Defining Scope of Coverage for Care of Vertebral Subluxation Under Medicare

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ABSTRACT

It is proposed that the Medicare Act be amended to provide for coverage of the assessment and care of vertebral subluxations without the requirement that a beneficiary has a concomitant musculoskeletal condition. The amendment should also provide for objective assessment of vertebral subluxation, prohibit the use of arbitrary "caps," and include coverage for examinations, imaging studies, and the use of specialized instrumentation to evaluate vertebral subluxation and how it affects the beneficiary's general health.

Key Words: *Chiropractic, Medicare, Vertebral Subluxation, instrumentation, x-ray*

Part I: Introduction

Health care in the United States currently consumes about one in every six dollars spent in the United States, and will consume an estimated one in every five dollars by the year 2015. It is projected that by the end of the next decade, the government will be paying about half of the nation's medical costs. A report from the Centers for Medicare and Medicaid Services estimated that both government and private spending for health care will average $12,320 per person in 2015, almost double the 2005 figure of $6,683. The nation's health care bill could total more than $4 trillion in ten years.[1] In 2005, Medicare provided coverage to 42.5 million people, spending $330 billion on benefits.[2] It is projected that Medicare Hospital Insurance program will become insolvent in 2019, and Medicare expenditures are projected to rise rapidly in coming decades as the baby-boom generation retires and health care costs continue to rise.[3]

These exploding costs are directly related to the system's focus on urgent care, to the exclusion of strategies that address health problems before they become costly and difficult to treat. Coverage of early interventions could result in significant cost savings.

Officials at the Center for Medicare Services (CMS) currently have exercised their discretion to limit coverage for early intervention services, such as care for vertebral subluxation, without weighing the long term financial and medical benefits of covering these services against their short term costs.

Vertebral subluxations are misalignments of the spinal bones which interfere with the function of the nervous system. Vertebral subluxations may exist without symptoms, and may exist independent of other medical conditions.[4] The Act provides for correction of vertebral subluxation by chiropractors as a covered benefit under Medicare. However, regulations exclude coverage for chiropractic care of vertebral subluxation unless it is accompanied by another covered condition.[5] In order to reduce the medical cost to society and to improve the quality of healthcare, Medicare's approach

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concerning the care of vertebral subluxation must undergo significant change.

Statutory language is needed which clarifies the existing law, eliminating the adverse effects of discretionary action by the CMS in interpreting the Medicare statute. Such language would pre-empt regulations and policies which exclude chiropractic care of vertebral subluxations without a secondary condition. Furthermore, costs could be controlled by specifying objective criteria for care, providing for accountability and oversight. This research report uses a four-step problem solving methodology. First, the report identifies a problem that appropriate legislation could resolve. The Medicare Act does not contain a comprehensive list of specific items or services eligible for Medicare coverage. Rather, it lists categories of items and services, and vests in the Secretary of Health and Human Services (HHS) the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program. An exception to this general rule is the statutory mandate for care of vertebral subluxations by a chiropractor.

Part I describes how previous drafters of Medicare legislation failed to consider how those administering the law might exercise their discretion to exclude coverage for specified services. The second step details whose and what behaviors comprise the problem—here the actions of the Center for Medicare Services (CMS), a national center. The CMS produces the Medicare Carriers Manual (the Manual), which is a compilation of Medicare rules and policies[6]. CMS officials have exercised their discretion to limit services for the care of vertebral subluxations.

Part II explains how existing regulations, decision-making processes, interests, and belief systems cause and allow CMS officials to limit coverage for cost-reducing services, such as care for vertebral subluxations without the requirement of a secondary condition.

Part III of this report addresses the legal and non-legal factors that affect the CMS officials' problematic behaviors. This includes issues of rule, opportunity, capacity, communication of the law, interest, process, and ideology. The third step in problem-solving requires the decision-maker to use logic to develop legislative solutions that address the identified causes of the difficulty, and select the most appropriate and cost-effective solution.

Part IV outlines a proposal that will overcome the legal and non-legal factors leading CMS officials to deny Medicare coverage for cost effective chiropractic services. The proposed bill will reduce CMS officials' discretion to deny coverage for care of vertebral subluxation, by requiring CMS officials to eliminate the need for a secondary diagnosis, use objective criteria to justify care, and prohibit the imposition of arbitrary caps. The final step in problem solving consists in monitoring and evaluating the legislation in action.

Part II. The Difficulty Medicare Legislation Must Address

A. Mini-introduction to Part II

This section describes the nature of the difficulty, details of the current system for addressing chiropractic coverage under Medicare, and describes the adverse effects of current policy.

