	0.7%	1.2%	1.5%	1.6%	1.5%
Other Errors	1.1%	0.5%	0.7%	0.9%	0.4%	-0.2%	0.0%	0.1%	0.2%	0.2%	0.2%	0.2%
IMPROPER PAYMENTS	**13.8%**	**11.4%**	**7.1%**	**8.0%**	**6.8%**	**6.3%**	**6.3%**	**9.8%**	**10.1%**	**5.2%**	**4.4%**	**3.9%**
CORRECT PAYMENTS	86.2%	88.6%	92.9%	92.0%	93.2%	93.7%	93.7%	90.2%	89.9%	94.8%	95.6%	96.1%

(4)

Table 3d summarizes the percent of total dollars improperly allowed by error category and contractor type.

Table 3d: Type of Error Comparison for 2006 and 2007

Type of Error	Nov 2006 Report	November 2007 Report				
	Total	Total	Carrier	DMERC	FI	QIO
No Documentation Errors	0.6%	0.6%	0.3%	0.2%	0.0%	0.1%
Insufficient Documentation Errors	0.6%	0.4%	0.3%	0.0%	0.1%	0.0%
Medically Unnecessary Errors	1.4%	1.3%	0.0%	0.1%	0.1%	1.0%
Incorrect Coding Errors	1.6%	1.5%	0.7%	0.0%	0.2%	0.6%
Other Errors	0.2%	0.2%	0.0%	0.0%	0.0%	0.1%
Improper Payments	4.4%	3.9%	1.3%	0.4%	0.5%	1.8%

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No Documentation Errors

No documentation means the provider did not submit any medical record documentation to support the services provided.(6) No documentation errors accounted for 0.6% of the total dollars all Medicare FFS contractors allowed during the reporting period. QIO data is categorized in a different manner than the data for Carriers/DMERCs/FIs; therefore, the QIO no documentation estimates include claims that are categorized as *insufficient documentation* for Carriers/DMERCs/FIs. This data breaks down by contractor type as follows:

Carrier	DMERC	FI	QIO	Total

0.3%	0.2%	0.0%	0.1%	0.6%

(7)

Table 4a is a combined list of the services with the highest projected improper payments due to no documentation errors for all contractor types. All series 4 tables are sorted in descending order by projected improper payments.

Table 4a: Top 20 Services with No Documentation Errors

Sort This Table

Carriers (HCPCS), DMERCs (HCPCS), FIs (Type of Bill), and QIOs (DRG)	No Documentation Errors		
	Paid Claims Error Rate	Projected Improper Payments	95% Confidence Interval
Neg press wound therapy pump (E2402)	45.0%	$86,444,132	21.2% - 68.8%
Budesonide non-comp unit (J7626)	23.6%	$51,254,280	7.3% - 39.9%
EF spec metabolic noninherit (B4154)	28.4%	$44,683,314	5.2% - 51.7%
Subsequent hospital care (99232)	1.6%	$40,805,994	0.4% - 2.8%
Levalbuterol non-comp unit (J7614)	10.1%	$36,280,922	(1.0%) - 21.3%
Methylprednisolone 80 MG inj (J1040)	76.3%	$35,478,476	50.7% -101.9%
Powered pres-redu air mattrs (E0277)	24.3%	$33,546,963	7.7% - 40.8%
EXT OR PROC UNREL TO PRINC DIAG (468)	2.1%	$25,784,514	(2.0%) - 6.2%
WND DEBR & SKN GRFT EXC HAND, MUSCSKEL & CON TIS DIS (217)	9.9%	$25,557,636	(9.4%) - 29.3%
Hospital-outpatient (HHA-A also)(under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00) (13)	0.1%	$23,524,563	0.0% - 0.1%
NUTR & MISC METAB DISOR AGE >17 W CC (296)	2.0%	$18,910,027	(0.1%) - 4.2%
Enteral feed supp pump per d (B4035)	11.1%	$18,607,701	0.2% - 21.9%
Office/outpatient visit, est (99213)	0.4%	$18,398,567	0.2% - 0.7%
SKN GRFT &/ DEBR - SKN ULCER/CELLU W CC (263)	6.2%	$14,403,457	(5.9%) - 18.3%
G.I. HEMORR W CC (174)	1.0%	$12,693,170	(0.4%) - 2.3%
MAJ JNT REPLACE/REATTACH - LO EXTREM (544)	0.3%	$12,424,318	(0.1%) - 0.6%
Albuterol ipratrop non-comp (J7620)	5.6%	$11,289,116	0.3% - 10.9%
Clinic-CORF (75)	6.6%	$10,975,557	(0.4%) - 13.6%
Heart image (3d), multiple (78465)	1.1%	$9,807,789	(1.0%) - 3.3%
HEART FAILURE & SHOCK (127)	0.3%	$9,581,644	(0.2%) - 0.8%
Overall	**0.6%**	**$1,603,325,203**	**0.4% - 0.7%**

The following are examples of No Documentation errors:

- A Fiscal Intermediary (FI) paid $144.80 for an Outpatient Clinic Visit. After multiple attempts to obtain supporting documentation, the provider sent the following statement: “Last documented visit on file 08/05. No records for date requested”. As a result, the CERT Contractor counted the entire payment as an error.
- A Carrier paid $446.16 for an office visit and an injection of Epoetin. After multiple attempts to obtain documentation, no documentation was ever received from provider. As a result, the CERT Contractor counted the entire payment as an error.
- A hospital submitted a short-term acute care inpatient claim for $3,640.91, which was paid. However, when the substantiating medical record was requested, the hospital failed to provide the record. Thus, the entire payment was recouped.

An unusual number of the claims sampled in Florida resulted in no documentation errors during the November report period. The no documentation errors in Florida accounted for 63.5% of the 0.6% national no documentation error rate. About three quarters of the claims with no documentation errors were submitted by DME suppliers while the remaining quarter was submitted by Part B providers.

For most of the DMERC claims scored as no documentation errors, the DME supplier was unreachable after their claims were sampled for the CERT program. This is attributable, at least in part, to the continued efforts of CMS and contractors finding and disabling or revoking provider numbers for providers not in compliance with CMS policies. Most of the providers who did not respond during the November report period were associated with provider numbers that were revoked some time during the sampling process.

A smaller number of Carrier claims in the sample resulted in no documentation errors due, in part, to ongoing fraud fighting efforts. In several cases, these claims were associated with provider numbers revoked in direct response to ongoing CMS efforts in Florida.

Based on findings in this report and observations from other monitoring activities, CMS has implemented safeguards to better ensure that only legitimate providers and suppliers receive Medicare payments. During this report period, CMS issued regulations that clarify and strengthen provider enrollment requirements and standards and increased efforts to deactivate or, when necessary, revoke billing privileges for providers and suppliers that are inactive or do not meet program requirements. Additionally, CMS has initiated three demonstration projects that target fraudulent business practices. The demonstrations focus on billing by suppliers of durable medical equipment, prosthetics, orthotics and supplies in south Florida and southern California, home health agencies in the greater Los Angeles and Houston areas and infusion therapy providers in south Florida.

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Insufficient Documentation Errors

Insufficient documentation means that the provider did not include pertinent patient facts (e.g., the patient's overall condition, diagnosis, and extent of services performed) in the medical record documentation submitted.(8)

Insufficient documentation errors accounted for 0.4% of the total dollars allowed during the reporting period. This data breaks down as follows:

Carrier	DMERC	FI	QIO	Total
0.3%	0.0%	0.1%	0.0%	0.4%

(9)

In several cases of insufficient documentation, it was clear that Medicare beneficiaries received services, but the physician's orders or documentation supporting the beneficiary's medical condition were incomplete. While these errant claims did not meet Medicare reimbursement rules regarding documentation, CMS could not conclude that the services were not provided.

In some instances, components of the medical documentation were located and maintained at a third party facility. For instance, although a lab may have billed for a blood test, the physician who ordered the lab test maintained the medical record. If the billing provider failed to contact the third party or the third party failed to submit the documentation to the CERT Contractor, CMS counted the claim as a full or partial insufficient documentation error.

Table 4b is a combined list of the services with the highest insufficient documentation paid claims error rates for Carriers/DMERCs/FIs. This table does not include QIOs.

Table 4b: Top 20 Services with Insufficient Documentation: Carriers/DMERCs/FIs/MACs

Sort This Table

Carriers (HCPCS), DMERCs (HCPCS), and FIs (Type of Bill)	Insufficient Documentation Errors		
	Paid Claims Error Rate	Projected Improper Payments	95% Confidence Interval
Hospital-outpatient (HHA-A also)(under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00) (13)	0.7%	$174,767,859	0.5% - 0.9%
Subsequent hospital care (99232)	3.6%	$94,476,515	2.7% - 4.5%
Clinic-hospital based or independent renal dialysis facility (72)	0.8%	$52,383,076	(0.1%) - 1.6%
Subsequent hospital care (99233)	3.1%	$40,170,148	1.9% - 4.4%
SNF-inpatient (including Part A) (21)	0.2%	$39,043,101	(0.0%) - 0.4%
Subsequent hospital care (99231)	7.1%	$35,308,892	3.1% - 11.0%
Therapeutic exercises (97110)	5.3%	$33,972,936	3.4% - 7.1%

Inpatient consultation (99255)	5.9%	$28,456,732	1.4% - 10.4%
Office/outpatient visit, est (99214)	0.7%	$26,903,868	0.3% - 1.1%
Hospital-inpatient or home health visits (Part B only) (12)	6.1%	$22,850,022	(1.0%) - 13.1%
Office/outpatient visit, est (99213)	0.5%	$21,759,655	0.3% - 0.7%
Office/outpatient visit, est (99211)	12.3%	$19,165,055	8.9% - 15.6%
SNF-inpatient or home health visits (Part B only) (22)	1.3%	$17,357,179	0.3% - 2.2%
Initial hospital care (99223)	2.3%	$16,810,848	0.4% - 4.1%
Manual therapy (97140)	7.8%	$16,571,551	4.5% - 11.1%
Special facility or ASC surgery-rural primary care hospital (eff 10/94) (85)	0.6%	$16,187,169	0.3% - 1.0%
HHA-inpatient or home health visits (Part B only) (32)	0.2%	$15,790,823	(0.2%) - 0.5%
Radiation treatment aid(s) (77334)	21.5%	$15,245,164	(11.9%) - 55.0%
Critical care, first hour (99291)	2.0%	$14,291,569	(0.7%) - 4.6%
Chiropractic manipulation (98941)	4.2%	$13,735,291	1.9% - 6.6%
All Other Codes	0.5%	$495,286,838	0.4% - 0.6%
Overall	**0.7%**	**$1,210,534,289**	**0.6% - 0.8%**

The following are examples of insufficient documentation errors:

- An FI paid $1,120.20 for Physical Therapy, in a skilled nursing facility SNF), Part B stay. The nurse reviewer was missing the documentation for the physician's order, therapy evaluation and plan of care, certified by the ordering physician. After multiple attempts to obtain the documentation, the CERT reviewer determined there was insufficient documentation to support the services billed and the CERT Contractor counted the entire payment as an error.
- A Carrier paid $139.69 for an inpatient consultation. Multiple attempts were made to obtain the documentation. Documentation received consisted of multiple copies of the discharge summary only. As a result, the CERT Contractor counted the claim line in error and recouped the entire amount.

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Medically Unnecessary Services

Medically Unnecessary Services includes situations where the CERT or HPMP claim review staff identifies enough documentation in the medical record to make an informed decision that the services billed to Medicare were not medically necessary. In the case of inpatient claims, determinations are also made with regard to the level of care; for example, in some instances another setting besides inpatient care may have been more appropriate. If a QIO determines that a hospital admission was unnecessary due to not meeting an acute level of care, the entire payment for the admission is denied.

Medically Unnecessary Service errors accounted for 1.3% of the total dollars allowed during the reporting period. This data breaks down as follows:

Carrier	DMERC	FI	QIO	Total
0.0%	0.1%	0.1%	1.0%	1.3%

(10)

For QIOs, this is often related to hospital stays of short duration where services could have been rendered at a lower level of care. A smaller, but persistent amount of medically unnecessary payment errors is due to unnecessary inpatient admissions associated with discharges to a skilled nursing facility.

Table 4c lists the top twenty medically unnecessary services for Carriers/DMERCs/FIs/QIOs.

Table 4c: Top 20 Medically Unnecessary Services: All Contractors

Sort This Table

Service Billed to Carriers (HCPCS), DMERCs (HCPCS), FIs (Type of Bill), and QIOs (DRG)	Medically Unnecessary Errors		
	Paid Claims Error Rate	Projected Improper Payments	95% Confidence Interval
ESOPH, GASTROENT & MISC DIG DISOR AGE >17 W CC (182)	11.9%	$164,182,142	8.8% - 15.0%
CAR DEFIBRILLATOR IMPL W/O CAR CATH (515)	8.0%	$145,493,621	1.2% - 14.9%
CHEST PAIN (143)	20.1%	$118,194,148	15.6% - 24.6%
NUTR & MISC METAB DISOR AGE >17 W CC (296)	10.7%	$99,252,860	7.2% - 14.2%
HHA-inpatient or home health visits (Part B only) (32)	1.0%	$87,615,724	0.1% - 2.0%
RENAL FAILURE (316)	4.9%	$82,828,870	2.7% - 7.1%
Blood glucose/reagent strips (A4253)	7.9%	$80,823,935	6.3% - 9.4%
MEDICAL BACK PROB (243)	15.5%	$58,879,136	9.6% - 21.5%
MAJ JNT REPLACE/REATTACH - LO EXTREM (544)	1.2%	$55,085,636	0.4% - 2.0%
OTH VAS PROC W CC W/O MAJ CV DX (554)	5.5%	$51,440,246	(0.0%) - 11.0%
HEART FAILURE & SHOCK (127)	1.4%	$47,473,236	0.7% - 2.0%
CIRC DISOR EXC AMI, W CAR CATH W/O COMPL DIAG (125)	9.8%	$45,758,977	4.2% - 15.4%
SNF-inpatient or home health visits (Part B only) (22)	3.3%	$44,616,705	2.2% - 4.4%
OTH CIRC SYS OR PROC (120)	9.6%	$42,310,159	0.8% - 18.5%
KIDNEY & URIN TRACT INFECT AGE >17 W CC (320)	4.1%	$42,156,470	2.1% - 6.2%
Special facility or ASC surgery-hospice (non-hospital based) (81)	0.5%	$40,197,740	(0.0%) - 1.0%
SYNCOPE & COLLAPSE W CC (141)	8.1%	$39,879,723	3.8% - 12.4%
Hospital-outpatient (HHA-A also)(under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00) (13)	0.2%	$39,165,227	0.0% - 0.3%
EXT OR PROC UNREL TO PRINC DIAG (468)	3.2%	$39,051,720	(2.6%) - 9.0%
DIABETES AGE >35 (294)	9.2%	$35,996,770	4.2% - 14.1%
Overall	**1.3%**	**$3,553,336,758**	**1.2% - 1.4%**

The following are examples of medically unnecessary services:

- An FI paid $91.56 for daily glucose monitor checks in a SNF, Part B stay. After review of the documentation, the nurse reviewer determined that there was no medical necessity for the daily testing. The CERT contractor counted the claim in error and the entire amount was recouped.
- An FI denied a CAT scan of the thorax with contrast as not medically necessary, based on their local coverage determination (LCD). The nurse reviewer determined that as a result of the FI denial, the low Osmolar contrast billed which paid $109.20 should also have been denied as not medically necessary. The money was recouped.
- A Medicare beneficiary with symptoms of abdominal pain and vomiting was admitted. No documentation to substantiate the medical necessity for inpatient admission was submitted to the QIO for review. Thus, an adjustment for the full payment of $6,077.76 was submitted.

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Incorrect Coding

Providers use standard coding systems to bill Medicare. For most of the coding errors, the medical reviewers determined that providers submitted documentation that supported a lower code than the code submitted (in these cases, providers are said to have *overcoded* claims). However, for some of the coding errors, the medical reviewers determined that the documentation supported a higher code than the code the provider submitted (in these cases, the providers are said to have *undercoded* claims).

Incorrect Coding errors accounted for 1.5% percentage of the total dollars allowed during the reporting period. This data breaks down as follows:

Carrier	DMERC	FI	QIO	Total
0.7%	0.0%	0.2%	0.6%	1.5%

(11)

A common error involved overcoding or undercoding E&M codes by one level on a scale of five code levels. Published studies suggest that under certain circumstances, experienced reviewers may disagree on the most appropriate code to describe a particular service. This may explain some of the incorrect coding errors in this report. CMS is investigating procedures to minimize the occurrence of this type of error in the future.

Table 4d lists the services with the highest paid claims error rates due to incorrect coding for Carriers/DMERCs/FIs/QIOs. Table 4e includes only undercoding errors for Carriers/DMERCs/FIs.

Table 4d: Top 20 Services with Incorrect Coding Errors: All Contractors

Sort This Table

Carriers (HCPCS), DMERCs (HCPCS), FIs (Type of Bill), and QIOs (DRG)	Incorrect Coding Errors		
	Paid Claims Error Rate	Projected Improper Payments	95% Confidence Interval
SNF-inpatient (including Part A) (21)	1.1%	$230,829,737	0.5% - 1.7%
Office/outpatient visit, est (99214)	5.7%	$230,221,581	5.2% - 6.3%
Subsequent hospital care (99233)	15.8%	$201,812,776	13.4% - 18.3%
Hospital-outpatient (HHA-A also)(under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00) (13)	0.6%	$156,040,424	0.4% - 0.8%
Office consultation (99244)	16.6%	$115,451,305	13.5% - 19.8%
Office/outpatient visit, est (99215)	16.0%	$112,823,175	13.7% - 18.4%
Inpatient consultation (99254)	14.3%	$105,362,727	11.8% - 16.9%
Initial hospital care (99223)	13.0%	$97,268,646	10.2% - 15.9%
Inpatient consultation (99255)	18.9%	$91,290,030	14.6% - 23.1%
Subsequent hospital care (99232)	3.2%	$82,373,354	2.4% - 3.9%
Office consultation (99245)	18.8%	$81,704,677	14.5% - 23.2%
Office/outpatient visit, new (99204)	21.2%	$70,693,512	17.0% - 25.5%
Office/outpatient visit, est (99213)	1.6%	$67,488,605	1.3% - 1.8%
SEPTICEMIA AGE >17 (416)	2.6%	$60,965,185	1.3% - 4.0%
PERM CAR PACER IMPL W MAJ CV DX/AICD LEAD/GNRTR (551)	5.0%	$46,407,417	0.3% - 9.8%
Office/outpatient visit, new (99203)	9.9%	$44,074,005	7.5% - 12.3%
Office consultation (99243)	9.1%	$42,425,964	6.8% - 11.4%
RENAL FAILURE (316)	2.5%	$41,971,743	1.2% - 3.7%
CIRC DISOR EXC AMI, W CAR CATH & COMPL DIAG (124)	4.6%	$39,782,666	(2.2%) - 11.5%
Special facility or ASC surgery-rural primary care hospital (eff 10/94) (85)	1.6%	$39,754,559	(0.1%) - 3.2%
Overall	**1.5%**	**$4,030,196,197**	**1.4% - 1.6%**

Table 4e: Top 20 Services with Underpayment Coding Errors: Carriers/DMERCs/FIs/MACs

Sort This Table

Carriers (HCPCS), DMERCs (HCPCS), and FIs (Type of Bill)	Underpayment Coding Errors		
	Paid Claims Error Rate	Projected Improper Payments	95% Confidence Interval
Hospital-outpatient (HHA-A also)(under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00) (13)	0.3%	$67,934,202	0.1% - 0.4%
Office/outpatient visit, est (99213)	0.7%	$29,172,251	0.5% - 0.9%
Office/outpatient visit, est (99212)	3.4%	$21,633,366	2.5% - 4.3%
SNF-inpatient (including Part A) (21)	0.1%	$15,247,258	(0.0%) - 0.1%
HHA-inpatient or home health visits (Part B only) (32)	0.1%	$12,800,989	0.0% - 0.3%
Darbepoetin alfa, non-esrd (J0881)	1.3%	$11,721,979	0.9% - 1.7%
HHA-outpatient (HHA-A also) (33)	0.2%	$11,701,399	(0.0%) - 0.4%
Subsequent hospital care (99231)	2.1%	$10,582,963	1.1% - 3.1%

Office/outpatient visit, est (99211)	3.0%	$4,649,056	1.4% - 4.6%
Clinic-hospital based or independent renal dialysis facility (72)	0.1%	$4,416,597	0.0% - 0.1%
Emergency dept visit (99283)	2.1%	$4,407,027	0.0% - 4.1%
Chiropractic manipulation (98940)	3.3%	$4,300,134	1.0% - 5.7%
Ground mileage (A0425)	0.7%	$3,884,281	(0.4%) - 1.7%
Special facility or ASC surgery-rural primary care hospital (eff 10/94) (85)	0.1%	$3,377,263	(0.0%) - 0.3%
Subsequent hospital care (99232)	0.1%	$2,709,199	0.0% - 0.2%
Epoetin alfa, non-esrd (J0885)	0.7%	$2,702,757	(0.6%) - 1.9%
Nursing fac care, subseq (99307)	2.7%	$2,687,956	0.5% - 4.8%
ESRD related svs 2-3 mo 20+y (G0318)	1.9%	$2,092,034	1.4% - 2.3%
Eye exam established pat (92012)	0.5%	$1,793,781	(0.0%) - 1.0%
Drain/inject, joint/bursa (20610)	0.6%	$1,658,182	(0.3%) - 1.5%
All Other Codes	0.0%	$39,595,161	0.0% - 0.1%
Overall	**0.1%**	**$259,067,836**	**0.1% - 0.2%**

The following are examples of coding errors:

- An FI paid $324.44 to a provider for three injections of Iron Sucrose. The provider had billed J1756, Iron sucrose, 1mg, 40 units. The nurse reviewer determined that the actual amount of the drug injected was 200 mg, thus 200 units. This coding error resulted in an underpayment to the provider of an additional $203.52.
- A Carrier paid $200.88 to a provider for an inpatient consult CPT code 99255 which requires 3 of 3 key components: a comprehensive history, a comprehensive exam, and high complexity medical decision making (MDM). Upon review it was determined that documentation supported downcode to CPT 99252 by meeting/ exceeding 3 of 3 components with detailed history, expanded problem focused (EPF) exam, and moderate complexity MDM. The overpayment collected was $126.10.
- A hospital submitted an inpatient admission claim coded for aspiration pneumonia and hypernatremia. The correct code for admission was dehydration and hypernatremia as the patient aspirated after admission; the payment difference between the two DRGs was $3,595.40.

The OIG and CMS have noted problems with certain procedure codes for the past several years. These problematic codes include CPT codes 99214 (office or other outpatient visit), 99232 (subsequent hospital care level 2) and 99233 (subsequent hospital care level 3). See Appendix E for more information on problematic codes.

Table 4f provides information on the impact of 1 level disagreement between Carriers and providers when coding evaluation and management codes.

Table 4f: Impact of One Level E&M (Top 20)

Sort This Table

Final E&M Code	Incorrect Coding Errors		
	Paid Claims Error Rate	Projected Improper Payments	95% Confidence Interval
Subsequent hospital care (99233)	17.4%	$353,688,093	12.4% - 22.4%
Office/outpatient visit, est (99214)	5.0%	$201,852,904	4.5% - 5.5%
Subsequent hospital care (99232)	4.0%	$106,983,044	2.5% - 5.4%
Office/outpatient visit, est (99213)	1.5%	$62,945,624	1.2% - 1.7%
Office/outpatient visit, est (99215)	8.5%	$60,046,630	7.0% - 10.1%
Inpatient consultation (99254)	7.3%	$53,518,550	5.6% - 9.0%
Emergency dept visit (99285)	3.9%	$32,242,941	2.6% - 5.2%
Office/outpatient visit, new (99203)	6.5%	$29,110,409	4.9% - 8.1%
Office consultation (99244)	3.9%	$27,339,020	2.7% - 5.2%
Office/outpatient visit, new (99204)	7.3%	$24,436,639	5.2% - 9.5%
Nursing fac care, subseq (99309)	8.1%	$23,732,570	5.9% - 10.3%
Office consultation (99243)	4.2%	$19,727,859	3.0% - 5.5%
Initial hospital care (99222)	6.2%	$19,534,920	4.3% - 8.2%
Office/outpatient visit, est (99212)	2.8%	$17,599,049	2.0% - 3.5%

Initial hospital care (99223)	1.6%	$11,900,426	0.7% - 2.5%
Subsequent hospital care (99231)	2.1%	$10,755,678	1.0% - 3.3%
Inpatient consultation (99253)	4.3%	$10,228,368	2.3% - 6.3%
Office consultation (99245)	2.3%	$10,018,566	1.0% - 3.6%
Emergency dept visit (99283)	2.1%	$4,519,651	0.5% - 3.7%
Nursing fac care, subseq (99308)	1.4%	$4,143,207	0.6% - 2.1%
All Other Codes	0.1%	$37,880,486	0.1% - 0.1%
Overall	**1.5%**	**$1,122,204,634**	**1.2% - 1.8%**

For more data pertaining to incorrect coding errors, see Appendix E.

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Other Errors

Under CERT, *other errors* include instances when provider claims did not meet billing requirements such as those for not covered or unallowable services and duplicate claim submissions.

Under HPMP, other errors include quality of care and billing errors. Billing errors include payments for claims where the stay was billed as non-exempt unit but was exempt, outpatient billed as inpatient, and HMO bills paid under FFS. Most other errors occur on claims for which QIOs are responsible.

Other errors accounted for 0.2% of the total dollars allowed during the reporting period. This data breaks down as follows:

Carrier	DMERC	FI	QIO	Total
0.0%	0.0%	0.0%	0.1%	0.2%

(12)

Table 4g lists the services with other errors and the associated paid claims error rate.

Table 4g: Top 20 Other Errors: All Contractors

Sort This Table

Carriers (HCPCS), DMERCs (HCPCS), FIs (Type of Bill), and QIOs (DRG)	Other Errors		
	Paid Claims Error Rate	Projected Improper Payments	95% Confidence Interval
CAR DEFIBRILLATOR IMPL W/O CAR CATH (515)	2.0%	$36,058,520	(1.3%) - 5.3%
Hospital-outpatient (HHA-A also)(under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00) (13)	0.1%	$32,826,092	0.0% - 0.2%
OTH KIDNEY & URIN TRACT PROC (315)	4.4%	$19,886,376	(3.9%) - 12.7%
Special facility or ASC surgery-hospice (non-hospital based) (81)	0.2%	$17,989,620	(0.1%) - 0.5%
HEART FAILURE & SHOCK (127)	0.4%	$15,454,241	(0.1%) - 1.0%
Subsequent hospital care (99232)	0.5%	$13,338,792	(0.1%) - 1.1%
CIRRHOSIS & ALC HEPATITIS (202)	5.4%	$11,390,106	(3.8%) - 14.6%
OTH VAS PROC W/O CC (479)	5.1%	$11,266,211	(2.8%) - 13.0%
ESOPH, GASTROENT & MISC DIG DISOR AGE >17 W CC (182)	0.8%	$10,932,132	0.2% - 1.4%
OTH PERM CAR PACER IMPL W/O MAJ CV DX (552)	1.1%	$10,320,202	(0.7%) - 3.0%
OTH EAR, NOSE, MTH & THRT DIAG AGE >17 (073)	17.3%	$7,595,274	(16.4%) - 51.1%
Initial hospital care (99223)	0.9%	$6,660,850	(0.3%) - 2.1%
DIABETES AGE >35 (294)	1.4%	$5,457,947	(0.5%) - 3.3%
PERCU CARDIOVAS PROC W DRUG-ELUT STENT W/O MAJ CV DX (558)	0.2%	$5,242,282	(0.1%) - 0.5%

CAR ARRHYTHMIA & CONDUCTION DISOR W CC (138)	0.6%	$4,940,844	(0.3%) - 1.4%
Subsequent hospital care (99233)	0.4%	$4,721,191	(0.2%) - 0.9%
PERCU CARVAS PROC W NON-DRUG-ELUT STENT W/O MAJ CV DX (556)	2.1%	$4,686,855	(1.1%) - 5.2%
CIRC DISOR EXC AMI, W CAR CATH W/O COMPL DIAG (125)	1.0%	$4,590,429	(0.8%) - 2.8%
SYNCOPE & COLLAPSE W CC (141)	0.9%	$4,467,090	(0.5%) - 2.3%
NON-EXT OR PROC UNREL TO PRINC DIAG (477)	1.3%	$4,305,102	(1.2%) - 3.9%
Overall	**0.2%**	**$425,069,191**	**0.1% - 0.2%**

The following are examples of other errors:

- **Not Covered or Unallowable Service error:** An FI paid $19.97 to a provider for Revenue Center Code 0250. Review of the medical record determined that the charge was actually for 3 Phenergan tablets administered in the Emergency Room. Oral medication administered meets the criteria for self-administered drugs and is statutorily excluded for payment by Medicare. The $19.97 was recouped from provider.
- **Duplicate Payment error:** An FI paid $102.84 to a provider for an emergency room visit and application of a short leg splint. Upon review of the Common Working File (CWF), the reviewer discovered that a claim identical to this claim had been paid 4 days prior. The entire claim amount was recouped.
- **Other error:** A Regional Home Health Intermediary (RHHI) paid $1554.88 for a Home Health episode of care. Upon review, the CERT nurse reviewer discovered that only 4 skilled nursing visits were performed and acknowledged as performed by the Home Health agency. It was determined that this claim should have fallen under a low utilization payment adjustment (LUPA) payment. The RHHI recouped $1,223.96 in overpayment to the provider.
- **Billing error:** A hospital billed for a short-term acute care inpatient stay. The case was determined to be a billing error and the payment was recouped because the provider billed this as an inpatient stay, however, the admission orders in the medical record indicated that an observation stay should have been billed. The dollars paid in error were $6,723.63.

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Paid Claims Error Rate by Contractor Type

Figures 3 and 4 summarize the paid claims error rate and projected improper payments during the reporting period for each type of contractor. This data breaks down by contractor type as follows:

Carrier	DMERC	FI	QIO	Total
1.3%	0.4%	0.5%	1.8%	3.9%

The following figures (Figures 3 and 4) detail the paid claim error rates and projected improper payments by contractor type.

Figure 3: Paid Claims Error Rates by Contractor Type

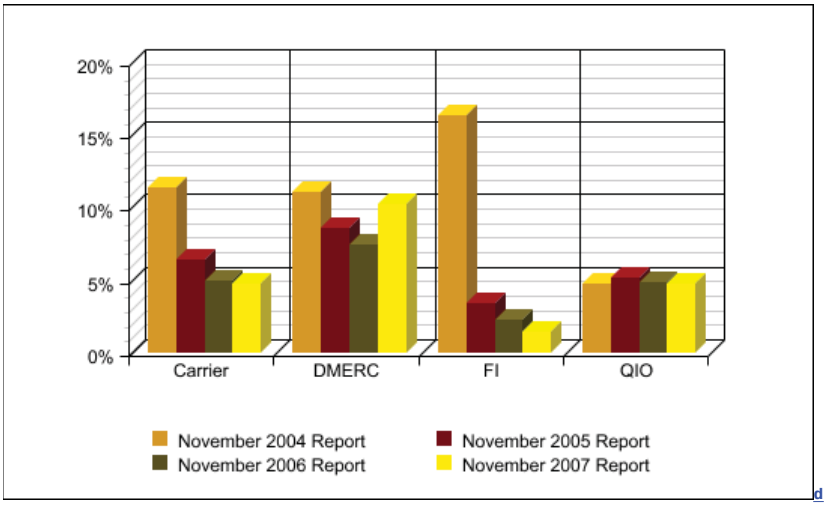
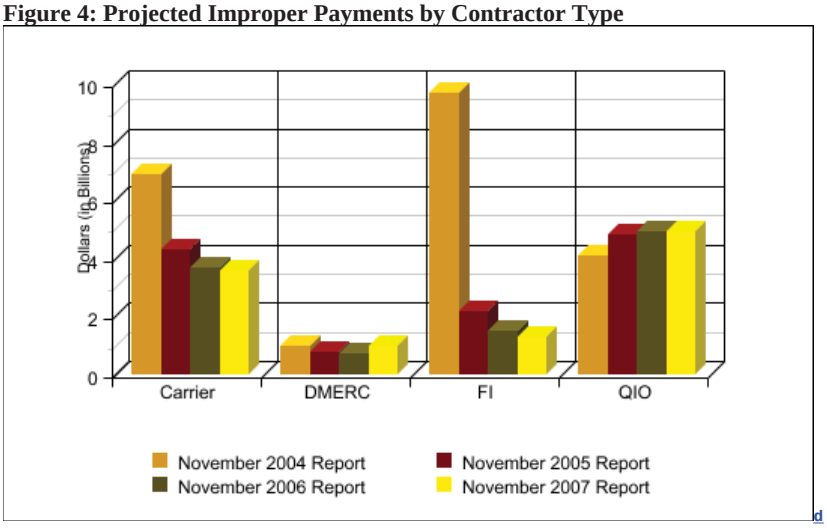


Figure 4: Projected Improper Payments by Contractor Type



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Contractor-Specific Error Rates

Beginning with the November 2007 Report, clusters are listed for each contractor that adjudicated claims during the sampling period. There may be some contractors listed that no longer process claims for Medicare FFS. In addition, MACs which began their contracts during the sampling period are listed, but may have less than a full year of data.

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Carrier-Specific Error Rates

Table 5 contains error rates and improper payment amounts for Carriers. It is sorted in descending order by error rate.

Table 5: Error Rates and Improper Payments: Carriers and MACs

Sort This Table

Carrier	Paid Claims Error Rate				Provider Compliance Error Rate
	Error Rate	Projected Improper Payments	Standard Error	95% Confidence Interval	
First Coast Service Options FL 00590	10.0%	$783,464,966	1.9%	6.2% - 13.8%	21.2%
Triple S, Inc. PR/VI 00973/00974	9.7%	$39,988,868	0.8%	8.1% - 11.2%	24.5%
Empire NJ 00805	7.0%	$234,545,967	0.8%	5.5% - 8.6%	29.2%
Empire NY 00803	6.5%	$255,243,467	0.7%	5.1% - 7.8%	16.3%
Noridian MAC Region 3 03002	5.5%	$10,531,313	0.9%	3.8% - 7.3%	19.3%
Average=	**4.8%**				
GHI NY 14330	4.7%	$17,403,719	0.5%	3.8% - 5.7%	22.9%
CIGNA NC 05535	4.5%	$107,659,193	0.8%	3.0% - 6.0%	11.8%
NHIC CA 31140/31146	4.4%	$302,121,034	0.4%	3.6% - 5.3%	12.5%
Cahaba AL/GA/MS 00510/00511/00512	4.4%	$180,088,478	0.5%	3.4% - 5.4%	17.3%
Palmetto SC 00880	4.0%	$43,489,882	0.5%	3.0% - 5.0%	15.7%
Trailblazer MD/DE/DC/VA 00901/00902/00903/00904	3.9%	$134,257,765	0.5%	3.0% - 4.9%	14.1%
Palmetto OH/WV 00883/00884	3.9%	$126,273,284	0.5%	3.0% - 4.8%	10.8%
BCBS AR RI 00524	3.9%	$8,584,513	0.5%	3.0% - 4.8%	15.4%
Noridian AK/AZ/HI/NV/OR/WA 00831/00832/00833/00834/00835/00836	3.9%	$140,126,116	0.8%	2.3% - 5.5%	13.8%
BCBS AR AR/NM/OK/MO/LA 00520/00521/00522/00523/00528	3.9%	$167,430,205	0.5%	2.9% - 4.8%	12.6%
Trailblazer TX 00900	3.8%	$195,827,556	0.4%	3.0% - 4.6%	14.8%
Noridian ND/CO/WY/IA/SD 00820/00824/00825/00826/00889	3.7%	$62,127,673	0.9%	2.0% - 5.4%	9.4%
WPS WI/IL/MI/MN 00951/00952/00953/00954	3.6%	$294,175,659	0.4%	2.8% - 4.4%	14.1%
HealthNow NY 00801	3.5%	$43,447,746	0.4%	2.6% - 4.3%	10.9%
BCBS KS/NE/W MO 00650/00655/00651	3.3%	$48,961,686	0.4%	2.5% - 4.2%	10.1%
Noridian UT 00823	3.3%	$10,273,321	0.5%	2.3% - 4.2%	16.3%
First Coast Service Options CT 00591	3.2%	$37,486,143	0.4%	2.5% - 3.9%	7.7%
NHIC ME/MA/NH/VT 31142/31143/31144/31145	3.2%	$74,467,507	0.5%	2.2% - 4.1%	10.1%
AdminaStar IN/KY 00630/00660	3.1%	$84,990,497	0.5%	2.1% - 4.1%	11.1%
HGSA PA 00865	3.0%	$93,647,474	0.6%	2.0% - 4.1%	10.7%
CIGNA TN 05440	3.0%	$53,940,509	0.4%	2.2% - 3.8%	12.6%
CIGNA ID 05130	2.1%	$4,492,925	0.3%	1.6% - 2.6%	14.2%
BCBS MT 00751	1.9%	$3,304,593	0.4%	1.2% - 2.6%	7.7%
Combined	**4.8%**	**$3,558,352,057**	**0.2%**	**4.3% - 5.2%**	**14.9%**

For paid claim error rates, provider compliance error rates and no resolution rates by contractor and provider type, see Appendix C.

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DMERC and DME MAC Error Rates

Table 6 contains error rates and improper payment amounts for both DMERC and DME MAC contractors. It is sorted in descending order by error rate.

Table 6: Error Rates and Improper Payments: DMERCs and DME MACs

Sort This Table

DMERCs and DME MACs	Paid Claims Error Rate				Provider Compliance Error Rate
	Error Rate	Projected Improper Payments	Standard Error	95% Confidence Interval	
Palmetto Region C 00885	17.7%	$770,026,748	2.5%	12.8% - 22.5%	27.1%
Noridian Administrative Services MAC Region D 19003	11.9%	$59,853,831	2.8%	6.3% - 17.5%	19.3%
Average=	**10.3%**				
NHIC MAC Region A 16003	4.2%	$32,691,723	0.7%	2.9% - 5.6%	11.9%
National Government Services MAC Region B 17003	4.0%	$46,543,790	0.5%	2.9% - 5.1%	10.4%
AdminaStar Region B 00635	3.9%	$38,978,608	0.9%	2.2% - 5.5%	11.7%
Tricenturion Region A 77011	3.7%	$27,101,350	1.2%	1.3% - 6.1%	8.9%
CIGNA Region D 05655	3.0%	$40,436,437	0.8%	1.3% - 4.6%	11.4%
Combined	**10.3%**	**$1,015,632,486**	**1.1%**	**8.1% - 12.5%**	**19.2%**

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FI-Specific Error Rates

Table 7 contains error rates and improper payment amounts for FIs. It is sorted in descending order by error rate.

Table 7: Error Rates and Improper Payments: FIs and MACs

Sort This Table

FIs	Paid Claims Error Rate			
	Error Rate	Projected Improper Payments	Standard Error	95% Confidence Interval
Anthem NH/VT 00270	6.2%	$27,633,859	4.7%	(3.0%) - 15.5%
UGS AS/CA/GU/HI/NV/NMI 00454	3.4%	$222,156,308	1.0%	1.4% - 5.4%
Trispan LA/MO/MS 00230	2.9%	$49,203,890	0.9%	1.1% - 4.6%
Noridian ID/OR/UT 00323/00325	2.2%	$20,287,872	1.0%	0.2% - 4.2%
COSVI PR/VI 57400	2.2%	$1,572,998	0.7%	0.9% - 3.5%
Palmetto NC 00382	2.0%	$32,113,273	0.7%	0.8% - 3.3%
Highmark Medicare Services DC/MD 00366	1.9%	$99,025,111	0.4%	1.1% - 2.6%
Anthem ME/MA 00180/00181	1.9%	$50,638,337	0.6%	0.6% - 3.1%
Noridian MAC Region 3 03001	1.6%	$4,550,179	0.4%	0.8% - 2.4%
Trailblazer CO/NM/TX 00400	1.6%	$71,209,287	0.4%	0.8% - 2.4%
Riverbend NJ/TN 00390	1.5%	$53,356,738	0.6%	0.4% - 2.6%
First Coast Service Options FL 00090	1.5%	$41,036,972	0.3%	0.9% - 2.1%
Average=	**1.5%**			
BCBS WY WY 00460	1.4%	$541,300	0.5%	0.5% - 2.4%
Mutual of Omaha (all states) 52280	1.4%	$132,139,337	0.3%	0.8% - 2.0%
Palmetto SC 00380	1.3%	$188,488,528	0.3%	0.8% - 1.8%
BCBS AR RI 00021	1.3%	$1,972,464	0.4%	0.5% - 2.0%

BCBS AR AR 00020	1.2%	$5,051,634	0.3%	0.7% - 1.8%
UGS WI/MI 00450/00452	1.2%	$89,186,173	0.6%	0.1% - 2.3%
Noridian MN/ND 00320/00321	1.2%	$12,382,711	0.5%	0.3% - 2.1%
AdminaStar IN/IL/KY/OH 00130/00131/00160/00332	1.1%	$85,539,881	0.2%	0.6% - 1.6%
Noridian AK/WA 00322	1.1%	$7,049,521	0.4%	0.4% - 1.8%
UGS VA/WV 00453	1.1%	$16,951,731	0.2%	0.6% - 1.6%
BCBS AZ AZ 00030	1.0%	$2,252,775	0.3%	0.4% - 1.6%
BCBS KS KS 00150	0.9%	$4,474,264	0.4%	0.1% - 1.7%
BCBS NE NE 00260	0.9%	$2,282,710	0.4%	0.1% - 1.7%
Empire CT/DE/NY 00308	0.9%	$39,747,571	0.2%	0.4% - 1.3%
Cahaba AL 00010	0.8%	$4,795,699	0.3%	0.3% - 1.4%
Veritus PA 00363	0.7%	$14,828,224	0.2%	0.3% - 1.1%
BCBS GA GA 00101	0.6%	$14,558,467	0.1%	0.4% - 0.9%
BCBS MT MT 00250	0.5%	$859,165	0.1%	0.2% - 0.7%
Chisholm OK 00340	0.4%	$1,292,964	0.1%	0.2% - 0.7%
Cahaba IA/SD 00011	0.3%	$12,683,181	0.1%	0.1% - 0.5%
Combined	**1.5%**	**$1,309,863,123**	**0.1%**	**1.2% - 1.7%**

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QIO-Specific Error Rates

Table 8 contains QIO specific short-term PPS acute care hospital error rates and improper payment amounts, total short-term PPS acute care hospital error rates and improper payment amounts, total PPS long term acute care hospital error rates and improper payment amounts, and total error rates and improper payment amounts for all types of facilities for which QIOs are responsible. It is sorted alphabetically by state.

Table 8: Error Rates and Improper Payments: QIOs

Sort This Table

QIOs	Paid Claims Error Rate			
	Error Rate	Projected Improper Payments	Standard Error	95% Confidence Interval
Alaska	1.1%	$1,555,525	0.3%	0.6% - 1.7%
Alabama	6.4%	$113,180,285	1.7%	2.9% - 9.8%
Arkansas	3.6%	$36,681,340	0.6%	2.5% - 4.6%
Arizona	5.7%	$79,086,760	0.8%	4.1% - 7.3%
California	4.6%	$383,130,721	0.7%	3.2% - 6.0%
Colorado	4.6%	$41,239,170	0.8%	3.2% - 6.1%
Connecticut	3.7%	$56,019,396	0.6%	2.7% - 4.8%
District of Columbia	3.8%	$17,639,168	0.6%	2.6% - 4.9%
Delaware	4.3%	$15,393,467	0.5%	3.3% - 5.3%
Florida	6.6%	$426,475,682	1.1%	4.5% - 8.7%
Georgia	4.1%	$109,368,411	0.6%	2.9% - 5.4%
Hawaii	3.6%	$9,187,289	0.4%	2.9% - 4.4%
Iowa	3.8%	$34,260,668	0.7%	2.5% - 5.2%
Idaho	2.9%	$7,627,689	0.5%	2.0% - 3.8%
Illinois	5.8%	$266,554,200	0.9%	4.1% - 7.6%

Indiana	4.5%	$96,649,457	0.7%	3.2% - 5.8%
Kansas	3.1%	$25,383,483	0.5%	2.1% - 4.2%
Kentucky	6.7%	$119,396,349	0.9%	5.0% - 8.5%
Louisiana	3.4%	$48,349,801	0.6%	2.2% - 4.5%
Massachusetts	7.1%	$180,022,304	0.8%	5.5% - 8.6%
Maryland	4.7%	$132,077,986	0.9%	2.8% - 6.5%
Maine	4.7%	$22,615,472	0.5%	3.7% - 5.8%
Michigan	5.2%	$219,271,223	0.7%	3.8% - 6.6%
Minnesota	3.9%	$59,035,653	0.6%	2.8% - 5.0%
Missouri	3.4%	$76,517,487	0.9%	1.7% - 5.0%
Mississippi	5.8%	$63,029,683	0.9%	4.1% - 7.5%
Montana	1.2%	$3,182,913	0.4%	0.5% - 1.9%
North Carolina	1.5%	$47,994,129	0.3%	0.9% - 2.2%
North Dakota	2.4%	$5,607,761	0.4%	1.6% - 3.3%
Nebraska	1.2%	$7,179,214	0.3%	0.6% - 1.9%
New Hampshire	3.8%	$14,269,816	0.5%	2.8% - 4.8%
New Jersey	5.0%	$180,625,800	0.8%	3.6% - 6.5%
New Mexico	7.6%	$29,023,271	0.9%	5.9% - 9.3%
Nevada	7.5%	$39,926,290	1.0%	5.5% - 9.6%
New York	5.0%	$385,389,445	0.9%	3.4% - 6.7%
Ohio	3.0%	$128,403,620	0.5%	2.0% - 4.1%
Oklahoma	2.9%	$34,608,449	0.5%	1.9% - 3.9%
Oregon	5.0%	$36,363,263	0.7%	3.7% - 6.3%
Pennsylvania	6.0%	$265,240,669	0.9%	4.3% - 7.7%
Puerto Rico	7.9%	$18,205,034	1.4%	5.2% - 10.6%
Rhode Island	3.8%	$12,417,826	0.5%	2.9% - 4.8%
South Carolina	5.2%	$82,399,798	0.8%	3.6% - 6.8%
South Dakota	3.6%	$9,456,541	0.5%	2.6% - 4.5%
Tennessee	2.4%	$58,568,540	0.5%	1.5% - 3.3%
Texas	6.8%	$449,730,615	1.2%	4.5% - 9.2%
Utah	4.7%	$20,542,823	0.6%	3.5% - 5.9%
Virginia	5.9%	$131,726,778	0.9%	4.1% - 7.7%
Vermont	4.6%	$7,577,893	0.6%	3.4% - 5.7%
Washington	2.1%	$33,203,651	0.4%	1.4% - 2.9%
Wisconsin	2.6%	$43,258,693	0.6%	1.5% - 3.8%
West Virginia	6.3%	$50,469,416	1.0%	4.3% - 8.2%
Wyoming	0.9%	$986,220	0.2%	0.6% - 1.3%
Short-term Acute Paid Claims	**4.8%**	**$4,736,107,139**	**0.2%**	**4.5% - 5.2%**
Long-term Acute Paid Claims	**4.8%**	**$202,506,834**	**0.5%**	**3.8% - 5.7%**
Denied Claims	**N/A**	**$9,241,619**	**N/A**	**N/A**
Total	**4.8%**	**$4,947,855,592**	**0.2%**	**4.5% - 5.2%**

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Error Rates by Type of Service

Table 9 displays the paid claims error rates for each type of service by type of error. This series of tables is sorted in descending order by projected improper payments. All estimates in this table are based on a minimum of 30 lines in the sample.

Table 9a: Top 20 Service Types with Highest Improper Payments: Carriers and MACs

Sort This Table

Service Type Billed to Carriers (BETOS codes)	Projected Improper Payment	Paid Claims Error Rate	95% Confidence Interval	Type of Error				
				No Documentation	Insufficient Documentation	Medically Unnecessary Services	Incorrect Coding	Other
Hospital visit - subsequent	$566,165,319	11.3%	10.0% - 12.7%	9.5%	33.0%	0.1%	53.6%	3.7%
Office visits - established	$560,692,977	5.7%	5.3% - 6.1%	6.3%	13.8%	1.3%	78.2%	0.4%
Consultations	$526,846,262	16.2%	14.7% - 17.7%	1.5%	10.3%	0.6%	86.9%	0.7%
Other drugs	$419,233,745	8.1%	2.7% - 13.5%	91.8%	3.0%	0.3%	4.9%	0.0%
All Other Codes	$346,383,361	1.2%	0.9% - 1.4%	25.1%	44.9%	4.2%	22.6%	3.3%
Minor procedures - other (Medicare fee schedule)	$181,008,293	7.0%	5.4% - 8.6%	10.2%	64.4%	13.4%	8.2%	3.8%
Hospital visit - initial	$166,663,414	14.5%	11.9% - 17.0%	5.4%	15.3%	0.0%	75.3%	4.0%
Office visits - new	$156,907,935	14.5%	12.3% - 16.6%	0.0%	2.3%	0.2%	96.9%	0.5%
Nursing home visit	$132,513,058	12.5%	10.6% - 14.3%	13.9%	16.3%	0.8%	68.9%	0.0%
Ambulance	$71,766,323	1.9%	1.0% - 2.8%	15.7%	31.0%	31.3%	21.5%	0.5%
Emergency room visit	$65,347,361	4.5%	3.2% - 5.8%	11.6%	15.7%	0.0%	72.0%	0.7%
Hospital visit - critical care	$59,111,799	7.8%	2.5% - 13.1%	10.2%	27.7%	0.0%	62.0%	0.0%
Chiropractic	$57,704,328	10.6%	7.8% - 13.3%	1.6%	50.8%	27.0%	19.1%	1.4%
Other tests - other	$49,321,081	3.8%	1.5% - 6.0%	25.2%	65.4%	0.0%	7.5%	1.9%
Ambulatory procedures - other	$48,253,791	5.7%	0.7% - 10.8%	72.8%	3.8%	1.1%	21.6%	0.7%
Lab tests - other (non-Medicare fee schedule)	$36,402,299	1.8%	1.0% - 2.6%	27.2%	34.6%	11.4%	20.5%	6.3%
Standard imaging - nuclear medicine	$25,870,344	1.5%	(0.9%) - 3.8%	83.0%	8.4%	0.0%	8.6%	0.0%
Oncology - radiation therapy	$25,327,359	1.9%	(0.4%) - 4.3%	0.0%	89.5%	0.0%	10.5%	0.0%
Specialist - opthamology	$24,910,618	1.2%	0.6% - 1.8%	27.5%	53.3%	0.0%	19.2%	0.0%
Specialist - other	$19,926,260	12.3%	5.3% - 19.3%	1.4%	31.9%	3.8%	63.0%	0.0%
Imaging/procedure - other	$17,996,131	4.9%	1.2% - 8.6%	44.8%	14.8%	17.1%	23.2%	0.0%
All Type of Services (Incl. Codes Not Listed)	**$3,558,352,057**	**4.8%**	**4.3% - 5.2%**	**20.7%**	**23.2%**	**2.8%**	**51.7%**	**1.6%**

Table 9b: Top 20 Service Types with Highest Improper Payments: DMERCs and DME MACs

Sort This Table

Service Type Billed to DMERCs (SADMERC Policy Group)	Projected Improper Payment	Paid Claims Error Rate	95% Confidence Interval	Type of Error				
				No Documentation	Insufficient Documentation	Medically Unnecessary Services	Incorrect Coding	Other

All Policy Groups with Less than 30 Claims	$228,032,498	15.4%	4.6% - 26.1%	54.2%	0.0%	44.2%	1.6%	0.0%
Nebulizers & Related Drugs	$167,572,569	15.3%	8.2% - 22.5%	60.5%	0.5%	23.5%	15.4%	0.1%
Negative Pressure Wound Therapy	$125,678,545	50.4%	27.5% - 73.3%	100.0%	0.0%	0.0%	0.0%	0.0%
Glucose Monitor	$114,464,254	9.5%	7.9% - 11.0%	10.2%	2.0%	76.2%	10.7%	1.0%
Enteral Nutrition	$109,383,911	18.9%	7.7% - 30.0%	77.3%	0.0%	15.6%	7.2%	0.0%
Support Surfaces	$33,855,619	20.1%	6.2% - 34.0%	99.8%	0.0%	0.2%	0.0%	0.0%
CPAP	$31,149,480	7.7%	4.1% - 11.3%	24.0%	20.3%	52.7%	1.3%	1.7%
Lower Limb Orthoses	$28,829,394	13.3%	0.4% - 26.2%	96.0%	0.0%	4.0%	0.0%	0.0%
Oxygen Supplies/Equipment	$27,376,887	1.3%	0.8% - 1.8%	25.6%	0.0%	59.2%	12.4%	2.7%
Wheelchairs Options/Accessories	$27,314,967	12.0%	(3.9%) - 27.9%	5.7%	0.5%	31.3%	0.4%	62.1%
All Other Codes	$22,024,283	3.0%	1.6% - 4.3%	32.3%	0.6%	55.2%	4.8%	7.1%
Wheelchairs Manual	$15,274,364	6.2%	3.9% - 8.4%	1.7%	3.2%	63.5%	23.5%	8.1%
Suction Pump	$14,458,892	53.1%	10.8% - 95.5%	87.5%	0.0%	12.5%	0.0%	0.0%
Immunosuppressive Drugs	$12,740,563	3.0%	0.4% - 5.6%	0.0%	0.0%	78.1%	0.0%	21.9%
Ostomy Supplies	$11,453,618	7.8%	0.5% - 15.0%	21.6%	0.0%	74.0%	4.4%	0.0%
Spinal Orthoses	$9,908,724	13.3%	(2.3%) - 28.9%	98.7%	0.0%	1.3%	0.0%	0.0%
Surgical Dressings	$9,827,558	10.8%	(1.7%) - 23.4%	89.3%	0.3%	10.4%	0.0%	0.0%
Diabetic Shoes	$8,198,843	4.9%	0.8% - 9.0%	10.9%	13.4%	52.6%	23.2%	0.0%
Respiratory Assist Device	$6,283,663	7.1%	0.5% - 13.7%	77.8%	0.0%	22.2%	0.0%	0.0%
Lenses	$5,909,435	8.7%	2.2% - 15.1%	5.6%	21.9%	68.5%	4.1%	0.0%
Upper Limb Orthoses	$5,894,418	14.2%	0.5% - 28.0%	93.4%	0.0%	6.6%	0.0%	0.0%
All Type of Services (Incl. Codes Not Listed)	**$1,015,632,486**	**10.3%**	**8.1% - 12.5%**	**56.8%**	**1.2%**	**33.5%**	**6.0%**	**2.5%**

Table 9c: Top 20 Service Types with Highest Improper Payments: FIs and MACs

Sort This Table

Service Type Billed to FIs (Type of Bill)	Projected Improper Payment	Paid Claims Error Rate	95% Confidence Interval	Type of Error				
				No Documentation	Insufficient Documentation	Medically Unnecessary Services	Incorrect Coding	Other
OPPS, Laboratory (an FI), Ambulatory (Billing an FI)	$421,368,707	1.7%	1.4% - 2.0%	5.6%	45.9%	9.3%	32.6%	6.6%
SNF	$363,049,661	1.6%	1.0% - 2.2%	2.3%	17.9%	12.7%	66.2%	0.9%
HHA	$203,642,462	1.4%	0.7% - 2.1%	0.0%	7.8%	55.8%	36.4%	0.0%
Other FI Service Types	$102,605,352	1.9%	1.0% - 2.9%	15.4%	23.6%	8.7%	49.3%	2.9%
			0.4% -					

Hospice	$90,422,892	1.0%	1.6%	9.1%	7.3%	44.5%	19.3%	19.9%
ESRD	$82,764,933	1.2%	0.3% - 2.1%	0.0%	63.3%	0.5%	36.1%	0.1%
Non-PPS Hospital In-patient	$35,359,132	0.7%	0.3% - 1.1%	2.4%	20.7%	0.4%	60.1%	16.5%
FQHC	$6,550,678	1.5%	0.5% - 2.5%	29.8%	70.2%	0.0%	0.0%	0.0%
RHCs	$3,310,678	0.6%	0.3% - 0.9%	31.6%	54.8%	0.0%	0.0%	13.6%
Free Standing Ambulatory Surgery	$788,627	0.2%	(0.1%) - 0.4%	0.0%	87.9%	0.0%	12.1%	0.0%
All Type of Services (Incl. Codes Not Listed)	**$1,309,863,123**	**1.5%**	**1.2% - 1.7%**	**4.6%**	**28.4%**	**19.0%**	**43.6%**	**4.4%**

Table 9d: Top 20 Service Types with Highest Improper Payments: QIOs

Sort This Table

Service Types for Which QIOs are Responsible (DRG)	Projected Improper Payment	Paid Claims Error Rate	95% Confidence Interval	Type of Error				
				No Documentation	Insufficient Documentation	Medically Unnecessary Services	Incorrect Coding	Other
CAR DEFIBRILLATOR IMPL W/O CAR CATH (515)	$204,177,351	11.3%	3.5% - 19.1%	0.0%	N/A	71.3%	11.1%	17.7%
ESOPH, GASTROENT & MISC DIG DISOR AGE >17 W CC (182)	$187,866,936	13.6%	10.4% - 16.8%	0.0%	N/A	87.4%	6.8%	5.8%
NUTR & MISC METAB DISOR AGE >17 W CC (296)	$140,453,656	15.1%	10.7% - 19.6%	13.5%	N/A	70.7%	14.6%	1.3%
CHEST PAIN (143)	$131,369,679	22.3%	17.4% - 27.2%	3.9%	N/A	90.0%	3.9%	2.2%
RENAL FAILURE (316)	$130,481,892	7.7%	5.1% - 10.2%	1.4%	N/A	63.5%	32.2%	2.9%
EXT OR PROC UNREL TO PRINC DIAG (468)	$100,766,418	8.2%	0.7% - 15.6%	25.6%	N/A	38.8%	35.7%	0.0%
HEART FAILURE & SHOCK (127)	$89,539,751	2.6%	1.5% - 3.6%	10.7%	N/A	53.0%	19.0%	17.3%
PERM CAR PACER IMPL W MAJ CV DX/AICD LEAD/GNRTR (551)	$85,870,116	9.3%	3.4% - 15.3%	5.9%	N/A	38.4%	54.0%	1.7%
SEPTICEMIA AGE >17 (416)	$73,456,343	3.2%	1.7% - 4.7%	7.2%	N/A	9.2%	83.0%	0.7%
MEDICAL BACK PROB (243)	$71,958,957	19.0%	12.4% - 25.6%	6.1%	N/A	81.8%	10.3%	1.8%
MAJ JNT REPLACE/REATTACH - LO EXTREM (544)	$70,029,794	1.5%	0.6% - 2.4%	17.7%	N/A	78.7%	1.1%	2.5%
KIDNEY & URIN TRACT INFECT AGE >17 W CC (320)	$66,733,368	6.5%	3.5% - 9.6%	0.3%	N/A	63.2%	33.7%	2.9%
OTH PERM CAR PACER IMPL W/O MAJ CV DX (552)	$66,527,926	7.3%	2.6% - 12.1%	0.0%	N/A	49.6%	34.9%	15.5%
OTH VAS PROC W CC W/O MAJ CV DX (554)	$64,803,227	6.9%	1.3% - 12.6%	0.0%	N/A	79.4%	18.7%	1.9%
PERCU CARDIOVAS PROC W DRUG-ELUT STENT W/O MAJ CV DX (558)	$64,660,050	3.0%	1.3% - 4.7%	2.6%	N/A	51.6%	37.7%	8.1%
CIRC DISOR EXC								

AMI, W CAR CATH & COMPL DIAG (124)	$59,347,270	6.9%	(0.2%) - 14.0%	0.0%	N/A	28.4%	67.0%	4.6%
OTH KIDNEY & URIN TRACT PROC (315)	$58,984,717	13.1%	1.5% - 24.7%	0.0%	N/A	30.2%	36.1%	33.7%
CHRON OBSTRUCTIVE PULM DIS (088)	$57,928,635	3.4%	2.0% - 4.9%	6.4%	N/A	56.1%	32.7%	4.8%
SIMP PNEUM & PLEURISY AGE >17 W CC (089)	$54,467,501	2.2%	1.0% - 3.4%	17.3%	N/A	8.8%	72.0%	2.0%
CIRC DISOR EXC AMI, W CAR CATH W/O COMPL DIAG (125)	$54,361,687	11.6%	5.7% - 17.6%	0.6%	N/A	84.2%	6.8%	8.4%
All HPMP	**$4,947,855,592**	**4.8%**	**4.5% - 5.2%**	**4.7%**	**N/A**	**58.0%**	**31.5%**	**5.8%**

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Paid Claim Error Rates by Provider Type

The table 10 series presents error rates by provider type. The tables include the top provider types based on improper payments for providers that bill each type of contractor. All estimates are based on a minimum of 30 lines in the sample. This series of tables is sorted in descending order by projected improper payments.

The CERT program is unable to calculate provider compliance error rates for FIs due to systems limitations.

Table 10a: Error Rates and Improper Payments by Provider Type: Carriers and MACs

Sort This Table

Provider Types Billing to Carriers	Paid Claims Error Rate				Provider Compliance Error Rate
	Error Rate	Projected Improper Payment Amount	Standard Error	95% Confidence Interval	
Internal Medicine	8.0%	$650,913,480	0.7%	6.7% - 9.4%	18.6%
Cardiology	4.6%	$292,056,119	0.5%	3.6% - 5.5%	19.5%
Family Practice	6.8%	$276,763,500	0.5%	5.8% - 7.8%	17.4%
General Practice	27.3%	$239,798,804	6.4%	14.8% - 39.8%	41.7%
Orthopedic Surgery	5.4%	$163,421,204	1.0%	3.4% - 7.4%	15.3%
Obstetrics/Gynecology	23.6%	$161,999,147	14.6%	(5.1%) - 52.3%	28.7%
Gastroenterology	8.4%	$118,560,416	1.1%	6.1% - 10.6%	17.3%
General Surgery	6.3%	$113,738,940	1.2%	4.0% - 8.6%	22.7%
Pulmonary Disease	7.1%	$107,941,782	0.9%	5.3% - 8.9%	15.7%
Neurology	8.8%	$92,896,999	1.3%	6.3% - 11.4%	26.6%
Hematology/Oncology	2.1%	$81,950,560	0.4%	1.2% - 2.9%	8.8%
Nephrology	5.8%	$77,958,485	0.9%	4.1% - 7.5%	14.9%
Urology	3.8%	$74,654,876	0.8%	2.2% - 5.5%	9.9%
Ambulance Service Supplier (e.g., private ambulance companies, funeral homes)	1.9%	$71,766,323	0.5%	1.0% - 2.8%	9.8%
Ophthalmology	1.6%	$70,602,966	0.4%	0.9% - 2.4%	9.8%
Psychiatry	8.9%	$70,413,523	1.6%	5.7% - 12.1%	18.8%

Physical Therapist in Private Practice	6.2%	$63,633,089	1.1%	4.2% - 8.3%	15.5%
Chiropractic	10.4%	$60,348,512	1.3%	7.8% - 13.1%	27.9%
Emergency Medicine	4.1%	$60,201,610	0.7%	2.8% - 5.4%	13.4%
Diagnostic Radiology	1.3%	$56,228,728	0.3%	0.6% - 2.0%	9.5%
Physical Medicine and Rehabilitation	7.7%	$53,337,061	1.6%	4.6% - 10.9%	16.1%
Clinical Laboratory (Billing Independently)	1.4%	$39,319,877	0.3%	0.8% - 2.1%	8.1%
Infectious Disease	11.0%	$38,063,145	2.1%	6.8% - 15.1%	27.0%
Podiatry	3.0%	$36,695,863	0.5%	2.1% - 3.8%	16.2%
Nurse Practitioner	6.4%	$36,334,958	1.5%	3.5% - 9.3%	15.4%
Otolaryngology	5.0%	$35,492,764	0.8%	3.3% - 6.6%	13.9%
Radiation Oncology	2.6%	$34,754,227	1.3%	(0.0%) - 5.2%	9.9%
Neurosurgery	9.5%	$32,679,218	4.3%	1.1% - 17.9%	17.6%
Thoracic Surgery	9.9%	$29,733,199	8.0%	(5.7%) - 25.6%	10.7%
Rheumatology	4.0%	$26,485,248	1.1%	1.8% - 6.2%	9.4%
Endocrinology	8.3%	$24,966,266	1.9%	4.5% - 12.2%	13.4%
Anesthesiology	1.7%	$21,651,417	0.6%	0.5% - 2.9%	10.1%
Dermatology	1.3%	$21,301,200	0.3%	0.7% - 1.9%	7.6%
Geriatric Medicine	14.8%	$20,900,776	5.2%	4.6% - 24.9%	20.5%
Hematology	11.0%	$18,810,115	8.7%	(6.0%) - 27.9%	15.4%
Optometry	3.3%	$18,713,784	0.9%	1.4% - 5.1%	14.8%
Vascular Surgery	4.8%	$17,353,366	1.8%	1.2% - 8.4%	15.1%
Occupational Therapist in Private Practice	19.4%	$15,201,952	5.2%	9.2% - 29.6%	28.6%
Medical Oncology	1.0%	$15,126,484	0.3%	0.4% - 1.7%	9.1%
Allergy/Immunology	11.0%	$13,251,138	4.5%	2.2% - 19.7%	24.5%
Critical Care (Intensivists)	7.3%	$13,130,857	2.6%	2.3% - 12.4%	24.9%
All Provider Types With Less Than 30 Claims	2.0%	$11,986,201	1.0%	0.0% - 4.0%	4.6%
Physician Assistant	3.1%	$11,904,616	0.8%	1.6% - 4.7%	13.6%
Plastic and Reconstructive Surgery	6.3%	$11,635,795	1.7%	3.0% - 9.6%	13.5%
Independent Diagnostic Testing Facility (IDTF)	0.9%	$9,794,111	0.5%	(0.1%) - 1.8%	14.3%
Pathology	1.1%	$9,308,693	0.5%	0.1% - 2.1%	13.7%
Colorectal Surgery (formerly proctology)	5.0%	$6,537,647	1.6%	1.7% - 8.2%	12.3%
Cardiac Surgery	1.9%	$6,429,696	0.8%	0.5% - 3.4%	13.0%
Pain Management	4.5%	$6,403,957	1.7%	1.2% - 7.9%	28.4%
Clinical Psychologist	2.3%	$5,425,419	0.7%	1.0% - 3.7%	19.7%
Pediatric Medicine	8.6%	$4,174,792	6.0%	(3.2%) - 20.4%	21.3%
Interventional Pain Management	3.2%	$2,615,181	2.0%	(0.8%) - 7.2%	17.1%
Nuclear Medicine	1.0%	$1,175,630	0.5%	0.0% - 2.1%	2.4%
Osteopathic Manipulative Therapy	2.7%	$990,090	1.0%	0.8% - 4.7%	12.5%
Portable X-Ray Supplier (Billing Independently)	0.2%	$450,229	0.2%	(0.2%) - 0.6%	10.0%
Clinical Social Worker	0.2%	$252,318	0.1%	(0.1%) - 0.4%	9.2%
Multispecialty Clinic or Group Practice	0.5%	$86,742	0.6%	(0.6%) - 1.6%	4.8%

Clinical Nurse Specialist	0.1%	$28,961	0.1%	(0.1%) - 0.3%	36.9%
Ambulatory Surgical Center	0.0%	$0	0.0%	0.0% - 0.0%	17.7%
Certified Registered Nurse Anesthetist (CRNA)	0.0%	$0	0.0%	0.0% - 0.0%	6.3%
Interventional Radiology	0.0%	$0	0.0%	0.0% - 0.0%	4.3%
Mass Immunization Roster Billers (Mass Immunizers have to roster bill assigned claims and can only bill for immunizations)	0.0%	$0	0.0%	0.0% - 0.0%	9.3%
Public Health or Welfare Agencies (Federal, State, and local)	0.0%	$0	0.0%	0.0% - 0.0%	6.2%
All Provider Types	**4.8%**	**$3,558,352,057**	**0.2%**	**4.3% - 5.2%**	**14.9%**

Table 10b: Error Rates and Improper Payments by Provider Type: DMERCs and DME MACs

Sort This Table

Provider Types Billing to DMERCs	Paid Claims Error Rate				Provider Compliance Error Rate
	Error Rate	Projected Improper Payment Amount	Standard Error	95% Confidence Interval	
Medical supply company not included in 51, 52, or 53	13.4%	$534,238,701	2.0%	9.5% - 17.3%	23.7%
Pharmacy	9.1%	$354,689,730	1.5%	6.1% - 12.0%	17.9%
Unknown Supplier/Provider	51.1%	$48,289,228	22.0%	7.9% - 94.3%	49.5%
All Provider Types With Less Than 30 Claims	19.5%	$42,315,763	8.7%	2.5% - 36.5%	22.0%
Medical Supply Company with Respiratory Therapist	2.9%	$25,017,017	0.6%	1.7% - 4.2%	9.6%
Medical supply company with orthotic personnel certified by an accrediting organization	1.5%	$4,226,468	1.3%	(1.1%) - 4.1%	5.5%
Podiatry	2.2%	$1,991,027	1.6%	(1.0%) - 5.4%	12.2%
Individual orthotic personnel certified by an accrediting organization	1.1%	$1,898,139	1.2%	(1.2%) - 3.5%	6.7%
Individual prosthetic personnel certified by an accrediting organization	0.9%	$1,202,387	0.7%	(0.4%) - 2.2%	4.5%
Ophthalmology	3.3%	$779,456	2.4%	(1.4%) - 8.1%	18.3%
Medical supply company with prosthetic/orthotic personnel certified by an accrediting organization	0.6%	$467,317	0.5%	(0.4%) - 1.7%	12.6%
Orthopedic Surgery	1.1%	$276,990	1.1%	(1.1%) - 3.3%	2.8%
Optometry	1.2%	$240,262	1.2%	(1.2%) - 3.6%	8.8%
All Provider Types	**10.3%**	**$1,015,632,486**	**1.1%**	**8.1% - 12.5%**	**19.2%**

Table 10c: Error Rates and Improper Payments by Provider Type: FIs and MACs

Sort This Table

Provider Types Billing to FIs	Paid Claims Error Rate			
	Error Rate	Projected Improper Payment Amount	Standard Error	95% Confidence Interval
OPPS, Laboratory (an FI), Ambulatory (Billing an FI)	1.7%	421,368,707	0.2%	1.4% - 2.0%
SNF	1.6%	363,049,661	0.3%	1.0% - 2.2%
HHA	1.4%	203,642,462	0.4%	0.7% - 2.1%
Other FI Service Types	1.9%	102,605,352	0.5%	1.0% - 2.9%
Hospice	1.0%	90,422,892	0.3%	0.4% - 1.6%
ESRD	1.2%	82,764,933	0.4%	0.3% - 2.1%
Non-PPS Hospital In-patient	0.7%	35,359,132	0.2%	0.3% - 1.1%
FQHC	1.5%	6,550,678	0.5%	0.5% - 2.5%

RHCs	0.6%	3,310,678	0.2%	0.3% - 0.9%
Free Standing Ambulatory Surgery	0.2%	788,627	0.1%	(0.1%) - 0.4%
Overall	**1.5%**	**1,309,863,123**	**0.1%**	**1.2% - 1.7%**

Table 10d: Error Rates and Improper Payments by Provider Type: QIOs

Sort This Table

Provider Types for Which QIOs are Responsible	Paid Claims Error Rate			
	Error Rate	Projected Improper Payments	Standard Error	95% Confidence Interval
Short-term Acute Paid Claims	4.8%	$4,736,107,139	0.2%	4.5% - 5.2%
Long-term Acute Paid Claims	4.8%	$202,506,834	0.5%	3.8% - 5.7%
Denied Claims	N/A	$9,241,619	N/A	N/A
Total	**4.8%**	**$4,947,855,592**	**0.2%**	**4.5% - 5.2%**

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2. Some columns and/or rows may not sum correctly due to rounding.
3. The 2003 entries were adjusted to account for high non-response rates. Including non-response, the national projected improper payments would have been $21.5B and the national paid claims error rate would have been 10.8%.
4. The 2003 entries were adjusted to account for high non-response rates. Including non-response, the national projected improper payments would have been $21.5B and the national paid claims error rate would have been 10.8%.
5. Some columns and/or rows may not sum correctly due to rounding.
6. Due to the extremely low insufficient documentation error rate for QIOs, any insufficient documentation errors have been added to the no documenation rate rather than the insufficient documentation category.
7. Some columns and/or rows may not sum correctly due to rounding.
8. Due to the extremely low insufficient documentation error rate for QIOs, any insufficient documentation errors have been added to the no documenation rate rather than the insufficient documentation category.
9. Some columns and/or rows may not sum correctly due to rounding.
10. Some columns and/or rows may not sum correctly due to rounding.
11. Some columns and/or rows may not sum correctly due to rounding.
12. Some columns and/or rows may not sum correctly due to rounding.
13. Due to the extremely low insufficient documentation error rate for QIOs, any insufficient documentation errors have been added to the no documenation rate rather than the insufficient documentation category.

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Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

MMA - Assignment of Physicians, Providers, and Suppliers to the Medicare Administrative Contractors (MACs)

Provider Types Affected

Providers, physicians and suppliers who bill Medicare contractors (fiscal intermediaries (FIs) including regional home health intermediaries (RHHIs), and carriers, including durable medical equipment regional carriers (DMERCs)) for their services

Key Points

The Centers for Medicare & Medicaid Services (CMS) is implementing significant changes to the Medicare fee-for-service program's administrative structure. This Medicare Contracting Reform (MCR) will:

- Integrate and simplify the administration of Medicare Parts A and B with primary A/B MACs which will process both Part A and Part B claims for the fee-for-service benefit;
- Make contracting dynamic, competitive and performance-based, resulting in more accurate claims payments and greater consistency in payment decisions; and
- Centralize information, creating a platform for advances in the delivery of comprehensive care.

Under MCR, there will be 23 Medicare Administrative Contractors (MACs) with no national MAC. These new MACs will include:

- Fifteen primary A/B MACs to serve the majority of all types of providers for Part A and Part B;
- Four specialty MACs to serve home health and hospice providers; and
- Four specialty MACs to serve durable medical equipment (DME) suppliers.

Disclaimer
This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

MACs will serve as the primary point of contact for provider enrollment, Medicare coverage and billing requirements training for providers, and the receipt, processing and payment of Medicare fee-for-service claims for Medicare providers' respective jurisdictions.

Medicare providers will be assigned to the local designated MAC based on their geographic location to the MAC which has jurisdiction for that benefit category and location.

Note: Please be aware that in the event that your current FI does not win the contract to serve the area where you are located, you will be required to be reassigned to the MAC that has won the jurisdiction for your area.

The new MAC jurisdictions will be more similar to each other in size than the existing fiscal intermediary (FI) and carrier jurisdictions. The workload allocation and the number of fee-for-service beneficiaries and providers in each MAC jurisdiction will be reasonably balanced. The jurisdictions of the eight specialty MACs will overlay the boundaries of the fifteen primary A/B MAC jurisdictions.

Background

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173) allows the CMS to take appropriate steps to transition from agreements under Section 1816 of the Social Security Act to contracts with Medicare Administrative Contractors (MACs) under section 1874A. The changes to Medicare's administration are designed to increase the efficiency of Medicare's claims processing and related functions. They will benefit Medicare providers and Medicare's enrollee population.

Additional Information

During the initial implementation phase (2005-2011) of the Medicare fee-for-service administrative contracting reform, CMS intends to issue Requests for Proposals (RFPs) to compete and award contracts for 23 MACs (four DME and four Home Health/Hospice MACs, and 15 primary A/B MACs).

The transition to the MAC administrative structure will be implemented through a series of acquisition cycles (9-12 months from solicitation to award). The subsequent workload transition to the new MAC system is projected to take 6-13 months after contract award.

Disclaimer
This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

Medicare's MAC Jurisdictions

Jurisdiction	States Included in Jurisdiction	Procurement Schedule	
	Specialty MAC Jurisdictions (DME and Home Health/Hospice)	RFP Issuance	Award Date
A	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont	DME March 2005 Home Health/ Hospice Sept. 2007	DME Jan. 2006 Home Health/ Hospice Sept. 2008
B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin		
C	Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virginia, and West Virginia		
D	Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Northern Mariana Islands, Oregon, South Dakota, Utah, Washington, and Wyoming		
Jurisdiction	Primary A/B MAC Jurisdictions	RFP Issuance	Award Date
1	American Samoa, California, Guam, Hawaii, Nevada, and Northern Mariana Islands	Sept. 2006	Sept. 2007
2	Alaska, Idaho, Oregon, and Washington	Sept. 2006	Sept. 2007
3	Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming	Sept. 2005	June 2006
4	Colorado, New Mexico, Oklahoma, and Texas	Sept. 2006	Sept. 2007
5	Iowa, Kansas, Missouri, and Nebraska	Sept. 2006	Sept. 2007
6	Illinois, Minnesota, and Wisconsin	Sept. 2007	Sept. 2008
7	Arkansas, Louisiana, and Mississippi	Sept. 2006	Sept. 2007
8	Indiana and Michigan	Sept. 2007	Sept. 2008
9	Florida, Puerto Rico, and U.S. Virgin Islands	Sept. 2007	Sept. 2008
10	Alabama, Georgia, and Tennessee	Sept. 2007	Sept. 2008
11	North Carolina, South Carolina, Virginia and West Virginia	Sept. 2007	Sept. 2008
12	Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania	Sept. 2006	Sept. 2007
13	Connecticut and New York	Sept. 2006	Sept. 2007
14	Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	Sept. 2007	Sept. 2008
15	Kentucky and Ohio	Sept. 2007	Sept. 2008

Disclaimer
This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

For additional information about the MCR process, please refer to http://www.cms.hhs.gov/MedicareContractingReform/ on the CMS web site.

CR4002, transmittal 670, *Realignment of States and Medicare Claims Processing Workload from DMERC Regions A, B, C and D to the DME MAC Jurisdictions A, B, C, and D* discusses phase 1 of the MAC acquisition and transition schedule. It can be found at http://www.cms.hhs.gov/transmittals/downloads/R670CP.pdf on the CMS web site.

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Benefit Description	You Pay After the calendar year deductible...
Chiropractic	
Chiropractic treatment limited to 12 visits and/or manipulations per year	PPO: $18 copayment (No deductible) Non-PPO: 30% of the Plan allowance and any difference between our allowance and the billed amount
Alternative treatments	
Acupuncture – by a doctor of medicine or osteopathy	PPO: $18 copayment (No deductible) Non-PPO: 30% of the Plan allowance and any difference between our allowance and the billed amount
Not covered: • *Services of any provider not listed as covered; see Covered providers on page 9* *Note: Benefits of certain alternative treatment providers may be covered in medically underserved areas; see page 9.*	*All charges*
Educational classes and programs	
Coverage is limited to: • Smoking Cessation – Up to $100 for one smoking cessation program per member per lifetime	PPO: All charges above the $100 lifetime maximum Non-PPO: All charges above the $100 lifetime maximum

Benefit Description	You Pay	
Home health services (cont.)	**Standard Option**	**Basic Option**
• *Services provided by a nurse, nursing assistant, health aide, or other similarly licensed or unlicensed person that are billed by a skilled nursing facility, extended care facility, or nursing home,* ***except*** *as included in the benefits described on page 69*	*All charges*	*All charges*
Chiropractic	**Standard Option**	**Basic Option**
• Initial office visit • Spinal manipulations • Initial set of X-rays ***Note:*** Benefits may be available for other covered services you receive from chiropractors in medically underserved areas. See page 11 for additional information.	Preferred: $15 copayment per visit (No deductible) Participating: 25% of the Plan allowance Non-participating: 25% of the Plan allowance, plus any difference between our allowance and the billed amount ***Note:*** Benefits are limited to 12 manipulations per calendar year. ***Note:*** Visits that you pay for while meeting your calendar year deductible count toward the limit cited above.	Preferred: $20 copayment per visit ***Note:*** Benefits are limited to 20 manipulations per calendar year. Participating/Non-participating: You pay all charges
Alternative treatments	**Standard Option**	**Basic Option**
Acupuncture ***Note:*** See page 61 for our coverage of acupuncture when provided as anesthesia for covered surgery. ***Note:*** See page 34 for our coverage of acupuncture when provided as anesthesia for covered maternity care. ***Note:*** We may also cover services of certain alternative treatment providers in medically underserved areas. See page 11 for additional information.	Preferred: 10% of the Plan allowance Participating: 25% of the Plan allowance Non-participating: 25% of the Plan allowance, plus any difference between our allowance and the billed amount ***Note:*** Acupuncture must be performed and billed by a physician or licensed acupuncturist. ***Note:*** Benefits for acupuncture are limited to 24 visits per calendar year. ***Note:*** Visits that you pay for while meeting your calendar year deductible count toward the limit cited above.	Preferred primary care physician: $20 copayment per visit Preferred physician specialist: $30 copayment per visit ***Note:*** You pay 30% of the Plan allowance for drugs and supplies. ***Note:*** Acupuncture must be performed and billed by a physician. Participating/Non-participating: You pay all charges
Not covered:	*All charges*	*All charges*

Alternative treatments - continued on next page

Benefits Description	You pay After the calendar year deductible...	
Chiropractic	**High Option**	**Standard Option**
Chiropractic services limited to: • 12 visits per calendar year for manipulation of the spine • X-rays, used to detect and determine nerve interferences due to spinal subluxations or misalignments • $25 per calendar year for chiropractic X-rays Note: No other benefits for the services of a chiropractor are covered under any other provision of this Plan. In medically underserved areas, services of a chiropractor that are listed above are subject to the stated limitations. In medically underserved areas, services of a chiropractor that are within the scope of his/her license and are not listed above are eligible for regular Plan benefits.	PPO and Non-PPO: All charges in excess of $20 per visit All charges in excess of $25 for X-rays of the spine Note: Visits and charges exceeding these amounts are not applied toward the calendar year deductible.	PPO and Non-PPO: All charges in excess of $20 per visit All charges in excess of $25 for X-rays of the spine Note: Visits and charges exceeding these amounts are not applied toward the calendar year deductible.
Not covered: • *Any treatment not specifically listed as covered* • *Adjunctive procedures such as ultrasound, electrical muscle stimulation, vibratory therapy, and cold pack application*	*All charges*	*All charges*
Alternative treatments	**High Option**	**Standard Option**
Acupuncture: Benefits are limited to 20 procedures per calendar year for medically necessary acupuncture treatments if performed by a Medical Doctor (M.D.) or Doctor of Osteopathy (D.O.)	PPO: 10% of the Plan allowance Non-PPO: 25% of the Plan allowance and any difference between our allowance and the billed amount	PPO: 15% of the Plan allowance Non-PPO: 35% of the Plan allowance and any difference between our allowance and the billed amount
Not covered: • *All other alternative treatments, including clinical ecology and environmental medicine* • *Any treatment not specifically listed as covered* • *Naturopathic services* *(Note: Benefits of certain alternative treatment providers may be covered in medically underserved areas; see page 10.)*	*All charges*	*All charges*
Educational classes and programs	**High Option**	**Standard Option**
Coverage is limited to: • Smoking Cessation – Up to $100 to aid in smoking cessation, per person, per lifetime, including related expenses such as drugs	PPO: All charges in excess of $100 Non-PPO: All charges in excess of $100	PPO: All charges in excess of $100 Non-PPO: All charges in excess of $100

Benefits Description	You pay After the calendar year deductible…
Chiropractic	
Chiropractic services limited to: • 12 visits per calendar year for manipulation of the spine • X-rays, used to detect and determine nerve interferences due to spinal subluxations or misalignments • $25 per calendar year for chiropractic X-rays Note: No other benefits for the services of a chiropractor are covered under any other provision of this Plan. In medically underserved areas, services of a chiropractor that are listed above are subject to the stated limitations. In medically underserved areas, services of a chiropractor that are within the scope of his/her license and are not listed above are eligible for regular Plan benefits.	PPO and Non-PPO All charges in excess of $20 per visit All charges in excess of $25 for X-rays of the spine Note: Visits and charges exceeding these amounts are not applied toward the calendar year deductible.
Not covered: • *Any treatment not specifically listed as covered* • *Adjunctive procedures such as ultrasound, electrical muscle stimulation, vibratory therapy, and cold pack application*	*All charges*
Alternative treatments	
Acupuncture: Benefits are limited to 20 procedures per calendar year for medically necessary acupuncture treatments if performed by a Medical Doctor (M.D.) or Doctor of Osteopathy (D.O.)	PPO: 5% of the Plan allowance Non-PPO: 25% of the Plan allowance and any difference between our allowance and the billed amount
Not covered: • *All other alternative treatments, including clinical ecology and environmental medicine* • *Any treatment not specifically listed as covered* • *Naturopathic services* *(Note: Benefits of certain alternative treatment providers may be covered in medically underserved areas; see page 11.)*	*All charges*
Educational classes and programs	
Coverage is limited to: • Smoking Cessation – Up to $100 to aid in smoking cessation, per person, per lifetime, including related expenses such as drugs	PPO: All charges in excess of $100 Non-PPO: All charges in excess of $100

Benefit Description	You pay After the calendar year deductible...	
Rehabilitative therapies	**Standard Option**	**Value Option**
Outpatient physical therapy, speech therapy, and occupational therapy Note: The annual $2,500 combined rehabilitative, chiropractic and alternative therapies maximum includes all covered services and supplies billed for these therapies. Note: For the purposes of this benefit, services and supplies provided by a doctor of osteopathy (D.O.) are included in the $2,500 benefit maximum. Note: Medically necessary outpatient physical or occupational therapy provided in a skilled nursing facility (SNF) is covered under this benefit if you are not confined in the SNF.	PPO: 10% of the Plan's allowance and all charges after the Plan has paid the $2,500 combined rehabilitative, chiropractic and alternative treatment therapy maximum Non-PPO: 30% of the Plan's allowance and any difference between our allowance and the billed amount. All charges after the Plan has paid the $2,500 combined rehabilitative, chiropractic and alternative treatment therapy maximum	PPO: 20% of the Plan's allowance and all charges after the Plan has paid the $2,500 combined rehabilitative, chiropractic and alternative treatment therapy maximum Non-PPO: 40% of the Plan's allowance and any difference between our allowance and the billed amount. All charges after the Plan has paid the $2,500 combined rehabilitative, chiropractic and alternative treatment therapy maximum
Not covered: • *All charges after the Plan has paid the annual $2,500 rehabilitative, chiropractic and alternative treatment therapies maximum* • *Exercise programs* • *Outpatient pulmonary rehabilitation* • *Outpatient cardiac rehabilitation programs* • *Massage therapy*	*All charges*	*All charges*
Hearing services (testing, equipment, and supplies)	**Standard Option**	**Value Option**
Hearing aids – one hearing aid and related services per ear per calendar year. Note: The calendar year deductible applies.	All charges over $200 for one hearing aid per ear	All charges over $200 for one hearing aid per ear
Hearing testing • Routine testing – one per calendar year • Non-routine testing Note: The calendar year deductible applies.	PPO: 10% of the Plan's allowance Non-PPO: 30% of the Plan's allowance and any difference between our allowance and the billed amount	PPO: 20% of the Plan's allowance Non-PPO: 40% of the Plan's allowance and any difference between our allowance and the billed amount
Not covered: • All charges after the Plan has paid the annual $200 per ear hearing aid maximum • Replacement batteries, service contracts	*All charges*	*All charges*

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Blue Cross and Blue Shield Service Benefit Plan - Basic Option	11	[1.8MB]		[459 KB]	GO	GO
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GEHA High Deductible Health Plan	34	[1.7 MB]		[460 KB]	GO	GO
Mail Handlers Benefit Plan	45	[2.5 MB]		[463 KB]	GO	GO
Mail Handlers Benefit Plan (HDHP)	48	[2.5 MB]		[463 KB]	GO	GO

NALC	32	[1.4 MB]		[462 KB]	GO	GO

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CHIROPRACTIC SERVICES UNDER MEDICARE

OFFICE OF INSPECTOR GENERAL

OFFICE OF ANALYSIS AND INSPECTIONS

AUGUST 1986

INSPECTION OF

CHIROPRACTIC SERVICES UNDER MEDICARE

RICHARD P. KUSSEROW
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Summary of Findings

- In CY 1984, Medicare Part B expenditures for chiropractic services were $93.6 million, as compared with $38.2 million in 1979 and $19.2 million in 1975. The average annual rate of growth in Medicare expenditures for chiropractic services between 1975 and 1984 was 18.7%. (An anticipated 50% growth in the supply for chiropractors over the next five years will probably increase this rate of growth.)