B. The Nature and Scope of the Difficulty's Superficial Manifestations

Medicare administrators exercise discretion to exclude coverage for minor or chronic conditions, so these conditions progress into serious and expensive conditions. This paper addresses one such condition, vertebral subluxation, as a cost-saving measure. In doing so, it is recognized that there are other preventive and wellness services that may also result in cost savings under Medicare. A comprehensive restructuring of The Act to place greater emphasis on early interventions would require extensive research regarding the cost-effectiveness and health impact of providing coverage for such services. This proposal affords the opportunity to assess the potential benefits of such an approach by focusing on one condition, vertebral subluxation, where there is evidence to suggest that significant cost savings will be realized.

1. Nature of the Difficulty--Dual Diagnosis Required for Coverage

This paper addresses the scope of Medicare coverage for the care of vertebral subluxations. Vertebral subluxations are misalignments of the spinal bones which interfere with the function of the nervous system. Current Medicare regulations and policies only cover care for acute and chronic vertebral subluxations if they are accompanied by a second qualifying condition. Therefore, a dual diagnosis is necessary: vertebral subluxation, plus a second, accompanying medical condition.

The Act requires that services must be "reasonable and necessary for the diagnosis or care of an illness or injury, or to improve the functioning of a malformed body member." Vertebral subluxation is an "illness or injury" in itself, and the purpose of care is to "improve the functioning" of the affected body member. Therefore, diagnosis and care of vertebral subluxation is a covered service independent of any accompanying medical conditions.

Chiropractic care entails the diagnosis and care of vertebral subluxations. Chiropractors correct vertebral subluxations by spinal adjustment. An adjustment is the gentle application of force, by hand or using an instrument, to the spine. In addition to offering spinal adjustments, chiropractors may offer advice concerning lifestyle issues which cause vertebral subluxations. Such causes include physical, emotional, and biochemical stress.

2. Cost savings associated with chiropractic care

Current Medicare policy does not include coverage for the care of vertebral subluxations alone. However, research demonstrates that preventive chiropractic care results in significant cost savings in persons over 65 years of age. The limitations imposed by CMS regulators may be costing taxpayers a great deal of money. The economic significance of the social problem amounts to billions of dollars.

Analysis of an insurance database compared 23 persons over

75 years of age receiving chiropractic care with 414 non-chiropractic patients. Those receiving chiropractic care reported better overall health, spent fewer days in hospitals and nursing homes, used fewer prescription drugs, and were more active than the non-chiropractic patients. Furthermore, the chiropractic patients reported 21% less time in hospitals over the previous 3 years.[7] 45% of Medicare's $278 Billion expenditures in 2003 were for hospital coverage.[8]

Another study surveyed 311 chiropractic patients, aged 65 years and older, who had received chiropractic care for 5 years or longer. To control for overall health status, patients in the study were asked to complete a general health survey.[9] Despite similar health status, chiropractic patients, when compared with US citizens of the same age, spent only 31% of the national average for health care services. The chiropractic patients also experienced 50% fewer medical provider visits compared with US citizens of the same age.[10]

A study by Muse & Associates examined the utilization, cost and effects of chiropractic services on Medicare program costs compared to similar data for beneficiaries treated by other provider types. The number of beneficiaries included numbered 5.8 M. 1.5 M (26.8%) received chiropractic care. Despite averaging more claims per capita than non-chiropractic patients, beneficiaries who received chiropractic care had lower average Medicare payments per capita for all Medicare services ($4,426 vs. $8,103), and had lower average payments per claim for Medicare services ($133 vs. $210). Aside from high levels of patient satisfaction and improved health behaviors, senior citizens receiving chiropractic care spent significantly less time in hospitals, reduced medical utilization, and spent much less on medical care than persons receiving chiropractic care.[11]

In contrast to the cost savings realized by persons receiving long-term chiropractic care, the availability of chiropractic care limited to the treatment of musculoskeletal disorders (in addition to or independent of vertebral subluxations) achieves only a modest financial benefit. An analysis was performed comparing health plan members with such chiropractic coverage and members of the same health plan without chiropractic coverage. Having chiropractic coverage was associated with a 1.6% decrease in total annual health care costs.[12] The most significant health benefits and cost savings were seen in patients who were under long-term care.

The social problem addressed by this proposal is that Medicare administrators have exercised their discretion to make medical decisions limiting Medicare coverage for care of vertebral subluxations. Limiting such care to persons with a "dual diagnosis," and designating the care of asymptomatic vertebral subluxations as uncovered "maintenance therapy" means that Medicare beneficiaries are being denied clinical services which reduce overall health care costs and improve quality-of-life.