- Many chiropractors would like to see expansion of Medicare coverage of chiropractic services to include x-ray, an initial diagnostic visit, routine laboratory services and physical therapy. In the absence of effective utilization controls, adoption of these recommendations would raise Medicare expenditures for chiropractic services from $93.6 million for CY 84 to more than $260 million in CY 87.

- Congress intended a specific limitation on Medicare coverage of chiropractic care by authorizing payment only for "...treatment by means of manual manipulation of the spine (to correct a subluxation demonstrated by x-ray to exist)..." Although the Part B carriers have systems in place which routinely deny claims for non-covered services provided by chiropractors such as laboratory tests and physical therapy, the x-ray requirement is not currently well enforced, may be unenforceable and is highly conducive to abuse.

- There are no standards commonly agreed upon by carriers or the profession regarding the appropriate frequency of chiropractic services. Denials of claims based on reviews triggered by frequency parameters have had little effect on the total volume or dollar value of paid services. In December 1985, HCFA mandated a review of all claims for chiropractic services involving more than 12 visits per year. It appears that this screen will result in a heavy administrative burden on the carriers with a limited relative pay-off.

- In order to establish a workable means of controlling utilization and cost, it is recommended that HCFA and the Department should consider submitting to Congress a legislative proposal which would continue to limit Medicare coverage of chiropractic services to treatment by means of manual manipulation to correct a subluxation demonstrated by x-ray; and cap the number of services allowed for a beneficiary at 12 per year. This would result in a savings of $23.9 million in CY 87.

I. Introduction

Purpose and Objectives

In the period January through May 1985, a national program inspection on Medicare coverage of chiropractic services was conducted by the Region V (Chicago) Office of Analysis and Inspections, Office of the Inspector General, Department of Health and Human Services.

This study was done in response to growing concerns regarding: the rapidly rising cost of chiropractic care under Medicare Part B; the possible implications of previously conducted OIG targeted investigations of chiropractors; an emerging perception that current Medicare legislation and regulations may not be administered in such a way as to provide intended limits on coverage; and a perception by chiropractors and others that the benefit does not adequately cover or reflect current patterns of practice.

The inspection had four general objectives:

- To develop an understanding of chiropractic as a profession as seen by its practitioners, schools and associations, as well as representatives of mainstream medicine.

- To explore with the chiropractic community how current Medicare legislation and regulations affect them and their patients, and in particular to discuss with them how they evaluate the x-ray requirement and handle billing.

- To gather and analyze data on patterns of chiropractic utilization and expenditures under Medicare, Part B.

- To examine how Medicare Part B carriers process chiropractic claims and to determine the effects of their screens and reviews.

Methods

In order to achieve these objectives, the inspection had three major segments:

- On-site discussions were held with 86 organizations and individuals in 13 states and the District of Columbia, selected to provide broad geographic and interest-group participation. Included were representatives of 12 chiropractic colleges, 15 chiropractic associations, 28 medical societies and hospital associations, and 22 third-party payers (Medicare Part B carriers and private payers), as well as representatives of HCFA and other policy experts.

- Telephone discussions were held with a representative sample of 145 chiropractors in eight states, who were randomly selected from lists of providers with billing numbers, provided by randomly selected Part B carriers.

- An analysis was made of the billing and payment histories of chiropractors in the telephone sample for claims processed in calendar year 1983, along with other data on Medicare billing and expenditure patterns provided by Part B carriers and HCFA. (See Appendix A for a discussion of sampling methodology for the telephone survey and the provider history review.)

II. Overview

What is Chiropractic?

The American Chiropractic Association describes the discipline as follows:

> "Chiropractic is a branch of the healing arts which is concerned with the human health and disease process. Doctors of chiropractic are physicians who consider man as an integrated being but gives special attention to spinal mechanics, neurological, vascular, and nutritional relationships...
>
> Chiropractic is built on three related scientific theories and principals...
>
> 1) Disease may be caused by disturbances of the nervous system ...
>
> 2) Disturbances of the nervous system may be caused by derangements of the musculoskeletal structure. Off-centerings (subluxations) of vertebral and pelvic segments represent common mechanical clinical findings in man ...
>
> 3) Disturbances of the nervous system may cause or aggravate disease in various parts or functions of the body ..."
> (American Chiropractic Association, Chiropractic; State of the Art, 1984. pp. 8-9

Medicare Coverage of Chiropractic Services

In 1972, PL 92-603 authorized limited Medicare Part B coverage of chiropractic services. In the final legislation, chiropractors were defined as physicians for coverage purposes, but payment was limited to : **"...treatment by means of manual manipulation of the spine (to correct a subluxation demonstrated by x-ray to exist) ..."** (Section 1861(r)(5), Social Security Act). There was considerable controversy surrounding the passage of this legislation which was adopted despite the recommendations and concerns about chiropractic as a form of treatment contained in the 1968 HEW report, Independent Practitioners Under Medicare. Almost every mainstream medical group also formally opposed passage.

Educational standards were set for chiropractors and payment could only be made for services provided in states where chiropractors were legally authorized to practice.

The regulations for this benefit further limited coverage to payment **"...only for the chiropractor's manual manipulation of the spine to correct a subluxation... which has resulted in a neuromusculoskeletal condition for which manipulation is an appropriate treatment."** (42 CFR 405.232b(c). Not included for coverage were other services that chiropractors were licensed in some states to perform, including: an initial diagnostic visit, adjunctive services (physical therapy), routine laboratory work and, most important, x-rays which are required by the legislation to justify treatment.

Utilization of and Expenditure for Chiropractic Services Under Medicare

The national figures on Medicare utilization of chiropractic services show minority but growing demand by the elderly for such care, with a rapid rate of growth for expenditures.

- In calendar year 1984, total Medicare expenditures for chiropractic services were greater than $93.6 million, as compared with $38.2 million in 1979 and $19.2 million in 1975. The average annual rate of growth in Medicare expenditures for chiropractic services between 1975 and 1984 was 18.7%. (An anticipated 50% growth in the number of chiropractors over the next five years will probably increase this rate of growth.)

- A report from the National Medical Care and Utilization Survey (published in 1984 by the National Center for Health Statistics) estimates that in 1980, 5.2% of the U.S. population, age 65 and over, received services from a chiropractor. This is greater than the percentage of persons in this age group which received services from a podiatrist (4.4%), and less than received services from an optometrist (9.2%), a nurse (18.1%) or an MD/DO (76.7%).

- OIG analysis of HCFA's 1983 prevailing charge summary data showed that manual manipulation of the spine was the 9th most frequently billed procedure under Medicare in 1983. This was exceeded only by such routine services as urinalysis, complete blood count, blood sugar, and follow-up hospital and office visits.

III. Chiropractic Today: A Continuing Paradox

Because heated controversy regarding chiropractic theory and practice continues to exist, it was decided early in the study to examine Medicare issues in the context of how the profession views itself and is viewed by others. On-site and telephone discussions with chiropractors, and their schools and associations, coupled with a review of background materials (many of which were provided by respondents) result in a picture of a profession in transition and containing a number of contradictions.

Growth of Acceptance by Patients and Society

Despite historical opposition from organized medicine, there has been a steady growth in the acceptance of chiropractic as a profession. There are now about 24,000 chiropractors in the United States and in 1985, 9847 students were enrolled in 15 chiropractic colleges. About 4% of the total US population receives some services from a chiropractor each year. As the result of law suits and other pressures, the American Medical Association has revised its code of ethics to allow some cooperation between physicians and chiropractors. Similarly, the Joint Commission on the Accreditation of Hospitals has revised accreditation standards to allow hospitals the option of including chiropractors on their staffs.

Chiropractors have been quite successful in obtaining recognition from Federal and State governments, and have been included in many governmental programs. For example:

- Chiropractors are now licensed in all states, although there is considerable variation in statutory definitions of the profession and of its scope of practice.
- Chiropractic services have limited coverage under Medicare and under Medicaid programs in about half the states. In all states, chiropractic services are covered under worker's compensation programs.
- In 20 states, legislation has been passed which mandates either coverage or offering of coverage of chiropractic services under private health insurance policies.
- Federal financial assistance is available to chiropractic students under the HEAL program. However, chiropractic colleges in general receive no state support.

Professional Organization and Practice

Chiropractors have organized their professional and educational structure into a format which to some extent mirrors mainstream medicine. There are two major (and competing) national organizations, the American Chiropractic Association and the International Chiropractors Association, state and local societies, specialty boards, a national Board of Chiropractic Examiners and a Council on Chiropractic Education which recommends policy and sets accreditation standards for chiropractic colleges across the United States.

Within the profession, there continues to be a debate between "straight" chiropractors who limit their activity to spinal manipulation therapy and "mixers" who use a variety of therapeutic techniques, most often different forms of physical therapy. It is recognized by many chiropractors that elaborate claims for universal efficacy of chiropractic care have been greatly overstated in the past, but there continues to be some disagreement within the profession regarding which conditions are appropriate for chiropractic care and regarding appropriate parameters for treatment.

During the field visits, chiropractors were asked how they viewed their position within the larger health care delivery system, and their relationship with orthodox medicine. The respondents maintained that, for many patients, the chiropractor can and should serve as a sort of gatekeeper, doing an initial diagnostic work up on patients, referring those for which chiropractic care is inappropriate. It is for this purpose that many chiropractors are seeking greater access to hospital diagnostic resources and physical therapy facilities, and expansion of their scope of practice in states where their activity is limited. However, many also conceded that most patients at an initial visit present such complaints as headaches or lower back pain, and view the chiropractor as a specialist dealing with a limited set of conditions.

Many of the respondents stressed the value of expanded scientific inquiry into the efficacy of chiropractic, and welcomed the continued upgrading of curriculum and admission standards at the colleges. They were eager to point out the increased time the colleges have allocated to teaching the basic sciences and stressed the increased numbers of PhDs on their faculties from such disciplines as chemistry, physiology, nutrition, etc.

The Problem Side of Chiropractic

Despite the evidence which was presented during the study regarding the increased emphasis on science and

professionalism in the training and practice of chiropractors, there also exist patterns of activity and practice which at best appear as overly-aggressive marketing and, in some cases, seem deliberately aimed at misleading patients and the public regarding the efficacy of chiropractic care. Teaching materials provided by one chiropractic college warn students of "cultists" within the profession which on one side are "anti-diagnosis, anti-therapeutics, pseudo-religious and stress one cause/one cure"; and, on the other extreme, use a "plethora of questionable elixirs, pseudo-medical concepts regarding treatment of specific disorders, and practice a variety of (questionable) healing philosophies."

During the study, discussions were held with reform-minded chiropractors who are in the process of forming a separate professional group of practitioners, the National Association of Chiropractic Medicine, that would set strict standards of ethical conduct and practice, and would actively work in cooperation with consumer groups and others to expose and rid the profession of questionable activities. To date, this group appears to have attracted only a small proportion of the profession. During the discussions, some representatives of schools and associations recognized that there continue to be problems with some of the chiropractors, but emphasized their minority status within the profession.

Examples of problem situations gathered during field visits included:

- Practice-building courses, popular with many chiropractors, advocate advertising techniques which suggest the universal efficacy of chiropractic treatment for every ailment known to humans. The chiropractor's staff is encouraged to reinforce this message even in regard to a patient's questioning the continued use of medication and other therapies prescribed by other physicians for life-threatening conditions and venereal disease.

- A newspaper in Iowa published a multi-part story on chiropractic where a reporter visited many chiropractors and got many different conflicting diagnoses and proposed treatment plans.

- There was testimony regarding patients who, on the basis of a limited examination, had been encouraged to sign contracts for a multi-year course of chiropractic therapy (payable in advance by Mastercharge, Visa or in easy installments).

- A major televison station in Chicago did an expose of cancer scams which heavily involved chiropractors in Illinois.

Prior to the start of this program inspection, OIG regional studies had uncovered problems with chiropractors vis a vis federal programs. Independent studies of chiropractic services conducted by the Chicago, Phildelphia and New York regional offices found serious recordkeeping problems. The office records did not support diagnostic information submitted with the claim; frequently, little else was documented beyond the patient's payment record (i.e. no complaint, no examination notes, no treatment notes or progress notes, no documentation for the taking of or evaluation of x-rays, etc.) Treatments billed for spinal ailments were in fact treatments for sinus problems, bed wetting, crossed eyes, sprained wrist. A review of office records showed patients receiving regular treatment, with little or no change, over long periods of time, some going as far back as late 1960s and early 1970s. In addition:

- For a sample of 21 patients, one New York chiropractor was unable to furnish treatment records for 19 patients, or x-rays for 16 patients.

- A Pennsylvania chiropractor billed Medicaid for the same-day treatment of a nine-member family, with no documentation of such in the office records.

- The Atlanta Regional Office has investigated a chiropractor who, using a medical doctor's provider number and signature stamp, billed Medicare for the x-rays and office visits, and also for physical therapy which was provided (if provided at all) by the chiropractor.

Some of these problems are not unique to chiropractors. But, at a time when chiropractors are pursuing greater legitimacy in the competition for limited health care dollars, caution should be exercised before any changes in coverage are considered.

IV. Chiropractic Under Medicare

The Social Security Act limits Medicare coverage for chiropractic services to **"treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist."** Because chiropractic theory regarding illness differed so greatly from mainstream medicine, the x-ray requirement was written into the benefit as an attempt to "control program costs by insuring that a subluxation actually exists" (from a 1978 GAO review of Medicare coverage of chiropractic). The consensus, from the chiropractic community as well as representatives of the health care field, is that the x-ray requirement has not served this purpose. As noted previously, Medicare expenditures for chiropractic services have increased at an annual rate of 18.7% between 1975 and 1984.

The responses in the telephone survey (supported by information gathered during the field visits) brought into question some of the other basic assumptions inherent in the coverage. There was no clear consensus as to what a subluxation is; furthermore, in the telephone survey:

- The majority (81%) stated that, on an older person's x-ray, more "wear and tear," osteoarthritis and osteoporosis will show up, and not subluxations per se.

- The majority of respondents (84%) said that there are subluxations that do not show up on x-rays.

- Nearly half stated that, when billing Medicare, they "could always find something" (by x-ray or physical examination) to justify the diagnosis, or actually "tailored" the diagnosis to obtain reimbursement.

- Many respondents in the telephone survey, in advocating a change in the benefit, volunteered that the majority of their Medicare patients had chronic conditions that would never be corrected, and were receiving what was essentially palliative or maintenance care for those conditions.

These responses raise serious questions as to the extent that Medicare is paying for conditions that do not meet the original intent of the law.

Subluxations and the X-ray Questions

Previous regional studies of selected chiropractors raised serious questions as to whether chiropractors were billing

only for treatment of subluxations visible on x-rays, as specified by the Medicare benefit. The 1974 ACA guidelines for Medicare claims review (later withdrawn) stated:

> "subluxations ... demonstrable by x-ray represent only a relatively small portion of spinal subluxations treated by Chiropractic Physicians. Clinical subluxations not necessarily demonstrable by x-ray, constitute the majority of spinal subluxations successfully treated by Chiropractic Physicians."

In our current study, the on-site discussions with chiropractic schools and associations went even further. As was summarized at one school: subluxations are a minor part of chiropractic practice, the term itself is out-of-date, and the x-ray requirement is a distortion of chiropractic which forces chiropractors to state a subluxation is present on an x-ray even when it is not.

Based on a 1979 New Zealand study of chiropractic praised by chiropractors in its fairness to their profession, chiropractors in the telephone survey were asked whether there were different categories of subluxations (such as "structural" and "functional") and whether there are subluxations that do not show up on x-rays. According to the New Zealand report, "structural" subluxations are generally visible on x-rays; "functional" subluxations may not be evident on x-rays because they relate to the functioning of a joint, as in impaired range of motion. While no clear consensus emerged around the structural/functional distinction itself, 84% of the respondents in this current study said that there are subluxations that are not visible on a standard x-ray, and their descriptions generally related to function (fixations, hyper/hypo-mobility).

Having gotten a consensus that some subluxations are not visible on x-rays, respondents gave a very different set of answers when asked whether chiropractors do anything different in treatment or billing when a Medicare patient's x-ray does not show a subluxation:

- 29% stated that one could "always find something" on the x-ray to justify the billing, but there was wide divergence as to whether this "something" correlated to the patient's complaint or treatment.

- 10% indicated that if they determined the subluxation by other means (i.e. physical examination and palpation) they billed it as though it appeared on the x-ray;

- 6% actually said they "adapted" their diagnosis to "what Medicare wants to hear." As one chiropractor said, "Do we change the diagnosis? I'll find a millimeter out of alignment or rotated on any x-ray ... It's called 'the insurance game'... I don't consider it lying - it's just learning how to function within the system ... [for example,] when you get to the allowed number of treatments, change the subluxation up or down one and give a new date of onset."

Examining the responses about the appropriateness of x-rays in relation to the age of patients helps provide at least an internal logic to the apparent contradictions in these responses. Eighty-one percent of the respondents indicated that the older a person, the greater the likelihood of conditions showing up on x-rays; however 87% of this subgroup specified general degeneration of the spine, osteoarthritis, osteoporosis, and not subluxations per se, as the kinds of things that would show up. The implication is that although there are subluxations that do not show up on x-rays, a chiropractor "can always find something" on an older person's x-ray that for Medicare purposes can be related to, or reinterpreted as, a subluxation.

The cost of an x-ray to justify Medicare reimbursement can often exceed the total reimbursement for the treatments themselves. Almost every chiroprctor interviewed complained that this high initial expense was unfair to a patient already on a limited income. However, a great many chiropractors, including those who disagreed with the x-ray requirement, admitted that they would x-ray the Medicare age group anyway, either to rule out inappropriate conditions (e.g., cancer) or to protect themselves from malpractice suits. This becomes an important consideration when looking at the requested coverage changes below.

Desire for Expansion of Medicare Coverage.

At the beginning of each telephone interview and again at the end, chiropractors were queried about changes they would like made in the Medicare benefit. Far and away, the biggest response (68%) was for coverage/reimbursement of x-rays. Thirty-one percent felt the x-ray requirement should be changed or eliminated, but many felt the x-ray should be reimbursed even if the requirement were dropped. From the discussion in the previous paragraph, it is unclear whether dropping the x-ray requirement will result in significantly fewer x-rays. Any shifting of x-ray costs from the patient to the program could mean substantial increases in Medicare expenditures.

Thirty-seven percent of the respondents felt that Medicare should expand coverage to include more or all of the chiropractors' scope of practice (i.e. what they had been taught and are licensed to perform). Linked with this group were 17% who specifically wanted coverage for physical therapy by chiropractors, 8% who wanted coverage for the initial examination, and 13% who wanted parity in coverage and/or reimbursement with mainstream medical practitioners. 18% recommended the liberalization or elimination of the limits on the number of allowable visits. The implementation of any of these recommendations would result in significant increases in Medicare payments, with no new effective control over quality or quantity of services.

The chiropractic schools and professional associations voiced support for all of these changes. In addition, many school representatives spoke of the need for federal funding for research, comparable to the research money available to medical schools.

As noted previously, it is unclear to what extent Medicare now pays for treatment of conditions that do not meet the original intent of the law. The chiropractic community seems to sidestep rather than clarify the ambiguities involved in the current program while requesting a major increase in coverage and costs for the Medicare program.

V. Billing and Payment Patterns for Chiropractors in the Sample

The actual pay-out of Medicare dollars for chiropractic services depends on both the volume and variety of claims which are submitted for payment and on how Part B carriers review and process them. There are differences in treatment philosophy and practice between chiropractors (as well as differences in patient preference) which result in a wide variance in both the number of services billed and in the types of covered and non-covered services that are included. As indicated above, there is a significant (but undetermined) volume of billing for correction of subluxations that do not show up on an x-ray.

Carriers have systems in place to deny claims for some non-covered services (e.g. physical therapy) but not others (e.g. manipulation of the spine where the subluxation is not demonstrated by x-ray). They have no common standards to determine the appropriate frequency of covered services and there is little consistency among carriers in the number of covered services per patient that are approved for payment. Less than 6% of all services billed are denied for utilization reasons. Because claims for chiropractic care include many services at small cost, and because the review of claims (beyond determination of completeness, and whether a service is covered) is labor intensive and expensive, carriers seldom review actual x-rays or office records. Denial of claims flagged by utilization screens has relatively little effect on Medicare payout. (See Appendix B for a more detailed discussion of these patterns than is presented below.)

Billing Patterns

The average number of services billed for a patient in the sample was 13.4 and the average number allowed for payment was 10.4. The average total dollars billed for a patient was $224, the average allowed was $131 and the average paid was $87. The average number of Medicare patients served by a chiropractor in the sample was 39.

These averages, however, mask the diversity across the full range of the scale. At the low end, about 28% of the patients only received between 1 and 5 services in a year that were billed to Medicare. At the high end, however, 19% of the patients received more than 20 services, almost half (47%) of all services billed. In the sample 14.3% of the chiropractors on average billed for more than 20 services for each Medicare patient seen.

Payment Patterns by Carriers

The Medicare Carriers Manual recognizes the somewhat ambiguous position of chiropractic and states that:

> "Implementation of the chiropractic benefit requires an appreciation of the disparate orientation of chiropractic theory and experience and those of traditional Medicine since there are fundamental differences regarding the etiology and theories of the pathogenesis of disease" (Sec. 2250)

The manual presents a system for classifying subluxations, a general discussion of treatment parameters and a schema for relating various symptoms to a particular area of the spine. The manual also lists examples of conditions for which manual manipulation of the spine is not an appropriate treatment. Some critics have suggested that this system has provided a blueprint for some chiropractors to work backward to identify the appropriate location of a subluxation for billing purposes, as opposed to treating and billing for a subluxation which has been identified on an x-ray.

Claims for payment for chiropractic services must include a statement of diagnosis and symptoms, specify the precise level of the spinal subluxation and must indicate that an x-ray film is available for carrier review. The carriers appear to spend a considerable amount of time assuring that the documentation on the claim is complete, but seldom is an actual x-ray or office record reviewed. Most carriers have instituted automated systems which (if the procedure is coded correctly) reject claims for non-covered services such as x-ray or physical therapy. The carriers have set up their own frequency parameters which flag for review the claims of patients whose number of covered services exceeds the carrier's established thresholds for review. There is little consistency nationally, and none at all in the sample carriers, regarding these parameters.

In the sample, 22% of all services submitted for payment were denied by the carriers. Of these, 16.7% were denied more or less automatically because they were duplicate bills or non-covered services, while only 5.3% were denied because they exceeded frequency parameters or failed to meet other utilization review criteria. There was little consistency among carriers in their overall denial rates which ranged in total between 2.7% and 47% of all services. Similarly, denials for non-utilization reasons ranged between 0.3% and 32.2%, and denials for utilization ranged between 0.8% and 14.8%.

An examination of how individual chiropractors fared in relation to the intensity with which they treated patients or billed for services showed only a limited relationship. Chiropractors that on the average billed for more than 20 covered services per patient per year had 20.6% of their covered services denied, but there was little variation in the percent of covered services denied for groups of chiropractors that on the average billed for 20 or fewer services per patient per year.

In order to bring at least partial consistency to frequency screens, HCFA in the fall of 1984 set up a pilot project which would require some carriers to review all claims for chiropractic care for chronic cases that exceeded one treatment per month. However, there was no common definition provided for chronic care. At the time this study was begun, there had been only partial participation in this project and at least one of the participants had modified HCFA's mandated frequency screens because too many cases would have been selected for additional intensive review.

When processing chiropractic claims, the carriers have had to individually impose administrative order on a situation where the standards for evaluating x-ray documentation are ambiguous and there is no concensus regarding the number of services a patient should receive. It seems clear that the x-ray requirement is ignored by some chiropractors. On a benefit/cost basis, the x-ray requirement may be unenforceable. This suggests the need for a change in the benefit which would provide a workable approach to limiting utilization as originally intended by Congress and which would reflect somewhat more clearly the current realities of chiropractic practice.

VI. Recommendations

- o HCFA and the Department should vigorously oppose any movement to expand the coverage of chiropractic services to include an initial diagnostic visit, x-ray, laboratory services or adjunctive therapy. In the absence of effective utilization controls, the cost of these proposals would more than double the cost of chiropractic care under the Medicare benefit in the next several years (from $93.6 million in CY 84 to more than $260 million in CY 87.)

Legislation was introduced in the 98th Congress which would remove the x-ray requirement for justifying chiropractic services and would expand Medicare coverage to payment for an appropriate x-ray, physical examination and related routine lab tests. Chiropractic associations and individual practitioners would also like to see coverage of adjunctive (physical therapy) services.

The financial impact of expansion would be great. A survey done by the American Chiropractic Association indicates that in 1984, the median bill for an initial visit to a chiropractor, including diagnostic tests, x-ray etc, was about $110. If bills at this amount were submitted for only half of the patients seen by chiropractors in the sample (and paid at 80%), the Medicare expenditures for the sample would increase more than 50%. Coverage of physical therapy would at a minimum increase cost by another 16% (the amount denied by carriers in the sample for non-covered services). Under an expanded program, (and assuming an annual rate of growth in the cost of chiropractic services of 18.7%) it is projected that in CY 87, total annual cost to Medicare for chiropractic services would more than double to $260 million. Given Medicare history relative to coverage of other physical therapy services, and the 50% expected increase in chiropractors over the next five years, the amount would probably be greater.

- o HCFA and the Department should consider submitting a legislative proposal to Congress which would:

  - Continue to limit Medicare coverage of chiropractic services to manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist.

  - Cap the number of services for which a patient could receive payment at 12 per year. All covered services over 12 visits would be automatically denied. ($23.9 million savings in CY 87.)

The carriers have in place systems which for the most part routinely deny payment for non-covered services, such as x-ray, laboratory tests or physical therapy, provided by chiropractors. However the requirement that Medicare cover only the treatment of those subluxations demonstrated by x-ray is not well enforced and may be unenforceable. Although the chiropractors in this study admit they sometimes bill for services in cases where the subluxation is not clearly demostrated by x-ray, the carriers have not found x-ray review to be cost effective. This is because there is little agreement among carriers, chiropractors or others regarding the criteria which should be used to determine which conditions of the spine (shown on an x-ray) are actually subluxations which require treatment. X-ray review is also labor intensive, relatively expensive and often the last step in the process of determining which claims should be paid.

In addition, the carriers indicate that even when an x-ray clearly shows a subluxation, there are no agreed upon standards regarding the appropriate number of services (manipulations) required to treat a given acute or chronic condition. Similarly, neither national chiropratic association has approved or endorsed any utilization review criteria. Given the ineffectiveness of these brakes on costs and utilization, a 12 service per year cap is recommended.

The impact of a 12 service cap on patients would be minimal. It would allow patients with chronic conditions one treatment a month and would encompass the number of services provided to a majority of the patients needing acute care. (Over two thirds of the patients in the sample received less than 12 covered services per year.) Patients who do not respond after 12 treatments would still have the option of seeking additional services in the traditional medical care system. The cap would also provide both patients and chiropractors with a known level of coverage against which treatment decisions could be made. The imposition of a cap would be similar to the dollar limitation which has been imposed on outpatient psychiatric services and on services provided by independent physical therapists.

In December 1985, HCFA mandated all carriers to implement a screen on chiropractic claims set at 12 services per year.

The manual issuance requires that "[m]edical necessity determinations must be made on all claims where the parameters are exceeded." Carriers are required to "[r]eview both those claims which exceed the parameters and those which do not." However there remains the question of what standards should be used to evaluate these claims.

If this screen is implemented with a level of development and review sufficient to deal with the problems raised by this inspection, the burden on the carriers could be quite heavy. We estimate that between 31% and 56% of the Medicare patients receiving chiropractic services will have their claims examined. This is the range between the proportion of patients with 12 or more approved services and the proportion with 12 or more billed services. Some will require more than one review because they will submit claims after the first batch of 12 is examined or because they are treated for more than one acute episode.

If a well developed review (with examination of an x-ray) costs at least $10, if 5.2% of the 31 million Medicare patients with part B coverage see a chiropractor each year, if 43.5% require review, and if each patient in the sample is reviewed 1.5 times, then the annual cost to the carriers will be $10.5 million. Since HCFA requires a 5 to 1 return on medical review/utilization review, the cariers would have to reduce total chiropractic pay out almost 50% to meet the standard. It may be argued that some reviews can be done for less than $10, but these would involve no additional contact with the chiropractor, no x-ray review and no consideration of evidence other than that which is submitted on the face of the claim.

Based on sample data, a 12-visit cap would annually save about 8.6% in Medicare expenditures for chiropractic services. Assuming an 18.7% annual rate of growth of the billings for chiropractic services, this would amount to about $13.4 million in savings from reduced payment for services in CY 87. To this can be added a reduction of $10.5 million per year, the estimated additional cost of the HCFA mandated screens, for a total savings of $23.9 million a year. (See Appendix C for a further discussion of the derivation of the impact of the cap.)

- The Department should examine the ways in which it can further encourage the submission of scientific research proposals by chiropractic colleges, which meet the standards applied to other projects supported by the National Institutes of Health.

There continues to be a debate within the chiropractic profession, and with outside observers, regarding the extent to which chiropractic should be accepted and judged only by the internal standards of the profession. This discussion has been influenced by the separatist approach which chiropractors have historically maintained and by their reaction to criticism from organized medicine.

As chiropractors seek access to mainstream resources and look for acceptance by a larger portion of the society, there would be value for all parties in finding a meeting ground where issues could be examined within a common set of ground rules and definitions. Increased access to research funding by chiropractic colleges would provide one point of mutual interaction between chiropractors and other health professions, and would serve to enhance the position of those segments of the profession that seek to improve the quality of chiropractic education and who would work to limit the use of questionable diagnostic and therapeutic techniques used by some chiropractors.

Appendix A

Sampling Methodology for Telephone Survey and Review of Provider Histories

In order to obtain a representative sample of carriers, providers and patients for use in the telephone survey and in review of provider histories, the following steps were taken:

(1) OIG headquarters staff obtained from HCFA a print-out of "Part B Expenditures for Chiropractors by Type of Service, Payment Records Processed 1/83 - 12/83." Each carier's percentage of total dollars paid was determined and multiplied times 10,000. Each carrier was assigned sequentially a block of numbers equal to its share of 10,000. Eg, carrier #1 was assigned numbers 1-154, carrier #2, numbers 155 - 245, etc.

(2) Ten numbers from a range of 1 to 10,000 were selected using a random number table, and carriers where selected whose block of numbers encompassed the selected numbers. Because we were sampling with replacement, 6 carriers were selected once and 2 carriers came up twice.

(3) From each carrier that was selected, a list of current chiropractors with provider numbers was requested. Using a random number table, 20 provider numbers were selected from each of the carriers that came up once and 40 chiropractors were selected from the 2 carriers that came up twice.

(4) Of the 200 chiropractors selected, telephone discussions were completed with 145.

(5) A complete provider history for CY 83 was requested for each provider selected. Because the list of provider numbers was current, but the billing histories were over a year old, only 152 provider histories were obtained.

Appendix B

Expanded Discussion of Treatment, Billing and Payment Patterns for Chiropractors in the Sample

Treatment and Billing Patterns

Of the 200 randomly selected chiropractors, 154 had payment histories indicating services had been billed for one or more Medicare beneficiaries in 1983. The remaining 46 chiropractors had an active Medicare billing number, but no bills had been received for processing because they were not then serving Medicare patients, or had moved, retired or expired. The 154 chiropractors served 5964 patients and provided 79,775 services that were billed to Medicare. The total dollar value of these services billed was $1,337,604, the amount allowed $785,349, and the amount paid $516,499.

- The average number of services billed for a patient was 13.4 and the average number allowed was 10.4.
- The average total dollars billed for a patient was $224, the average allowed $132, and the average paid $87.
- The average number of Medicare patients served by a chiropractor (for which a bill was submitted) was 39.
- The average total number of services billed by a chiropractor for all patients served was 518, and the average number of services allowed and paid was 404.
- The average total dollar value of services billed by a chiropractor was $8686, allowed was, $5100, and paid $3354.

But further consideration should be given to patterns at the high and low ends of the treatment scale. Table 1 below presents a breakdown of patients and services by frequency of services billed per patient. Table 2 illustrates treatment patterns in a somewhat different way by grouping chiropractors according to the average number of services billed for all the patients in their practice, and showing the percent of all patients served by each group of chiropractors and the percent of all billed services that were provided.

Table 1

Number, Percent, and Cumulative Percent of Patients and Services Billed by Number of Services Billed Per Patient

Number of Services Billed	Number of Patients	% of Patients	Cumulative % of Patients in Sample	Number of Services Billed	% of All Services Billed	Cumulative % of Services Billed
1-5	1,688	28.3%	28.3%	5,185	6.5%	6.5%
6-10	1,449	24.3	52.6	9,015	11.3	17.8
11-15	1,038	17.4	70.0	16,035	20.1	37.9
15-20	644	10.8	80.8	11,727	14.7	52.6
21 +	1,145	19.2	100%	37,813	47.4	100%
Total	5,964	100%		79,775	100%	

As indicated in Table 1, about half (52.6%) of the patients in the sample received 10 or fewer services that were billed to Medicare. This is fairly evenly divided between the 28.3% of the patients that received between 1 and 5 services and the 24.3% that received between 6 and 10 services. At the other extreme, 19.2% of the patients received more than 20 services and accounted for almost half (47.4%) of all services billed. The distribution of these high-use patients tapers off fairly quickly, but extends far to the right. For example, 11.7% of the patients received between 21-30 services (25% of all services billed), and 4.1% of the patients received between 31-40 services (11.2% of all services billed). The highest user was a patient that had 153 services billed to Medicare in 1983.

Table 2

Number, Percent, and Cumulative Percent of Chiropractors, Patients Served and Services Billed by Average Number of Services Billed Per Patient

Average Number of Services Billed Per Patient	Number of Chiro-practors	% of all Chiroprac-tors (Cum. %)	Number of Patients Served	% of all Patients Served (Cum. %)	Number of Services Billed	% of all Services Billed (Cum. %)
1-5	19	12.3% (12.3%)	200	3.4% (3.4%)	807	1% (1%)
>5-10	38	24.7 (37)	1,253	21.0 (24.4)	10,213	12.8 (13.8)
>10-15	55	35.7 (72.7)	2,710	45.4 (69.8)	33,626	42.2 (56)
>15-20	20	13.0 (85.7)	1,315	22 (91.8)	23,309	29.2 (85.2)
>20	22	14.3 (100%)	486	8.2 (100%)	11,820	14.8 (100%)
Total	154	100%	5,964	100%	79,775	100%

Table 2 provides a view of the billing and service patterns of chiropractors in the sample broken out by the relative intensity of their practice - the average number of services billed for each Medicare patient they served. The median chiropractor provided on the average between 10 and 15 services that were billed. At the low end 12.3% of the chiropractors (serving 3.4% of the patients) averaged between 1 and 5 services per patient. At the other end, 14.3% of the chiropractors averaged more than 20 services per patient, served 8.2% of all patients in the sample, and accounted for 14.8% of all services billed.

There are a number of explanations for these differences in billing patterns. Although Medicare pays only for manual manipulation of the spine, some chiropractors obviously provide other services such as x-ray and adjunctive services which are included on the bills submitted. In addition, there continue to be differences in treatment philosophy between "straights" and "mixers" which might account for some variation. Chiropractors also have differing views regarding which conditions are appropriate for chiropractic treatment and there are indications that a proportion of the profession advocates regular maintenance and preventive care that may not be specifically related to either an acute episode or a specific, chronic condition. There are no commonly accepted frequency parameters for care which have been agreed upon at the national level by the profession, and standards previously adopted have been withdrawn.

An important reason for the variation in frequency which must be considered is patient preference. The high percentage of patients receiving between 1-5 and 6-10 services, suggests that there are a number of elderly persons who go to a chiropractor seeking relief for a particular acute episode or who may see a chiropractor briefly and discontinue treatment. There are also economic incentives (co-payments and deductibles) which would operate to modify utilization all across the scale.

Part B Carrier Processing and Payment of Claims

The actual payment for chiropractic services under Medicare depends on the processing of claims by the Part B carriers. The Medicare Carrier Manual recognizes the somewhat ambiguous position of chiropractic and states that:

> "Implementation of the chiropractic benefit requires an appreciation of the disparate orientation of chiropractic theory and experience and those of traditional medicine since there are fundamental differences regarding the etiology and theories of the pathogenesis of disease." (Sec. 2250)

The Medicare Carrier's Manual presents a system for classifying subluxations, a very general discussion of treatment parameters and a schema for relating various symptoms to a particular area of the spine. The manual also lists examples of conditions for which manual manipulation of the spine is not an appropriate treatment, e.g. rheumatoid arthritis, muscular distrophy, multiple sclerosis, emphysema, etc. Some critics have suggested

that this system provides a blueprint for some chiropractors to work backward to identify the appropriate location of the subluxation based on a complaint, as opposed to treating a subluxation which has been identified on an x-ray or by other means.

Claims for payment of chiropractic services require more documentation than is required for comparable services provided by an MD or DO. In addition to a statement of a diagnosis and symptoms, a claim for chiropractic services must:

> "Specify the precise level of spinal subluxation, contain certification on all bills by the treating chiropractor that an x-ray film is available for carrier review demonstrating a subluxation at the specified level of the spine; and include identification of the treatment phase and adjustment - e.g. second, fifth, tenth treatment." (Sect. 4118B)

The carriers appear to spend a considerable amount of time assuring that written documentation is available on the face of the claim submitted. Claims without this documentation should routinely be denied. But only in the most unusual cases is there any review of a chiropractor's actual office records to compare what is written on the claim with what has been recorded in the patient's history. Seldom is an actual x-ray film reviewed. One chiropractor that serves on a carrier professional review committee,interviewed as part of the field study, discribed the quality of some office records and x-rays that he had reviewed as an embarassment to the profession.

Most of the carriers have instituted claims processing systems which should (if the procedure is coded correctly) easily and automatically reject all claims for non-covered services such as x-ray, laboratory or physical therapy provided and billed by a chiropractor. As indicated and discussed further below, over 75% of all the rejections of services for payment are on the basis of lack of documentation or for submission for payment of a non-covered service.

Once non-covered services have been eliminated, the covered manual manipulation of the spine services are evaluated for necessity. The carriers have set up their own frequency parameters which flag for review the claims of patients whose number of covered services exceeds the carrier's established limits. There is little consistency nationally, and none at all among the carriers in the sample, regarding these frequency screens.

In order to bring at least partial consistency to these frequency screens, HCFA in the fall of 1984 set up a pilot project, which would require some carriers to review all claims for chiropractic care for chronic cases which exceeded one treatment per month. However, there was no common definition provided for chronic cases. At the time this study was begun, there had been only partial participation in this pilot project, and at least one of the participants had modified HCFA's mandated frequency screens because too many cases would have been selected for additional intensive review.

The extreme variation in dealing with chiropractic claims among carriers in the sample is illustrated in Table 3 below which presents the number and percent of services denied by each carrier in its sample, broken down by "Non-UR" (non-covered services, etc) and UR (Exceeding frequency screens, etc.) reasons.

Table 3

Number of Services Billed and Number and Percentage of Services Denied by Non-Utilization Review and Utilization Review Categories.

Carrier	Services Billed In Sample	Number and % of Services Denied		
		Non-UR (%)	UR (%)	Total (%)
A	10,972	37 (0.3%)	265 (2.4%)	302 (2.7%)
B	9,979	556 (5.6)	661 (6.6)	1,217 (12.2)
C	4,698	177 (3.8)	247 (5.3)	424 (9.0)
D	10,418	2,280 (21.9)	147 (1.4)	2,427 (23.3)
E	14,430	3,904 (27.1)	122 (0.8)	4,026 (27.9)
F	11,805	1,553 (13.2)	960 (8.1)	2,513 (21.3)
G	10,073	3,245 (32.2)	1,493 (14.8)	4,738 (47.0)
H	7,400	1,600 (21.6)	351 (4.7)	1,951 (26.3)
Total	79,775	13,352 (16.7%)	4,246 (5.3%)	17,598 (22.0%)

As indicated in Table 3, 22% of all billed chiropractic services presented for payment are denied. This ranges among carriers from 2.7% to 47.0%. Denial rates for non-UR reasons range from 0.3% to 32.2%, and averages 16.7% Denial for UR reasons range from 0.8% to 14.8% and averages 5.3%. Over 75% of all denials are for non-UR reasons; that is, the services were not covered by Medicare. Less than 25% are because the number of services provided exceeded one of the various frequency screens. Given the low dollar amount paid per chiropractic service, low rate of UR denial and the high cost of development, the IG seriously questions the cost effectiveness of edits in controlling chiropractic utilization.

Another way of considering the carrier's handling of claims is to examine the patterns of denials for utilization reasons after claims for non-covered services and duplicate bills have been removed. Table 4 below shows distribution of chiropractors, the number of patients they serve and services they bill arrayed by the relative intensity of covered services (total services billed less non-covered services) which they bill. It also shows the relative denial rates for covered services which were billed.

Table 4

Number and Percent of Chiropractors, Patients Served and Services Billed after Denial for Coverage; and Percent of Services Denied for Utilization Review Reasons by Average Number of Services Billed per Patient after Denial for Non-covered Services

Average Number of Services Billed Per Patient After Denial for Non-covered Services	Number of Chiropractors (%)	Number of Patients Served (%)	Number of Services Billed After Denial for Coverage (%)	Percent of Services Denied for UR
1-5	21 (14%)	284 (4.8%)	1,103 (1.7%)	1.5%
>5-10	56 (38)	2,155 (36.2)	16,769 (25.2)	4.1
>10-15	49 (33)	2,308 (38.7)	28,246 (42.5)	7.7
>15-20	15 (10)	1,117 (18.7)	17,986 (27.1)	5.0
>20	7 (5)	93 (1.6)	2,319 (3.5)	20.6
Total	148 (100%)	5,957 (100%)	66,423 (100%)	6.4%

As indicated in Table 4, over 10% of the chiropractors in the sample (serving 18.7% of the patients) bill for an average of between 15-20 covered services (manual correction of a subluxation) per year. Approximately 5% of the chiropractors (serving about 1.6% of the patients) bill for an average of more than 20 services per year. As would be expected, the carriers rejected for payment only 1.5% of the covered services billed by chiropractors who bill for between 1-5 services per patient. There is relatively little difference in the denial rates for providers who billed between 5-10, 10-15 and 15-20 services per year. The carriers denied 20.6% of covered services for chiropractors that billed for more than 20 services.

Across the board, however, there is no statistical relationship between the average number of covered services billed and the denial rate for services that exceed frequency parameters. That is, knowing the relative intensity with which a chiropractor provides covered services to his patients does not allow one to predict at what rate services will be denied because frequency or other UR screens are exceeded.

Appendix C

Estimation of the Effect of a 12 Service Cap

1) For the 152 chiropractors in the sample that billed patients for one of more services in CY 83, the following information was gathered: total number of services billed and allowed; total dollars billed, allowed and paid; total number of patients served; total number of services denied for (a) utilization and (b) non-utilization reasons, and total dollar value of services denied for (a) utilization reasons.

2) It was assumed that the effect of a cap could only be projected on the basis of a reduction in allowed services and allowed dollars. That is, no credit could be taken for any reduction in billed services that the carriers would have made had there not been a cap in effect.

3) The average number of allowed services per patient (total allowed services/total patients served) was determined for each chiropractor. The chiropractors were divided into two groups: (A) chiropractors with an average number of allowed services equal to or less than 12 and (B) chiropractors with an average number of allowed services greater than 12.

4) A new variable (total dollars paid after the cap) was created for each chiropractor. For chiropractors in the (3A) group (providers with an average number of services allowed per patient equal to or less than 12):

Total dollars paid after the cap =
Total dollars paid.

For chiropractors in the (3B) group (providers with an average number of services allowed greater than 12.

Total dollars paid after the cap =
12 X Total patients served x (Total dollars paid/Total services allowed).

(5) The Percent of dollars saved under the cap =

$$1 - \left(\frac{\text{Weighted} \sum (\text{Total dollars paid after cap})}{\text{Weighted} \sum (\text{Total dollars paid})} \right) = .085.$$

(6) Because of the lack of availability of data, we were forced to make the final estimate of savings based on the average number of services billed. We know that some patients served by chiropractors with an average number of services per patient allowed equal to or less than the cap, had allowed services greater than the cap; and that some patients served by chiropractors with an average number of services allowed per patient greater than the cap have an allowed number of services less than the cap. For purposes of computation it is assumed these two groups would balance out.

(7) The projected dollar savings for 1987 assumed a 18.7% annual rate of growth and was computed as follows:

Dollar savings in CY 87 =

1984 Medicare expenditures for chiropractic services x
Annual rate of growth for three years x
Percent of dollars saved under the cap =

$93.6 million x(1.187 x 1.187 x 1.187) x .085 =

$13.3 million.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CHIROPRACTIC CARE

Controls Used by Medicare, Medicaid, and Other Payers

JUNE GIBBS BROWN
Inspector General

SEPTEMBER 1998
OEI-04-97-00490

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OEI's Atlanta Regional Office prepared this report under the direction of Jesse J. Flowers, Regional Inspector General and Christopher Koehler, Deputy Regional Inspector General. Principal OEI staff included:

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EXECUTIVE SUMMARY

PURPOSE

To describe how Medicare, Medicaid, and private insurers control chiropractic benefits.

BACKGROUND

The Balanced Budget Act of 1997 required the Health Care Financing Administration (HCFA) establish new utilization guidelines for Medicare chiropractic care by January 1, 2000. It also eliminated the X-ray requirement. In addition, New York recently enacted legislation requiring private insurers to include chiropractic coverage in their benefits packages.

We initiated two inspections to better understand the impact of these changes on the Medicare and Medicaid programs and to learn more about utilization controls. This report, "CHIROPRACTIC CARE: Controls Used by Medicare, Medicaid, and Other Payers, (OEI-04-97-00490)" describes Medicare, Medicaid, and private insurers' mechanisms for controlling expenditures and protecting the chiropractic benefit from potential waste and abuse. A companion report, "CHIROPRACTIC CARE: Medicaid Coverage, (OEI-06-97-00480)" describes current and expected chiropractic care benefits under State Medicaid programs.

Medicare, Medicaid, and private insurers do not consider control of chiropractic benefits a high priority or an area of major concern. All commented that more could be done to control utilization of the benefit but that resources are better spent controlling other more costly benefits.

FINDINGS

We found that Medicare, Medicaid, and private insurers rely on utilization caps, X-rays, physician referrals, co-payments, and post and prepayment reviews, in varying degrees, to control utilization of chiropractic benefits. Utilization caps are the most widely used, but these and other controls did not detect or prevent unauthorized Medicare maintenance treatments.

Utilization Caps Are the Most Widely Used Control Mechanisms

Ninety-five percent of Medicare and 46 percent of Medicaid programs use soft caps that can be exceeded with appropriate justification. Hard caps, which cannot be exceeded, are used by 50 percent of Medicaid programs and 94 percent of private insurers. Federal costs for Medicaid chiropractic benefits can exceed those for Medicare because Medicaid utilization caps are typically higher than those for Medicare.

X-rays Provide Little Control of Chiropractic Benefits

Few private insurers or Medicaid agencies require X-rays to document treatment necessity. Medicare currently requires X-rays; however, elimination of the X-ray requirement should have little impact on chiropractic controls since most contractors do not use X-rays as a control mechanism.

Physician Referral Is Commonly Used as a Control Mechanism for Managed Care, but Not for Fee-For-Service Plans

Sixty-eight percent of Medicaid and 66 percent of private managed care organizations used physician referrals to help control chiropractic utilization. However, only 8 percent of Medicaid and 9 percent of private fee-for-service plans required physician referrals. None of the Medicare fee-for-service plans required physician referrals.

Co-payments, Coinsurance, and Deductibles are Used to Help Control Chiropractic Benefits by Medicare and Private Insurers, but Not by Medicaid

Private insurers' co-payments ranged from $5 to $15 while Medicare coinsurance equaled 20 percent of approved charges. Both private insurers and Medicare used annual deductibles. Private insurers' deductibles ranged from $200 to $500 and Medicare's deductible equaled $100.

Prepayment Reviews Do Not Control Chiropractic Benefits

Medicare and Medicaid contractors typically do prepayment reviews, however, it is basically a forms verification process. For those claims that exceed the soft caps, Medicare and Medicaid medical necessity prepayment reviews are mostly paper audits.

Post Payment Reviews are Used by Medicaid, but Not by Medicare, to Help Control Chiropractic Benefits

Sixty-five percent of Medicaid contractors use post payment reviews to help control chiropractic utilization. Medicare contractors, however, rarely conduct post payment reviews of chiropractic claims.

Unauthorized Chiropractic Maintenance Treatments are Not Detected and Prevented

HCFA policies preclude Medicare reimbursements for chiropractic maintenance treatments. However, only 40 percent of Medicare respondents claimed to do utilization reviews to identify and prevent such treatments. Our analysis identified over $68 million in probable chiropractic maintenance treatments in 1996. If left unchecked, this could result in as much as $447 million in improper Medicare payments from 1998 through 2002.

RECOMMENDATIONS

This report describes controls used by Medicare, Medicaid, and other payers for chiropractic benefits. Utilization caps were the most widely used control mechanism. Needless to say, their intent is to limit the quantity of services. However, neither the utilization caps, nor any of the other controls, detected and prevented reimbursements for unauthorized Medicare chiropractic maintenance treatments.

Accordingly, we recommend that HCFA develop system edits to detect and prevent unauthorized payments for chiropractic maintenance treatments. HCFA may do so by:

- requiring chiropractic physicians to use modifiers to distinguish the categories of the spinal joint problems (i.e. acute, exacerbation, recurrence, and chronic), and

- requiring all Medicare contractors to implement system utilization frequency edits to identify beneficiaries receiving consecutive months of minimal therapy.

COMMENTS

The HCFA Administrator, the Assistant Secretary for Planning and Evaluation (ASPE), and the Assistant Secretary for Management and Budget (ASMB) commented on our report. The full text of their comments are in appendix C.

The HCFA concurred with our recommendations. The Balanced Budget Act of 1997 required HCFA to develop utilization guidelines for chiropractic care. In developing such guidelines, HCFA will develop modifiers to distinguish categories of spinal joint problems, and utilization frequency edits as we recommended.

ASPE agreed that edits to identify inappropriate billings seemed desirable. However, ASPE commented that our use of "averages," on pages four through six, to summarize the range of utilization caps was inappropriate because they did not reflect "real practice." Our report provides the reader both the average utilization caps and the actual utilization caps for all Medicare and Medicaid respondents.

Further, ASPE suggested that more information is needed to substantiate two State Medicaid Administrators' claims that physician referrals are effective controls for chiropractic services. Specifically, ASPE wanted to know how these States measured effectiveness. Additionally, ASPE noted that it would be helpful to know how the use of chiropractic services is distributed between managed care and fee-for-service providers. These questions were not part of the scope of this study. However, we plan to continue our analysis of chiropractic services and utilization in the future. These and other questions are likely topics for inclusion in future analysis.

ASMB expressed serious concerns about the methodology we used to estimate payments for probable inappropriate chiropractic maintenance treatments. Specifically, ASMB was concerned about our use of a 10 percent estimate to represent the Medicare population who received

chiropractic care for chronic conditions. The 10 percent estimate, furnished by the American Chiropractic Association, is a universal percentage estimate of the population at large. Demographic data and specific analysis is not available to differentiate between the Medicare population and the population at large. However, we contacted several Medicare Carrier Medical Directors who stated, based on their reviews of Medicare chiropractic claims, that the 10 percent appeared to be a reasonable estimate for the Medicare population.

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INTRODUCTION

PURPOSE

To describe how Medicare, Medicaid, and private insurers control chiropractic benefits.

BACKGROUND

Chiropractic Treatment

Chiropractic treatment is becoming more commonplace with consumers, and gaining wider acceptance in the medical profession. Chiropractors treat neuromusculoskeletal disorders and related functional clinical conditions including, but not limited to, back pain, neck pain and headaches. Chiropractic care is most commonly sought for treatment of back pain. Back pain is one of the most common and costly problems affecting adults. An estimated 50 percent of adults experience back pain each year and almost 20 percent have frequent back pain.

A common chiropractic treatment for low back pain is spinal manipulation. Chiropractors use either their hands or hand held devices to perform manual spinal manipulations. Manual manipulations are most commonly performed to correct a subluxation of the spine. According to chiropractic theory, a subluxation is an incomplete dislocation, off centering, misalignment, fixation or abnormal spacing of vertebrae or intervertebral units. The Department of Health and Human Services, Agency for Health Care Policy and Research, has documented spinal manipulation to be a recommendable method of symptom control for low back pain in adults.[1]

Growth in Number of Chiropractors

The chiropractic profession is licensed in all States and the District of Columbia. All licensed chiropractors are entitled by law to use either the title doctor of chiropractic or chiropractic physician. Approximately 55,000 chiropractors actively practice today, while less than 14,000 existed in 1970, according to the U.S. Census. The number of chiropractors has outgrown the U.S. population by three-fold. In 1970, almost seven chiropractors practiced per 100,000 U.S. residents. By 1997, this had increased to over 20 chiropractors per 100,000 residents.

Medicare Chiropractic Eligibility

In 1965, title XVIII of the Social Security Act created Medicare to provide health insurance for people 65 and over, people who are disabled, and persons with permanent kidney failure. Medicare has two parts: Hospital Insurance (Part A) and Medical Insurance (Part B). In 1972, Section 273 of the Social Security Amendment (P.L. 92-603) expanded the definition of physician under Part B of Medicare to include chiropractors. This made chiropractors eligible to participate

[1] Agency for Health Care Policy and Research, Pub No. 95-0642, December 1994, Acute Low Back Problems in Adults

in the Medicare program. However, the only Medicare reimbursable chiropractic treatment is manual manipulation of the spine to correct a subluxation demonstrated by X-ray.

Medicaid Chiropractic Eligibility

In 1965, title XIX of the Social Security Act created Medicaid as a program to provide medical assistance for certain individuals and families with low incomes and resources. This program is jointly funded by the Federal and State governments. Within broad Federal guidelines each State (1) establishes its own eligibility standards, (2) sets the type, amount, duration, and scope of services, (3) establishes rate of payment for services, and (4) administers the program.

In 1972, when chiropractors were recognized as physicians and became eligible to participate in Medicare, chiropractors also became eligible to participate in Medicaid. Under Medicaid, however, chiropractic services are not a mandatory benefit, but rather an optional service. Therefore, it is within each State's discretion whether to include chiropractic services in their Medicaid program. If offered, each State also establishes its own levels of services. However, according to Federal policy for Medicaid, chiropractic services should be limited to manual manipulation of the spine and X-ray services. Currently, 30 State Medicaid fee-for-service programs offer chiropractic services.

Private Insurers Chiropractic Benefits

Many private insurers now offer chiropractic benefits. The scope of chiropractic services are consumer driven. We found insurance plans ranging from no chiropractic coverage to substantial chiropractic coverage. Several insurers stated that they view the chiropractic benefit as a service they must provide to remain competitive. Moreover, they expect users of chiropractic services to "max-out" the benefit each year.

Chiropractic Controls

The Balanced Budget Act of 1997 required the Health Care Financing Administration (HCFA) establish new utilization guidelines for Medicare chiropractic care by January 1, 2000. It also eliminated the X-ray requirement. In addition, New York recently enacted legislation requiring private insurers to include chiropractic coverage in their benefits packages.

We initiated two inspections to better understand the impact of these changes on the Medicare and Medicaid programs and to learn more about utilization controls. This report, "CHIROPRACTIC CARE: Controls Used by Medicare, Medicaid, and Other Payers, (OEI-04-97-00490)" describes Medicare, Medicaid, and private insurers' mechanisms for controlling expenditures and protecting the chiropractic benefit from potential waste and abuse. A companion report, "CHIROPRACTIC CARE: Medicaid Coverage, (OEI-06-97-00480)" describes current and expected chiropractic care benefits under State Medicaid programs.

Medicare, Medicaid, and private insurers all use a variety of mechanisms to help control their chiropractic benefit. However, most did not consider control of this benefit a high priority or an

area of major concern. In fact, over 50 percent of Medicare and 60 percent of Medicaid respondents considered the chiropractic benefit to be a small part of their overall programs. Both Medicare contractors and State Medicaid agencies commented that more could be done to control utilization of the chiropractic benefit, but that resources are currently better spent controlling other more costly benefits. Also, private insurers were not concerned with controlling utilization, but it was because of their strict utilization caps rather than the size of the benefit.

SCOPE AND METHODOLOGY

We surveyed Medicare contractors, Medicaid agencies, and private insurers. More specifically, we surveyed:

- all Medicare fee-for-service Part B contractors,
- the 10 largest, by number of enrollees, Medicare managed care organizations from 10 different States,
- all 50 State Medicaid agencies, and the District of Columbia (each were sent a two-part survey - one for their fee-for-service contractors and one for their largest, by number of enrollees, managed care organizations), and
- twenty private insurers (10 judgmentally selected Federal employee health benefit plans, and benefit managers for the 10 largest, by number of employees, private sector companies).

In instances where respondents did not answer every survey question, our percentages are based on the number who responded.

In addition to the surveys, we did on-site evaluations of one Medicare fee-for-service contractor, one Medicare managed care organization, two Medicaid fee-for-service contractors, and three Medicaid managed care organizations. Moreover, we interviewed officials with the Indiana Chiropractic Association, the American Chiropractic Association, and the Carrier Medical Director Chiropractic Clinical Workgroup.

Finally, we used a 1 percent sample of HCFA's 1996 National Claims History data to determine if Medicare contractors paid claims in accordance with HCFA policies, and to quantify the extent of chiropractic utilization. Appendix A further details our scope and methodology.

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We conducted our inspection between October 1997 and December 1997. We conducted this inspection in accordance with *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

We found that Medicare, Medicaid, and private insurers use a variety of techniques to control utilization of chiropractic benefits. Allowable chiropractic benefits vary in both quantity and type of treatments. Along with varying benefits come varying controls. Typical controls include utilization caps, X-rays, physician referrals, co-payments, and post and prepayment reviews. Utilization caps are the most widely used, but these and other controls did not detect or prevent unauthorized Medicare maintenance treatments.

UTILIZATION CAPS ARE THE MOST WIDELY USED CONTROL MECHANISMS

Limiting the number of visits by establishing utilization caps was the most widely used control mechanism reported by all groups surveyed. A companion report on chiropractic benefits for Medicaid beneficiaries discusses benefits, treatment limits, and exceptions in detail (Chiropractic Care: Medicaid Coverage, OEI-06-97-00480).

Utilization caps are most commonly broken down into two separate types - soft caps and hard caps.

Soft caps are established service limits that can be exceeded with appropriate justification. For example, one such justification would be documentation that a beneficiary has aggravated an existing condition.

Hard caps, as the name implies, are concrete service limits or dollar amounts that cannot be exceeded for any reason within a specified time frame.

Table 1 shows the average soft and hard utilization caps for respondents included in our survey.

TABLE 1

AVERAGE SOFT AND HARD UTILIZATION CAPS

	MEDICARE	MEDICAID	PRIVATE
SOFT CAPS	21	28	N/A
HARD CAPS	N/A	104	27

Ninety-five Percent of Medicare and 46 Percent of Medicaid Programs Use Soft Caps

Ninety-five percent (52 of 55) of all Medicare survey respondents said they use soft caps. The soft caps ranged from 11 to 52 treatments per year, with 12 treatments being the most common. On average, the Medicare respondents used a soft cap of 21 treatments. Table 2 shows chiropractic soft caps used by the Medicare respondents included in our survey.

# Treatments	11	12	18	22	24	28	29	30	40	46	48	51	52
Respondents	1	29	3	1	4	3	1	1	2	1	2	1	3

HCFA requires all Medicare contractors to establish soft caps. Each contractor, however, determines the level of the cap (i.e. the number of treatments). HCFA further requires all Medicare contractors to evaluate the effectiveness of their caps on a quarterly basis. Based on these evaluations, HCFA granted 5 percent (3 of 55) of its contractors permission to deactivate their chiropractic caps. The three contractors documented that their soft caps were not cost effective. Instead, they now focus on post payment reviews to identify aberrant providers.

Forty-six percent (12 of 26) of States that provide chiropractic benefits reported using soft caps. The soft caps ranged from 1 to 80 treatments per year, with the average being 28 treatments. Table 3 shows chiropractic soft cap limits used by State Medicaid Agencies.

# Treatments	1	6	10	12	18	20	24	30	48	60	80
Respondents	1	1	1	1	1	1	2	1	1	1	1

Fifty Percent of Medicaid Programs and 94 Percent of Private Insurers Use Hard Caps

Half (13 of 26) of the States that provide chiropractic benefits reported using hard caps to control their Medicaid chiropractic benefits. The hard caps ranged from 12 to 365 treatments per year. The average hard cap is 104 treatments, however, this includes three States that allow one treatment per day. Excluding these three States, the average Medicaid hard cap is 29 treatments. Table 4 shows the chiropractic hard caps used by State Medicaid agencies.

# Treatments	12	18	20	24	25	50	56	365
Respondents	2	1	1	3	1	1	1	3

Ninety-four percent (16 of 17) of private insurers relied on hard caps to control benefit utilization. The 16 private insurers used 11 utilization caps and 5 financial caps. The utilization caps ranged from 12 to 60 treatments per year, with the average being 27 treatments. Table 5 shows the chiropractic utilization hard caps used by private insurers.

# Treatments	12	20	24	25	26	30	40	60
Respondents	2	2	1	1	1	2	1	1

The financial caps, used by private insurers, ranged from $225 to $2,000 per year, with the average being $1,035. Table 6 shows the chiropractic financial hard caps used by private insurers.

TABLE 6

PRIVATE CHIROPRACTIC FINANCIAL HARD CAPS TREATMENTS PER YEAR

$ Cap	$225	$250	$700	$2000
Respondents	1	1	1	2

Federal Costs for Medicaid Chiropractic Benefits Can Exceed That for Medicare

Twenty-six States offer Medicaid chiropractic benefits. However, we limited our comparative analysis of Medicaid and Medicare Federal costs for chiropractic benefits to 24 States. We did so because one State did not have a Medicaid utilization cap and the Medicare contractor in another State did not have a utilization cap.

The Federal reimbursement rates and cost per treatment rates for Medicaid chiropractic treatments are typically lower than they are for Medicare. Medicaid Federal matching reimbursement rates for the 24 States ranges from 50 percent to over 73 percent with 60 percent being the average. This is lower than Medicare, where Federal costs are 80 percent of allowed charges. Likewise, the average Federal cost for Medicaid manual manipulations of the spine is only $8.92, but for Medicare the average Federal cost is $18.92.

However, overall Medicaid Federal costs for chiropractic services can exceed the cost for such services paid for by Medicare. This is because Medicaid's utilization caps are significantly higher than Medicare's. Sixty-seven percent (16 of 24) of States offering chiropractic care through their Medicaid fee-for-service programs have higher utilization caps than Medicare. In one State, for example, the Medicare utilization cap is 12 treatments per year while the Medicaid utilization cap is 50 treatments.

Medicaid's average utilization cap for the 24 States is 71 treatments per year, whereas Medicare's average utilization cap is only 19 treatments per year. Federal costs, at the maximum utilization cap for Medicaid chiropractic benefits, average $554 per person, whereas in Medicare it is only $365 per person.

X-RAYS PROVIDE LITTLE CONTROL OF CHIROPRACTIC BENEFITS

Few Medicaid Agencies and Private Insurers Require X-rays to Document Treatment Necessity

Thirty-one percent (8 of 26) of Medicaid programs require X-rays. However, 58 percent (15 of 26) of Medicaid programs will reimburse chiropractors for X-rays.

Only 12 percent (2 of 17) of private insurers require X-rays to ensure appropriateness of chiropractic claims.

Elimination of the X-ray Requirement Should Have Little Impact on Chiropractic Controls since Most Medicare Contractors Do Not Use X-rays as a Control Mechanism

Seventy-eight percent (43 of 55) of Medicare respondents claimed X-rays were not essential for ensuring the appropriateness of chiropractic claims. They said chiropractic benefit control would not be affected by the Balanced Budget Act of 1997, which eliminates the X-ray requirement by the year 2000. Several respondents commented that they do not use X-rays, but rather they compare diagnosis with treatment plans to determine appropriateness of treatments.

The remaining 22 percent (12 of 55) said elimination of the X-ray requirement would impact their ability to verify spinal subluxations.

PHYSICIAN REFERRAL IS COMMONLY USED AS A CONTROL MECHANISM FOR MANAGED CARE, BUT NOT FOR FEE-FOR-SERVICE PLANS

Physician Referral Is Common for Managed Care Plans

In 68 percent (15 of 22) of Medicaid managed care organizations and 66 percent (4 of 6) of private managed care organizations, physician referrals are required to obtain chiropractic care. According to the American Chiropractic Association, this common managed care gatekeeper practice restricts access to chiropractic care.

Private insurers typically use physician referrals in conjunction with hard caps to control chiropractic utilization. Only one private insurer used physician referrals as its only control mechanism.

Few Fee-For-Service Programs Require Physician Referral

Overwhelmingly, Medicare, Medicaid, and private insurers allow direct access to chiropractors without a physician referral. No Medicare fee-for-service program required physician referral for access to chiropractors.

Only 8 percent (2 of 26) of Medicaid fee-for-service programs require physician referrals to access chiropractic services. The two Medicaid programs that do require physician referrals, however, said physician referral is a very effective control mechanism. It allows primary care physicians to monitor and coordinate clients' health care needs.

About 9 percent (1 of 11) of private fee-for-service insurers require physician referrals to access chiropractic services.

CO-PAYMENTS, COINSURANCE, AND DEDUCTIBLES ARE USED TO HELP CONTROL CHIROPRACTIC BENEFITS BY MEDICARE AND PRIVATE INSURERS, BUT NOT BY MEDICAID

Medicare and private insurers require co-payments, coinsurance, or deductibles. Medicaid programs, however, typically do not require co-payments, coinsurance, or deductibles.

A co-payment is a set amount beneficiaries must pay when they visit a physician. The private insurers in our survey had co-payments ranging from $5.00 to $15.00 per chiropractic treatment. These co-payments are common in both managed care and fee-for-service plans.

Coinsurance is the percentage of medical expenses for which a patient is responsible. For Medicare Part B services, coinsurance equals 20 percent of approved charges.

A deductible is the amount a beneficiary must pay before a health plan begins payment for covered services. Medicare has a $100 annual deductible for Part B services, including chiropractic treatments. Private insurers' yearly deductibles ranged from $200 to $500 per year. These deductibles applied to all physician services, including chiropractic care.

Medicaid fee-for-service programs required co-payments in only three States. These co-payments ranged from 50 cents to $2.00 per chiropractic visit. Likewise, only one Medicaid managed care organization responded that a co-payment was required -- $1.00 per visit.

Such patient cost sharing may be important when considering how best to control chiropractic utilization. A study by the Agency for Health Care Policy and Research suggests that the actual out-of-pocket expense a patient incurs greatly affects their use of chiropractic services.[2] To illustrate, the study shows that when patients have to share 25 percent or more of the cost, they decrease their chiropractic usage by half.

PREPAYMENT REVIEWS DO NOT CONTROL CHIROPRACTIC BENEFITS

[2] Agency for Health Care Policy and Research, Pub No. HS06920, 1996, The Affect of Cost Sharing on the Use of Chiropractic Services

Medicare and Medicaid Contractors Typically Do Prepayment Reviews, However, it Is Basically a Forms Verification Process

All Medicare and Medicaid contractors conduct prepayment reviews. However, the reviews are merely computerized edits or manual reviews to ensure that claim forms are properly completed. The level of prepayment review for Medicare and Medicaid is similar and usually includes the following edits:

- appropriate procedure codes,
- appropriate diagnosis codes,
- date of X-ray,
- date of first treatment falling within a specified time period of the X-ray date,
- appropriate physician identification number, and
- no more than one treatment per day.

Medicare and Medicaid Prepayment Reviews for Medical Necessity Are Paper Audits

Medicare and Medicaid policies require that all services be medically necessary. However, Medicare and Medicaid contractors generally do not verify the medical necessity of chiropractic treatments.

Medicare and Medicaid contractors, for example, typically review claims for medical necessity only if they exceed their soft caps. One Medicare contractor's policy states "services exceeding more than what Medicare allows, in a given time frame, are subject to review for medical necessity." Another commented that "we review every claim for medical necessity that exceeds the cap." A Medicaid agency said "medical necessity must be documented in order to receive additional treatments (beyond the utilization cap)."

Medical necessity reviews in excess of the caps, however, are paper audits. Contractors typically determine medical necessity by verifying that a claim form was completed properly. They verify that the diagnosis codes are from the approved list. In addition, they verify that comments, such as "aggravated existing condition," are on the claim form. In effect, such reviews are "check the appropriate box" edits, and not verification that services are truly medically necessary. Patient records and other documentation of medical necessity are typically not reviewed.

POST PAYMENT REVIEWS ARE USED BY MEDICAID, BUT NOT BY MEDICARE, TO HELP CONTROL CHIROPRACTIC BENEFITS

Medicaid Contractors Use Post Payment Reviews to Help Control Chiropractic Utilization

Sixty-five percent (17 of 26) of State Medicaid fee-for-service agencies monitor and control chiropractic claims using post payment reviews. The reviews are typically limited to quarterly

Surveillance and Utilization Review Surveys. Such reviews identify aberrant providers. Three States said they do not do more extensive individual reviews due to the small nature of the chiropractic program and the limited number of problem claims found in the past.

Medicare Contractors Rarely Conduct Post Payment Reviews of Chiropractic Claims

HCFA policy requires Medicare contractors to conduct focused medical reviews and comprehensive medical reviews. A focused review is a treatment specific audit, whereas a comprehensive review is a provider specific audit. It is up to the contractors to determine which benefits to review. All Medicare respondents conduct these reviews, however, most had focused little to no activity on chiropractic benefits since 1994.

Eighteen percent (10 of 55) of Medicare respondents claimed to conduct focused reviews of chiropractic benefits. Since 1994, three of the 10 respondents claimed to have saved about $759,000 as a result of focused reviews. However, of the respondents, one accounted for over 99 percent of those savings. The remaining seven respondents conducted, on average, less than two focused reviews per year.

Thirty-six percent (20 of 55) of Medicare respondents claimed to conduct comprehensive reviews of chiropractic benefits. Ten respondents claimed their comprehensive reviews resulted in financial savings totaling about $330,500. However, one of the respondents accounted for about 71 percent of those savings. The remaining respondents conducted varying numbers of reviews resulting in such things as educational efforts and a couple of fraud referrals.

UNAUTHORIZED CHIROPRACTIC MAINTENANCE TREATMENTS ARE NOT DETECTED AND PREVENTED

According to HCFA policy,[3] chiropractic maintenance treatments are not authorized for payment. However, our analysis of a 1 percent sample of HCFA's National Claims History database showed that in 1996, Medicare likely paid for 28,889 chiropractic maintenance treatments. These inappropriate maintenance treatments cost Medicare $688,821. This projects to over $68 million for the Medicare program in 1996. Projected over five years, Medicare reimbursements for unauthorized chiropractic maintenance treatments is about $447 million.

Chiropractic Coverage Policies

HCFA's Medicare Carrier Manual identifies treatment of acute and chronic subluxations as Medicare reimbursable conditions. Maintenance treatments, however, are not a covered service.

HCFA and local carrier policies, and Agency for Health Care Policy and Research guidelines, show that chiropractic treatment for acute conditions should consist of intense treatments early on with additional treatments tapering off quickly. To illustrate, the HCFA approved Medicare Part

[3] HCFA Medicare Carrier Manual, section 2251.1

B Model Local Medical Review Policy for Chiropractic Service calls for "vigorous therapy" the first month, "less vigorous therapy" the second month, and finally, "minimum therapy" of up to four treatments the third month.

However, HCFA and local carrier policies allow chiropractic treatment for chronic conditions. Such conditions require less frequent treatments than acute conditions. A patient's condition is considered chronic if it has existed for an extended period of time. A chronic condition is not expected to be completely resolved, but continued chiropractic therapy is expected to result in some functional improvement. Hence, chiropractic treatments may need to extend over long periods.

On the surface, it seems difficult to distinguish between unauthorized chiropractic maintenance treatments and authorized treatments for chronic conditions. The treatment patterns are similar. Unauthorized chiropractic maintenance treatments are generally indicated by consecutive months of minimal therapy of four treatments or less. Likewise, authorized chiropractic treatments for chronic conditions are generally indicated by four or fewer treatments per month for an extended time period.

It is possible, however, to distinguish between the two. To illustrate, a utilization frequency analysis of chiropractic treatments will enable carrier staff to identify potential unauthorized maintenance treatments. However, some of these treatments could be for authorized chronic conditions. Therefore, carrier staff must also review individual claims documentation to identify treatments for chronic conditions. Beneficiary symptoms and chiropractor diagnosis are two pieces of claims information that allow carrier staff to distinguish between treatments for chronic conditions and maintenance.

Estimated Medicare Reimbursement for Maintenance Treatments

To estimate potential unauthorized Medicare reimbursements for chiropractic maintenance treatments, we conducted a utilization frequency analysis of chiropractic treatments in 1996. Thereafter, we adjusted our findings to exclude possible treatments for chronic conditions. In making the adjustment, we did not review individual claims, but rather we used an estimate on the extent of chronic conditions nationwide.

We based our utilization frequency analysis on a 1 percent sample of HCFA's 1996 National Claims History file. We used the local model policy criteria of minimum therapy of four treatments or less in the third and final month of treatment. We then identified beneficiaries with treatment utilization of two or more consecutive months of minimum therapy. This analysis identified beneficiaries who received either maintenance or chronic chiropractic treatments (see appendix A for additional information on our methodology).

HCFA data files did not distinguish between treatments for acute or chronic conditions. Therefore, we adjusted our findings by deleting chiropractic treatments for possible chronic conditions. To do so, we used information provided by the American Chiropractic Association. That research showed that 10 percent of chiropractic conditions are chronic. After eliminating

beneficiaries with chronic conditions from our analysis, we concluded that 7,594 Medicare beneficiaries received 28,889 probable unauthorized maintenance treatments at a cost of $688,821. Table 7 summarizes maintenance treatments in 1996.

TABLE 7

NUMBER OF MEDICARE BENEFICIARIES RECEIVING UP TO FOUR CHIROPRACTIC TREATMENTS DURING TWO OR MORE CONSECUTIVE MONTHS IN 1996

# Beneficiaries	# Consecutive Months	Probable Maintenance Treatments	Allowed Amounts
3,298	2	5,259	$125,058
1,486	3	4,370	$104,321
855	4	3,545	$84,788
563	5	3,090	$74,388
348	6	2,256	$53,751
247	7	1,881	$45,103
187	8	1,585	$37,462
128	9	1,204	$28,298
138	10	1,504	$36,012
88	11	962	$23,356
256	12	3,233	$76,284
7,594		28,889	$688,821

Our findings in Table 7 are based on a 1 percent sample, therefore, we projected them to the Medicare population. We concluded that 759,400 Medicare beneficiaries received 2,888,900 probable chiropractic maintenance treatments at a cost to the Medicare program of $68,882,100. Assuming chiropractic reimbursements continue to increase by 6.87 percent per year, Medicare reimbursements for unauthorized chiropractic maintenance treatments, over a five year window (1998-2002), would be about $447 million.

At the request of HCFA officials, we included the above information, broken out by State, in appendix B.

R E C O M M E N D A T I O N S

This report describes controls used by Medicare, Medicaid, and other payers for chiropractic benefits. Utilization caps were the most widely used control mechanism. Needless to say, their intent is to limit the quantity of services. However, neither the utilization caps, nor any of the other controls, detected and prevented reimbursements for unauthorized Medicare chiropractic maintenance treatments.

Accordingly, we recommend that HCFA develop system edits to detect and prevent unauthorized payments for chiropractic maintenance treatments. HCFA can do so by:

- requiring chiropractic physicians to use modifiers to distinguish the categories of the spinal joint problems (i.e. acute, exacerbation, recurrence, and chronic), and

- requiring all Medicare contractors to implement system utilization frequency edits to identify beneficiaries receiving consecutive months of minimal therapy.

COMMENTS

The HCFA Administrator, the Assistant Secretary for Planning and Evaluation (ASPE), and the Assistant Secretary for Management and Budget (ASMB) commented on our report. The full text of their comments are in appendix C.

The HCFA concurred with our recommendations. The Balanced Budget Act of 1997 required HCFA to develop utilization guidelines for chiropractic care. In developing such guidelines, HCFA will develop modifiers to distinguish categories of spinal joint problems, and utilization frequency edits as we recommended.

ASPE agreed that edits to identify inappropriate billings seemed desirable. However, ASPE commented that our use of "averages," on pages four through six, to summarize the range of utilization caps was inappropriate because they did not reflect "real practice." Our report provides the reader both the average utilization caps and the actual utilization caps for all Medicare and Medicaid respondents.

Further, ASPE suggested that more information is needed to substantiate two State Medicaid Administrators' claims that physician referrals are effective controls for chiropractic services. Specifically, ASPE wanted to know how these States measured effectiveness. Additionally, ASPE noted that it would be helpful to know how the use of chiropractic services are distributed between managed care and fee-for-service providers. These questions were not part of the scope of this study. However, we plan to continue our analysis of chiropractic services and utilization in the future. These and other questions are likely topics for inclusion in future analysis.

ASMB expressed serious concerns about the methodology we used to estimate payments for probable inappropriate chiropractic maintenance treatments. Specifically, ASMB was concerned about our use of a 10 percent estimate to represent the Medicare population who received chiropractic care for chronic conditions. The 10 percent estimate, furnished by the American Chiropractic Association, is a universal percentage estimate of the population at large. Demographic data and specific analysis is not available to differentiate between the Medicare population and the population at large. However, we contacted several Medicare Carrier Medical Directors who stated, based on their reviews of Medicare chiropractic claims, that the 10 percent appeared to be a reasonable estimate for the Medicare population. Additionally, HCFA's implementation of our recommendations will produce demographic data needed to more precisely differentiate chiropractic chronic care use by Medicare beneficiaries.

APPENDIX A

SCOPE AND METHODOLOGY

Medicare

We had 55 responses to the Medicare fee-for-service survey. We received responses for all 50 States. The additional five responses are detailed in Table 1.

TABLE 1	
MEDICARE RESPONSES	
	# of responses
50 States	50
California - serviced by 2 contractors	1
Missouri - serviced by 2 contractors	1
New York - serviced by 3 contractors	2
District of Columbia	1
Total	55

Medicaid

Our sample population consisted of 26 State fee-for-service programs that offered a chiropractic benefit to the majority of their Medicaid population. Although 30 State fee-for-service programs reported offering some type of chiropractic service to Medicaid beneficiaries, four States only offered a very limited benefit to children as part of their Early and Periodic Screening, Diagnostic and Treatment program. Due to the limited scope of those four programs, we excluded them from our sample.

Although we surveyed both State Medicaid fee-for-service and managed care programs, for the purposes of this study we limited our primary Medicaid focus to those 26 State programs offering a chiropractic benefit through the traditional fee-for-service environment. Observations made regarding State Medicaid managed care programs will be noted by specifically referring to that group.

Utilization Caps

Seven Medicare utilization caps and nine State Medicaid utilization caps are based on time periods other than one year. For such States, we annualized their utilization caps accordingly. For example, one State reported a utilization cap of 76 treatments in 540 days. Annualized, the cap is 51 treatments.

Probable Maintenance Treatments

To identify probable maintenance treatments we took several steps. First, we used a 1 percent sample of HCFA's 1996 National Claims History file and identified 13,974 Medicare beneficiaries who received 122,047 chiropractic treatments at a cost of $2,937,668. Next we did a utilization frequency analysis of this data and identified 8,990 beneficiaries with two or more consecutive months of minimal therapy (1-4 treatments). These beneficiaries received 41,094 chiropractic treatments at a cost of $982,588. We considered this subpopulation to be receiving unauthorized maintenance treatments or treatments for chronic conditions.

In order to account for the chronic conditions, we used information provided by the American Chiropractic Association that showed that 10 percent of chiropractic conditions are chronic. To be conservative, we assumed that the full 10 percent of chronic conditions were included in our sample. Therefore, we took 10 percent of the 1 percent figures and subtracted them from our subpopulation figures. For example, we took 10 percent of the $2,937,668 and subtracted it from our subpopulation treatment costs of $982,588. This resulted in probable unauthorized maintenance charges, adjusted for chronic conditions, of $688,821.

We used the same process to reduce the number of beneficiaries to 7,594 and the number of chiropractic treatments to 28,889. Since these numbers are based on a 1 percent sample, we project them to the Medicare population to conclude that 759,400 Medicare beneficiaries received 2,888,900 probable chiropractic maintenance treatments at a cost to the Medicare program of $68,882,100.

Using Part B Extract and Summary System data for 1994 through 1997, we calculated the growth in Medicare chiropractic payments. This growth averaged 6.87 percent per year. We then used this growth rate to predict reimbursements for maintenance treatments for 1998 through 2002. Accepting that the $68.8 million in maintenance costs for 1996 would continue to go unchecked, and applying the 6.87 percent average growth, Medicare reimbursements for chiropractic maintenance treatments can cost in excess of $447 million from 1998 through 2002.

Private Insurers

Of the 20 private insurers surveyed, 10 were judgmentally selected Federal employee health benefit plans, and the other 10 were benefit managers for the largest, by number of employees, private sector companies.

All 10 Federal employee plans responded, two of which had both a "high" and a "standard" option. Therefore, we have 12 Federal employee plan responses.

Seven of the 10 private sector companies responded, two of which offered both fee-for-service and managed care plans. Therefore, we have 9 private sector company responses.

Combined, we received 21 private insurer responses to our chiropractic survey. However, four private insurers did not offer chiropractic benefits. Therefore, we based our analysis on the 17 private insurers that offered chiropractic benefits.

We included private insurers in our inspection for comparison purposes. We do not attempt to generalize to the private insurance population.

A P P E N D I X B

STATE	TOTAL CHIROPRACTIC TREATMENTS	TOTAL ALLOWED CHARGES	MAINTENANCE TREATMENTS	ALLOWED MAINTENANCE CHARGES	
NH	413	$9,902	147	$3,577	36.1%
DC	59	$1,586	20	$540	34.0%
IA	5,802	$130,193	1,975	$44,109	33.9%
VT	333	$7,889	111	$2,583	32.7%
SD	784	$17,343	231	$5,085	29.3%
MI	6,994	$175,359	2,019	$50,296	28.7%
MO	2,671	$58,477	756	$16,440	28.1%
GA	2,654	$63,211	745	$17,662	27.9%
DE	312	$7,863	85	$2,129	27.1%
MA	2,059	$53,678	545	$14,147	26.4%
OH	4,685	$111,027	1,232	$28,650	25.8%
ND	858	$19,600	221	$5,037	25.7%
AZ	2,415	$60,058	618	$15,285	25.5%
PA	7,340	$178,658	1,869	$45,255	25.3%
IL	6,739	$156,487	1,719	$39,517	25.3%
ME	1,035	$25,737	259	$6,471	25.1%
NM	349	$8,036	86	$1,990	24.8%
UT	512	$12,093	127	$2,973	24.6%
VA	1,878	$44,046	456	$10,449	23.7%
KY	1,213	$25,875	292	$6,065	23.4%
OR	1,598	$37,751	377	$8,834	23.4%
IN	2,277	$50,692	535	$11,758	23.2%
WA	3,635	$90,893	841	$21,081	23.2%
CA	8,133	$208,445	245	$47,839	23.0%
CO	1,059	$25,343	1,881	$5,818	23.0%
CT	1,237	$33,982	281	$7,762	22.8%
WY	223	$5,114	51	$1,160	22.7%
NY	7,988	$210,107	1,833	$47,299	22.5%
MN	2,916	$68,753	1,123	$15,008	21.8%
NJ	5,092	$137,541	645	$30,038	21.8%
TN	2,623	$59,188	1,045	$12,702	21.5%
WI	4,719	$107,771	567	$23,200	21.5%
MT	507	$11,360	107	$2,409	21.2%
WV	464	$10,443	100	$2,189	21.0%
KS	2,911	$67,623	608	$13,849	20.5%
AK	188	$5,179	37	$1,046	20.2%
NC	2,253	$50,867	457	$10,119	19.9%
TX	7,445	$172,613	1,481	$34,071	19.7%
AL	1,157	$25,410	231	$4,985	19.6%
NE	1,988	$44,682	390	$8,720	19.5%
FL	6,701	$166,095	1,294	$31,948	19.2%
MD	860	$20,989	162	$3,947	18.8%
ID	704	$15,722	127	$2,786	17.7%
SC	800	$17,540	145	$3,102	17.7%
AR	1,701	$38,920	287	$6,594	16.9%
NV	650	$16,521	106	$2,695	16.3%
RI	192	$4,972	30	$773	15.5%
PR	79	$1,632	12	$252	15.4%
LA	1,069	$23,820	163	$3,572	15.0%
HI	155	$4,169	22	$604	14.5%
MS	546	$11,758	67	$1,471	12.5%
OK	1,058	$24,267	130	$2,924	12.0%
Unknown	14	$388	0	$0	0.0%

A P P E N D I X C

COMMENTS ON THE DRAFT REPORT

We present, in full, comments from the HCFA Administrator, the Assistant Secretary for Planning and Evaluation (ASPE), and the Assistant Secretary for Management and Budget (ASMB).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: AUG 10 1998

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

OFFICE OF INSPECTOR GENERAL
98 AUG 11 P 2:47

SUBJECT: Office of Inspector General (OIG) Draft Reports on Chiropractic Care: "Controls Used by Medicare, Medicaid, and Other Payers," (OEI-04-97-00490) and "Medicaid Coverage," (OEI-06-97-00480)

We reviewed the above-referenced reports that describe the current and anticipated chiropractic care benefits provided under each state Medicaid program and how Medicare, Medicaid, and private insurers control chiropractic benefits. The report recommends that The Health Care Financing Administration (HCFA) develop system edits which will detect and prevent unauthorized payments for chiropractic maintenance treatments.