3. Health Benefits of Chiropractic Care for Vertebral Subluxations

Vertebral subluxations may exist with or without symptoms, and may exist independent of other medical conditions. If left uncorrected or when complicated by other conditions, which may or may not be covered under Medicare, they can progress to the point where they significantly compromise the patient's quality-of-life. For example, vertebral subluxations may result in spinal degenerative changes[13, 14, 15] Furthermore, vertebral subluxations compromise neural integrity and may influence organ system function and general health[16, 17] . A review of literature summarizing the health benefits of long-term chiropractic care is located in the appendix.

C. Chiropractic Coverage for Care of Vertebral Subluxation Under Medicare

Congress passed Public Law 92-603 in 1972, amending section 1861(r) of the Social Security Act (the Act). The law defines chiropractors as physicians who are eligible for Medicare reimbursement. The Act limited chiropractic services to manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist. The Act is implemented by federal regulations.

The Federal Register details the general principles of coverage: "Medicare payment is contingent upon a determination that a service meets a benefit category, is not specifically excluded from coverage, and the item or service is 'reasonable and necessary'…no payment may be made or any expenses incurred for items or services that are not 'reasonable and necessary' for the diagnosis and care of illness or injury or to improve the functioning of a malformed body member.[18]

Section 410.21(b) of the Code of Federal Regulations (CFR) codifies the Act and further limits medical reimbursement for care of subluxations. Medicare only covers care of subluxations that are accompanied by a second neuromusculoskeletal condition. The statute leaves the determination of what care is appropriate to the discretion of Medicare administrators and carriers. The problem is that subluxation of the spine *is* a "neuromusculoskeletal condition for which manual manipulation is appropriate care." This provision has been applied by carriers to limit coverage to persons suffering from a designated symptomatic condition other than vertebral subluxation alone.

1. National Coverage Determinations

Federal regulations (64 FR 22619) established procedures for developing national coverage determination (NCD). An NCD is binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. The NCD is the formal instruction to claims processing contractors regarding how to process claims, including issuing payment only when certain clinical conditions are met.

2. Local Coverage Determinations

In the absence of a specific NCD, coverage determinations are made locally by the Medicare contractors within the boundaries established by the law through local coverage determinations (LCDs). The dual diagnosis requirement legally restricts coverage of certain chiropractic care. This results from a complicated and regionally-variable, coverage system.

D. The Behaviors that Constitute the Difficulty

The Act allows Medicare to cover medical services, medical devices, surgical procedures, and diagnostic services, but generally does not identify specific covered or excluded items or services. An exception is the section providing for chiropractic services. Here, the Act specifically provides coverage for the care of vertebral subluxations.

The original Medicare legislation addressing chiropractic services covered care by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist. To reduce expenditures, CMS instituted the dual diagnosis requirement, and the original requirement that the subluxation be demonstrated by x-ray to exist was eliminated by statute in 1999.

Authority to promulgate specific regulations is delegated to the Center for Medicare Services (CMS). Failure of legislators to specifically include care of vertebral subluxation by chiropractors without the requirement of a secondary diagnosis has resulted in the promulgation of rules and policies by CMS and local carriers that exclude this service from coverage under Medicare. The individuals engaging in the problematic behavior include staff of the Center for Medicare Services (CMS), and the local carriers who administer Medicare benefits.

1. How CMS Regulations are Promulgated

CMS provides notice of intent to issue a new regulation or modify an existing regulation by publication in the Federal Register. A proposed regulation also solicits public comments during a comment period. It sets forth proposed amendments to the Code of Federal Regulations (CFR), but does not amend the CFR. By law, anyone can participate in the rulemaking process by commenting in writing on the regulations CMS proposes. CMS encourages public input and carefully considers these comments before it develops a final regulation. CMS generally receives public comments on its proposed regulations.

The comment period specifies how long CMS will accept public comments. Usually, the record – or docket – stays open for comments at least 30 days for Medicaid regulations and 60 days for Medicare regulations, though some comment periods may differ. After considering public comments that it receives by the close of the comment period, CMS may develop and publish a final regulation.[19]

2. Local Coverage Determination (LCD)

In the absence of national policy, Local Coverage Determinations (LCD) are developed to specify criteria that describe whether the item/service is covered and under what clinical circumstances the item/service is considered to be reasonable and necessary. Medicare Contractors are responsible for determining local coverage based on the advice and input of medical and specialty societies, and review of current medical practice, clinical data and research studies.