We concur with the report recommendations. Our detailed comments follow.

OIG Recommendations

HCFA should: (1) require chiropractic physicians to use modifiers to distinguish categories of spinal joint problems (i.e., acute, exacerbation, recurrence, and chronic); and (2) require all Medicare contractors to implement system utilization frequency edits which will identify beneficiaries receiving consecutive months of minimal therapy.

HCFA Response

We concur. HCFA is developing utilization guidelines as specified in section 4513(c) of the Balanced Budget Act of 1997 (BBA). Section 4513(c) requires two actions: (1) the deletion of the x-ray requirement for chiropractic coverage; and (2) the development of utilization guidelines for chiropractic services in cases in which a subluxation has not been demonstrated by x-ray to exist. The implementation date for these provisions is January 1, 2000. We believe the OIG report recommendations will be addressed by the forthcoming action in response to the BBA. Once the utilization guidelines are developed, we will be able to develop modifiers and edits as necessary.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Washington, D.C. 20201

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TO: June Gibbs Brown
Inspector General

FROM: Margaret A. Hamburg, M.D.
Assistant Secretary for Planning and Evaluation

SUBJECT: OIG Draft Reports on Chiropractic Care -- COMMENTS

We were pleased to have the opportunity to review these two draft reports concerning chiropractic care in the Medicaid program and controls on chiropractic benefits used by Medicare, Medicaid and private insurers.

We offer the following observations based on our review:

- While the development of edits or other mechanisms to identify inappropriate billings for chiropractic care certainly seems desirable, Medicare contractors must weigh the returns on investment in this activity against the returns likely on other investments of their resources for administration.

- The two State Medicaid programs that use physician referral in fee-for-service cite this requirement as a very effective means of control. More information is needed to substantiate this observation by State officials. How do these States measure the effect of physician referral? Is physician referral the only tool these States use to control spending on and/or use of chiropractic benefits? If they use other measures, how do they isolate the effect of physician referral? Finally, do these States factor in to their assessment of effectiveness the additional cost to the State of physician visits that may be necessary for the referral?

- To assess the relative importance of controls in Medicaid managed care compared to fee-for-service, it would be helpful to know how utilization of chiropractic services is distributed between these two sectors and the Medicaid populations they may roughly reflect (i.e., low-income families and SSI eligibles, respectively).

- The use of weighted averages (pp. 4-6) to summarize the range of utilization caps is inappropriate. The average values, which do not reflect real practice by any state or contractor, are actually meaningless and may mislead. For example, although 28 treatments/year is cited as the average among Medicaid plans that cover chiropractic services, not a single state actually has 28/year as its cap. Even more striking, the 104/year among plans with a hard cap doesn't even come close to any of the hard caps actually used by any of the 13 states that use them.

If you have any questions, please contact Julia Paradise of my staff at 690-6476 or jparadis@osaspe.dhhs.gov.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

JUL 31 1998

MEMORANDUM TO: June Gibbs Brown
Inspector General

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FROM: John J. Callahan
Assistant Secretary for Management and Budget

SUBJECT: OIG Draft Reports on Chiropractic Care

Thank you for the opportunity to review the draft OIG reports entitled "Chiropractic Care - Medicaid Coverage (Ref. OEI-06-97-00480), and Chiropractic Care - Controls Used by Medicare, Medicaid and Other Payers (Ref. OEI-04-97-00490). For your consideration, we have comments on both reports as follows:

The manner of Data Collection for Both Reports

With respect to the manner of data collection, we believe that the collection of this information has Paperwork Reduction Act (PRA) implications. As we have recently discussed, we encourage you to establish a coherent OIG-wide approach to compliance with PRA requirements.

Chiropractic Care - Medicaid Coverage

While the report provides much useful information, more discussion of the methodology might be helpful. Also, we noted that there is one state - Utah - with a consistent upward trend in Chiropractic expenses. Are you aware of any reason for this growth?

Chiropractic Care - Controls

Methodology

We have serious reservations concerning the methodology used to estimate the incidence of chiropractic maintenance treatments billed to Medicare and the "probable" inappropriate payment estimates of $68 million ($447 million over five years). We do not believe the study's methodology supports these estimates. The application of a universal percentage estimate of chiropractic "conditions" to Medicare claims for chiropractic services does not seem to account for differences between all chiropractic services and those for which insurance claims are submitted, not to mention the differences in service usage, condition, etc. between the universe of chiropractic patients and Medicare chiropractic patients. Without: a) some extensive demographic analysis: b) a comparison of frequency of service utilization and insurance

coverage information for all chiropractic patients v. Medicare chiropractic patients, or c) a small subsample of claims which have actually been reviewed, there is nothing to validate your estimates. We recommend eliminating the estimates of inappropriate payment from the report.

We hope our comments have been useful. Questions can be addressed to Frank Burns on 690-6353.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Utilization Parameters for Chiropractic Treatments

JUNE GIBBS BROWN
Inspector General

NOVEMBER 1999
OEI-04-97-00496

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended by Public Law 100-504, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

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OEI's Atlanta Regional Office prepared this report under the direction of Jesse J. Flowers, Regional Inspector General and Christopher Koehler, Deputy Regional Inspector General. Principal OEI staff included:

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June Gibbs Brown
Inspector General

OIG Final Report: "Utilization Parameters for Chiropractic Treatments," OEI-04-97-00496

Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

This report identifies potential impacts of implementing a chiropractic utilization review parameter of either 18 or 12 chiropractic treatments (manual manipulations of the spine) per year.
Dr. Grant Bagley, Director, Coverage and Analysis Group, Office of Clinical Standards and Quality, Health Care Financing Administration; and Dr. Grant Steffin, Chair, Chiropractic Medical Directors, Chiropractic Work Group requested this analysis following our presentation on chiropractic controls at a meeting of the Chiropractic Work Group.

The Health Care Financing Administration (HCFA) convened the Chiropractic Work Group to assist in developing new chiropractic policies required by the 1997 Balanced Budget Act. The Chiropractic Work Group considered two options, a utilization review parameter of 18 treatments per year and one of 12 treatments per year.

Dr. Bagley asked us to assist the Chiropractic Work Group by compiling 1997 chiropractic utilization data. Additionally, he asked that we quantify the potential impacts of implementing the two options -- utilization review parameters of 18 or 12 treatments per year.

Implementing either option would ensure that Medicare pays for all chiropractic services that Medicare beneficiaries are entitled to and would help prevent payments for services not authorized under the program. By requiring carriers with high chiropractic utilization review parameters to implement lower review parameters, Medicare outlays would be reduced. One carrier has demonstrated the effect of reducing chiropractic utilization parameters. That carrier cut its chiropractic parameter in half and saved almost $3 million with virtually no change in program administrative costs. By establishing utilization review parameters at 18 or 12 beginning in 2000, we estimate annual Medicare outlays would be reduced by about $19.4 or $30.2 million respectively. We, however, recommend a parameter of 12. This is the most commonly used parameter (29 of 55 carriers), and it would require the least administrative change for carriers overall.

The 18 or 12 treatments per year would be a maximum review parameter that carriers would be allowed to use. Therefore, carriers with lower existing review parameters could remain unchanged. However, some carriers may choose to increase their existing parameters up to the new maximum review parameter. To the extent that this happens, our savings estimates would be reduced. The HCFA commented that they are using the information in this report in their effort to establish chiropractic utilization guidelines. The full text of their comments is attached.

BACKGROUND

A utilization review parameter is not a "hard" cap but rather a "soft" cap. That is, it does not establish a threshold above which Medicare payments will not be made. Instead, a utilization review parameter establishes a point at which a carrier will review each additional claim for medical necessity. The carriers, however, can review any and all claims if they so choose. The HCFA allows each carrier to establish its own utilization review parameter for chiropractic treatments. In 1997, carrier utilization review parameters ranged from 11 to 52 treatments per year.[1] Three carriers did not have chiropractic utilization review parameters. Table 1 shows the various utilization review parameters and the number of carriers with each parameter.

TABLE 1

MEDICARE CHIROPRACTIC UTILIZATION REVIEW PARAMETERS - 1997

Parameters	11	12	18	22	24	28	29	30	40	46	48	51	52	0
# of Carriers	1	29	3	1	4	3	1	1	2	1	2	1	3	3

SCOPE AND METHODOLOGY

This report is based on calendar year 1997 data collected as part of our chiropractic controls study,[2] and data extracted from a 1 percent sample of HCFA's 1997 National Claims History file.

Our analysis covers Medicare Part B carriers for all 50 States and the District of Columbia. California and Missouri were serviced by two carriers and New York was serviced by three carriers. Therefore, we have information from 55 carriers. Our analysis covers about 1.4 million Medicare beneficiaries receiving almost 12.2 million chiropractic treatments at a cost of over $310 million.

To estimate the potential Calendar Year 2000 savings, we used HCFA's Part B Extract and Summary System data and calculated the growth in Medicare chiropractic payments from 1994 through 1997. During this time period, the chiropractic benefit grew at an average of 6.87 percent per year. We applied this growth rate to our calculated 1997 savings to estimate potential Calendar Year 2000 savings.

We did not collect parameter information for the Railroad Retirement Board nor Puerto Rico. Therefore, we excluded them from our analysis. Additionally, we excluded six carriers whose contracts were terminated part way through 1997, prior to our data collection efforts. We included parameter and utilization data for the carriers that took over for the six terminated carriers.

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[1] Seven Medicare utilization parameters are based on time periods other than one year. For such carriers, we annualized their parameters accordingly. For example, one carrier reported a parameter of 76 treatments in 540 days. Annualized, the parameter is 51.

[2] CHIROPRACTIC CARE: Controls Used by Medicare, Medicaid, and Other Payers (OEI-04-97-00490)

Additionally, we analyzed utilization data for Florida Blue Cross, spanning October 1, 1991 to September 30, 1993. We used 1 percent samples of HCFA's 1991 - 1993 National Claims History files for this analysis.

REDUCING PARAMETERS WILL PROBABLY RESULT IN REDUCED UTILIZATION

Reducing chiropractic review parameters is likely to result in a reduction in actual utilization and the corresponding cost to Medicare. To test this premise, we analyzed the results achieved by Florida Blue Cross.

Reduced Utilization Review Parameters Equates to Program Savings

Beginning in Fiscal Year 1993, Florida Blue Cross cut its chiropractic utilization review parameter in half.[3] To test our assumption, we analyzed chiropractic utilization data, one year before and after Florida Blue Cross reduced its parameter. Table 2 displays the number of beneficiaries and treatments processed through Florida Blue Cross.

TABLE 2

FLORIDA BLUE CROSS BENEFICIARIES AND TREATMENTS

Fiscal Year	Beneficiaries	Treatments
FY 92	1,245	10,516
FY 93	1,253	9,215

Source: 1 percent sample of HCFA's National Claims History File.

The number of beneficiaries receiving chiropractic treatments grew by less than 1 percent (0.64) from FY 92 to FY 93. Had Florida Blue Cross not reduced its utilization review parameter, we estimate that they would have paid for 10,584 chiropractic treatments in FY 93 - a 0.64% increase over FY 92.

As a result of the parameter reduction, Florida Blue Cross actually paid for 9,215 chiropractic treatments. Multiplying the 1,369 saved treatments (10,584-9,215) by the FY 93 treatment rate ($21.50) results in estimated savings of $29,434. As our data is from a 1 percent sample, projected to the population, Florida Blue Cross saved the Medicare Trust Fund over $2.9 million by reducing its chiropractic utilization review parameter.

[3] HCFA considers utilization parameters to be confidential information. Therefore, we do not enumerate the Florida BCBS parameters.

Reduced Utilization Review Parameters Does Not Significantly Increase Administrative Costs

All claims that exceed a utilization review parameter should be reviewed for medical necessity. Therefore, reducing the chiropractic utilization review parameter would result in an increase in the number of requests for services that would require medical review and an associated increase in carrier medical review administrative costs.

However, based on the experience of Florida Blue Cross, the increased medical review workload will be short lived. To illustrate, during the 6 months prior to the utilization review parameter reduction, the claims denials, as a percent of total claims submitted, averaged 23 percent per month. During the 6 months immediately following the utilization review parameter reduction, the claims denials, as a percent of total claims submitted, increased to an average of 27 percent per month. Over the next 6 months, the percent of claims denied decreased to essentially what it was before the Florida carrier reduced its utilization parameter - 24 percent per month. In the last month of this period, the percent of claims denied had dropped to slightly below 23 percent.

POTENTIAL IMPLICATIONS OF ESTABLISHING A MAXIMUM UTILIZATION REVIEW PARAMETER OF 18 CHIROPRACTIC TREATMENTS PER YEAR

If HCFA implemented a maximum utilization review parameter of 18 chiropractic treatments per year beginning in 2000, it could save the Medicare Trust Fund over $19.4 million.

Implementing a parameter of 18 treatments per year would directly impact 22 of the 55 carriers. The remaining 33 carriers would not be directly impacted by a maximum review parameter of 18 as they already have parameters of 18 or less. Table 3 displays chiropractic utilization grouped by carrier utilization review parameters.

TABLE 3

CHIROPRACTIC UTILIZATION IN EXCESS OF 18 TREATMENTS

	Parameter <= 18	Parameter >18
# Carriers	33	22
Total Beneficiaries	7,923	6,209
# Beneficiaries Who Exceed 18 Treatments	337	867
% Beneficiaries Who Exceed 18 Treatments	4.25%	13.96%
Total Treatments	60,301	61,518
# Treatments in Excess of 18	3,147	9,448
% Treatments in Excess of 18	5.22%	15.36%

To quantify the impact, we compared utilization in carriers with parameters equal to or less than 18 treatments and those with parameters greater than 18 treatments per year. We included the three carriers with no set parameters in the group that had parameters greater than 18.

We used the 33 carriers with existing parameters of 18 or less treatments as our baseline population. Based on our assumption, if the 22 high-end carriers reduced their parameters to 18 treatments per year, their actual utilization should fall in line with the baseline population. Therefore, the high-end carriers, as shown in Table 3, would see their treatments, in excess of 18, fall from over 15 percent to about 5 percent.

This reduction within the 22 high-end carriers would equal 6,237 fewer treatments in excess of 18. The average 1997 reimbursement rate was $25.49 per treatment.[4] Therefore, had the 22 high-end carriers imposed utilization review parameters of 18 treatments in 1997, they would have saved the Medicare Trust Fund $159,011. Our analysis is based on a 1 percent sample. If we project to the population, the 1997 Medicare Trust Fund savings would have exceeded $15.9 million.

Further, assuming a continued growth rate of 6.87 percent per year, we estimate that implementing a maximum utilization review parameter of 12 treatments per year beginning Calendar Year 2000 could result in Medicare Trust Fund savings of over $19.4 million.

POTENTIAL IMPLICATIONS OF ESTABLISHING A MAXIMUM UTILIZATION REVIEW PARAMETER OF 12 CHIROPRACTIC TREATMENTS PER YEAR

If HCFA implemented a maximum utilization review parameter of 12 chiropractic treatments per year beginning in 2000, it could save the Medicare Trust Fund almost $30.2 million.

Implementing a parameter of 12 treatments per year would directly impact 25 of the 55 carriers. The remaining 30 carriers would not be directly impacted by a maximum review parameter of 12 as they already have parameters of 12 or less. Table 4 displays chiropractic utilization grouped by carrier utilization review parameters.

TABLE 4

CHIROPRACTIC UTILIZATION IN EXCESS OF 12 TREATMENTS

	Parameter <= 12	Parameter >12
# Carriers	30	25
Total Beneficiaries	7,592	6,540
# Beneficiaries Who Exceed 12 Treatments	335	869
% Beneficiaries Who Exceed 12 Treatments	4.41%	13.29%
Total Treatments	58,455	63,364
# Treatments in Excess of 12	6,921	17,225
% Treatments in Excess of 12	11.84%	27.18%

[4] We calculated the average reimbursement rate from our 1997 data, based on the total allowed charges and the total number of treatments for the 55 carriers.

To quantify the impact, we compared utilization in carriers with parameters equal to or less than 12 treatments and those with parameters greater than 12 treatments per year. We included the three carriers with no set parameters in the group that had parameters greater than 12.

We used the 30 carriers with existing parameters of 12 or less treatments as our baseline population. Based on our assumption, if the 25 high-end carriers reduced their parameters to 12 treatments per year, their actual utilization should fall in line with the baseline population. Therefore, as shown in Table 4, the high-end carriers would see their treatments, in excess of 12, fall from over 27 percent to about 12 percent.

This reduction within the 25 high-end carriers would equal 9,723 fewer treatments in excess of 12. The average 1997 reimbursement rate was $25.49 per treatment. Therefore, had the 25 high-end carriers imposed utilization review parameters of 12 treatments in 1997, they would have saved the Medicare Trust Fund $247,862. Our analysis is based on a 1 percent sample. If we project to the population, the 1997 Medicare Trust Fund savings would have exceeded $24.7 million.

Further, assuming a continued growth rate of 6.87 percent per year, we estimate that implementing a maximum utilization review parameter of 12 treatments per year beginning Calendar Year 2000 could result in Medicare Trust Fund savings of over $30.2 million.

RECOMMENDATIONS

In requesting this analysis, Dr. Bagley and Dr. Steffin did not ask us to make recommendations. However, in light of our current and our previous analysis, we believe that it would be appropriate for us to do so.

It is important to emphasize up front that we view the goal of establishing controls on Medicare payments for chiropractic benefits as twofold: to ensure that Medicare pays for all chiropractic services that Medicare beneficiaries are entitled to; and to prevent making payments for services not authorized under the program.

In our earlier report, "Chiropractic Care: Controls Used by Medicare, Medicaid, and Other Payers (OEI-04-97-00490), we showed that use of utilization review parameters alone was not enabling Medicare carriers to detect and prevent payments for maintenance treatments, which are not authorized under the Medicare program. Hence, we recommended that additional measures be taken, such as requiring chiropractic physicians to use modifiers to distinguish the categories of spinal joint problems and requiring all Medicare contractors to implement system utilization frequency edits to identify beneficiaries receiving consecutive months of minimal therapy.

We did not make any recommendations regarding utilization review parameters, also referred to as utilization caps. However, we do not wish that omission to be interpreted as a lack of support for utilization caps. Our intention was to offer additional measures that could be used, in conjunction with utilization caps, to safeguard against payments for unauthorized maintenance payments. Thus, we wish to take this opportunity to clarify that we do recommend that utilization caps be used.

With regard to the type of cap, we recommend that they be the "soft" caps, which are the subject of this report. These caps do not automatically disallow payments for services above the cap. Rather they trigger a more intensive review of claims to ensure that the billed services are necessary and covered. Such soft caps are consistent with the twofold goal described in the opening paragraphs of our recommendations.

With regard to the number of services specified by the cap, we recommend that the maximum be 12. Our analysis in this report clearly demonstrates that Medicare savings would be higher with a cap of 12 rather than 18 treatments per year. This is the number most commonly used by Medicare carriers; 29 of the 55 carriers already have chiropractic utilization parameters set at 12 treatments per year. Therefore, implementing a utilization parameter of 12 will result in the least administrative change for carriers overall.

It is important to restate that the goal of utilization parameters is to ensure that carriers pay for all valid claims, and only valid claims. Our recommendation of a cap of 12 rather than a cap of 18 in no way implies that chiropractic services should be limited to a specific number.

It does, however, imply a tradeoff in terms of resources and potential vulnerabilities. The lower cap of 12 potentially increases the number of claims that need to be reviewed for medical necessity, thereby increasing administrative costs. Adopting a higher cap of 18 could reduce the administrative costs, but increase the potential of invalid claims paid and thereby increase the costs associated with improper payments.

At present, we have no reliable data about the costs on both sides of this trade off--e.g., we do not know the cost of increased reviews associated with utilization caps at either 12 or 18 treatments per year. However, we believe that the approaches we recommended in our prior report, when used in connection with a standardized utilization cap, would increase the chances of avoiding improper payments while not increasing administrative costs. The Florida Blue Cross experience supports this expectation.

No matter which level of services is chosen for the utilization caps, we recommend that data about the cost of administering them, related edits and frequency screens, and medical reviews be collected and analyzed with a view to finding the best mix of these controls and re-calibrating them after 1 or 2 years of experience.

COMMENTS

The HCFA commented that they are using the information in this report in their effort to establish chiropractic utilization guidelines. The full text of their comments is attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: OCT 26 1999

TO: June Gibbs Brown
Inspector General

FROM: Michael M. Hash
Deputy Administrator

SUBJECT: Office of Inspector General Report: "1997 Utilization Data for Chiropractic Medical Directors, Chiropractic Work Group" (OEI-04-97-00496)

Thank you for the opportunity to review the above referenced report and we have the following comments. As you know, the Health Care Financing Administration convened the Chiropractic Work Group to assist in developing new chiropractic policies required by the Balanced Budget Act of 1997. We asked the OIG to assist the Chiropractic Work Group by compiling 1997 chiropractic utilization data. Specifically, we asked the OIG to examine: (1) a maximum utilization parameter of 18 chiropractic treatments per year, and (2) a maximum utilization parameter of 12 chiropractic treatments per year.

The information provided in the report will be very helpful as we assess our options in establishing chiropractic utilization guidelines. We are continuing our consideration as to the most appropriate utilization screen that will maintain program integrity, protect the Medicare beneficiary, represent a reasonable and viable threshold, and reflect the best interests of all involved parties.

We note, further, that the OIG recommended continuing data analysis and would like to take this opportunity to state that we look forward to working with you in this endeavor.

We appreciate the effort that went into this report, and thank you for the opportunity to comment on it. If you have any questions, please contact Dorothy Honemann, 410-786-5702.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CHIROPRACTIC SERVICES IN THE MEDICARE PROGRAM:

PAYMENT VULNERABILITY ANALYSIS

Inspector General

June 2005
OEI-09-02-00530

Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

OBJECTIVE

To determine the underlying causes of, and potential ways to reduce, vulnerabilities associated with Medicare payments for chiropractic services.

BACKGROUND

In 1972, Congress passed Public Law 92-603, which amended section 1861(r) of the Social Security Act (the Act) to define chiropractors as physicians who are eligible for Medicare reimbursement, but only for manual manipulation of the spine to correct a subluxation, or malfunction of the spine. Federal regulations (42 CFR § 410.21(b)) further limit Medicare payment to treatment of subluxations that result in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. In addition to these specific provisions, sections 1862(a)(1)(A) and 1833(e) of the Act require that all services billed to Medicare, including chiropractic manipulations, be medically necessary and supported by documentation.

The Medicare Carriers Manual (the Manual) outlines additional coverage criteria for chiropractic services billed to Medicare.[1] Pursuant to section 2251.2 of the Manual, the existence of a subluxation must be documented through an X-ray or physical examination and chiropractic services must be provided as part of a written plan of care that should include specific goals and measures to evaluate effectiveness. Section 2251.3 of the Manual states that chiropractic treatment ". . . must provide a reasonable expectation of recovery or improvement of function." The same Manual section states that ". . . ongoing maintenance therapy is not considered to be medically necessary under the Medicare program," and is therefore noncovered.

Chiropractic has experienced considerable growth in Medicare, from 11.2 million services and $255 million allowed in 1994 to 21 million services and $683 million allowed in 2004. In previous studies, published in 1986, 1998, and 1999, the Inspector General found that a

[1] At the time of our study, the references to the Medicare Carriers Manual were accurate. The Centers for Medicare & Medicaid Services has since moved to web-based manuals. The Carriers Manual sections cited in this report are now found in the Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, sections 30.5 and 240.

significant vulnerability existed in connection with chiropractic services, particularly concerning maintenance care.[2]

To gain a deeper understanding of the underlying causes of these vulnerabilities and ways to reduce them, we selected a simple random sample of 400 Medicare services (total allowed amount = $12,638.38) submitted by chiropractors and allowed in 2001. We contracted with practicing chiropractors who reviewed each service according to a standard protocol, which was based on Medicare coverage guidelines and requirements. The review instrument solicited information about the beneficiary's chiropractic treatment as a whole and about the individual sampled service in particular. This enabled the reviewers to determine if the services billed to Medicare were covered, coded correctly, and properly documented. In particular, it enabled the reviewers to determine the extent to which payments were made for maintenance services, which are not covered under Medicare. Based on the results of this review, we also determined the likelihood of services being noncovered depending on the number of services billed per episode of care. Knowing this, Medicare carriers can make informed choices regarding the level of effort to expend in reviewing questionable billings based on billing patterns.

Because we only reviewed services provided by chiropractors in 2001, our sample results cannot be extrapolated to other periods. Accordingly, we make no inferences to chiropractic error rates in subsequent years.

FINDINGS

Maintenance services were the most common type of noncovered chiropractic services that Medicare paid for in 2001. Medicare carriers routinely deny all chiropractic claims that do not carry a code for spinal manipulation, which is, by law, the only treatment for which chiropractors may be reimbursed. Our medical reviewers found that although billed with an allowable code, 57 percent of these services did not meet Medicare coverage criteria (i.e., were noncovered). In addition, 16 percent were miscoded or billed at the wrong level of spinal manipulation, and 6 percent were undocumented. Twelve percent had

[2] *Utilization Parameters for Chiropractic Treatments* (OEI-04-97-00496), *Chiropractic Care: Controls Used by Medicare, Medicaid, and Other Payers* (OEI-04-97-00490), *and Inspection of Chiropractic Services under Medicare* (OAI-05-86-00002).

multiple errors, yielding an overall error rate of 67 percent, resulting in $285 million in improper payments.

Medical reviewers determined that the majority of inappropriately paid services were maintenance treatments ($186 million in allowed payments), which Medicare defines as medically unnecessary, and are therefore not covered. Another 14 percent ($65 million) were found to be medically unnecessary for other reasons. Medicare also allowed $24 million for services billed with a spinal manipulation code that were actually extraspinal manipulations or non-manipulative treatment, such as massage. Apart from coverage issues, upcoding was also a significant problem, resulting in a $15 million overpayment.

Supporting documentation for chiropractic services rarely met all Medicare Carriers Manual requirements. The Manual requires that specific supporting documentation be present in the chiropractic record. Nearly 94 percent of chiropractic services, though, lacked at least one of the supporting documentation elements listed in section 2251.2 of the Manual (including those that were completely undocumented). The lack of one or more of these elements did not automatically lead us to conclude a service was noncovered, although these determinations were often related. For instance, 34 percent of chiropractic services were not supported by an evaluation that met the Manual's specific requirements for documenting a subluxation. Most, but not all, of these services were also determined to be noncovered.

Lack of medical necessity is directly related to service volume. As chiropractic care extends beyond 12 treatments in a year, it becomes increasingly likely that individual services are medically unnecessary. The likelihood of a service being medically unnecessary increases even more significantly after 24 treatments. Accordingly, identifying and carefully scrutinizing services beyond a certain frequency threshold could result in significant savings. Although frequency-based controls are common among carriers and in the private sector, the Centers for Medicare & Medicaid Services (CMS) does not have a national policy addressing their use.

Carrier controls to prevent overutilization are inconsistent. Although all carriers have some mechanisms to prevent and recoup improper payments for chiropractic services, a significant vulnerability surrounding this benefit persists.

RECOMMENDATIONS

Based on the volume of medically unnecessary, undocumented, and noncovered services allowed, chiropractic services represent a significant vulnerability for the Medicare program. Therefore, we recommend that CMS take the following actions:

Ensure that chiropractic services comply with Medicare coverage criteria. CMS should require that its carriers or Program Safeguard Contractors conduct service-specific reviews of chiropractic services to identify improper payments. CMS should also implement national frequency-based controls to target high-volume services for review, since our medical review identified a strong correlation between high service volume and lack of medical necessity. When conducting reviews of individual providers, it is imperative that reviewers collect the entire records associated with services selected as part of a service-specific review. Several records we reviewed would have appeared legitimate for any one particular day of service; however, that day's documentation was repeated verbatim for the entirety of the patient's treatment.

Require that its carriers educate chiropractors on Medicare Carriers Manual requirements for supporting documentation. Many chiropractors seem unaware of the specific documentation requirements outlined in the Manual. CMS should address this lack of knowledge by directing its carriers to issue provider bulletins reminding chiropractors of their responsibilities.

In addition to these recommendations, we have forwarded information on the noncovered, miscoded, and undocumented services identified in our sample to CMS for appropriate action.

AGENCY COMMENTS AND OIG RESPONSE

In its comments on our draft report, CMS agreed with our findings and recommendations. The agency has clarified its chiropractic coverage criteria and indicated that most carriers are taking steps to reduce chiropractic error rates, including targeted educational efforts and service-specific medical reviews. In addition, as of October 1, 2004, CMS has required that chiropractors use the –AT modifier to indicate that a service is not maintenance; only claims to which this modifier is attached are payable.

We appreciate CMS's response to our report, and support the steps the agency is currently undertaking to help prevent paying for noncovered, miscoded, and undocumented services.

CMS noted in its comments that while this Office of Inspector General (OIG) study projected that 67 percent of the chiropractic services allowed by Medicare did not meet program requirements, CMS's Comprehensive Error Rate Testing (CERT) program identified a claims paid error rate of approximately 16 percent for claims submitted by chiropractors in 2002. CMS further noted that differences in the methodological approaches accounted for the significantly different rates. CMS recognized that OIG's review of a beneficiary's entire course of treatment enabled us to determine that approximately 40 percent of all chiropractic services are attributable to maintenance care, and thus are not covered under Medicare. In contrast, the CERT paid claims error rate is based on a review of a single claim, which limits its ability to detect uncovered maintenance costs.

We agree with CMS and would like to emphasize that the purpose of this inspection was to determine the underlying causes of, and potential ways to reduce, vulnerabilities associated with payments for chiropractic services. It was not designed to reproduce, or to review, the CERT paid claims error rate. In addition to the different methodological approaches that are noted above, the CERT used 2002 data, whereas our data was drawn from 2001. Hence, our results cannot be compared directly to the CERT program results.

Furthermore, chiropractic payment errors, while a significant vulnerability, contribute only minimally to the overall CERT national paid claims error rate. Medicare allowed approximately $191 billion for Medicare fee-for-service claims in 2001. Chiropractic services accounted for $500 million, or 0.26 percent of this amount. Therefore, the chiropractic-specific error rate has minimal influence on the overall CERT error rate for fee-for-service claims.

Given that Medicare payments for chiropractic services have continued to increase since 2001, the need for a more effective way to eliminate inappropriate maintenance payments is crucial. We recognize that it may not be practical for the CERT program to expend its limited resources to collect the extensive documentation that we used in our review. Therefore, in the future, CMS may wish to conduct additional studies outside the scope of the CERT program to determine cost-efficient ways to address chiropractic payment errors.

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INTRODUCTION

OBJECTIVE

To determine the underlying causes of, and potential ways to reduce, vulnerabilities associated with Medicare payments for chiropractic services.

BACKGROUND

Chiropractic: History and Practice

According to the American Chiropractic Association, the profession's largest association, chiropractic is "a form of health care aimed primarily at enhancing a patient's overall health and well-being without the use of drugs or surgery."[3] Central to chiropractic philosophy and practice is the use of manual manipulation to correct a subluxation of the spine. Etymologically, the term "subluxation" simply means a partial dislocation of a joint. Although a single standard definition of subluxation in the chiropractic context does not exist, the term is generally used by chiropractors to describe "a complex of functional and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health."[4]

Chiropractic has established itself and grown as a profession since it was founded in 1895. The practice is now licensed in all 50 States, and at least 16 accredited chiropractic colleges confer Doctor of Chiropractic degrees on their graduates. In 1970, there were approximately 13,000 licensed chiropractors in the United States. According to the Bureau of Labor Statistics, that number grew to 50,000 in 2000. Both the Bureau and the American Chiropractic Association predict that the number of chiropractors will continue to increase in the future.

Patients most often seek out chiropractors for treatment of back pain, especially low back pain. Low back pain is a pervasive American health

[3] "Chiropractic: A Rapidly Growing Profession." Consumers/Media. American Chiropractic Association. Retrieved October 23, 2003, http://www.amerchiro.org/media/growing_profession.shtml.

[4] "Chiropractic Paradigm." Association of Chiropractic Colleges. Retrieved October 24, 2003, http://www.chirocolleges.org/missiont.html.

problem, from which approximately 31 million citizens suffer at any given time.[5]

Medicare Coverage of and Requirements for Chiropractic Services

General provisions of the Social Security Act (the Act) govern Medicare reimbursement of all services, including chiropractic services. Section 1862(a)(1)(A) of the Act states that ". . . no payment may be made [under the Medicare title for services that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Section 1833(e) requires that providers furnish "such information as may be necessary in order to determine the amounts due" in order to receive Medicare payment. Related regulations at 42 CFR § 411.15(k) and 42 CFR § 424.5(a)(6) implement these provisions of Federal law.

On October 30, 1972, Congress passed the Social Security Amendments of 1972, extending Medicare reimbursement to chiropractors, but only for manual manipulation of the spine to correct a subluxation demonstrated by an X-ray.[6,7] Federal regulations (42 CFR § 410.21(b)) further limit Medicare chiropractic coverage to treatment of subluxations that result in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. Restricting reimbursement to spinal manipulation means Medicare may pay chiropractors for only three Current Procedural Terminology (CPT) codes: 98940 (*Chiropractive Manipulative Treatment; spinal, one to two regions*), 98941 (*three to four regions*), and 98942 (*five regions*). In 2001, CPT code 98942 accounted for fewer than 10 percent of the chiropractic services allowed by Medicare, with each of the lower-level CPT codes accounting for approximately 45 percent of the total.

The Balanced Budget Act of 1997 removed the X-ray requirement as of January 1, 2000, and instructed the Secretary of the Department of Health and Human Services to establish utilization guidelines for

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5 Jensen, M., M. Brant-Zawadzki, N. Obuchowski, et al. "Magnetic Resonance Imaging of the Lumbar Spine in People Without Back Pain." New England Journal of Medicine 1994; vol. 331: 69-116. Cited in: "Back Pain Statistics." American Chiropractic Association. Retrieved October 24, 2003, http://www.amerchiro.org/media/whatis/benefits.shtml.

6 Note that no payment is provided to chiropractors for services other than manual manipulation of the spine; i.e., X-rays and other diagnostic tests are not covered services when performed by chiropractors.

7 The chiropractic provisions (section 273) of the Social Security Amendments of 1972 modified section 1861(r)(5) of the Act.

subluxations not evidenced by an X-ray. Guidelines for demonstrating a subluxation are found in section 2251.2 of the Medicare Carriers Manual (the Manual).[8] The Manual defines a subluxation as "a motion segment, in which alignment, movement integrity, and/or physical function of the spine are altered although contact between joint surfaces remains intact." If used, an X-ray generally must be taken between 12 months before and 3 months after the start of treatment. A physical examination must identify at least two criteria for treatment, one of which must be asymmetry/misalignment or a range of motion abnormality. The other criterion can be pain/tenderness or changes in the associated soft tissue.

No matter how the presence of a subluxation is established, section 2251.3 of the Manual stipulates that beneficiaries also must present "a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function." Furthermore, section 2251.3 of the Manual states that ". . . [a] treatment plan that seeks to prevent disease, promote health and prolong and enhance the quality of life, or therapy that is performed to maintain or prevent deterioration of a chronic condition is not a Medicare benefit. Once the maximum therapeutic benefit has been achieved for a given condition, ongoing maintenance therapy is not considered to be medically necessary under the Medicare program." In other words, Medicare covers only treatment of acute or chronic subluxations, not preventive or maintenance care.[9] The Manual also lists eight absolute and five relative contraindications regarding manual manipulation of the spine, such as acute fractures of the spine or severe demineralization of the bones. Such conditions preclude the use of or impart significant risk to spinal manipulation.

Section 2251.2 of the Manual requires that chiropractors document an initial history of the patient's complaint and establish a treatment plan.

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[8] At the time of our study, the references to the Medicare Carriers Manual were accurate. The Centers for Medicare & Medicaid Services has since moved to web-based manuals. The Carriers Manual sections cited in this report are now found in the Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, sections 30.5 and 240.

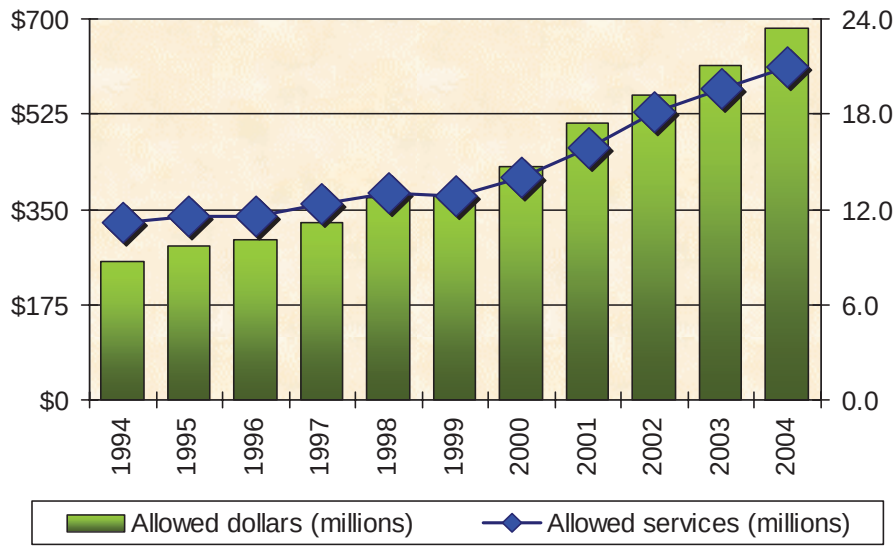
[9] Revisions to the Medicare Carriers Manual issued on May 28, 2004, further clarify the definition of maintenance care. Since our inspection focused on services provided in 2001, we cite here the definition effective during that year.

The treatment plan should include the expected duration and frequency of the patient's treatment, specific treatment goals, and objective measures against which to evaluate effectiveness. Though supporting documentation must be kept in the medical record, it need not normally be submitted to the carrier for a claim to be processed and paid.

Growth in Medicare Chiropractic Services

Medicare reimbursement of chiropractic services has increased dramatically in recent years. In 1994, the program allowed $255 million for 11.2 million services for chiropractic manipulation. By 2004, those numbers had grown to $683 million and 21 million services allowed. As shown in Figure 1, the rate of growth in annual services and dollars allowed has accelerated since the X-ray requirement was lifted in 2000. For a detailed analysis on the effect of removing the X-ray requirement, see Appendix B.

FIGURE 1
Medicare reimbursement for chiropractic has grown more rapidly since 2000.



Source: National Claims History Part B 1 Percent Files, 1994 – 2002 and Medicare Part B Extract and Summary System, 2003 - 2004

Prior Inspector General Work

In November 1999, the Office of Inspector General (OIG) responded to a request from the Centers for Medicare & Medicaid Services (CMS) to analyze the potential impact of establishing chiropractic utilization review thresholds at either 18 or 12 treatments per year. In *Utilization Parameters for Chiropractic Treatments* (OEI-04-97-00496), OIG concluded that the proposed thresholds would have saved Medicare $19.4 million and $30.2 million, respectively, in 2000, and that relatively few beneficiaries would be affected by either parameter.

Therefore, OIG recommended that CMS institute a national utilization review threshold of 12 services per year. CMS ultimately did not adopt a national frequency threshold and continues to leave the matter to individual carriers' discretion.

In September 1998, OIG released a report entitled *Chiropractic Care: Controls Used by Medicare, Medicaid, and Other Payers* (OEI-04-97-00490). Based on an analysis of the National Claims History Data File, the OIG estimated that $68 million of the $294 million Medicare spent on chiropractic treatments in 1996 was for chiropractic maintenance treatments.

In 1986, OIG released a report entitled *Inspection of Chiropractic Services under Medicare* (OAI-05-86-00002). OIG found that because of disagreement about the ability of an X-ray to reveal a subluxation, the existing X-ray requirement was not well enforced, might actually have been unenforceable, and was highly conducive to abuse. In addition, the report described a lack of standards within the chiropractic profession and a number of questionable practices. For these reasons, OIG concluded that chiropractic constituted a serious vulnerability to the Medicare program.

METHODOLOGY

We used multiple methodologies to accomplish our objectives. The primary method was medical review of chiropractic records. We also interviewed carriers, analyzed historical claims data, and accessed external Government data sources. Point estimates with confidence intervals for selected statistics and the results of statistical tests for selected comparisons from the findings are contained in Appendixes C and D, respectively.

Medical Review[10]

We defined our universe as 91 percent of services provided by chiropractors in 2001 and allowed by Medicare.[11] This universe

[10] For a more detailed discussion of the medical review methodology, refer to Appendix A.

[11] A data processing error prevented us from using 100 percent of claims. The original data was contained in five compressed files. We decompressed these files and merged them into a single population data set. However, one of the smaller files failed to read into our population data set correctly, and therefore, contributed far fewer claims than expected to the population. Most of the omitted claims were for beneficiaries with Medicare numbers associated with the Railroad Retirement Board or the State of Massachusetts.

contained 14,497,406 claims with a total allowed amount of $457,444,574.32. To make statistically valid projections of the dollar value of all noncovered, miscoded, or undocumented chiropractic services allowed in 2001, we selected a simple random sample of 400 Medicare services from this universe. The total allowed amount in our sample was $12,638.38. We then identified and contacted the chiropractor listed on each claim for service to request records for the beneficiary's entire course of treatment.[12]

We contracted with practicing chiropractors to review each service according to a standard protocol, which was based on Medicare coverage guidelines and requirements. The review instrument solicited information about the beneficiary's chiropractic treatment as a whole and about the individual sampled service in particular. This enabled the reviewers to determine if the services billed to Medicare were covered, coded correctly, and properly documented. In particular, it enabled the reviewers to determine the extent to which payments were made for maintenance services, which are not covered under Medicare.

The results of our review of the 400 sampled services were not shared with the Medicare carriers who paid the chiropractors for these services. Further, the level of information that we collected would not generally be available to those carriers unless they were to conduct a comprehensive medical review of a particular chiropractor or patient.

After completing their review, the contractors returned the completed instruments to us for data entry. We analyzed the medical reviews using the statistical software packages SAS and SUDAAN. For a more detailed discussion of this methodology, see Appendix A.

Based on the results of this review, we also determined the likelihood of services being uncovered depending on the number of services billed per episode of care. Knowing this, Medicare carriers can make informed choices regarding the level of effort to expend in reviewing questionable billings based on billing patterns.

[12] We were unable to contact two chiropractors and removed the two claims associated with these chiropractors from consideration. In addition, the chiropractors identified on four claims failed to respond to our repeated requests for records—these services were considered undocumented.

Because we only reviewed services provided by chiropractors in 2001, our sample results cannot be extrapolated to other periods. Accordingly, we make no inferences to chiropractic error rates in subsequent years.

Additional Methods

We conducted telephone interviews with all Medicare carriers using a standardized interview guide. We also collected policy guidance that had been issued by each carrier to its provider community. We researched carriers' Local Medical Review Policies, as well as laws, regulations, and policy, concerning the chiropractic benefit.

We reviewed literature from chiropractic organizations and other sources to gather background on chiropractic and help refine our medical review instrument. Information from Government sources, such as the Agency for Healthcare Research and Quality and the Bureau of Labor Statistics, provided background and comparative trend data. Lastly, we collected and tabulated information gleaned from online brochures for Federal Employee Health Benefits Plans.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

Maintenance services were the most common type of noncovered chiropractic services that Medicare paid for in 2001

In 2001, Medicare allowed approximately $457 million for the 14.5 million chiropractic services in our universe. Based on our medical review, although billed with allowable spinal manipulation codes, 57 percent of these services did not meet Medicare coverage criteria (i.e., were noncovered). An additional 16 percent were miscoded or billed at the wrong level of spinal manipulation, and 6 percent were undocumented. Twelve percent had multiple errors, yielding an overall error rate of 67 percent. Figure 2 groups the improperly paid services in our sample by the type of error and gives statistical projections of these errors to the population.