Local Coverage Determination of Medicare is done by each state's individual Medicare providers under the direction of CMS regulations. Individual state carriers will use and may publish this information to their providers, and variance in published data to provider is not uncommon. The level of evidence required for new/revised LCD development is found in the Provider Integrity Manual (PIM).[20] As described in the Medicare PIM, LCDs are to be based on the strongest evidence available. In order of preference, LCDs are based on published authoritative evidence derived from definitive randomized clinical trials or other definitive studies; and general acceptance by the medical community (standard of practice), as supported by sound medical evidence. Such evidence includes scientific data or research studies published in peer-reviewed medical journals; or consensus of expert medical opinion (i.e., recognized authorities in the field); or medical opinion derived from consultations with medical associations or other healthcare experts.[21]

Acceptance by individual healthcare providers, or even a limited group of healthcare providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community.[22] The broad range of available evidence is considered and its quality is evaluated before a conclusion is reached.

The LCD Reconsideration Process is a mechanism by which interested parties can request a revision to a LCD. The following describes the requirements in order for reconsideration to be eligible. The request must be submitted in writing and must identify the language that the requestor wants added to or deleted from the LCD. Requests shall include a justification supported by new evidence, which may materially affect the LCD's content or basis. When articles or textbooks are cited, copies of the published documents must be included.

CMS directs policy coverage on the necessity of chiropractic care and diagnoses that are utilized. Medicare coverage is limited to procedures that are "medically necessary." The decision by a state carrier to publish a list to its providers does not preclude their use of the CMS protocol for review of medical necessity. Under CFR 410.21(b), Medicare does not look only at subluxation for diagnosis, but requires a secondary diagnosis to establish medical necessity and to determine care allowance. This means that the beneficiary must have two diagnoses related in order to cover subluxation care: a diagnosis of subluxation; and a diagnosis of a secondary condition. A diagnosis of subluxation alone is insufficient to trigger coverage. Some carriers publish a list of secondary diagnoses categorizing short-, moderate- and long-term care, and some have not elected to do so. In jurisdictions where carriers have not provided this information, chiropractors lack the information necessary to determine the extent, if any, of coverage for a given case presentation. A typical LCD describes coverage, *inter alia*, as follows:

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 care (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the functional status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative care is considered maintenance therapy and is not covered.[23]

CMS limits care of vertebral subluxations not associated with a secondary condition by defining them as "maintenance therapy," which is not a covered condition. CMS's defines Maintenance therapy is as follows:

> A care plan that seeks 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 care becomes supportive rather than corrective in nature, the care is then considered maintenance therapy. Chiropractic maintenance therapy is not considered to be medically reasonable or necessary under the Medicare program, and is therefore not payable… [24]

This proposal provides for care of vertebral subluxation without the requirement for a second diagnosis. The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration of subluxation 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 care but some require very little care. In the first several days, care may be quite frequent but decreasing in frequency with time or as improvement is obtained. Chronic spinal joint condition (e.g., loss of joint mobility or other joint problems) 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 (scar) tissue has developed. This condition may require a longer care time.[25]

The Connecticut LCD goes on to list 98 specific conditions, at least one of which must be present) in addition to vertebral subluxation) for coverage under Medicare. A list of these conditions is included in Appendix A. The list is applicable only to the jurisdiction covered by the LCD. For many, if not most conditions on the list, evidence of efficacy and effectiveness are lacking. Indeed, there are organic conditions for which stronger evidence exists. The current policy represents the application of a political agenda to limit chiropractic care to persons with musculoskeletal conditions, rather than the objective application of evidence.

The CMS personnel who produce the manual and the local carriers who promulgate LCDs have exercised their discretion to limit the availability of care for vertebral subluxations without a secondary diagnosis. The result of this is that services which they determine to be maintenance care is excluded from coverage. The complexity of the process makes it impossible to fully catalogue the incremental harm imposed by the dual diagnosis requirement in different jurisdictions.

E. Who Benefits and Who Suffers --Adverse Impact of Current Policy

Seniors seeking care for vertebral subluxation can only obtain care if there is an additional qualifying musculoskeletal condition present, and the care is likely to be extremely limited. A Medicare beneficiary who wants chiropractic care, but is not suffering from a secondary, covered condition must usually pay out of pocket. Supplemental insurance may contain similar limitations. In the absence of coverage, the patient must do without, or wait until a secondary condition results, and accept what may be inadequate care because of services being capped.

If a Medicare beneficiary can afford to pay for care out of pocket, then it is not necessary to provide such care as a Medicare benefit. However, Medicare policy does not apply this standard to other components of coverage. Coverage is not dependent on beneficiaries' ability to pay for medical services.[26] Medicare beneficiaries have paid for coverage throughout a lifetime, and it would be unfair to deny them benefits merely because some have greater personal financial resources than others. If care for a condition is specified by statute, it is a benefit which is available to all covered persons.

F. Mini-Conclusion

This proposal addresses the difficulty of regulators using their discretion to promulgate and implement regulations that limit access to chiropractic services for the care of vertebral subluxations without the requirement for a secondary diagnosis. Coverage should be based upon objective evidence, rather than be limited by arbitrary caps.

Part III. Explanations of the Causes of Problematic Behaviors

A. Mini-introduction

This section will focus on institutional causes of the problematic behavior—exclusion of coverage for chiropractic care of vertebral subluxations as a preventive, health promotion strategy. Institutional causes of behaviors that are barriers to good governance and development will be followed

by a description of how the proposed bill will solve those problems.

B. Factors for Each Role Occupant and Implementing Agency Rule

CMS issues Internet-Only Manuals (IOMs) that are CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. The directives issued by CMS specifically exclude "maintenance therapy." Chapter 15, section 30.5 of Pub. 100-02, Benefits Policy Manual provides, *inter alia*:

> 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 care 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."

Medicare coverage for preventive services is very limited. For example, an Initial Preventive Screening Examination (IPPE) is available to all Medicare beneficiaries whose Part B coverage begins on or after January 1, 2005. The examination includes an electrocardiogram, and requires no specific diagnosis. However, this is a once in a lifetime benefit per beneficiary, and must be furnished within six months of the beneficiary's effective date of coverage.[27]

In reference to the directive limiting chiropractic care, CMS relied on Section 1862 (a) (1) (A) of the Social Security Act. This Section of the Act states no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or care of illness or injury or to improve the functioning of a malformed body member." This gives CMS the ability to make medical decisions. Members of a Practicing Physicians Advisory Council (PPAC) hear testimony and advise the Secretary of Health and Human Services and the administrator of CMS on proposed changes in regulations and carrier manual instructions. The PPAC is composed of 15 members (11 of which must be MD's or DO's, the remaining members may include dentists, podiatrists, optometrists and chiropractors), who must have submitted at least 250 claims for physicians' services in the previous year. There is only one chiropractor serving on the PPAC.[28] Section 1862 (a) (1) (A) of the Social Security Act represents a barrier to Medicare coverage of chiropractic preventive or health promoting services.

The discretion conferred on CMS and carriers is the cause of the problematic behavior: exclusion of coverage for so-called "maintenance care." CMS defines "maintenance" services as follows:

> A care 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 care becomes supportive rather than corrective in nature, the care is then considered maintenance therapy.[29]

The Manual Section 2251.3 states that ". . . ongoing maintenance therapy is not considered to be medically necessary under the Medicare program," and is therefore noncovered. Appeals processes address whether the policy has been applied as written, and if due process requirements are met. They, however, do not provide for a challenge to the validity of the policies themselves.

The existing Medicare law covers care of vertebral subluxations. However, as administered, there must also be an additional, identifiable, symptomatic musculoskeletal condition associated with it. Furthermore, Medicare administrators have attempted to impose arbitrary "caps" based upon number of visits, rather than objective diagnostic evidence. "Maintenance care" or wellness services are not covered. These limitations are not in the Medicare statute, but are the result of discretionary policies implemented by those administrating the law.[30] This proposal would specify, by statute, the scope of preventive chiropractic coverage for the care of vertebral subluxations. This will eliminate the ability of CMS and local carriers to arbitrarily deny these services.

Opportunity and Capacity

Regulations cannot contradict statutes. General and Local Coverage Determinations cannot contradict regulations. In the case of Medicare coverage for chiropractic care of vertebral subluxation, the limitation on preventive care is imposed by rule, not statute. It is proposed that the Medicare Act be amended to provide statutory coverage for chiropractic care of vertebral subluxation independent of the current requirement that the patient also has an additional qualifying neuromusculoskeletal condition. Defining the scope of chiropractic coverage in the statute will resolve the problem by eliminating the opportunity and capacity for CMS and local carriers to limit such coverage. Without a change in the statute, CMS and local carriers will be able to continue to exercise their discretion to arbitrarily deny these services.

Communication of the Law

There is no evidence that the problematic behavior is caused by ignorance of law, or failure to communicate the law to the primary role occupants. The primary role occupants are CMS and the local carriers. CMS has access to the statutory law, and local carriers are provided with manuals and updated CMS policies.

Interest

This category refers to the role occupants' perception of their own costs and benefits. Expectations by legislators, influenced by society's current perception of costs and benefits, will affect the behavior of CMS in promulgating regulations. Legislators are under pressure to contain

Medicare costs, and will expect implementing agencies to do so.

CMS and local carriers will take this ideology into account when promulgating regulations, and making coverage determinations. Pressure to contain Medicare costs make it unlikely that these role occupants would authorize coverage for services which they perceive would raise costs. Even if they were persuaded that the long-term savings would significantly exceed the short-term costs, they may be reluctant to take a position that would incur immediate additional costs.