Figure 2: Noncovered and Miscoded Chiropractic Services

	Sample (400 Total Services)		Projected	
Type of error	Services	Allowed Amount	Services (Proportion)	Allowed Amount (Millions)
Noncovered:				
- Not medically necessary: maintenance	*161*	*$5,144.85*	*0.40*	*$186*
- Not medically necessary: other	*57*	*$1,790.59*	*0.14*	*$65*
- Not manual manipulation of the spine	*21*	*$668.89*	*0.05*	*$24*
- (Both medically unnecessary and not manipulation of the spine)	*(13)*	*($396.95)*	*(0.03)*	*($14)*
Total noncovered	**226**	**$7,207.38**	**0.57**	**$261**
Total coded at wrong level (net)	**64**	**$410.31**	**0.16**	**$15**
Undocumented:				
- Non-response	*3*	*$89.63*	*	*
- Missing documentation	*21*	*$661.78*	*0.05*	*$24*
Total undocumented	**24**	**$751.41**	**0.06**	**$27**
(Overlapping errors)	***(49)***	***($504.17)***	***(0.12)***	***($18)***
Total	***265***	***$7,864.93***	***0.67***	***$285***

Source: Medical Review of Year 2001 Services by Practicing Chiropractors. The * indicates the *n* for that cell is too small to reliably project. Totals may not be equal to the sum of individual rows due to rounding.

Noncovered: Not medically necessary. Section 1862(a)(1)(A) of the Act excludes services that are not reasonable and necessary from Medicare coverage. However, 55 percent of the chiropractic services allowed in 2001, totaling $251 million, did not meet Medicare criteria for medical

necessity. Most of these services (74 percent of medically unnecessary services—40 percent overall) were correctly billed as spinal manipulations but met Medicare's definition of maintenance care—which section 2251.3 of the Manual defines as not medically necessary, and is therefore not covered. In general, the remainder were not medically necessary because they did not bear a therapeutic relationship to the patient's condition, did not provide a reasonable expectation of recovery or functional improvement, or were provided with excessive frequency or duration.

Noncovered: Not manual manipulation of the spine. Section 1861(r)(5) of the Act clearly states that Medicare may reimburse chiropractors only for manual manipulation of the spine. Chiropractors, though, received approximately $24 million from the Medicare program and its beneficiaries in 2001 for services other than manual manipulation of the spine. These chiropractors bypassed Medicare's coverage limitations by submitting claims with a manipulation code that was allowable but did not match the service actually provided. Documentation for several services showed that the chiropractor actually performed an extraspinal adjustment (e.g., shoulder or knee adjustment) rather than spinal work. Other chiropractors billed non-manipulative treatment, such as muscle work or network spinal analysis, as spinal manipulation. Our medical reviewers, who are practicing chiropractors, noted that some of this treatment was acceptable from a chiropractic standpoint, and may have been beneficial to the patient.

Coded at wrong level. Medicare allowed $85 million for spinal manipulations billed for the incorrect number of regions according to the documentation. The net cost to the program, i.e., the amount actually allowed for these services less the amount that would have been allowed if the services had been billed correctly, was $15 million. Coding errors generally involved upcoding, which is billing a more complex and higher-paying service than the one documented in the medical record. Approximately 69 percent of services billed for spinal manipulation on five regions (CPT code 98942) were upcoded, compared to 21 percent of services billed for manipulation on three to four regions (CPT code 98941).

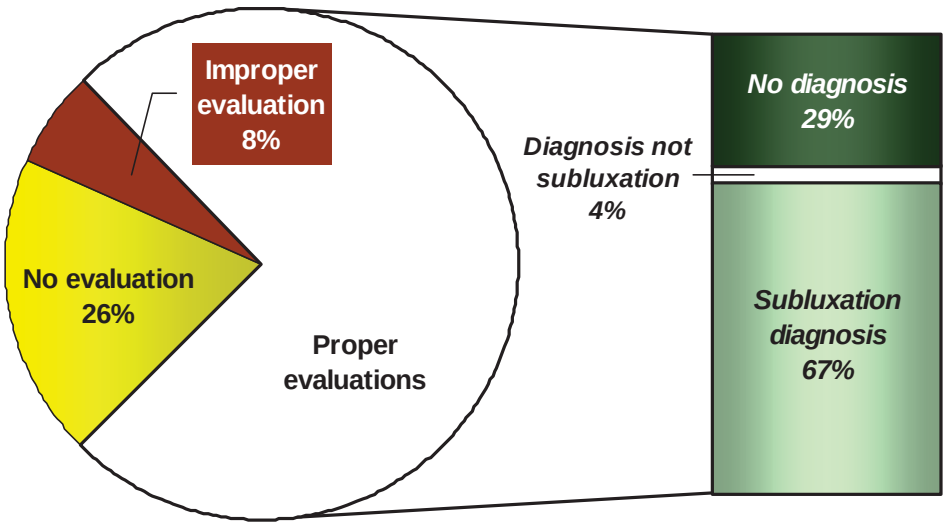
Undocumented. Chiropractors did not provide substantiating documentation for approximately 6 percent of the services billed to Medicare. Despite repeated requests, we did not receive the medical records related to three of the chiropractic services in our sample. The

chiropractors who rendered an additional 21 of the services provided us with records that did not substantiate that any service was rendered on the date claimed. Based on these findings, we estimate that Medicare may have allowed approximately $27 million in 2001 for undocumented chiropractic services. Although some cases of missing documentation may be attributable to billing errors (e.g., putting the wrong date on the claim form), others may represent services not rendered. In any case, claims for services that lack sufficient documentation to show that care was provided do not meet the requirements of section 1833(e) of the Act.

Supporting documentation for chiropractic services rarely met all Medicare Carriers Manual requirements

Separate from the completely undocumented services previously discussed, nearly 94 percent of chiropractic services lacked some or all of the supporting documentation that section 2251.2 of the Manual requires. The lack of one or more of these elements did not automatically lead us to conclude that a service was noncovered, although these determinations were often related. For example, even if each visit did not include a history and physical, which is required by section 2251.2 of the Manual, the service rendered on that day was not automatically deemed to be medically unnecessary by the chiropractic reviewers. Therefore, we did not include lack of supporting documentation as a subcategory of "noncovered" in the first finding, and we do not project an improperly allowed amount merely related to deficiencies in supporting documentation.

FIGURE 3
Many services do not meet Medicare requirements for documenting a subluxation.



Source: Medical Review of Year 2001 Claims by Practicing Chiropractors

Approximately 34 percent of services were not supported by an evaluation of the patient that met the Manual's requirements for documenting a subluxation. In fact, there was no evaluation at all in the medical record for 26 percent of services; the remaining 8 percent were supported by tests that did not meet the requirements established in the Manual. Furthermore, more than one-third of "proper" evaluations—those meeting Medicare rules for demonstrating the presence of a subluxation—resulted in no diagnosis (29 percent) or a diagnosis other than subluxation of the spine (4 percent).

Though a documentation requirement, chiropractors infrequently developed treatment plans for their Medicare patients. Just 28 percent of chiropractic services were provided as part of a written plan of care, and only 23 percent of those plans included specific treatment goals and objective measures to evaluate progress towards those goals. The absence of specific goals was a strong indicator of unnecessary care; only 14 percent of services associated with specific, written goals were medically unnecessary compared to 61 percent of those without written goals.

Though infrequently evaluated for them, Medicare beneficiaries rarely present contraindications to chiropractic treatment.

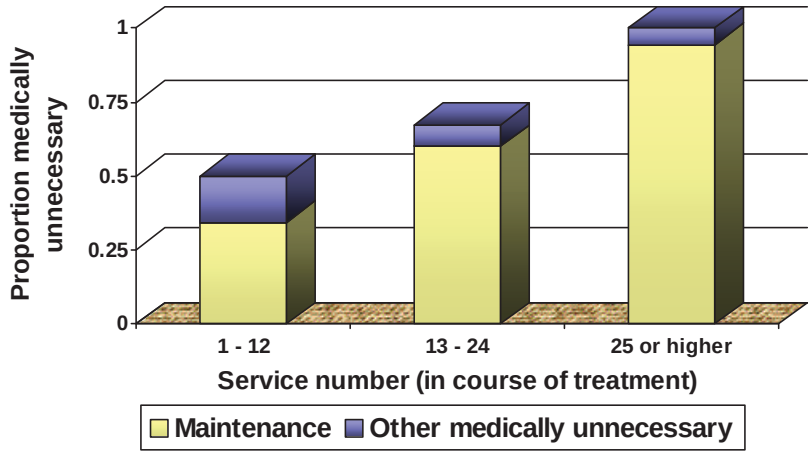
Chiropractors do not routinely evaluate patients for conditions mentioned in the Manual, such as severe demineralization of the bones or spinal malignancies, which could contraindicate spinal manipulation. We found that 66 percent of all chiropractic services were not preceded by an evaluation sufficient to detect such contraindications. Although potentially compromising quality of care, we found no cases where this omission led to complications, and only 21 percent of the evaluations that were conducted revealed the presence of even a relative contraindication. In 18 percent of these cases (1 percent overall), our reviewers believed that the dangers presented by the beneficiary's condition outweighed the potential benefits of chiropractic treatment.

Lack of medical necessity is directly related to service volume

When chiropractic care extends beyond 12 treatments in a year, it becomes increasingly likely that individual services are medically unnecessary. As shown in Figure 4 (next page), services provided among the first 12 in a course of treatment to a particular beneficiary by the same chiropractor were approximately 50 percent likely to be medically unnecessary. That likelihood increased

to approximately 67 percent for services between the 13th and 24th and to 100 percent for services beyond the 24th. In addition, these medically unnecessary services are more likely to be maintenance in nature at higher service volumes.

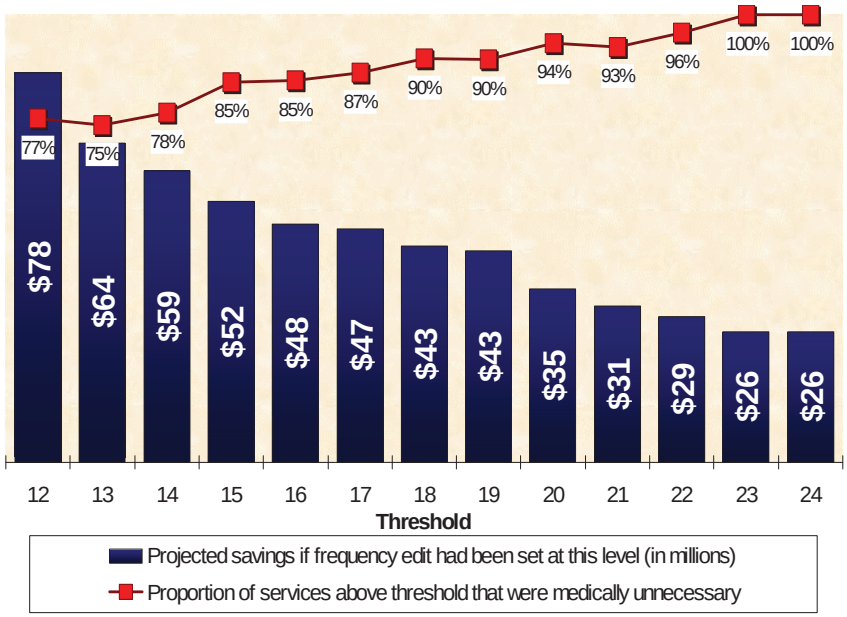
FIGURE 4
Higher-volume services are more likely to be medically unnecessary, particularly maintenance.



Source: Medical Review of Year 2001 Claims by Practicing Chiropractors

Given the link between medical necessity and service volume, reviewing services that exceed a certain volume threshold could result in significant savings. Figure 5 shows the proportion of all services beyond specific thresholds that were medically unnecessary and the projected savings if carriers had identified and disallowed these services. See Appendix A for further explanation of Figures 4 and 5.

FIGURE 5
Lower frequency thresholds would have resulted in greater savings, but captured more covered care.



Source: Medical Review of Year 2001 Claims by Practicing Chiropractors

Carriers and private plans commonly use frequency edits to limit utilization and limit improper payments.

Medicare carriers and private Federal Employee Health Benefits (FEHB) plans often manage chiropractic utilization through frequency controls, which are based on the number of adjustments provided. These frequency-based controls generally fall into one of two categories: soft caps (also called frequency edits) and hard caps. With either type of cap, the payer determines the number of services it will routinely allow during a specified time period, usually 1 year. The payer tracks the number of services each patient receives and generally pays all claims up to this frequency threshold without question. Payers that use soft caps suspend payment for any services that are billed beyond the threshold and request additional documentation from the chiropractor. If the documentation demonstrates that continued treatment is medically necessary, the claims are paid. Payers that use hard caps do not pay for services beyond the established frequency threshold, even if they are medically necessary.

Fourteen of nineteen carriers (74 percent) currently use soft caps as their primary means of limiting inappropriate payments, and none use hard caps. Individual carriers decide if they want to use the caps and also establish their own frequency thresholds. Historically, most carriers imposed a frequency threshold of 12 visits on chiropractic services. Due, at least in part, to complaints from chiropractors who believed the 12-visit limit had become a *de facto* hard cap, many carriers have raised their thresholds or eliminated them altogether. Figure 6 shows the frequency thresholds currently employed by carriers and the distribution of these controls among the States.[13]

Figure 6: Frequency Edits Used by Medicare Carriers

Frequency threshold	12 or fewer services	13 to 24 services	More than 24 services	No frequency edit
Number of carriers using threshold	3	8	6	6
Number of States with threshold	4	18	12	22

Source: Carrier Interviews Conducted by Office of Evaluation and Inspections Analysts in 2003

[13] Some carriers serve more than one State and use different thresholds in each. Similarly, some States are served by multiple carriers, each with its own limit. In such instances, the carrier or State is counted once in each category into which one of its edits falls. "States" include the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.

In contrast to Medicare carriers, all but one of the FEHB plans that use frequency-based controls to limit chiropractic utilization impose hard caps. Instead of capping the number of services, some FEHB plans limit the total dollar amount they will pay for chiropractic services or the duration of care. In addition, many FEHB plans do not offer any chiropractic coverage, and others require prior authorization or a referral from a medical physician before they will pay for care. Others have no controls other than a member co-payment. Figure 7 shows the controls used by the 132 FEHB plans listed on the Office of Personnel Management's Web site.

Figure 7: Controls on Chiropractic Services Used by FEHB Plans

Type of control	No coverage	Co-pay only	Prior auth. or referral	Freq. cap	Financial cap	Duration cap
Number of plans	20	36	26	36	8	6

Source: Year 2003 FEHB Brochures Accessed through http://www.opm.gov/insure/03/html/blinks.asp

Carriers support a national policy on frequency limits.

At least six carriers would like CMS to develop and enforce a national frequency edit or a hard cap on chiropractic services.[14] One carrier noted that when the 12-visit thresholds were nearly ubiquitous, chiropractors generally accepted them; however, when some carriers changed or eliminated their thresholds, other carriers were pressured by chiropractors in their jurisdictions to follow suit.

Although generally opposed to frequency-based controls, the provider community has previously accepted the idea of a national frequency cap. The American Chiropractic Association expressed support for a national cap in an October 21, 1999, letter to the Director of the Office of Clinical Standards and Quality at the Health Care Financing Administration (currently CMS). Based on the recommendations of a representative panel of chiropractors, the letter states that "[a threshold of 18 services] reflects the consensus of the chiropractic profession" and is clinically relevant.[15]

[14] We did not ask carrier staff their opinions on a national frequency edit; these six volunteered this opinion when asked for their general comments about the Medicare chiropractic benefit.

[15] Specifically, the panel supported an "18 + 6" utilization review parameter where a threshold of 18 services would be used as a soft cap and 24 as a hard cap.

Carrier controls to prevent overutilization are inconsistent

All 19 carriers have mechanisms in place to prevent and recoup improper chiropractic payments. Controls may include pre-payment edits that suspend or deny claims based on information from the submission, as well as pre- or post-payment medical review. Every carrier denies claims from chiropractors for noncovered CPT codes and claims for chiropractic CPT codes from non-chiropractors. In addition, every carrier except one uses computer edits that suspend or deny claims with improper diagnosis codes. As previously discussed, 15 carriers use frequency edits to control utilization. Some carriers use chiropractors, medical physicians, or, more commonly, nurses to conduct medical review before they pay claims that have been flagged through frequency edits. Other carriers conduct a non-medical claims audit of flagged claims. A number of carriers indicated they automatically deny claims that exceed their frequency threshold unless the claim meets certain criteria, such as having a particular diagnosis code.

Carriers vary widely in the resources they devote to monitoring chiropractic utilization. For example, the number of pre-payment claims reviews conducted by carriers averaged from zero at some carriers to approximately 85,000 per year at one large carrier. Some of the less active carriers depend entirely on diagnosis-based edits to identify improper claims, meaning that as long as a claim is submitted with a covered diagnosis code, it will be paid. The use of post-payment reviews is equally inconsistent. Although most carriers indicated they might conduct post-payment reviews of chiropractic services, only three provided evidence that any were conducted recently, and one of those had done only two. One large carrier noted that post-payment reviews are now the province of the Program Safeguard Contractors. The variation observed among the carriers may be due, in part, to different philosophies regarding controlling chiropractic claims. For example, some carriers believe that oversight of chiropractic services is not a priority for CMS, given limited budgets and the relatively small amount of money associated with chiropractic services.

RECOMMENDATIONS

Based on the volume of noncovered, miscoded, and undocumented services that were paid, we conclude that chiropractic services represent a significant vulnerability for the Medicare program. As more beneficiaries avail themselves of chiropractic care, the amount of money lost to medically unnecessary, non-manipulation, and undocumented services is likely to increase unless appropriate controls are instituted.

Therefore, we recommend that CMS:

Ensure that chiropractic services comply with Medicare coverage criteria.
Given the strong correlation between the number of services a beneficiary receives and the likelihood a service is not medically necessary, CMS should implement a national frequency edit to target high-volume services—which are especially likely to be medically unnecessary—for medical review. Carriers or Program Safeguard Contractors should then obtain and review the records of beneficiaries targeted by the frequency edit in order to identify and collect overpayments.

Many services that would not exceed even a very low frequency threshold were medically unnecessary, undocumented, not spinal manipulation, or miscoded. Therefore, in addition to whatever frequency control is chosen, CMS should require that its carriers or Program Safeguard Contractors conduct routine service-specific reviews of chiropractic services. When conducting reviews of individual providers, it is imperative that reviewers collect the entire records associated with services selected as part of a service-specific review. Several records we reviewed would have appeared legitimate for any one particular day of service; however, that day's documentation was repeated verbatim for the entirety of the patient's treatment.

Require that carriers educate chiropractors on Medicare Carriers Manual requirements for supporting documentation.
Many chiropractors seem unaware of the specific documentation requirements outlined in section 2251.2 of the Manual. CMS should address this lack of knowledge by directing its carriers to issue provider bulletins reminding chiropractors of their responsibilities. Due to the relationship we found between the lack of treatment plans and medically unnecessary services, the bulletins should especially emphasize this requirement.

In addition to these recommendations, we have forwarded information on the noncovered, miscoded, and undocumented services identified in our sample to CMS for appropriate action. As mentioned in the methodology, the results of our review of the 400 sampled services were not shared with the Medicare carriers who paid the chiropractors for these services.

AGENCY COMMENTS

In its comments on our draft report, CMS agreed with our findings and recommendations. The agency has clarified its chiropractic coverage criteria and indicated that most carriers are taking steps to reduce chiropractic error rates, including targeted educational efforts and service-specific medical reviews. In addition, as of October 1, 2004, CMS has required that chiropractors use the –AT modifier to indicate that a service is not maintenance. Only claims to which this modifier is attached are payable. The full text of CMS's comments begins on page 19.

OIG RESPONSE

We appreciate CMS's response to our report, and support the steps the agency is currently undertaking to help prevent paying for noncovered, miscoded, and undocumented services.

CMS noted in its comments that while this OIG study projected that 67 percent of the chiropractic services allowed by Medicare did not meet program requirements, CMS's Comprehensive Error Rate Testing (CERT) program identified a claims paid error rate of approximately 16 percent for claims submitted by chiropractors in 2002. CMS further noted that differences in the methodological approaches accounted for the significantly different rates. In particular, CMS recognized that OIG's review of a beneficiary's claims during their entire course of treatment enabled us to determine that approximately 40 percent of all chiropractic services are attributable to maintenance care, and thus are not covered under Medicare. In contrast, the CERT paid claims error rate is based on a review of a single claim, which limits its ability to detect uncovered maintenance costs.

We agree with CMS and would like to emphasize that the purpose of this inspection was to determine the underlying causes of, and potential ways to reduce, vulnerabilities associated with payments for chiropractic services. It was not designed to reproduce, or to review, the

CERT paid claims error rate. In addition to the different methodological approaches that are noted above, the CERT used 2002 data, whereas our data was drawn from 2001. Hence, our results cannot be compared directly to the CERT program results.

Furthermore, chiropractic payment errors, while a significant vulnerability, contribute only minimally to the overall CERT national paid claims error rate. Medicare allowed approximately $191 billion for Medicare fee-for-service claims in 2001. Chiropractic services accounted for $500 million, or 0.26 percent of this amount. Therefore, the chiropractic-specific error rate has little influence on the overall CERT error rate for fee-for-service claims.

Given that Medicare payments for chiropractic services have continued to increase since 2001, the need for a more effective way to eliminate inappropriate maintenance payments is crucial. However, we recognize that it may be impractical for the CERT program to expend its limited resources to collect the extent of documentation used in our review. Therefore, in the future, CMS may wish to conduct additional studies outside the scope of the CERT program to determine cost-efficient ways to address chiropractic payment errors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

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OFFICE OF INSPECTOR GENERAL

DATE: NOV 26 2004

TO: Daniel R. Levinson
Acting Inspector General
Office of Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: "Chiropractic Services in the Medicare Program: A Significant and Costly Vulnerability" (OEI-09-02-00530)

Thank you for the opportunity to review and comment on the above-referenced draft report. Chiropractic services have experienced considerable growth in Medicare, from 11.2 million services and $255 million allowed in 1994 to 18.1 million services and $560 million allowed in 2002. In previous studies, published in 1986, 1998, and 1999, the OIG found that a significant vulnerability existed in connection with chiropractic services, particularly concerning maintenance care. The Centers for Medicare & Medicaid Services (CMS) has been working to identify and ameliorate improper payments accordingly.

The CMS generally agrees with the recommendations in this report and with the OIG's assertion that many chiropractors submit erroneous claims to the Medicare program. While the OIG study projected that 67 percent of the chiropractic services allowed by Medicare did not meet program requirements, CMS' Comprehensive Error Rate Testing (CERT) program, identified a paid claims error rate of approximately 16 percent for claims submitted by chiropractors in 2002. The CMS and the OIG reviewed these two findings and concluded that differences in the methodological approaches for each project accounted for the significantly different rates. In particular, the OIG's review of a beneficiary's claims over time and the determination that a significant portion of the services met Medicare's definition of maintenance care, and, thus, are not covered under Medicare, accounted for over 40 percent of the projected error rate. The CERT paid claims error rate is based on a review of a beneficiary's claim at a single point in time and limits the finding of services meeting the definition of maintenance care.

The CMS appreciates the time and resources the OIG has invested to ensure that services billed to Medicare, including chiropractic manipulations, are medically necessary and supported by documentation. We share the OIG's concern with the identified improper payments and we are committed to reducing them. As a result, we have initiated a

number of steps, including enhanced provider education, to reduce improper payment for chiropractic services. Our detailed responses to the OIG's specific recommendations are outlined below.

OIG Recommendation

Ensure that chiropractic services comply with Medicare coverage criteria.

CMS Response

The CMS is taking steps to address this recommendation. In order to help chiropractors bill Medicare correctly, effective October 1, 2004, chiropractors must include the Acute Treatment (AT) modifier if active/corrective treatment is being performed, or no modifier if maintenance therapy is being performed. Medicare Carriers will deny chiropractic claims that do not contain the AT modifier. The CMS also recently issued a "Medlearn Matters" Web-based educational article to inform chiropractors, and their billing staff, on a nation-wide basis of chiropractic billing requirements.

Additionally, as referenced earlier, CMS' CERT program identified an approximately 16 percent paid claims error rate for claims submitted by chiropractors. Accordingly, most Medicare Carriers have included medical review of chiropractic services and local educational interventions in their Medical Review Strategy. Carriers will identify those chiropractic services/providers who present the greatest vulnerability, and will target their medical review work and resources appropriately. The CMS will monitor and track Carriers' efforts to reduce the paid claims error rate for chiropractic services.

OIG Recommendation

Require that carriers educate chiropractors on Medicare Carriers Manual requirements for supporting documentation.

CMS Response

The CMS recently revised its manuals (in Change Request (CR) 3449) to more clearly distinguish what chiropractic services are and are not payable. Pursuant to this CR, providers are being educated on how to appropriately bill for chiropractic services. In addition, contractors are always required to educate providers when they deny claims.

The CMS would like to thank the OIG for their effort in issuing this report. It contains valuable information about vulnerabilities and improper payments related to chiropractic services. The CMS looks forward to continuing to work collaboratively with the OIG to ensure the integrity of the Medicare Trust Fund.

Attachment

APPENDIX ~ A

Detailed Methodology

We defined our universe for the review as allowed services provided in 2001 by chiropractors (specialty code 35). Due to an internal processing error that was only discovered during the analysis phase, our actual universe was limited to 91 percent of such services.[16] From this universe of 14,497,406 services (with a total allowed amount of $457,444,574.32), we selected a simple random sample of 400.

Next, we matched the Unique Physician Identification Number (UPIN) and carrier-assigned provider identification number of the chiropractor who submitted the claim to the national UPIN registry in order to obtain the chiropractor's name and mailing address. A significant number of claims failed this match. We first attempted a manual Internet search for these unmatched UPINs; if unsuccessful, we telephoned carrier staff in order to obtain a valid name and address.

After obtaining mailing addresses, we sent letters to each chiropractor, requesting medical and billing records for each beneficiary associated with that doctor. The letter requested that the chiropractor include all records for the beneficiary, not just those for services rendered in 2001. A significant number of these initial letters were returned as undeliverable. We used Internet searches or called carriers to obtain correct addresses. Ultimately, we were unable to contact two chiropractors, representing one sample service each; we removed these two from consideration.

If we did not receive a response within approximately 5 weeks, we sent a second letter to the initial address. The second mailing also revealed a significant number of incorrect addresses, which we resolved in the manner described above. If we received no response after the second mailing, we obtained phone and/or fax numbers from the Internet or the carriers and telephoned or faxed the nonrespondents. Although we managed to contact every chiropractor except the two mentioned above, three did not provide records, and one sent records after the study period had been closed for more than a month.

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[16] The original data was contained in five compressed files. We decompressed these files and merged them into a single population data set. However, one of the smaller files failed to read into our population data set correctly, and therefore, contributed far fewer claims than expected to the population. Most of the omitted claims were for beneficiaries with Medicare numbers associated with the Railroad Retirement Board or the State of Massachusetts.

We organized each record and placed it into a folder to which the beneficiary's 2001 claims history was appended. We sent these folders to our medical review contractor, who forwarded them to chiropractic consultants for review. Each consultant/reviewer is a currently practicing chiropractor with experience in reviewing Medicare claims. We had previously developed a review instrument based on Medicare coverage criteria with the assistance of the medical review contractor. Before beginning the review, we met with the chiropractors to finalize the review protocol and to orient the reviewers to its use. The review instrument solicited information about the beneficiary's chiropractic treatment as a whole and about the individual sampled service in particular; the majority of the findings are based on the individual service questions.

After reviewing the records, the chiropractors returned the completed instruments to the contractor for quality control, who then forwarded them to us for entry into a data set. All analysis of the medical reviews, which included merging our data with census and other outside sources of information, was conducted using the statistical software packages SAS and SUDAAN.

Note on factors associated with medical necessity. We tested medical necessity as the response variable in a logistic regression with the following factors: the number of previous services allowed for the chiropractor-beneficiary combination in 2001, the absence of a treatment plan with stated goals, the presence of CPT code 98941 on the claim, the service being in the first month of treatment, and the urban/rural characteristics of the county where the service was billed. The number of prior services, the presence of CPT code 98941, and being in the first month of treatment were significant at the 95 percent confidence level.

Note on Figures 4 and 5. To obtain the estimates for the proportions of chiropractic services that were not medically necessary for Figures 4 and 5, we first determined the position of the sample service in the beneficiary's series of treatments. That is, we determined, for each claim, the number of services that had been previously allowed for that chiropractor-beneficiary combination in 2001. For Figure 4, we then grouped the sample services into the categories shown in Figure 4 (1 to 12 services, 13 to 24 services, 25 or more services) depending on the number of prior services allowed and determined the proportion of services in each category that were medically unnecessary. For Figure

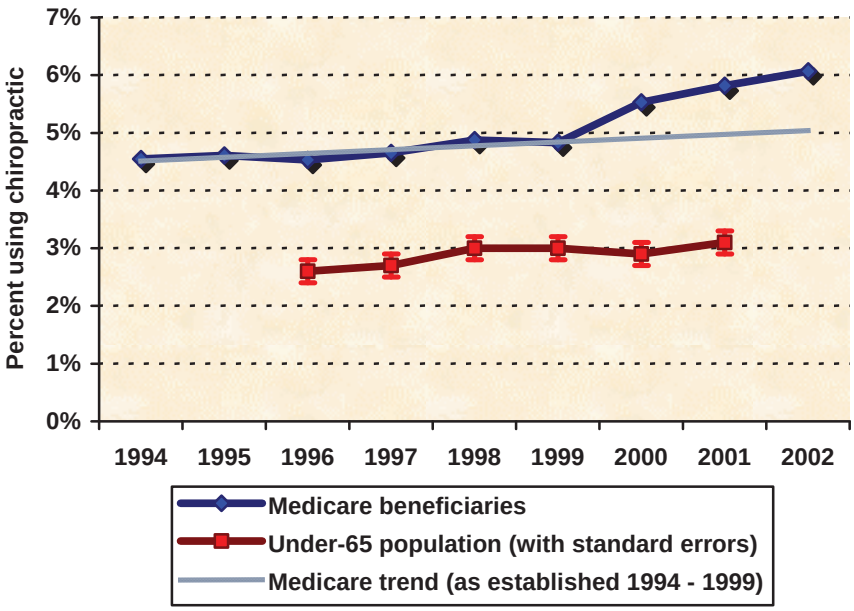
5, on the other hand, we determined the proportion of all services exceeding each threshold analyzed that were medically unnecessary. Hence, the numerator (medically unnecessary services) for each estimate in Figure 5 includes all services from the "25 or more" group from Figure 4, since the highest threshold analyzed was 24 services.

APPENDIX ~ B

Further Discussion of the Effects of Removing the X-ray Requirement

National Claims History data strongly suggest that removing the X-ray requirement spurred an increase in the number of beneficiaries receiving chiropractic care. As shown in Figure A-1, the proportion of Medicare beneficiaries using chiropractic services grew fairly steadily from 4.6 percent in 1994 to 4.8 percent in 1999, at a rate that approximately mirrored that in Americans less than 65 years old.[17] In 2000, the Medicare proportion jumped to 5.5 percent, roughly 2.5 times the combined increase from the previous 5 years, with no evidence that this change was reflected in the under-65 population. Medicare did not issue any policy changes other than removal of the X-ray requirement, or experience any shifts in its population (such as changes in the proportion of beneficiaries in rural areas) that would account for this increase.

FIGURE A-1
Medicare chiropractic utilization grew more rapidly after 1999 compared to the general population.

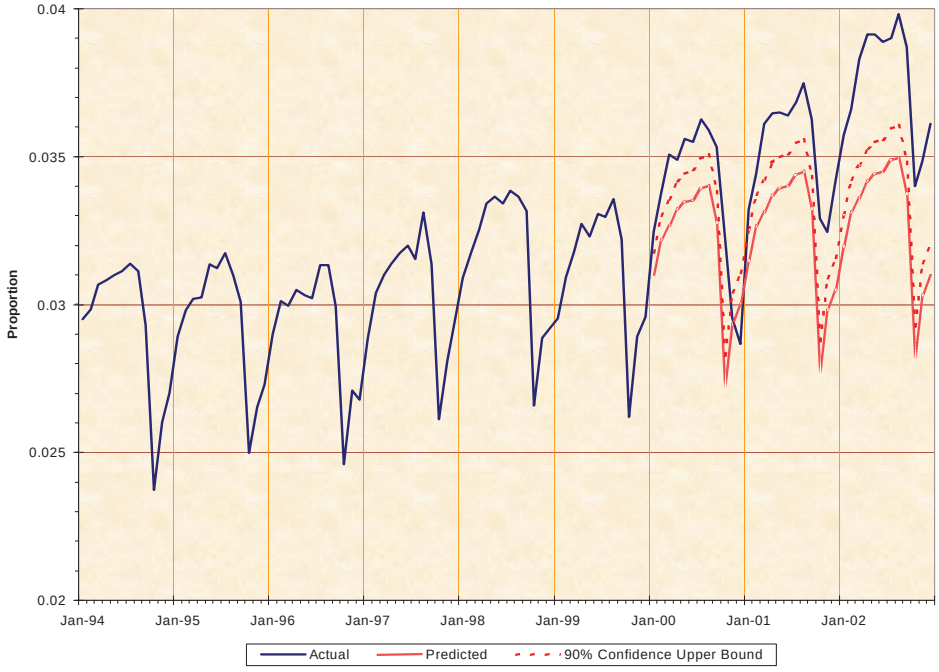


Source: National Claims History Part B 1 Percent Files, 1994 to 2002 and Agency for Healthcare Research and Quality Medical Expenditure Panel Survey, 1996 to 2001

[17] The under-65 population data from the Medical Expenditure Panel Survey is only available for the years displayed.

We used a commercial time series program called ITSM 2000 to develop an auto-regressive moving average model of the proportion of beneficiaries who received chiropractic services in each month from January 1994 to December 1999. Using this model, we forecast this proportion and produced the upper bound of a 90 percent confidence interval for each month from January 2000 to December 2002. As shown in Figure A-2, the actual proportion of beneficiaries who received chiropractic services surpasses the 90 percent confidence upper bound of our projection in nearly every month since the removal of the X-ray requirement.

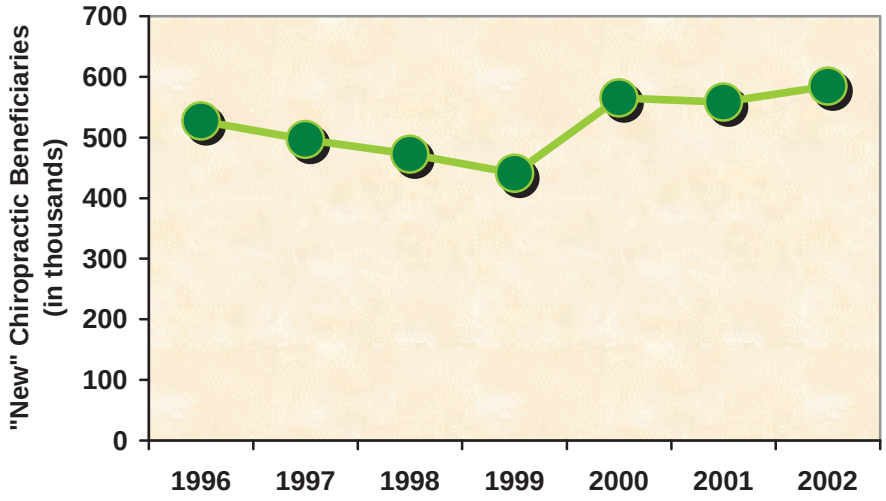
FIGURE A-2
Elimination of the X-ray requirement coincides with greater-than-expected growth in the proportion of beneficiaries who receive chiropractic services.



Source: National Claims History Part B 1 Percent Files, 1994 to 2002

As shown in Figure A-3, the number of "new" chiropractic beneficiaries (those who had never previously received a chiropractic service in Medicare), increased dramatically after the removal of the X-ray requirement, from approximately 441,000 beneficiaries in 1999 to 565,000 beneficiaries in 2000.[18] One possible explanation stems from Medicare's inability to pay for diagnostic tests ordered or performed by a chiropractor. Although a radiologist or medical physician may order and be reimbursed for tests on a patient referred by a chiropractor, the cost for X-rays may be assumed by the chiropractor or passed on to the beneficiary in many cases. Prior to January 2000, many chiropractors and beneficiaries may have been unwilling to shoulder the cost for X-rays, and hence the requirement may have served as a cost barrier to covered chiropractic care.

FIGURE A-3
The number of "new" chiropractic beneficiaries increased dramatically after removal of the X-ray requirement.



Source: National Claims History Part B 1 Percent Files, 1994 to 2002

[18] We used the 1 percent National Claims History files from 1994 to 2002 to formulate the numbers of "new" beneficiaries. Therefore, it is possible that some of the "new" chiropractic beneficiaries in each year shown had actually received chiropractic services sometime prior to 1994.

APPENDIX - C

Confidence Intervals for Selected Statistics

Statistic	N	Point Estimate	95% Confidence Interval
Total amount improperly allowed for chiropractic services	400	$285 million	$263 million to $306 million
Proportion of chiropractic services that were noncovered, miscoded, and/or undocumented	397	0.67	0.62 to 0.71
Proportion of chiropractic services that were noncovered	397	0.57	0.52 to 0.62
Proportion of chiropractic services that were miscoded	397	0.16	0.12 to 0.20
Proportion of chiropractic services that were undocumented	397	0.06	0.04 to 0.08
Proportion of chiropractic services that had at least two errors	397	0.12	0.09 to 0.16
Amount allowed for medically unnecessary services	400	$251 million	$228 million to $274 million
Proportion of services that were medically unnecessary	397	0.55	0.50 to 0.60
Amount allowed for maintenance services	400	$186 million	$164 million to $209 million
Proportion of services that were maintenance	397	0.40	0.36 to 0.45
Amount allowed for other medically unnecessary services	400	$65 million	$49 million to $81 million
Proportion of services that were medically unnecessary for other reasons	397	0.14	0.11 to 0.18
Amount allowed for services other than manual manipulation of the spine	400	$24 million	$14 million to $35 million
Proportion of services that were other than manual manipulation of the spine	397	0.05	0.03 to 0.08
Total amount allowed for noncovered services	400	$261 million	$238 million to $283 million
Net excess amount allowed for miscoded services	400	$15 million	$9 million to $20 million

Confidence Intervals for Selected Statistics, cont.

Statistic	N	Point Estimate	95% Confidence Interval
Amount allowed for undocumented services	400	$27 million	$16 million to $38 million
Allowed amount counted multiple times for services with multiple errors	400	$18 million	$11 million to $25 million
Ratio of maintenance services to medically unnecessary services	218	0.74	0.68 to 0.80
Proportion of other medically unnecessary services that were not therapeutic or did not provide a reasonable expectation of recovery	57	0.61	0.49 to 0.74
Total amount allowed for documented spinal manipulations billed with an incorrect code	400	$85 million	$66 million to $104 million
Proportion of services billed with CPT code 98942 that were upcoded	26	0.69	0.51 to 0.87
Proportion of services billed with CPT code 98941 that were upcoded	143	0.21	0.14 to 0.27
Proportion of services that were undocumented	397	0.06	0.04 to 0.09
Proportion of services that failed to meet at least one supporting documentation requirement	373	0.94	0.91 to 0.96
Proportion of documented services not supported by an evaluation that met Medicare guidelines	373	0.34	0.29 to 0.39
Proportion of documented services not supported by any evaluation	373	0.26	0.21 to 0.30
Proportion of documented services associated with an evaluation that fails requirements	373	0.08	0.05 to 0.11
Proportion of services with a proper evaluation that do not have a diagnosis meeting guidelines	250	0.33	0.27 to 0.39

Confidence Intervals for Selected Statistics, cont.

Statistic	N	Point Estimate	95% Confidence Interval
Proportion of services with a proper evaluation that have no diagnosis in record	250	0.29	0.23 to 0.34
Proportion of services with a proper evaluation that have a non-subluxation diagnosis in record	250	0.04	0.02 to 0.07
Proportion of services with a proper evaluation that have a subluxation diagnosis in record	250	0.67	0.61 to 0.73
Proportion of services provided as part of a written plan of care	373	0.28	0.23 to 0.32
Proportion of plans with goals and measures	103	0.23	0.15 to 0.31
Proportion of plans with goals that are medically unnecessary	35	0.14	0.03 to 0.26
Proportion of plans without goals that are medically unnecessary	338	0.61	0.56 to 0.66
Proportion of services where no evaluation for contraindications has occurred	397	0.66	0.61 to 0.71
Proportion of services with evaluations which revealed contraindications	135	0.21	0.14 to 0.28
Proportion of services with contraindications where risks outweighed benefits	28	0.18	0.04 to 0.32
Proportion of all services where risks from contraindications outweighed benefits	397	0.01	0.00 to 0.03
Proportion of services where 12 or fewer prior services allowed that are medically unnecessary	324	0.50	0.45 to 0.56
Proportion of services where 13 to 24 prior services allowed that are medically unnecessary	55	0.67	0.55 to 0.80
Proportion of services where more than 24 prior services allowed that are medically unnecessary	18	1.00	0.81 to 1.00

APPENDIX ~ D

Significance Tests for Selected Comparisons

Comparison		Test Result	P-value
Medically unnecessary services by number of services, *pairwise t-tests* (Bonferroni threshold = 0.016667)	12 or fewer services versus 13 to 24 services	-2.45	0.0146
	12 or fewer services versus more than 24 services	-17.87	0.0000
	13 to 24 services versus more than 24 services	-5.17	0.0000
Medically unnecessary services by presence of a treatment plan with specific goals, *chi-square test*		24.91	0.0000

ACKNOWLEDGMENTS

This report was prepared under the direction of Paul Gottlober, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Deborah Harvey, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff that contributed include:

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We would like to thank our medical review contractor and the individual chiropractors who performed the review, as well as the carrier staff who participated in our interviews and assisted us in obtaining contact information for the chiropractors whose services were selected for review.

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Office of Evaluation and Inspections
Region VII
1201 Walnut Street, Suite 934
Kansas City, Missouri 64106

December 12, 2007

«CHIROPRACTOR_FNAME» «CHIROPRACTOR_LNAME»
«STREET»
«CITY», «STATE» «ZIP»

Dear Dr. «CHIROPRACTOR_LNAME»:

The United Stated Department of Health & Human Services, Office of Evaluation and Inspections, conducts national program evaluations on issues of interest to Department officials, members of Congress, and the public. As the oversight agency for the Centers for Medicare & Medicaid Services (CMS), we frequently conduct evaluations regarding Medicare. We are currently conducting an evaluation examining chiropractic services.

Medicare billing records indicate that **«BENE_FNAME» «BENE_LNAME»** was seen on **«DOS».** Please send us copies of ***all*** medical **and** billing records for services provided to **«BENE_FNAME» «BENE_LNAME» [HICN: «HICN»; DOB: «BENE_DOB»]** 6 months prior to **«DOS»** or the first visit at which the patient was seen for this problem that includes **«DOS»**, whichever is greater, through the end of the treatment episode. You should include documentation from the entire treatment episode. The ending date of records should include the patient's final visit for this problem or the end of 2006, whichever is later. Please also include the CMS-1500 and ensure that the medical records contain the history and physical examinations, including history of present illness, beneficiary's family and past medical history, and plan of care, if available. Please submit the requested documentation no later than **January 8, 2008**, using the enclosed pre-addressed label with this letter to:

OIG Project Office (FMAS-CAT)
11300 Rockville Pike, Suite 712
Rockville, Maryland 20852-3015

OR, you may fax them to (301)770-7703.