Process

CMS officials must follow the Medicare Act. Carriers must comply with the regulations. There is no evidence that the problem of limiting coverage for chiropractic preventive services is caused by failure of CMS and carriers from obeying the law. The problem is a result of exercising their lawful discretion to limit coverage for care of vertebral subluxations.

The current statute fails to define relevant terms, resulting in the ability of the administrative agency to create its own definitions, or to use definitions from other sources. The statute is also silent on how clinical need is determined. Furthermore, the current statute requires documentation of the presence of vertebral subluxation, but fails to provide coverage for specific diagnostic services.

Ideology

Under the current law, CMS and carriers may exercise their discretion concerning the extent of chiropractic coverage. Ideology influences the exercise of discretion. There are several ideologies which may influence the behavior of CMS officials and local carriers. These include an attitude that coverage for acute or serious conditions should be given priority over expenditures for early intervention and preventive services. Another problem may be the belief that chiropractic services are an unnecessary luxury, and that such services have little effect on reducing overall health care costs.

Furthermore, there may be a belief that chiropractic maintenance services are wholly ineffective, from a medical perspective. Another possible problem is a culture within CMS and the carriers that their job is to lower costs, and that this is best accomplished by limiting covered services.

Part IV. Solutions

A. Mini-introduction

The solution is to require coverage for clinically documented care for vertebral subluxation without a mandate that a co-morbid musculoskeletal condition be present, prohibit arbitrary "caps" on the number of covered visits, and provide for the objective assessment of vertebral subluxations..

B. Alternative Proposals

1. Continue the Status Quo

Current Medicare coverage limits chiropractic care of vertebral subluxation to persons who also have a qualifying neuromusculoskeletal disorder robust enough to be covered. The requirement of a dual diagnosis is facially absurd. If Medicare were required to cover care of hypertension, it would be unreasonable to limit such coverage only to persons with heart diseases, diabetes or cancer merely to save costs.

As discussed in Section E below, despite similar health status, senior citizens receiving chiropractic care, when compared with US citizens of the same age, incurred lower health care expenses, and experienced fewer medical provider visits than the non-chiropractic patients. Coverage of chiropractic care for care of vertebral subluxations without requiring a secondary diagnosis will save money, and may reduce unnecessary suffering. The cost of continuing the status quo could amount to billions of dollars.

2. Amend the CMS rules

A second alternative is to amend the rules. This would be a less drastic approach than amending the Medicare Act. Amendment at the rule level would have the advantage of greater flexibility than a statutory change. There are two problems with this approach. Amendment of the regulations would, at best, be a temporary solution, subject to the discretion of CMS; and, promulgation of regulations is subject to the ideology and interest issues discussed above. Limiting administrative discretion can only be accomplished at the statutory level.

3. Issue a National Coverage Determination

A National Coverage Determination has the advantage of being a lower level process than promulgation of a regulation. It is less costly and less burdensome than passing a statute or making a regulation. Issuing a National Coverage Determination is an unsatisfactory solution because an NCD cannot contradict a statute or regulation. The current statute does not adequately limit the discretion of CMS in making regulations, and the current CMS regulation excludes chiropractic coverage of "maintenance care." The law must be addressed at the statutory level to effectively solve the problem.

4. Create a New Agency to Administer the Chiropractic Benefit

The problem is a product of failure to limit the discretion of the administering agency. Creating a new agency to administer the chiropractic benefit is an alternative solution. This is unsatisfactory for several reasons: 1) It would involve more complex legislation than the proposal to limit discretion; 2) It would still require action at the statutory level; 3) There would be high costs associated with the establishment and staffing of a new agency; 4) Two parallel agencies would be wasteful, redundant, and result in administrative inconsistencies.

5. Change the PPAC Procedures to Favor Coverage of Preventive Services

Changing the procedures of the PPAC to embrace a model of prevention is an option with the potential for transformative change. However, the PPAC is still encumbered by The Act and CMS rules and regulations restricting coverage The Act requires that services must be "reasonable and necessary for the diagnosis or care of an illness or injury, or to improve the functioning of a malformed body member." This approach would have broad implications, affecting many provider groups. It would require extensive resources, and require a statutory change. However, there is no evidence that such a statutory change would resolve the problem of requiring a dual diagnosis for coverage of care of vertebral subluxations.

6. Remove the Dual Diagnosis Requirement, but Cap Coverage

One concern with removing the dual diagnosis requirement is that it would result in unlimited coverage, solely at the discretion of the practitioner. Therefore, the use of caps, either in an annual dollar amount, or an annual visit limit, is tempting. This approach leads to a serious contradiction. If a service is medically necessary, it should be covered regardless of how frequently it occurs. If it is not medically necessary, it should not be covered. It would be absurd to cap coronary care at one heart attack per year, or only allow coverage for two fractures every ten years. Determination of medical necessity should be based on objective clinical criteria.

7. Tie Coverage to the Use of Nationally Recognized Guidelines

Nationally recognized guidelines exist for the diagnosis and care of vertebral subluxations. These guidelines have been accepted for inclusion in the National Guideline Clearinghouse, sponsored by the U.S. Agency for Health Care Research Quality and in partnership with the American Medical Association and the American Association of Health Plans. These guidelines have been selected for inclusion in ECRI's *Healthcare Standards: Official Directory*. ECRI is the organization that maintains the World Health Organization's official healthcare standards and guidelines archive.[31] The problem with this approach is that clinical practice guidelines soon become obsolete. This approach is overly prescriptive, and would excessively limit CMS discretion.

8. Amend the Medicare Statute as Suggested in the Proposed Bill

This proposal is the least complex and most economical solution that has been identified. It will solve this problem by defining the extent of chiropractic coverage by statute. CMS and local carriers are required to follow the Medicare Act. When the extent of coverage is determined by statute, CMS and local carriers can no longer exercise discretion to require a secondary diagnosis. It would require CMS to base coverage upon objective clinical evidence, while preserving CM S discretion in determining technical issues. This would avoid obsolescence caused by an overly prescriptive statute. It would also preserve the existing CMS mechanisms providing for accountability and transparency in the promulgation of rules, and the appeals process for beneficiaries and providers.

C. Details of the Proposal's Major Provisions

The proposal limits the discretion of administrators, including CMS and individual carriers, in the application of the benefit for care of vertebral subluxation by chiropractors. It does so by:

1. **Defining relevant terms.** The proposal will eliminate the problems associated with using vague or ambiguous terms by defining them in the statute.

2. **Defining criteria for clinical necessity and documentation.** The proposal will provide sufficient clarity to ensure that the objective of the bill is not compromised, yet allow sufficient flexibility in implementation to provide for technical innovation.

3. **Prohibiting arbitrary caps for services.** The proposal provides that care be based upon documented clinical need, rather than arbitrary "caps" which limit the number of covered visits per year.

4. **Defining which specific services will be covered under the program.** The proposal will define which diagnostic services are covered.

5. **Providing for transparency and accountability in the administration of the chiropractic benefit, care of vertebral subluxation.** Statutory language must be designed to balance statutory inclusion of specified services, while providing for administrative flexibility in the administration of benefits. The law will be implemented by CMS to ensure that administration is congruent with other Medicare benefits.

D. How the Proposed Solution Addresses the Causes of the Difficulty

The proposal limits the discretion of CMS and carriers. It does so by defining the chiropractic services covered under Medicare, and establishing requirements for coverage. It expands the scope of chiropractic coverage to include diagnostic services necessary to diagnose vertebral subluxations, and eliminates the requirement of a secondary diagnosis.

E. Costs and Benefits of the Proposed Solution

Chiropractic services constitute a very small portion of Medicare expenditures. Medicare allowed $191 billion for Medicare fee-for-service claims in 2001. Chiropractic services accounted for $500 million, or 0.26 percent of this amount. In 2004, the figure for chiropractic services was $683 million, with total Medicare spending amounting to $297

billion, resulting in 0.22 percent of total Medicare expenditures going to chiropractic services. The $683 million was paid for 21 million services. The resulting average cost per service is $32.52. A sampling of 400 Medicare services billed in 2001 found that 40% were for noncovered maintenance/preventive care. The cost of such services amounted to $186 million.

As noted in Part II B (3) of this report, studies have shown that patients over 65 years of age who received chiropractic care for five years or longer had 50% fewer medical provider visits and spent only 31% of the national average for health care services.

Including Medicare coverage for care of vertebral subluxations, without a requirement for a second diagnosis, would result in significant cost savings. Using an average of 12 visits per year at $32.52 each, the resulting cost would be an average of $390.24. The Muse study reported that beneficiaries who received chiropractic care had lower average Medicare payments per capita for all Medicare services ($4,426 vs. $8,103). Thus, for a cost of approximately $400 per person, potential savings of over $3,000 could be realized.