Your participation in this study is mandatory. The *Inspector General Act*, the *Social Security Act*, and the *Health Insurance Portability and Accountability Act (HIPAA)* give us the authority to access all records required for the operation and oversight of the Medicare program, including patient records. The *Inspector General Act* also gives our office the authority to require, by subpoena if necessary, the production of all records necessary in the performance of our oversight mission.

You do not need an additional release from the patient to send the information to our office. The Medicare Health Insurance Claim Form (CMS Form 1500) includes language

whereby the beneficiary consents to the release of certain information, including access to records. Under the health information privacy regulation that implements the Health Insurance Portability and Accountability Act of 1996 (HIPAA), providing the information we are requesting is a permitted disclosure since it: (a) is "required by law" (see 45 CFR §§ 164.512(a), 154.501), and (b) will be used for "health oversight" activities by the Inspector General, which meets the definition of a "health oversight agency" (see 45 CFR §§ 164.512(d), 164.501). You should be aware that section

164.512(d) of the HIPAA regulations permits disclosure to the Inspector General for health oversight activities such as this evaluation, without written consent or authorization from the patient. In addition, I can assure you that the Office of Evaluation and Inspections is deeply committed to maintaining the confidentiality of patient health information.

If you do not have a record for the listed beneficiary, or have another reason to believe you have received this request in error, please explain your circumstances on the enclosed cover page and return it to us at the address listed above. Otherwise, please submit the records and cover page **no later than January 8, 2008**. Again, you may fax the records to (301)770-7703.

If you have any questions or concerns regarding this study, please contact our office at 1-800-241-2527 between 8:00 am and 4:00 pm Central Time. Please specify that you are calling about the "chiropractic services evaluation" so that the individual answering your call can direct you to the appropriate person. If you have any questions specifically about the medical record request, please contact Diana Haitz at (301)770-7702, ext. 109. Thank you for your cooperation.

Sincerely,

Brian Pattison
Regional Inspector General
for Evaluation and Inspections

enclosures (cover page & mailing label)

Authority for our request for information is found in the *Inspector General Act* (5 U.S.C. App. 6 at §§ 2, 4, and 6) and in Title II of the *Health Insurance Portability and Accountability Act* (42 U.S.C. 1320a-71c(a)). As the oversight agency for CMS, the Office of Inspector General has access to the same information that is available to the CMS.

Medical Record Documentation Cover Page

For Chiropractic Service Billed with the Acute Treatment (AT) Modifier

Patient Name: **«BFNAME» «BLNAME»** Patient HICN: **«HICN»**

Date of Birth: **«FDT»**

Please provide the name and phone number of a contact person in case we need any additional information.

Name:_____

Title:_____

Phone Number: _____

If you do not have a record for the patient above, or have another reason to believe you received this request in error, please explain:

_____

_____

_____

_____

_____

_____

_____ _____

Print Name Signature

Please mail this cover page with the medical record documentation back to us at:

OIG Project Office (FMAS-CAT)
11300 Rockville Pike, Suite 712
Rockville, Maryland 20852-3015

You may also fax the medical record documentation and/or cover sheet to (301) 770-7703.

Pages 847 through 852 redacted for the following reasons:

(b)(5) Draft

American Chiropractic Association

June, 18, 2009

American Chiropractic Association: Latest OIG Report Policy Conclusions Flawed

A report by the Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS) entitled "Inappropriate Medicare Payments for Chiropractic Services" was released May 6. As part of its larger strategic plan for promoting chiropractic's full inclusion within the Medicare program and national health reform, the American Chiropractic Association (ACA) has been actively monitoring the work plans of the OIG and, as a result, had been awaiting the report's release.

ACA views the recently released report as flawed; specifically, ACA strongly disagrees that the data noted in the report supports the policy proposals set forth by the OIG, and will relay these concerns to policymakers.

A coalition including ACA, the Association of Chiropractic Colleges (ACC), the Congress of Chiropractic State Associations (COCSA), and the Federation of Chiropractic Licensing Boards (FCLB) has been diligently working to assist doctors of chiropractic with navigating the Medicare documentation requirements.

A full response to this report will be communicated in the coming weeks.

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Medicare: May 2009 OIG Report

Print This Page

READ THE FULL ACA RESPONSE TO THE REPORT (pdf)

In May of 2009, the Department of Health and Human Services Office of Inspector General (OIG) released the Report "Inappropriate Medicare Payments for Chiropractic Services" (OEI-07-07-00390). The objectives stated in the Report were to determine the extent to which: 1) chiropractic claims allowed in 2006 for beneficiaries receiving more than 12 services from the same chiropractor were appropriate, 2) controls ensured that chiropractic claims were not for maintenance therapy, 3) claims data can be used to identify maintenance therapy, and 4) chiropractic claims were documented as required.

The OIG came to four conclusions: 1) Medicare inappropriately paid $178 million out of $466 million for chiropractic claims in 2006, 2) Efforts to stop payments for maintenance therapy have been largely ineffective, 3) Claims data lack information to identify maintenance therapy, 4) Chiropractors often do not comply with Medicare documentation requirements.

It is the opinion of the American Chiropractic Association that the May 2009 OIG Report fails to provide the information necessary to evaluate the appropriateness of the claims review methodology they used to arrive at key conclusions regarding the level of inappropriate Medicare payments to doctors of chiropractic. It is probable that the methods used resulted in an overestimate of inappropriate claims paid. Further, the ACA feels that the window of time between the release of the 2005 OIG Report and the initiation of data collection in 2006 for this Report did not allow sufficient time for meaningful change to occur within the chiropractic profession, and that it is too soon to conclude that efforts to stop Medicare payments for maintenance care have been unsuccessful. Numerous chiropractic organizations took immediate action to address issues of documentation standards and maintenance care in 2005 and we believe that significant progress has been made since that time. This premise is supported by the fact that 1) the documentation error rate identified in the 2009 OIG Report was significantly lower than that presented in the 2005 Report and 2) CMS CERT Reports saw a drop in overall error rates from 16 percent in 2006 to 11 percent in 2007 for chiropractic services.

Links

- ACA Press Release, May 7, 2009
- Full ACA Response to May 2009 OIG Report
- June 2005 OIG Report & Task Force Info
- OIG Webpage---All Reports Related to Chiropractic

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Chiropractors Flunk Medicare

By Spencer 4 June 2009 No Comment

Washington DC - The ACA has been funding a campaign for further inclusion into the Medicare system of the United States. Some may say that this is unnecessary and the money should be spent in other ways while other argue for equality between professional reimbursement for medical services. Regardless of the stance an individual Chiropractor may take there has been a new report published regarding Chiropractic care and the Medicare system's payment plan.

The Office of the Inspector General (OIG), a division of the Department of Health and Human Services, has issued a report generated from the audit of 188 random patient files regarding improper payment to chiropractors. They cite evidence from the

files where therapies were miscoded, undocumented, or deemed maintenance therapies instead of active therapies. In total this accounts for 47 percent of the Chiropractic claims that were submitted in 2006, for a total of $178 million in inappropriate payments.

The ACA has since released a letter to the OIG responding with criticism to the methodology used in producing the report. The response indicates errors within the data collection process and its effectiveness and accuracy with regard to suggested remedies. They also suggest that the data collected does not support the recommendations perpetuated by the report.

As a profession we can look at this report in two manners, as a direct attack on chiropractic by the OIG and possible argument to reduce the Chiropractic benefit in Medicare, or a wake up call to better manage our patients within the Medicare system. In this case the ability to move past criticizing others and undergoing self-evaluation is a far greater tool. As a profession we need to maintain the highest standards of care for our patients, but we can clearly see that is not happening when nearly half of all claims submitted result in inappropriate payments.

While considering the ramifications of ineffective data collection and the poor quality of suggested remedies there can be no question that the Chiropractic profession needs to make a stronger statement in the Medicare system. The only way to do this is maintain proper records with treatment dates and outcome objectives as well as noting day to day improvements and changes. Record keeping is the heart of the Medicare system and has been shown as erroneous at best regardless of the manner in which the data was implemented.

Overall the ACA has placed a great significance on the OIG report's outcome measures when we are failing to maintain our own patient outcome measure in records. This is ironic but a battle worth fighting. As a profession we need to step up and maintain appropriate records, and we need to support our national and state associations who uphold the professions interests in policy and oversight. Without these organizations representing us we could see huge implications in the way Chiropractic care is recognized and reimbursed by all insurance carriers. Moreover, we would not have the power to govern our profession to maintain appropriate treatment and records. Its time to make a name for Chiropractic and provide the services our patients deserve - proper documentation and appropriate outcome measures.

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Foundation for Vertebral Subluxation

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A Review and Analysis of the Office of Inspector General's Report:

INAPPROPRIATE MEDICARE
PAYMENTS FOR
CHIROPRACTIC SERVICES

May 2009

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Introduction

The Office of the Inspector General of the Department of Health and Human Services released a report dated May 2009 entitled: Inappropriate Medicare Payments for Chiropractic Services. The stated objective of the report was to:

> To determine the extent to which:
>
> (1) chiropractic claims allowed in 2006 for beneficiaries receiving more than 12 services from the same chiropractor were appropriate,
>
> (2) controls ensured that chiropractic claims were not for maintenance therapy,
>
> (3) claims data can be used to identify maintenance therapy, and
>
> (4) chiropractic claims were documented as required.

According to the OIG report, Medicare inappropriately paid $178 million for chiropractic claims in 2006. This was out of $466 million in total claims paid. According to the medical claims reviewers hired by the OIG to conduct this investigation, the bulk of the inappropriate payments were for maintenance therapy which amounted to $157 million. Miscoded and undocumented claims accounted for the rest.

This is not the first time the OIG has asserted that there were "significant vulnerabilities" related to Medicare payments for chiropractic care. Reports in 1986, 1998 and 1999 also alleged problems related to payment for maintenance therapy.

According to this most recent OIG report the previous studies recommended frequency edits or caps on the number of chiropractic claims allowed. In 2005 the OIG stated that 40 percent of allowed chiropractic claims were for maintenance therapy and they asserted that any visits over 12 in a year were likely to be for maintenance care.

As a result, the OIG recommended that carriers conduct routine reviews of chiropractic services, implement frequency-based controls, target high-volume services for review and educate chiropractors on Medicare documentation requirements. This is what led to the massive effort in the profession to hold continuing education programs on Medicare and the PART system.

There are several concerns with this most recent report from the OIG that include methodology, bias, and most distressing – perhaps a complete lack of understanding regarding the nature of the management of vertebral subluxation. The remainder of this report will outline these concerns and make recommendations to address them.

Methodological Concerns

Medical Reviewers

According to the OIG Report the primary method used to achieve their objectives was "medical review of records" supporting chiropractic claims. In order to do that they contracted with a "medical review contractor" that assisted them in "…data collection, selecting medical reviewers, and reviewing medical records."

The medical reviewers were chiropractors selected by the OIG and the contractor who had "…previous experience in reviewing chiropractic services provided to Medicare beneficiaries…"

It was these chiropractors, presumably paid for their medical review role and presumably already working with the carriers in a review capacity, who determined whether each sampled claim was considered active/corrective treatment or maintenance therapy. These presumably paid reviewers also determined whether the use of the AT modifier was supported by the documentation, and whether there was proper coding and documentation.

The OIG report contains some very serious accusations and statements concerning the practice of chiropractic. It is disturbing to say the least that the basis for these accusations stems from the opinions of chiropractors acting as paid reviewers for the OIG. Also disturbing is the very real possibility that the chiropractors hired to perform these reviews are already working within the medical review field generally and for the Medicare carriers specifically. Given the highly biased statements made by carrier staff and documented in this OIG report one has to be concerned that these reviewers also share this bias.

Further to the concerns regarding the chiropractic reviewers is that we have no knowledge of the political, professional and philosophical perspectives of these reviewers. There is not a chiropractor in the profession, nor likely a layperson, who is not aware that there are contentious issues surrounding the concept of vertebral subluxation. The profession is also generally aware that those chiropractors who contend that there is debate as to the significance and even existence of vertebral subluxation tend to be chiropractors who gravitate toward working in the medical review business.

If the chiropractors hired by the OIG to conduct these reviews have personal and worldviews that suggest that subluxations are insignificant or even non existent then clearly this would potentially taint their findings and thus call into question the results of this evaluation.

It is recommended that the profession request the identities and qualifications of the chiropractors who participated as medical reviewers in this evaluation. Further, it is recommended that the profession demand that these reviewers reveal how much of their income is derived from medical review activities and how much of their time is spent in

active practice. If they care for Medicare beneficiaries it is suggested that a random sample of their records and claims be reviewed to ensure that they are indeed following the same standards that they are opining on regarding their colleagues. The profession should also request the identity of the medical review contractor hired to participate in this investigation.

Carrier Staff Interviews

The process for evaluation utilized by the OIG included structured interviews with carrier staff. The OIG report includes a number of direct quotes from those structured interviews that are used to buttress the OIG argument regarding the inappropriate management by the chiropractors in their sample. It is concerning that there are no positive comments from the carrier staff or medical reviewers. In fact, some of the comments seem blatantly inappropriate coming from someone charged with such responsibilities. Some statements by staff include non referenced statistical data that cannot be verified in the report so the reader (the public) is left to assume it must be factual given it is contained in a government report.

Others of the quotes reveal a complete and blatant disregard on the part of the carrier staff to even utilize the very parameters being evaluated in this investigation with one stating, remarkably, that its not worth it financially because the amount of money involved is negligible.

The following are selected quotes and statements from carrier and medical review staff contained in the OIG report:

> "Three to four years ago we looked at distribution among three codes, looking at those using 98942 frequently. The percentage of abuse with 98942 was 80 percent or greater."
>
> Carrier staff, PSC staff, and medical reviewers for this study agreed that the AT modifier did not prevent inappropriate payments for maintenance therapy. Carrier staff readily indicated, "By putting an AT modifier on a claim, chiropractors are getting paid, and they know they will get paid."
>
> Staff from another PSC investigating suspicious chiropractic claims said, "from a [targeted] medical review standpoint, we see lots of chiropractors billing with the AT modifier when not appropriate. I would say at least 95 percent of AT modifier use is wrong. It is a big issue."
>
> Staff from another carrier noted in reference to their post payment review process, "As we continue to do complex medical review, we continue to deny about 90 percent of reviewed claims."

One carrier reported difficulty in implementing an internal frequency threshold. After the carrier adjusted its frequency threshold, some chiropractors changed their billing behavior by submitting claims up to the threshold to avoid review.

Carrier staff explained that they no longer have hard caps because of guidance from CMS and opposition from the chiropractic community. A CMS staff member noted, "Years ago, some [carriers] had auto-deny limits and one by one, they got rid of them because of political pressure."

Although CMS has hard caps in other disciplines, staff indicated that the lack of clinical evidence would make establishing frequency thresholds for chiropractic claims difficult. However, staff from 10 carriers indicated that they would welcome hard caps on chiropractic claims. Similarly, the 2005 OIG report noted that six carriers would like hard caps.

Staff from a PSC responsible for program integrity in five major cities across 16 States explained, "We have to prioritize our work by the most egregious crimes. We don't look at chiropractic claims and the AT modifier specifically because the money is not [significant when reviewing] individual providers."

Carrier staff indicated that documentation for chiropractic claims was poor. Staff at one carrier stated, "Several providers blatantly tell us that they don't have time to document the way we want."

Staff at another carrier stated that chiropractors do not agree with documentation requirements and believe them to be too time consuming.

A staff member from one carrier explained that: When reviewing a specific service, we often don't get a treatment plan if it was created at the first visit for the episode-this is no more than what we ask from [medical doctors]. The general trend is that [the patient will] be treated for several months, three to four times per month, but there's no documentation of a treatment plan or any goals.

One of the medical reviewers explained that it is common for chiropractors to have treatment plans that include frequency, duration, and goals but that these treatment plans often are verbal and consequently not always documented.

Another medical reviewer indicated, "In my 29 years of practice, I rarely saw documentation of a plan which included frequency,

> duration, goals, and objective measures. While these guidelines are in the [Medicare] Manual, they apparently have not been incorporated into the profession."

Presumably the quotes and comments included in the report are not a complete record of statements gathered. There is no way to know based on the report whether these quotes represent the majority of those gathered in the structured interviews or whether quotes that supported the contentions of the OIG were the ones that were used.

Based on these concerns it is recommended that the profession request a copy of the structured interview questions that were utilized in this investigation and that all responses received during the evaluation be provided so that a full review can be made and these quotes/statements can be put in context with the totality of the interviews.

Review of Literature

The OIG report states that they also accomplished their objectives by reviewing recent chiropractic literature. However there is no discussion of that literature in the report and an Appendix, Reference section or Bibliography listing that literature is not provided. Considering that a good amount of literature has been published in the past several years related to the management of vertebral subluxation it seems reasonable that we would want to be assured that this was not a limited review that was conducted and that those conducting the review possess appropriate credentials.

It is therefore recommended that the profession request a detailed description of the methodology used to conduct the literature review, that a complete list of the literature reviewed be provided and an explanation given for literature, guidelines and other documents that were not included. The identity and qualifications of those who conducted the review should be provided. Finally, the OIG should explain how the literature informed their evaluation.

Management of Vertebral Subluxation

The OIG report contains the following statement:

> As required by the Social Security Act, Medicare pays only for medically necessary chiropractic services, which are limited to active/corrective manual manipulations of the spine to correct subluxations. Chiropractors must use the acute treatment (AT) modifier to identify services that are active/corrective treatment and must document services in accordance with the Centers for Medicare & Medicaid Services' (CMS) "Medicare Benefit Policy Manual" (the Manual) when submitting claims. When further improvement cannot reasonably be expected from continuing care, the services are considered maintenance therapy, which is not medically necessary and therefore not payable under Medicare.

The OIG report continues:

> As required by the Social Security Act (the Act), Medicare pays only for reasonable and necessary chiropractic services, which are limited to active/corrective manual manipulations of the spine to correct subluxations. A chiropractic service "must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function." The Centers for Medicare & Medicaid Services (CMS) "Medicare Benefit Policy Manual" (the Manual) allows chiropractors an opportunity to produce functional improvement or arrest or retard deterioration for subluxations within a reasonable and generally predictable period of time. When further improvement cannot reasonably be expected from continuing care and the services become supportive rather than corrective, the services are considered maintenance therapy. The Manual provides that maintenance therapy is not considered a medically necessary chiropractic service and is therefore not payable under Medicare.

Any reasonable person reading these statements would understand this to mean that the primary management goals when addressing vertebral subluxation are to arrest or retard deterioration for subluxations. Once a subluxation is reduced or taken to a point where no further improvement can be made then the care is considered maintenance. Other than arguments regarding the non therapeutic nature of some types of chiropractic care – such statements are more likely than not thought to be reasonable by those who consider vertebral subluxation to be a pathophysiological process which can be objectively identified and amenable to intervention.

Thus, Medicare specifically states that they will only pay for care that is directed at "correcting" vertebral subluxations and additionally, Medicare has repeated references to functional improvement related to the correction, reduction, or arrest of vertebral subluxation. This could not be any clearer.

The issue becomes muddy where Medicare states this must be done "… within a reasonable and generally predictable period of time." It is suggested that this nexus, between the mandate Medicare is giving to the chiropractic profession relative to its responsibility toward correcting subluxation and its insistence that there is some known reasonable and predictable period of time in which this happens, is a significant reason for the ongoing disconnect between the OIG and the clinicians.

There is no clinical research that reveals this "reasonable and predictable period of time" yet Medicare insists there is, the carriers assume it is around 12 visits and the medical reviewers reinforce this absolute figment of everyone's imagination.

In addition to this issue we have the on-going issues where Medicare is holding the chiropractic profession to a standard which it does not hold medical providers to. Medicare routinely pays for medical services to address chronic conditions such as heart disease, diabetes and others without considering this "maintenance therapy."

The only thing we know for sure is that vertebral subluxations can be reliably identified using objective means and that reduction of vertebral subluxation can thus be identified through reliable means. Further, functional outcome assessments including objective measures of the components of vertebral subluxation, physiological abnormalities secondary to vertebral subluxation and quality of life issues affected by subluxation can all be objectively measured.

It is these objective measures that must be used to determine whether or not a Medicare beneficiary has obtained a correction or stabilization of their subluxation(s) and not whether or not they have had more than 12 visits or whether or not the patient has a disease, disorder or syndrome tied to the vertebral subluxation. It is suggested that most chiropractors would contend that subluxations in and of themselves are detrimental and that even in the absence of a related condition they should be arrested or corrected. This fundamental confusion and disconnect between what typical chiropractors are trying to accomplish clinically and what Medicare is trying to force them to do poses serious ethical issues for the chiropractor. And we see this reflected in the frustration of the writers of the OIG report, the comments by the carrier staff and the medical reviewers.

These issues have repercussions beyond the OIG report both in Medicare and in any debate surrounding chiropractic inclusion in health plans – specifically management of vertebral subluxation.

Therefore, this fundamental disconnect must be resolved in order to put to rest the ongoing issues related to reimbursement for chiropractic services. In order to do that it is recommended that a rethinking of the role of chiropractic in Medicare be undertaken. At a time when the chiropractic profession is struggling to even remain relevant in the the discussion of a national health plan it should use this as an opportunity to stake its claim on its unique and strategic competitive advantage.

While jockeying to try and make sure chiropractic is included in Medicare or any other national health plan such that the profession is able to provide any and all services that are within its scope, the profession must demand, *without compromise,* that at a minimum those services include the identification and management of vertebral subluxation. Further, that such management include care that is directed toward the arrest or correction of subluxation and include whatever means are generally accepted within the profession to accomplish such clinical goals. Additionally, whatever outcome measurement tools have been established as valid and reliable in objectively documenting the existence of a subluxation and its reduction must also be included - otherwise the profession is given a mission without the necessary resources to accomplish it.

Finally, any determination of the reasonableness or necessity of chiropractic care by a third party must include consideration of whether or not the subluxation has been arrested or corrected and such determinations must be made by reviewing objective assessments of outcome.

Screens and Caps

There can be no mistaking that the OIG is strongly advocating for the implementation of caps on the number of visits paid to chiropractors. This is suggested numerous times throughout the report. While CMS suggests that such action will not be taken in the short run it is suggested that without a vigorous response to this report such a recommendation will eventually be entertained – whether in Medicare and/or in the coming national health plan.

Education

Repeatedly the OIG refers to educational sessions that were undertaken by them in an effort to reinforce the documentation, billing and coding rules that have become such a contentious issue. In fact, the OIG at times seems exasperated that so much education was done yet the results of the evaluation reveal a worsening of the situation. Yet the OIG sees only one side of the issue and asserts that it's the chiropractors who must not be getting it - and the statements by the carrier staff even suggest that chiropractors are simply ignoring these mandates on purpose. This is quite disturbing considering that any fair evaluation has to take into consideration whether or not the educational programs were effective. Why isn't this possibility entertained by the OIG? Were any of the programs offered by the OIG or the carriers evaluated? If so what were the results of those evaluations? If not – why not?

There have been numerous anecdotal reports form the profession of a great deal of frustration arising at these "educational sessions" stemming from the perception on the part of the chiropractors that the M edicare representatives were uninformed at best and ignorant at worst regarding the nature of the chiropractic clinical landscape. Other stories include outright contempt towards chiropractors being displayed by the carrier representatives. It would be disturbing to say the least if these anecdotes have any basis in fact.

It is recommended that the profession seek to gather reports from attendees at these educational sessions to substantiate these anecdotes and the profession should attempt to gather any and all course evaluations that were completed by providers of these programs in order to assess learner concerns about them. Many of them were sponsored by the post graduate departments of chiropractic institutions so evaluation data should be readily available.

Documentation

As outlined in the OIG report the Medicare Manual provides documentation requirements as follows:

> Initial visit.
>
> 1. Subluxation(s) demonstrated by x-ray or physical examination (physical examinations must demonstrate at least two of the four following criteria: pain/tenderness, asymmetry/misalignment, abnormal range of motion, and tissue/tone changes, one of which must be either asymmetry/misalignment or abnormal range of motion),
> 2. Diagnosis of subluxation(s),
> 3. Patient history (lists such items as symptoms and past health history),
> 4. Description of present illness,
> 5. Treatment plan (includes a recommended level of care, specific treatment goals, and objective measures to evaluate treatment effectiveness),
> 6. Physical examination, and
> 7. Date of initial treatment.
>
> Subsequent visit.
>
> 1. Patient history (lists such items as changes since last visit),
> 2. Physical examination, and
> 3. Documentation of treatment provided at each visit.

The interpretation of clinical records and the judgment used to determine whether or not a particular threshold has been met to state with certainty that some review criteria was met is extremely subjective. For example, the OIG report itself states:

> For example, even if not all visits included patient histories and descriptions of present illnesses, which are required by Medicare, the records were still reviewed.

If one looks at the documentation rules there is no requirement that descriptions of present illnesses be included in follow-up visits. However, this statement from the OIG report suggests that there is. If the OIG report reveals such confusion about the medical review criteria one can only imagine the discrepancies that arose amongst the reviewers themselves once the process got underway.

The OIG report does not state whether or not the chiropractic reviewers followed a structured review process when evaluating the sample records. There is also no explicit description of the review process. For example were files reviewed only by one chiropractor or was each file reviewed by multiple reviewers followed by additional reviews to resolve any discrepancies and to arrive at a consensus? If such a process was

not followed this calls into serious question the validity and reliability of the review process itself. Was there any training required for the chiropractors prior to the beginning of the review process? Coupled with potential conflicts of interest and potential bias - a flawed review process may have tainted any conclusions arrived at in this report.

It is recommended that the profession inquire as to the nature of the review process and that an explicit description of that process be provided.

Involvement of Stakeholders

Best practices in program evaluations suggest that all stakeholders should be included in the process. Clearly, this evaluation did not include input or feedback from the chiropractors whose records were evaluated, the patients or the profession itself. Based on comments by carrier staff and medical reviewers there are concerns that they are highly biased. It should be of concern to the profession that all stakeholders were not included and that that at least two of the major participants in the evaluation itself may be biased and may have financial conflicts of interest.

It is recommended that the profession strongly voice its objection to the lack of involvement of all stakeholders and that the profession seriously question the objectivity of an evaluation based upon potentially biased participants.

Quality Standards for Inspections

In their work, the Inspectors General apply the Quality Standards for Inspections http://www.ignet.gov/pande/standards1.html and the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency encourage the consistent application of these standards throughout the Inspector General community.

The following are several instances where this Medicare OIG report may have failed to abide by those standards.

> *Competency*
>
> The inspection organization needs to ensure that the personnel conducting an inspection collectively have the knowledge, skills, abilities, and experience necessary for the assignment…
>
> When reviewing technical or scientific topics, it may be appropriate to use the services of a subject matter expert.

As outlined in the foregoing report there is no assurance that the personnel involved in this investigation possess the requisite knowledge, skills, abilities and experience to conduct such an investigation. Further, considering the technical and scientific issues surrounding vertebral subluxation - the very entity that the investigation centered on – there is no information provide as to whether or not subject matter experts were involved

in the process. Given the highly bias nature of the carrier and reviewer staff comments the level of concern on this issue is heightened.

Independence

> Inspectors and inspection organizations have a responsibility to maintain independence so that opinions, conclusions, judgments, and recommendations will be impartial and will be viewed as impartial by knowledgeable third parties. The independence standard should be applied to anyone in the organization who may directly influence the outcome of an inspection and includes both Government and private persons performing inspection work for an OIG.
>
> Having preconceived ideas toward individuals, groups, organizations, or objectives of a particular program that could bias the inspection. (f) Having biases, including those induced by political, ideological, or social convictions, that result from employment in or loyalty to a particular type of policy, group, organization, or level of government.

As pointed out in the foregoing report there are numerous instances of biased and derogatory comments towards chiropractors on the part of carrier staff and reviewers involved in the inspection. There can be no question based on these comments alone that individuals involved in the process were biased. Additionally, as stated in this review of the OIG report, the chiropractic profession includes individuals who actually question the existence or the significance of vertebral subluxation. Were some of these individuals involved in the reviewing aspect of this inspection this would have inserted significant ideological convictions into the process. The OIG should provide information including vitae concerning those individuals utilized as paid reviewers for this inspection.

Professional Judgment

> Evidence is gathered and reported in a fair, unbiased, and independent manner and report findings, conclusions, and recommendations are valid and supported by adequate documentation…

Beyond the blatant biased and derogatory comments by carrier staff and medical reviewers involved in this inspection there is no evidence provided which substantiates the numerous statements by these individuals – especially with regard to statistics quoted and given as facts which are nothing more than hearsay? Clearly there was a lack of judgment in this regard.

Planning

> Research—Consistent with the inspection objectives, inspection research includes a review of existing data, discussions with program and other appropriate officials, literature research, and a review of pertinent

> websites and other internet accessible materials to gather information that will facilitate understanding of the program or activity to be inspected. Research should help to identify the criteria applicable to the evaluation of the program or activity. Examples of possible criteria include: laws, regulations, policies, procedures, technically developed standards or norms, expert opinions, prior periods' performance, performance of similar entities, performance in the private sector, and best practices of leading organizations. Research should attempt to identify the results of previous reviews that may be relevant to the inspection, and inspectors should follow up on known significant findings and recommendations that directly relate to the current inspection. Inspectors need to assess the validity and reliability of the data gathered.

While the OIG report suggests that it reviewed the literature in regard to the topic of this investigation there is no evidence provide regarding what literature was reviewed, what type of review was conducted, who conducted it or how that literature informed the framers of the report. One can have no confidence that this quality standard was followed absent that information. Additionally, there is no evidence provided that the validity and reliability of the data gathered was assessed.

Data Collection and Analysis

> The sources of information should be described in the supporting documentation in sufficient detail so that the adequacy of the information, as a basis for reaching conclusions, can be assessed. Information should be of such scope and selected in such ways as to address pertinent questions about the objectives of the inspection and be responsive to the informational needs and interests of specified audiences. The procedures and mechanisms used to gather information should ensure that the information is sufficiently reliable and valid for use in meeting the inspection objectives. For example, inspectors need to ensure the validity and reliability of data obtained from computer-based systems that is significant to the inspectors' findings. Inspectors will use professional judgment in determining whether information is sufficiently reliable and valid.
>
> Qualitative and quantitative information gathered in an inspection should be appropriately and logically presented and documented in work papers, to ensure supportable interpretations.

As previously stated literature was not cited, the structured interview survey was not provided and professional judgment was not brought to bear in regards to the statements put forward as facts by carrier staff and medical reviewers.

Evidence

> The following guidelines should be considered regarding evidence:

1. Evidence should be sufficient to support the inspection findings. In determining the sufficiency of evidence, inspectors should ensure that enough evidence exists to persuade a knowledgeable person of the validity of the findings.

2. To be competent, evidence should be reliable and the best obtainable by using reasonable collection and evaluation methods. The following presumptions are useful in judging the competency of evidence: (a) Evidence obtained from an independent source may be more reliable than that secured from an organization being inspected. (b) Evidence developed under an effective system of internal controls generally is more reliable than that obtained where such controls are lacking or unsatisfactory. (c) Evidence obtained through direct physical examination, observation, or computation may be more reliable than evidence obtained through less direct means. (e) Testimonial evidence obtained from an individual who is not biased or who has complete knowledge about the area usually is more competent than testimonial evidence obtained from an individual who is biased or has only partial knowledge about the area.

This standard is not met to the extent that a knowledgeable person familiar with the issues is not persuaded of the validity of the findings. The medical reviewers were paid chiropractors who were hired based upon their history of having previously served as paid reviewers for carrier staff. There is no convincing argument that these reviewers were independent. Statements made by carrier staff and medical reviewers that are damaging, with some even suggesting criminal behavior - along with unverified statistics, were used in this report as if factual without verifying their veracity.

Records Maintenance

All relevant documentation generated, obtained, and used in supporting inspection findings, conclusions, and recommendations should be retained for an appropriate period of time.

It is hoped that this standard was upheld and that appropriate documents as outlined in this review will be made available to the profession for review.

Measurement

Mechanisms should be in place to measure the effectiveness of inspection work.

Previous inspections of a similar nature have been conducted on this issue and the OIG has stated that previous reports and training have not resulted in what they suggest is an appropriate change in behavior of the part of practicing chiropractors. Given this contention what evaluation has been done of the effectiveness of the inspection work done thus far by the OIG? The bold assumption is made by the drafters of this OIG report

that fault lay at the feet of chiropractors however, what of the alternate suggestion that perhaps the policies and procedures of the OIG, HHS, carrier staff and medical reviewers are ineffective, obtuse, contradictory and not based on sound science. The profession should call for an evaluation of the effectiveness of this program and its staff that takes into consideration this alternate view.

Recommendations

Based upon the foregoing review of the OIG report the following recommendations are made:

1. It is recommended that the profession request the identities and qualifications of the chiropractors who participated as medical reviewers in this evaluation.
2. It is recommended that the profession demand that the medical reviewers involved in the evaluation reveal how much of their income is derived from medical review activities (including but not limited to Medicare) and how much of their time is spent in active practice as some states have rules and regulations governing this activity.
3. If the chiropractic reviewers provide care for Medicare beneficiaries it is suggested that a random sample of their records and claims be reviewed to ensure that they are indeed following the same standards that they are opining on regarding their colleagues.
4. The quotes and comments of carrier staff and medical reviewers appear to be biased and there is no way to know if these quotes represent the majority of those gathered in the structured interviews or whether quotes that supported the contentions of the OIG were the ones that were used. Based on these concerns it is recommended that the profession request a copy of the structured interview questions that were utilized in this investigation and that all responses received during the evaluation be provided so that a full review can be made and these quotes/statements can be put in context with the totality of the interviews.
5. It is recommended that the profession request a detailed description of the methodology used to conduct the literature review.
6. It is recommended that a complete list of the literature reviewed be provided and an explanation given for literature, guidelines and other documents that were not included.
7. The identity and qualifications of those who conducted the literature review should be provided.
8. The OIG should explain how the literature reviewed actually informed their evaluation.
9. It is recommended that the OIG address the fundamental confusion and disconnect between what typical chiropractors are trying to accomplish clinically and what Medicare is trying to force them to do. This disconnect is reflected in the frustration of the writers of the OIG report, the comments by the carrier staff and the medical reviewers and should not be ignored.
10. It is recommended that the profession seek to gather reports from attendees at educational sessions related to the previous OIG reports and recommendations. The profession should attempt to gather any and all course evaluations that were

completed by providers of these programs in order to assess learner concerns about them.

11. It is recommended that the profession inquire as to the nature of the medical review process and that an explicit description of this process be provided. Questions regarding the nature of the file reviews, how discrepancies were resolved, and training of the reviewers are examples of specific issues that should be addressed.
12. It is recommended that the profession strongly voice its objection to the lack of involvement of all stakeholders and that the profession seriously question the objectivity of an evaluation based upon potentially biased participants.
13. It is recommended that the profession demand, *without compromise,* that Medicare services include the identification and management of vertebral subluxation at a minimum and that other diseases, disorders and syndromes not be required to be present in order for this to take place.
14. The profession should vigorously oppose the implementation of caps on the number of visits paid to chiropractors.

Foundation for Vertebral Subluxation

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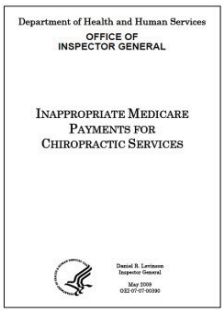

Office of Inspector General Releases Scathing Report on Chiropractic – Chiropractors Respond

FOR IMMEDIATE RELEASE

Office of Inspector General Releases Scathing Report on Chiropractic – Chiropractors Respond

ATLANTA, Georgia – June 1, 2009

The Office of the Inspector General of the Department of Health and Human Services released a report dated May 2009 entitled: Inappropriate Medicare Payments for Chiropractic Services. The stated objective of the report was to:

> To determine the extent to which:
>
> (1) chiropractic claims allowed in 2006 for beneficiaries receiving more than 12 services from the same chiropractor were appropriate,
>
> (2) controls ensured that chiropractic claims were not for maintenance therapy,
>
> (3) claims data can be used to identify maintenance therapy, and
>
> (4) chiropractic claims were documented as required.

According to the OIG report, Medicare inappropriately paid $178 million for chiropractic claims in 2006. This was out of $466 million in total claims paid. According to the medical claims reviewers hired by the OIG to conduct this investigation, the bulk of the inappropriate payments were for maintenance therapy which amounted to $157 million. Miscoded and undocumented claims accounted for the rest.

This is not the first time the OIG has asserted that there were “significant vulnerabilities” related to Medicare payments for chiropractic care. Reports in 1986, 1998 and 1999 also alleged problems related to payment for maintenance therapy. In 2005 the OIG stated that 40 percent of allowed chiropractic claims were for maintenance therapy and they asserted that any visits over 12 in a year were likely to be for maintenance care.

“There are several concerns with this most recent report from the OIG that include methodology, bias, and most distressing – perhaps a complete lack of understanding

regarding the nature of the management of vertebral subluxation" stated Matthew McCoy DC, MPH a chiropractor, public health researcher and Vice President of the Foundation for Vertebral Subluxation.

In a report that analyzed the OIG investigation McCoy details methodological concerns including that the OIG paid chiropractors to review these claims and used chiropractors who have a history of reviewing claims for Medicare carriers suggesting that there may be a conflict of interest. Further concerns arise from disparaging comments towards chiropractors from Medicare carrier staff and medical reviewers contained within the report. Some comments by the staff and reviewers even suggest widespread fraudulent conduct on the part of chiropractors participating in Medicare.

"These comments by carrier staff and medical reviewers appear unsubstantiated and reveal significant bias and flaws in the study. They never should have been published, and may cause significant damage to patients served by the chiropractic profession" stated Dr. Christopher Kent a chiropractor, attorney and President of the Foundation for Vertebral Subluxation.

Medicare pays chiropractors for treatment to correct vertebral subluxations which are misalignments and/or abnormal movement of spinal bones that interfere with nerve function. However, Medicare will only pay for subluxation correction if there are other diseases, disorders or syndromes related to the subluxation – not for the correction of subluxation in and of itself. This, according to McCoy, is the fatal flaw in Medicare policy when it comes to chiropractic.

"Vertebral subluxations are detrimental in and of themselves – its like saying they won't pay for the treatment of heart disease until you are in the midst of a heart attack" stated McCoy.

Making matters worse is an ongoing battle between chiropractors and the carriers who administer Medicare on how many visits it takes to correct a vertebral subluxation. The inappropriate payments alleged by the OIG may simply be a disconnect in determining whether the care being provided is corrective or what is commonly called maintenance care – Medicare will not pay for maintenance chiropractic care.

According to McCoy "The OIG, the carriers and the paid medical reviewers who work for them expect chiropractors to sit back and accept their allegations that all this care for seniors who typically suffer from a number of concurrent health conditions and have advanced spinal arthritis is unnecessary because it goes beyond 12 visits. Its ludicrous. Correcting a subluxation takes time and in this population a lot longer than one month."

In fact, research has not yet shown how long it takes on average to correct subluxations. For this reason doctors generally rely on standards of care and practice guidelines for guidance on how often and for how long someone needs care. "According to chiropractic practice guidelines accepted by the National Guideline Clearinghouse the parameters being used to measure subluxation should be monitored for reduction and stabilization of subluxation components" stated Kent. "There are objective instruments to measure functional outcomes. These should prevail over the opinions of conflicted parties."

One problem with this approach is that Medicare will not pay chiropractors for anything except spinal manipulation which means that none of the tests that chiropractors routinely do to determine the severity of subluxation and monitor its correction are covered under Medicare. This leaves chiropractors in a Catch 22. It is also completely at odds with how all other providers are compensated under Medicare.

"Medicare expects chiropractors to correct subluxations but will not pay for the tests necessary to determine if a patient has one or to determine if they have been corrected. Instead they arrive at this arbitrary 12 visit formula where everyone is supposed to be cured" remarked McCoy. "These are our tax dollars at work."

Speaking of tax dollars, according to a review done by Foundation for Vertebral Subluxation Board Member Dr. Curtis Fedorchuk, Board Member of the Foundation for Vertebral Subluxation, the total cost of Medicare in 2006 was $339 billion with the total paid by Medicare to chiropractors totaling $187 million equaling .00055% of the total.

"That we are even arguing about this is symptomatic of the government's failure to respond effectively to the health care crisis" stated Fedorchuk. "In at least two chiropractic studies on senior citizens we find that those seniors undergoing

chiropractic use and spend less money on drugs, are hospitalized less, are less likely to end up in nursing homes, are more active and actually save Medicare money. Instead of trying to stop chiropractors from seeing Medicare patients they should be encouraging its use. One wonders about the motivation of the carriers."

In a series of policy recommendations the Foundation for Vertebral Subluxation recommends that chiropractors urge the federal government to allow the profession to fulfill Congress' intent when it added subluxation correction to Medicare and reimburse them for the care necessary to correct and monitor subluxations.

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Dr. Scott J. Heun's
CHIROTHOUGHTS©

THURSDAY, MAY 14, 2009

Medicare or Medi-Scare?

This excerpt was sent to me today in an email. It originated from Dr. Leonard from the Wisconsin Chiropractic Association.

Subject: Will Medicare Fire Chiropractic Based on OIG Finding?

Will Medicare Fire Chiropractic?

Attached is a copy of a report issued by the Office of Inspector General (OIG) on payments made to chiropractors for Medicare services. The audit's findings were as follows:

Medicare inappropriately paid $178 million for chiropractic claims in 2006, representing 47 percent of claims meeting our study criteria.

Efforts to stop payments for maintenance therapy have been largely ineffective.

Claims data lack initial visit dates for treatment episodes, hindering the identification of maintenance therapy.

Chiropractors often do not comply with the Manual documentation requirements.

88% of the reviewed claims had inappropriate payments for "maintenance therapy", 26% for undocumented care, and 6% for miscoded care. 20% of the claims had multiple errors. Separate from the undocumented claims counted as errors, 83 % of chiropractic claims failed to meet one or more of the documentation requirements.

In the past, when reports regarding the chiropractic profession have been required by Congress, the reports were inexcusably delayed. This report seems to have been issued at a time calculated to do maximum damage to the chiropractic profession – in the middle of the debate over health care reform.

If the chiropractic profession does not immediately and aggressively respond to the conclusions of this report, every one of our competitors will point to this report as an excuse to disregard the chiropractic profession as decisions are made on the benefits to be included or the reforms that are to be made in the health

MISSION STATEMENT

It is my sincere desire to help as many chiropractors as possible to succeed in providing exceptional patient care in an ethical and honest manner, and in so doing, succeed professionally, personally, and financially.

MY RECOMMENDED READINGS

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BLOG ARCHIVE

ABOUT ME

DR. SCOTT HEUN

I am a chiropractor, seasoned clinician

care reform bill.

We believe the report has a critical flaw in that its definition of “maintenance therapy” is discriminatory and it is nearly impossible to apply to a particular case via a review of chiropractic documentation.

The Medicare policy manual defines “maintenance therapy” as follows:

Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. For information on how to indicate on a claim a treatment is or is not maintenance, see §240.1.3.

Discrimination

First, it is critical to note that Medicare has a different standard for chiropractors than it does for medical providers. Medicare routinely pays for the medical treatment of symptomatic chronic conditions including heart disease, rheumatoid arthritis, diabetes, macular degeneration, allergies, and many others. On the other hand, Medicare states that chiropractic adjustments “performed to maintain or prevent deterioration of a chronic condition” are maintenance therapy. For Medicare patients, medical treatment that keeps a chronic or degenerative condition from worsening is accepted; but it is a violation of the law for chiropractors to provide the same standard of care to their patients.

Definition of maintenance care

When a Medicare patient presents with another episode of a chronic condition, their chiropractor cannot know whether it is a new problem or an exacerbation of a previous problem until he/she examines the patient (which Medicare will not pay for). At this point, if the chiropractor determines the pain is due to an exacerbation of a previous problem, they are supposed to guess, based on the current deterioration of the patient’s spine, whether or not this treatment plan will fully resolve the problem because if it merely prevents deterioration of the condition to the point where, for instance, it might require expensive surgery, a chiropractor violates the law by providing care.

The chiropractic profession has never challenged this absurd definition of maintenance therapy. It appears to have been written by an individual without specialized knowledge of the needs of the elderly with regard to their spinal problems. The overwhelming percentage of Medicare patients who seek care from chiropractors are suffering from chronic conditions. If a chiropractor is able to document that acute symptomtology is present, these patients should not be viewed by Medicare to be receiving maintenance therapy.

and mentor.
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Other problems

The OIG report also found that 26% of the audited claims had inappropriate payments for undocumented care. Clearly there should be no payment for chiropractic services when a chiropractor fails to document their clinical interaction with the patient. However, the basis for these determinations was opinions of reviewers hired by OIG.

OIG stated they "worked with the medical review contractor to select chiropractors with previous experience in reviewing chiropractic services provided to Medicare beneficiaries to serve as medical reviewers for this study". The chiropractic profession is all too familiar with the bias of chiropractic reviewers who skew their opinion to retain their employment relationship. Without an unbiased review of the credentials of those performing this "review" work, the chiropractic profession should insist that an unbiased third party with impeccable credentials confirm the accuracy of these "reviews".

Because time is of the essence, the response of the profession to this report needs to be widely disseminated to members of Congress and the Obama administration before our competitors seek to destroy our credibility in the negotiations over national health care reform.

Regards,

Russ Leonard
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POSTED BY DR. SCOTT J. HEUN AT 1:04 PM
LABELS: MEDICARE, OR IS IT MEDI-SCARE?

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MAC
MICHIGAN ASSOCIATION OF CHIROPRACTORS

June 23, 2009

Secretary Kathleen Sebelius
U.S. Department of Health & Human Services
200 Independence Avenue S.W., Room 120F
Washington, D.C. 20201

Dear Secretary Sebelius:

This letter is in response to the Medicare Office of the Inspector General's (OIG) May 2009 report, "Inappropriate Medicare Payments for Chiropractic Services." The Michigan Association of Chiropractors (MAC) believes there are two major mitigating factors that must be addressed when analyzing the data from this report:

(1) That the OIG definition of "maintenance therapy" is discriminatory against doctors of chiropractic, and
(2) That the findings and recommendations outlined in the report are flawed, and that the methods used by the OIG may have resulted in an overestimate of inappropriate claims.

With Congress currently negotiating which services will be included in the health care reform bill – especially the services to be included in the government-sponsored plan that is expected to compete with private insurance plans – it is critical that you view the report of the OIG with the following factors in mind.

Discriminatory Definition of "Maintenance Therapy"

The Medicare policy manual defines 'maintenance therapy" as follows:

> *"Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition.*
>
> *When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chronic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy."*

It is critical to note that Medicare has a different standard for chiropractors than it does for medical providers – they routinely pay for the medical treatment of symptomatic chronic conditions, including heart disease, rheumatoid arthritis, diabetes, macular degeneration, allergies, etc. Yet, Medicare states that chiropractic adjustments "performed to maintain or prevent deterioration of a chronic condition" are maintenance therapy.

In essence, this means that for Medicare patients, medical treatment that keeps a chronic or degenerative condition from worsening is accepted, but it is a violation of Medicare policy for chiropractors to provide the same standard of care to their patients.

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The overwhelming majority of Medicare patients who seek care from doctors of chiropractic are suffering from chronic conditions. If a chiropractor is able to document that symptomology or functional improvement is present, these patients should not be viewed by Medicare to be receiving maintenance therapy.

Methods Used by the OIG

OIG Report Finding: Medicare inappropriately paid $178 million out of $466 million for chiropractic claims in 2006, representing 47 percent of all allowed chiropractic claims that met the study criteria.

The OIG restricted data collection to episodes of chiropractic care that resulted in claims for more than 12 visits by the same doctor of chiropractic – a subpopulation of chiropractic claims that they have previously identified as more likely to meet their definition of maintenance care.

The MAC believes that a random sample from a more appropriate population of chiropractic claims would have resulted in a much smaller estimate of inappropriate claims paid. Chiropractic claims account for 0.15 percent of total Medicare Claim expenditures. The Centers for Medicare & Medicare Services' (CMS) 2006 National Claims History Part B Carrier file shows 22,964,790 chiropractic claims with a total allowed amount of more than $762 million. A random sample from this more representative population of chiropractic claims would have yielded a smaller estimate of inappropriate claims paid.

OIG Report Finding: Efforts to stop payments for maintenance therapy have been largely ineffective.

The MAC believes that this statement cannot be properly assessed due to the small gap of time between the first OIG report and the current one. The first report was released in 2005. The current report assesses claims data from 2006, a mere one year later. We believe that the following factors have influenced the findings of the OIG:

- Again, this report is based on 2006 claims data and was not released until 2009. We are confident that a review of current claims would show a marked improvement.
- The use of the AT modifier only began in 2005. It is unclear if adequate training on the use of this modifier occurred during the one year between its introduction and the claims analyzed in the report.
- Because of the lack of information provided in the Report regarding claims review protocols, it is unclear to what extent the OIG findings are based on actual claims paid for maintenance care versus active care that was insufficiently documented.
- The Report also makes several references to the 2005 OIG report. The 2005 Report, based on 2001 data, found that 67% of chiropractic claims were paid inappropriately, with the majority of this (40%) attributed to claims identified as maintenance care. The 2009 OIG report, based on 2006 data, found that 47% of chiropractic claims were inappropriately paid, with less than 34% attributed to maintenance care. It is important to note that, in the 2005 Report, the sampling frame for the claims review was global chiropractic claims, while the 2009 Report limited data collection to those claims with 12 or more visits, a group which they had previously identified as more likely to be problematic. If, in fact, the problem with inappropriately billed maintenance care claims is getting worse, as the 2009 OIG Report suggests, these numbers from 2001 to 2006 should have substantially INCREASED, rather than DECREASED.

OIG Report Finding: Claims data lack information to identify maintenance therapy.

The MAC disagrees that claims data lack information to identify maintenance therapy. We believe that the AT modifier is the appropriate tool to use for this purpose. Gaps in appropriate use of the AT modifier identified in the Report can be attributed to

1) an understandable learning curve for the chiropractic profession in learning to use the AT modifier correctly from 2005 to 2006
2) documentation errors, which continue to be seriously addressed by the profession

It is also important to note the OIG Report states that, in order to identify active/corrective treatment and thereby distinguish it from maintenance therapy, it is useful to identify the start of a new treatment episode. However, claims data do not indicate when an episode begins. This information is already required in box 14 of the CMS claims form completed by doctors of chiropractic.

OIG Report Finding: Chiropractors often do not comply with Medicare documentation requirements.

The OIG Report released in June 2005 found that nearly 95% of chiropractic claims reviewed contained documentation errors. The response of the chiropractic profession – including the MAC – was immediate. We immediately boosted efforts to include proper documentation workshops at all of our conventions and many stand-alone seminars. The Medicare Chiropractic Guide and Medicare Chiropractic Billing Guide have been posted on our website for members to download.

The efforts of statewide organizations such as the MAC – not to mention the national chiropractic organizations (ACA, ICA, COCSA, etc.) – were largely put into effect in late 2005 and 2006, too late to be reflected in the 2009 OIG claims review. This position is supported by the fact that:

1) The documentation error rate identified in the 2009 OIG Report was significantly lower than that presented in the 2005 Report
2) CMS CERT Reports saw a drop in overall error rates from 16 percent in 2006 to 11 percent in 2007 for chiropractic services

Thank you for your attention to this critical matter. As the debate regarding health care reform moves on, I hope you will take into account the above factors prior to making any decision regarding the inclusion of chiropractic in any health care reform bill.

Sincerely,

Donald M. Reno D.C.

Donald M. Reno, DC
President

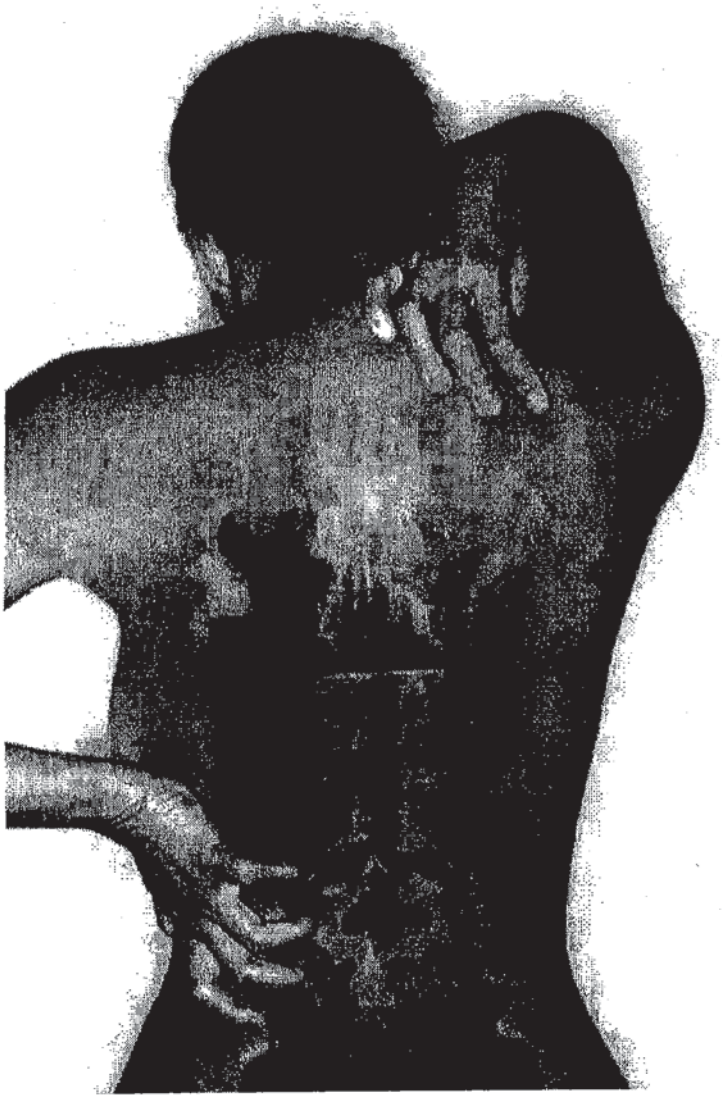
Attachment: MAC "Understanding Chiropractic"

UNDERSTANDING CHIROPRACTIC

The Chiropractic Approach to Health Care

Doctors of Chiropractic (DCs) are licensed health care professionals concerned with the diagnosis, treatment and prevention of neuromusculoskeletal disorders, and the effects of these disorders on the nervous system and general health.

DCs use natural and conservative methods of treatment and respect the human body's ability to heal itself. DCs treat the biomechanics, structure, and function of the spine, and its effects on the muscle and nerve systems, and take into account the role played by the proper function of these systems in the preservation and restoration of health. Spinal integrity is an important factor in promoting healing through chiropractic and is achieved without surgery or drugs.



Chiropractic Care is Unique

Chiropractic care involves manipulation/adjustment of the joints (spine or extremity) and associated therapy to promote spinal integrity. DCs manipulate/treat the joint dysfunction (subluxation) by using the hands, or a handheld instrument. DCs diagnose injuries and neuromusculoskeletal disorders, and treat individuals for pain, such as headaches, joint pain, neck pain, low-back pain and sciatica. DCs also treat osteoarthritis, carpal tunnel syndrome, tendonitis, sprains and strains, and a variety of other non-neuromusculoskeletal conditions.

Chiropractic Education

Candidates must complete a minimum of three years of college-level courses prior to entering chiropractic school. Completion of a Doctor of Chiropractic degree requires four to five years of professional coursework. The education of a chiropractor is similar in total classroom hours to that of a medical doctor. An average of 4,822 hours is required in chiropractic schools, compared with 4,667 hours in medical schools.

Basic science courses comprise nearly 30 percent of the total hours in both chiropractic and medical school programs, and the two programs have comparable hours in biochemistry, microbiology and pathology. Chiropractors receive more training in anatomy and physiology, while medical doctors receive more training in public health. The 4,822 hours of classroom instruction in chiropractic school include 1,416 hours in basic science, 1,975 hours in diagnostic and treatment methods, and 1,431 hours in clinical internship.

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Chiropractic colleges focus on chiropractic principles, diagnosis, orthopedics, physiologic therapeutics and nutrition. Three areas – manipulative/adjustive techniques/ spinal analysis, physical/clinical laboratory diagnosis, and diagnostic imaging – account for more than half of the education in clinical sciences. During their internship, chiropractors complete two years of hands-on clinical experience focusing on manipulation/adjustment as the primary treatment procedure. The emphasis in chiropractic clinical sciences is clearly on diagnosis and manipulative/adjustive therapy.

Clinical Competency

A chiropractic graduate must pass national licensing board examinations before receiving a license to practice. The multi-part examination is comprised of written and practical clinical sections. Prior to 1965, a DC took the same basic science board examination as a medical doctor. Today, the examination is separate, but equivalent, to the medical examination. The principal testing agency for the chiropractic profession is the National Board of Chiropractic Examiners (NBCE). The top goals in administering standardized exams are the promotion of high standards of competence and assistance to the state licensing agencies in assessing competence.

Chiropractic Works and Saves Money

In the U.S., the total annual cost for health care and lost productivity related to low-back pain is estimated to be nearly $100 billion! Research indicates that low-back pain is the most expensive source of workers' compensation costs in North America.

Numerous studies show chiropractic is an effective and efficient means of natural healing. Below are just some of these studies and their findings.

The Manga Report

The Manga Report is the most comprehensive analysis of low-back pain to date. Commissioned by the Ontario Ministry of Health, the report shows chiropractic treatment is cost-effective, safe, has a high rate of patient satisfaction, and is more effective than medical treatment for low-back pain.

The report recommends management of low-back pain be moved from medical doctors to chiropractors and found that injured workers with low-back pain returned to work much sooner when treated by chiropractors than by medical doctors. The report also notes evidence that patients are much more satisfied with chiropractic management of low-back pain than with medical management.

The Manga Report concluded: "There would be highly significant cost savings if more management of low-back pain was transferred from physicians to chiropractors. Users of chiropractic care have significantly lower health care costs, especially inpatient costs, than those who use medical care only."

Archives of Internal Medicine Study

A study published in the October 11, 2004 edition of the *Archives of Internal Medicine* compared 700,000 health plan members with a chiropractic benefit with 1 million members of the same plan who did not have the chiropractic benefit. The study found that members with chiropractic coverage had lower annual total health care expenditures per member per year ($1,463 vs. $1,671). Having chiropractic coverage was associated with a 1.6% decrease in total annual health care costs at the health plan level. Also, patients with chiropractic coverage had lower average back pain episode related costs ($289 vs. $399).

The AMI Study

In this study, a chiropractic network in which DCs performed all patient examinations, treatments, and procedures at their own discretion was constructed. Recommended follow-up visits, choice of appropriate treatment, and ancillary therapies utilized did not require approval from an MD. The original study, which focused on the years 1999-2002, found decreases of: 43 percent in-hospital admissions per 1,000; 58.4 percent in hospital days per 1,000; 43.2 percent in outpatient surgeries and procedures per 1,000; and, 51.8 percent in pharmaceutical costs. It noted that: "The AMI experience seems to indicate that a nonpharmaceutical/nonsurgical orientation can reduce overall health care costs significantly and yet deliver high quality care."

This study was updated in 2007, covering the years 2003-2005. The results of the original study were confirmed, with demonstrated decreases of 60.2 percent in in-hospital admissions, 59 percent in hospital days, 62 percent in outpatient surgeries and procedures, and 85 percent in pharmaceutical costs.

The Stano Study

This study, conducted by Oakland University Economics Professor Dr. Miron Stano, found that, when costs of advanced imaging and referrals to physical therapists and other providers were added, chiropractic care costs for chronic patients were 16 percent lower than medical care costs. If the study would have included hospitalization or surgical costs, two very expensive medical treatments for low-back pain, or over-the-counter medications, the savings from chiropractic would have been even greater. Additionally, chiropractic patients showed

an advantage over medical patients in pain, disability, and satisfaction outcomes.

The Procedures Study

This study demonstrates that chiropractic care leads to lower costs by reducing the rates of surgery, advanced imaging, inpatient care, and plain-film radiographs in patients with low-back and neck pain. The study examined the claims data from a managed care health plan over a four-year period. The use rates of the high-cost procedures mentioned above were compared between employer groups with and without a chiropractic benefit. For patients with both low back and neck pain, the use rate of all four of these categories was lower in the group with chiropractic coverage. See the table below.

The study concludes: "Among employer groups with chiropractic coverage compared with those without such coverage, there is a significant reduction in the use of high-cost and invasive procedures for the treatment of back pain."

The North Carolina Study

This study looked at more than 43,000 workers' comp. claims over a 19-year period (1975-1994) and found dramatic differences in the average treatment costs between chiropractic patients, medical patients, and patients treated by both. The analysis revealed that the average total cost of an injured worker's claim managed by a medical doctor was $21,774 more than claims managed by a DC. For chiropractic patients, however, average treatment costs were only $663, roughly 18 percent of the cost of medical care, and 13 percent of the cost of combined care.

Additionally, injured workers treated by chiropractors experienced lost work days for an average of 33 days – 143 days less than workers seeing an MD, and more than 200 days less than workers treated by MDs and DCs, and hospital inpatient and outpatient care costs for medical patients were $1,995 and $2,161 more per worker, respectively, than for chiropractic patients.

The study concluded: "It seems likely that substantial savings to the workers' compensation system would be possible if chiropractic services were increased in North Carolina."

The British Medical Research Council Study

The British Medical Research Council conducted a 10-year study that showed chiropractic care was significantly more effective than medical treatment for patients with chronic and severe pain.

The Annals of Internal Medicine Study

This study compared the effectiveness of manual therapy, physical therapy, and continued care by a general practitioner in patients with nonspecific neck pain. The success rate at seven weeks was twice as high for the manual therapy group (68.3 percent) as for the continued care group. Manual therapy scored better than physical therapy on all outcome measures. Additionally, patients receiving manual therapy had fewer absences from work than patients receiving physical therapy or continued care, and manual therapy resulted in statistically significant less analgesic use than continued care.

The Nevada Workers' Compensation Study

This study found loss of work time under chiropractic care is less than one-third of the time lost under medical care. The study also found that the average medical cost per patient was 260 percent higher than the average chiropractic cost.

Chiropractic Resource Organization Study

Another recent study published on the Chiropractic Resource Organization website reported the cost of treating episodes of low-back pain was 28 percent lower in patients whose health plan provided chiropractic coverage compared to health plans without coverage. And, total health care costs were 12 percent less for patients in plans that reimbursed for chiropractic services.

The Oakland University Study

Oakland University found "patients who received chiropractic care incurred significantly lower health care costs than patients treated solely by medical or osteopathic physicians." Total insurance payments were 30 percent higher for patients who elected medical care only.

Results from the Procedures Study

	Low-Back Pain		Neck Pain	
Procedure	**Per-Episode Decrease**	**Per-Patient Decrease**	**Per-Episode Decrease**	**Per-Patient Decrease**
Surgery	32.1 percent	13.7 percent	49.4 percent	31.1 percent
CT/MRI	37.2 percent	20.3 percent	45.6 percent	25.7 percent
Inpatient Care	40.1 percent	24.8 percent	49.5 percent	31.1 percent
Radiographs	23.1 percent	2.2 percent	36.0 percent	12.5 percent

The Texas Workers' Compensation Report

The Texas Chiropractic Workers' Compensation Report found the average claim for a worker with a low-back injury was $15,884. If a chiropractor provided at least 90 percent of the care, however, the average cost declined by more than 50 percent, to $7,632.

American Journal of Managed Care Study

This study found chiropractic care was substantially more cost-effective than conventional care. The authors also concluded that properly managed chiropractic care can yield outcomes, in terms of surgical requirements and patient satisfaction, that are equal to those of non-chiropractic care, at a substantially lower cost per patient.

The Utah Study

The Utah Study compared the cost of chiropractic care to the cost of medical care for conditions with identical diagnostic codes and found that cost was almost 10 times higher for medical than for chiropractic claims. Also, the number of work days lost was nearly ten times higher for those who received medical care.

The Florida Study

The Florida Study showed patients receiving chiropractic care rather than medical care had lower treatment costs by more than 50 percent.

Chiropractic is Mainstream

A study in the May 2000 issue of the *Journal of Manipulative and Physiologic Therapeutics* found chiropractic patients expressed much greater satisfaction with chiropractic rather than overall medical care (90 percent to 52 percent). Also, a higher proportion of chiropractic patients (56 vs. 13 percent) reported their low-back pain was better or much better, whereas nearly one-third of medical patients reported their low-back pain was worse or much worse.

The *American Journal of Medicine* reported on studies that investigated the risks between spinal manipulation and other treatments for the same conditions. For instance, one analysis concluded there was no evidence that nonsteroidal anti-inflammatory drugs (NSAIDs) were any more effective than spinal manipulation, but the risk of serious complications or death was between 100 and 400 times greater with NSAIDs. In another review, estimates of serious gastrointestinal events from NSAIDs were 1 per 1,000 patients, whereas complications of cervical manipulations were 5 to 10 per 10 million treatments.

Additional studies by noted chiropractic researcher BP Symons, the RAND Corporation and Duke University all found cervical manipulation, when performed by a qualified, licensed DC, is extremely safe and effective. In fact, the Duke study said cervical spinal manipulation "has a very low risk of serious complications," which may be "one of its appeals over drug treatment."

The Federal government and the U.S. court system have also recognized chiropractic. The Agency for Health Care Policy and Research (AHCPR) released guidelines stating that the risk of serious complications from lumbar spine manipulation is rare and that manipulation should be pursued before considering surgery.

Additionally, in the case of Wilk v. American Medical Association, the U.S. Supreme Court cited specific studies that showed that chiropractors "are twice as effective as medical physicians and physical therapists in the care and alleviation of neuromechanical problems."

Finally, the limitations of conventional medicine and the desire for less invasive medical treatment has led many patients to seek therapy through practitioners of complementary and alternative medicine such as chiropractors. A 1998 article discussing trends in alternative medicine in the *Journal of the American Medical Association (JAMA)* noted that 42 percent of Americans used some form of alternative therapy in 1997, and made an estimated 629 million visits to alternative medicine practitioners, exceeding the number of visits to primary care physicians that year. In fact, chiropractic is now the third largest health care profession in the world.

A report by *Solucient*, the nation's leading source of health care business information, confirmed the growing popularity of chiropractic care, which rose 91 percent between 1999 and 2001. The report noted: "Physicians are increasingly recommending CAM, especially for chronic conditions, such as back problems." Researchers at the Stanford University School of Medicine reported that chiropractic had the second-highest rate of physician referral (40 percent) among CAM providers.

Information provided by the Michigan Association of Chiropractors and the American Chiropractic Association.

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AMERICAN CHIROPRACTIC ASSOCIATION (ACA)
RESPONSE TO THE OFFICE OF INSPECTOR GENERAL REPORT: INAPPROPRIATE MEDICARE PAYMENTS FOR CHIROPRACTIC SERVICES (MAY 2009: OEI-07-07-00390)

June 9, 2009

Christine Goertz DC, PhD
Susan McClelland
Jaime Mulligan

SUMMARY
In May of 2009, the Department of Health and Human Services Office of Inspector General (OIG) released the Report "Inappropriate Medicare Payments for Chiropractic Services" (OEI-07-07-00390). The objectives stated in the Report were to determine the extent to which: 1) chiropractic claims allowed in 2006 for beneficiaries receiving more than 12 services from the same chiropractor were appropriate, 2) controls ensured that chiropractic claims were not for maintenance therapy, 3) claims data can be used to identify maintenance therapy, and 4) chiropractic claims were documented as required.

The OIG came to four conclusions: 1) Medicare inappropriately paid $178 million out of $466 million for chiropractic claims in 2006, 2) Efforts to stop payments for maintenance therapy have been largely ineffective, 3) Claims data lack information to identify maintenance therapy, 4) Chiropractors often do not comply with Medicare documentation requirements.

It is the opinion of the American Chiropractic Association that the May 2009 OIG Report fails to provide the information necessary to evaluate the appropriateness of the claims review methodology they used to arrive at key conclusions regarding the level of inappropriate Medicare payments to doctors of chiropractic. It is probable that the methods used resulted in an overestimate of inappropriate claims paid. Further, the ACA feels that the window of time between the release of the 2005 OIG Report and the initiation of data collection in 2006 for this Report did not allow sufficient time for meaningful change to occur within the chiropractic profession, and that it is too soon to conclude that efforts to stop Medicare payments for maintenance care have been unsuccessful. Numerous chiropractic organizations took immediate action to address issues of documentation standards and maintenance care in 2005 and we believe that significant progress has been made since that time. This premise is supported by the fact that 1) the documentation error rate identified in the 2009 OIG Report was significantly lower than that presented in the 2005 Report and 2) CMS CERT Reports saw a drop in overall error rates from 16 percent in 2006 to 11 percent in 2007 for chiropractic services.

BACKGROUND, DATA COLLECTION METHODS AND FINDINGS (excerpted from the OIG Report) *As required by the Social Security Act, Medicare pays only for medically necessary chiropractic services, which are limited to active/corrective manual manipulations of the spine to correct subluxations. Chiropractors must use the acute treatment (AT) modifier to identify services that are active/corrective treatment and must document services in accordance with the Centers for Medicare & Medicaid Services' (CMS) "Medicare Benefit Policy Manual" (the Manual) when submitting claims. When further improvement cannot reasonably be expected from continuing care, the services are considered maintenance therapy, which is not medically necessary and therefore not payable under Medicare. We identified allowed claims with the AT modifier for beneficiaries with more than 12 claims from the same chiropractor in 2006. We then contracted with a medical review contractor to review medical records from a simple random sample of 188 claims. For each treatment episode, the medical records were reviewed to identify the initial visit and subsequent visits (if relevant) to determine whether each sampled claim was active/corrective treatment or maintenance therapy, the extent to which chiropractors supported their use of the AT modifier with proper documentation indicating active/corrective treatment, whether claims were coded properly, and whether documentation met the Manual requirements. FINDINGS: 1) Medicare inappropriately paid $178 million out of $466 million for chiropractic claims in 2006, 2) Efforts to stop payments for maintenance therapy have been largely ineffective, 3) Claims data lack information to identify maintenance therapy, 4) Chiropractors often do not comply with Medicare documentation requirements.*

ACA REPONSE TO OIG FINDINGS

1) Medicare inappropriately paid $178 million out of $466 million for chiropractic claims in 2006, representing 47 percent of all allowed chiropractic claims that met the study criteria

A) It is important to note that the OIG restricted data collection to those episodes of chiropractic care that resulted in claims for more than 12 visits by the same doctor of chiropractic. This is a subpopulation of chiropractic claims they have previously identified as significantly more likely to meet their definition of maintenance care. Chiropractic claims account for 0.15% of total Medicare claim expenditures. CMS' 2006 National Claims History Part B Carrier file shows 22,964,790 chiropractic claims with a total allowed amount of $762,148,017. A random sample from this more representative population of chiropractic claims would have yielded a significantly smaller estimate of inappropriate claims paid.

B) Estimates of inappropriate Medicare payments for chiropractic claims are based entirely on review of medical records, yet the Report does not provide information on development and standardization of documentation review protocols, or training and certification of medical reviewers. There are two areas of the claims review process used in this Report that require rigorous methods to ensure the results are credible – assessment of maintenance care and the use of appropriate documentation standards. The protocol for determining the distinction between appropriate documentation of

maintenance care, which is not a benefit currently covered by Medicare, and documentation of acute/chronic care, which is a covered benefit, using medical records, must be clearly operationalized through the use of standardized record review criteria. There is no indication in the Report that this occurred. The second area pertains to the general documentation standards used to assess chiropractic claims for new and returning patients. The Report provides no information regarding how medical reviewers were trained and certified to assess the appropriateness of documentation pertaining to history, examination, presentation of present illness, and treatment plan records. Of particular concern are the standards used to determine documentation of a complete patient history, complete description of present illness, complete physical examination, and complete treatment plan. It is not clear what standards were used to determine that documentation was "complete," given the majority of claims reviewed did, in fact, include a patient history, description of present illness, physical examination findings, and a treatment plan. The ACA has placed a Freedom of Information Act request for copies of the protocols, training tools, and credentialing standards used by medical reviewers for this study.

2) Efforts to stop payments for maintenance therapy have been largely ineffective. The American Chiropractic Association feels it is too soon to assess whether or not efforts to stop payments for maintenance therapy have been effective. First, the use of the AT modifier was not widely implemented until 2005, only one year before the data provided in this report was collected. It is unclear if adequate training occurred during this early implementation period. Second, because of the lack of information provided in the Report regarding claims review protocols, it is unclear to what extent the OIG findings are based on actual claims paid for maintenance care versus active care that was insufficiently documented. Finally, the Report makes several references to the 2005 OIG report. The 2005 Report, based on 2001 data, found that 67% of chiropractic claims were paid inappropriately, with the majority of this (40%) attributed to claims identified as maintenance care. The 2009 OIG report, based on 2006 data, found that 47% of chiropractic claims were inappropriately paid, with less than 34% attributed to maintenance care. It is important to note that, in the 2005 Report, the sampling frame for the claims review was global chiropractic claims, while the 2009 Report limited data collection to those claims with 12 or more visits, a group which they had previously identified as more likely to be problematic in this area. If, in fact, the problem with inappropriately billed maintenance care claims is getting worse, as the 2009 OIG Report suggests, these numbers from 2001 to 2006 should have substantially INCREASED, rather than DECREASED.

3) Claims data lack information to identify maintenance therapy. The American Chiropractic Association disagrees that claims data lack information to identify maintenance therapy. We believe that the AT modifier is the appropriate tool to use for this purpose. Gaps in appropriate use of the AT modifier identified in the Report can be attributed to 1) an understandable learning curve for the chiropractic profession in learning to use the AT modifier correctly from 2005 to 2006, 2) documentation errors, which continue to be seriously addressed by the profession. It is also important to note the OIG Report states that, in order *to identify active/corrective treatment and thereby*

distinguish it from maintenance therapy, it is useful to identify the start of a new treatment episode. However, claims data do not indicate when an episode begins. This information is already required in box 14 of the CMS claims form completed by doctors of chiropractic.

4) Chiropractors often do not comply with Medicare documentation requirements. The OIG Report released in June 2005 found that nearly 95% of chiropractic claims reviewed contained documentation errors. The response of the chiropractic profession, including the American Chiropractic Association (ACA), was immediate. A Task Force on this issue was formed as a collaborative effort between the ACA, the Association of Chiropractic Colleges (ACC), the Federation of Chiropractic Licensing Boards (FCLB) and the Congress of Chiropractic State Associations (COCSA). The ACA created a documentation manual and made it available to the profession, at cost, for two years. A webinar was created and made available to the profession at no charge and documentation standards were added to the ACA web site, which is also open to the profession. The ACC tightened up documentation standards requirements in chiropractic educational institutions, emphasizing Medicare requirements, and also distributed Medicare education articles. The FCLB encouraged member boards to require hours in documentation for re-licensure, and COCSA encouraged member associations to emphasize Medicare and documentation educational seminars. In addition, all four organizations met with CMS to discuss documentation requirements and attended a presentation by CMS contractors regarding medical review standards for chiropractic claims. These efforts were largely put into effect in 2006, too late to be reflected in the OIG claims review, which also occurred in 2006. This position is supported by the fact that 1) the documentation error rate identified in the 2009 OIG Report was significantly lower than that presented in the 2005 Report and 2) CMS CERT Reports saw a drop in overall error rates from 16 percent in 2006 to 11 percent in 2007 for chiropractic services.

In Summary, it is the opinion of the American Chiropractic Association that the May 2009 OIG Report fails to provide the information necessary to evaluate the appropriateness of the claims review methodology they used to arrive at key conclusions regarding the level of inappropriate Medicare payments to doctors of chiropractic. It is probable that the methods used resulted in an overestimate of inappropriate claims paid. Further, the ACA feels that the window of time between the release of the 2005 OIG Report and the initiation of data collection in 2006 for this Report did not allow sufficient time for meaningful change to occur within the chiropractic profession, and that it is too soon to conclude that efforts to stop Medicare payments for maintenance care have been unsuccessful. Numerous chiropractic organizations took immediate action to address issues of documentation standards and maintenance care in 2005 and we believe that significant progress has been made since that time. This premise is supported by the fact that 1) the documentation error rate identified in the 2009 OIG Report was significantly lower than that presented in the 2005 Report and 2) CMS CERT Reports saw a drop in overall error rates from 16 percent in 2006 to 11 percent in 2007 for chiropractic services.

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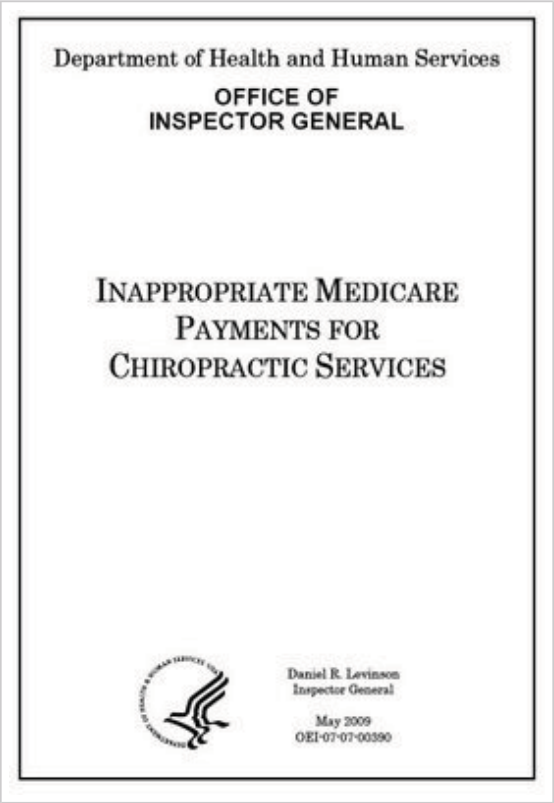
PHYSICAL THERAPY DIAGNOSIS

COMPLIANCE THROUGH COMPETENCE

FRIDAY, MAY 15, 2009

Chiropractors need help in writing treatment notes


Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INAPPROPRIATE MEDICARE PAYMENTS FOR CHIROPRACTIC SERVICES

Daniel R. Levinson
Inspector General

May 2009
OEI-07-07-00390

A new report from the Office of the Inspector General (OIG) on chiropractic services furnished to Medicare patients shows that chiropractors have as much trouble, or more, than physicians or physical therapists in writing notes on their patient care that show:

- medical necessity (need)
- progress
- skill (decisions)

"Medicare inappropriately paid $178 million for chiropractic claims in 2006 (from a total of $466 million in Medicare chiropractic claims) ...

- *88% of the reviewed claims had inappropriate payments for 'maintenance therapy'*
- *26% for undocumented care*
- *6% for miscoded care*
- *20% of the claims had multiple errors*

SHARE PTD WITH YOUR PEERS!

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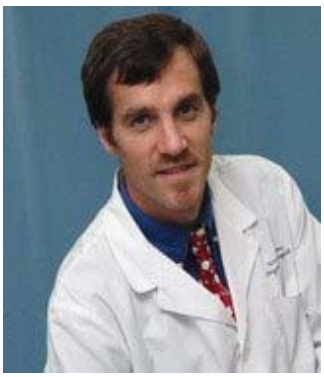
Tim Richardson, PT

HELPFUL BLOGS THAT I READ

The Health Care Blog
Opening Physician's Notes to Patients - By STEVE DOWNS Today's Boston Globe ran a story (page one, no less!) announcing our grant to Beth Israel Deaconess Medical Center to run a three-site demon...
6 hours ago

PNHP's official Blog
Senate Finance proposes unaffordable underinsurance - The Senate Finance Committee members were informed by the Congressional Budget Office that the impact their preliminary reform proposal would have on the f...
6 hours ago

Evidence Based Rehab
What is a PT? Whatch and See... -

- *83 % of chiropractic claims failed to meet one or more of the documentation requirements."*

The Comprehensive Error Rate Testing program Paid Claims Error Rate for chiropractors, PM&R physicians and physical therapists in private practice (PTPP) shows the following error rates for the last three years:

CERT Program Provider Error Rates	2006	2007	2008
PM&R Physicians	**9.1%**	7.6%	8.9%
Physical Therapists in Private Practice	11.3%	**6.1%**	**7.0%**
Chiropractors	16%	11%	10.5%

The provider type with the lowest Paid Claims Error Rate is in **bold**.

The Executive Director of the Wisconsin Chiropractic Association, Russ Leonard, has called the OIG Report 'discriminatory' because the Medicare definition of 'maintenance therapy' seems to prevent chiropractors from performing chiropractic adjustments "...to maintain or prevent deterioration of a chronic condition."

Since physical therapists are held to the same standard for maintenance therapy the chiropractors claim of discrimination seems unfounded.

The OIG has been no less kind to physicians performing physical therapy - in 2002, the OIG found that 91 percent of PT billed by physicians and allowed by Medicare did not meet Medicare guidelines which resulted in $136 million in improper payments.

Physical therapists aren't off the hook either - reports of individual physical therapists receiving inappropriate payments from Medicare in Texas and Florida have surfaced recently.

What can provider do to show need skill and progress?

When writing your notes, try to answer these questions:

1. Why are you treating this patient?

13 hours ago

MyPhysicalTherapySpace.com
EIM Receives Small Business Award!! - EIM won the 2009 Greater Louisville Inc. (GLI) Inc.credible Award for an outstanding small business. This award plays tribute to the top small businesses i...
1 day ago

Medicare Update
Bipartisan Policy Center Releases Health Care Reform Proposal - On July 17, 2009, the Bipartisan Policy Center (BPC), and former Senators Howard Baker, Tom Daschle, and Robert Dole, released a health care reform proposal ...
1 day ago

Moving Forward
Hang Up the White Coats? - As APTA continues to roll out our new "Move Forward" branding campaign to members and urges them to "live the brand," I found a couple of recent articles i...
2 days ago

NPA Think Tank
I'm back and so here's a link - General apologies and regrets for the long delay between posts. One of the things I was up to was presenting at the annual APTA Conference in Baltimore wit...
4 days ago

MTABC - Evidence informed resources on pain
Illness behavior in patients on long-term sick leave due to chronic musculoskeletal pain - Patricia Olaya-Contreras; Jorma Styf Background and purpose Methods for identification of patients with illness behavior in orthopedic settings are still b...
1 week ago

2. How much do you expect them to improve?
3. How long will it take?
4. How much will it cost?
5. What factors (eg: co-morbidities, compliance, family or social issues) may delay or prevent you from meeting these goals?

An excellent tool that can help you answer questions #1,#2 and #3 is a baseline self-report questionnaire.

For example, the Neck Disability Index (NDI), developed by a chiropractor, is a simple, cost-effective tool to show medical necessity and, applied over time, progress.

A complete literature review on the NDI is available in the May 2009 Journal of the Orthopedic and Sports Physical Therapy Association.

Chiropractors treating Medicare patients may need to learn new techniques and gain new tools for developing a Medicare plan of care for rehabilitation.

One of the specific requirements from the OIG report is the development of a chiropractic treatment plan for each patient that...

- includes a recommended level of care
- specific treatment goals
- and objective measures to evaluate treatment effectiveness

The tools needed to measure treatment effectiveness exist, on the sidebar of this blog, and elsewhere.

For a free e-mail tutorial on writing Bulletproof treatment notes using free, public domain tools, like the NDI, sign up below.

POSTED BY TIM RICHARDSON, PT AT 12:14 PM
LABELS: CERT REPORTS, MEDICARE, OIG CHIROPRACTOR, PHYSCAL THERAPY

DISQUS COMMENTS

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Ian Edwards' Home Page
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5 Comments

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- *Libby* 1 month ago
  I have previously subscribed to your Bulletproof PT website but now I can't get to any of the info. The only page that shows up is the page in which you need to enter your email and name. Is something malfunctioning or am I doing something incorrectly? Thanks for your help.
  - Like
  - Report
  - Reply
  - More ▾
- *cervelo58* 1 month ago
  Libby,

  I just checked and your name was successfully entered onto the list - you
  should have recieved message #1.

  Bulletproof is 14 messages set 7 days apart that are actionable and have
  links to free public-domain resources that will help private practice PTs
  improve decision-making.

  The website is available at
  www.BulletproofPT.com<http://www.bulletproofpt.... is routinely
  updated with proprietary and public content.

  Let me know if you have any questions about the content of Bulletproof.

The latest news on Health Care
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Tim
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- *Dr David Black* 4 weeks ago
Good reports and notes are essential when claiming from a health care provider.
Dr.David Black
  - Like
  - Report
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  - More ▾

- *Guest chiropractor* 3 weeks ago
Great article.

I am a 20+ year chiropractor and am working to improve documentation. My view is that the treatments are warranted and effective in most cases, but the documentation elements are not being completed as demanded by Medicare.

I do a very good job of resolving pain and disability for patients. I am not so skilled at writing a book about each patient encounter.

I appreciate your comments and suggestions, as well as public domain tools.
  - Like
  - Report
  - Reply
  - More ▾

- *cervelo58* 3 weeks ago
Dear Chiro2100,
Good news.

If the treatments are effective as you say they you should be able to
measure a treatment effect.

Validated self report questionnaires are being studied and proposed for all
Medicare post-acute settings, probably by mandate around 2011. These will
likely be computer-based, e-mail surveys carried out by third parties or
based in your clinic. I can't imagine why chiropractic wouldn't be included
in this group.

Physical therapists are currently undergoing a culture shift - we are

December (6)
November (4)
October (5)

'phasing in' doctors of physical therapy comfortable with validated outcome
tools and probabilistic diagnostic models while some of the 'old guard (I
have 17 years) are finding themselves 'behind the times'.

I see no reason why chiropractic couldn't undergo a similar evolution
towards using these simple tools to prove your outcomes.

Tim

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FREE TUTORIAL

Do you want to learn how to consistently, accurately and honestly generate physical therapy notes and charts demonstrate Bulletproof decision making?

Now you can have Bulletproof Physical Therapy Charts by taking our free e-mail home study course.

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Sleep better knowing your decision making is Bulletproof!

I want Bulletproof PT decision making!

MAKE BETTER DECISIONS WITH THESE BOOKS!

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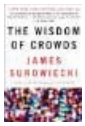
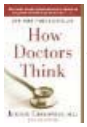
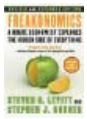


The Wisdom of Crowds
James Surowiecki (Paperback - Aug 16, 2005)
$10.17



How Doctors Think
Jerome Groopman (Paperback - Mar 12, 2008)
$10.37

Learn how physicians make decisions.



Freakonomics [Revised and Expanded]: A …
Steven D. Levitt, Stephen J. Dubner (Hardcover …
$19.77

Find unusual correlations in ordinary events.

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TIMRICHARDSON, PT IS IN PRIVATE PRACTICE IN AT MEDICAL ARTS REHABILITATION, INC. THE CLINIC WEBSITE IS AT WWW.MEDICALARTSREHAB.COM .

TIM IS WORKING ON A NEW BOOK THAT DESCRIBES THE INTERSECTION OF CURRENT EVIDENCE-BASED PHYSICAL THERAPY AND FEDERAL PAYMENT POLICY. THE BOOK WILL BE CALLED **BULLETPROOF PT DECISIONS**. TIM CAN BE REACED AT TIMRICHPT@BULLETPROOFPT.COM .

"COMPLIANCE TROUGH COMPETENCE"

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SITEMETER

sitemeter