F. Monitoring Performance

Existing agencies, primarily CMS, will continue to provide performance monitoring. New procedures mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (2003 Act) will soon offer quicker resolution to appeals by Medicare beneficiaries, providers and suppliers. The 2003 Act creates an expedited appeals process. A beneficiary may file a request for expedited access to judicial review at the same time as, or after, filing a request for an Administrative Law Judge (ALJ) hearing. A review entity made up of three reviewers who are ALJs or members of a Departmental Appeals Board (DAB) has 60 days after receipt of the request to issue a written decision. If the review entity fails to act within 60 days of receipt of the request, the beneficiary may skip ALJ and DAB review and go directly to district court.[32]

1. Hearings and Appeals

The Social Security Administration (SSA) formerly handled the Medicare hearings function. The Office of Medicare Hearings and Appeals (OMHA) located within the Department of Health and Human Services (HHS) now handles Medicare appeals. The changes will help ensure that fee-for-service Medicare claims appeals are resolved within the 90-day timeframe mandated by the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act of 2000 (BIPA).

Medicare beneficiaries, physicians, and suppliers have extensive rights to appeal individual coverage determinations made by Medicare fee-for-service claims processing contractors or Medicare+Choice health plans. Where there is no national policy, beneficiaries and providers may appeal local claims processing contractor and health plan policy. Where there is national policy, they may appeal how contractors and health plans apply that policy to individual cases. This process is to ensure that beneficiaries know about their rights. It is also designed to improve oversight of Medicare+Choice plan appeals processes, and to improve the timeliness and consistency of ALJ decisions.[33]

2. Beneficiary Input on National Coverage Determinations

Medicare claims processing contractors are given discretion to set local coverage policy in areas where national policy has not yet been set. However, when Medicare issues national coverage decisions, they are binding on all Medicare contractors, Medicare+Choice plans, peer review organizations, and, in some cases, ALJs.

The new process makes clear that any member of the public may request a review of a national coverage policy determination at any time. Individuals requesting such a review need only submit the request in writing, along with new medical and scientific evidence that merits consideration, or an analysis of Medicare's decision demonstrating that a material misinterpretation was made in the evaluation of evidence.[34]

G. Mini-conclusion

Research cited in Part II B (3) indicates that senior citizens receiving chiropractic care spend less on medical care and have fewer medical provider visits than senior citizens who do not receive such care. The proposal addresses the problem of Medicare administrators using their discretion to limit coverage for chiropractic care of vertebral subluxation without requiring a secondary condition. The proposal resolves the problem by statutory limitation of this discretion.

Part V. Conclusion

Medicare legislation has resulted in CMS and local carriers exercising their discretion to exclude coverage for chiropractic care of vertebral subluxation unless the patient was also suffering from a second qualifying condition. This proposal limits discretion, and specifies those services eligible for coverage. The statutory language also defines relevant terms, and establishes criteria for documenting vertebral subluxation.

The proposal would contain statutory language which (1) clarifies the existing law to eliminate the adverse effects of discretionary action by CMS; (2) controls costs by specifying care criteria; and (3) provides for accountability and monitoring of its implementation.

Appendix A

Review of Studies Demonstrating General Health Benefits of Chiropractic Care

A large retrospective assessment of subluxation-based chiropractic care on self-related health, wellness and quality of life. After surveying 2,818 respondents in 156 clinics, a strong connection was found between persons receiving chiropractic care and self-reported improvement in health, wellness and quality-of-life. 95% of respondents reported that their expectations had been met, and 99% wished to continue care.[35] In an online survey with 3018 respondents by Miller, 62% responded affirmatively when asked, "Although you feel healthy, would you follow your family member's lead and visit a doctor who focuses on wellness and prevention just so you can stay feeling that way?"[36]

A study evaluating the role of chiropractic care in persons undergoing inpatient addiction care consisted of a three arm randomized clinical trial with two control groups (one receiving usual medical care, and the other placebo controlled). This was a single blind study utilizing subluxation-centered chiropractic care implemented in a residential addiction care setting. Care was administered five days per week over a period of 30 days, for a total of 20 care encounters. A total of 98 subjects (14 female and 84 male) were enrolled in the year-and-a-half long study. 100% of the Active (chiropractic) group completed the 30-day program, while only 24 (75%) of the Placebo group receiving a simulated chiropractic adjustment and 19 (56%) of the Usual Care group completed 30 days.[37]

The Active group showed a significant decrease in anxiety while the placebo group showed no decrease in anxiety. The frequency of visits to the Nurse's station was monitored during the course of the study. Of those in the Active care group, only 9% made one or more visits, while 56% of the Placebo group and 48% in the Usual Care group made such visits. This poor performance by the Placebo group suggests that the favorable results obtained in those persons receiving chiropractic care are not attributable to a placebo effect. A 100% retention rate was achieved in a residential care setting using subluxation-centered chiropractic. The possible physical and neurological mechanisms for such a response are described in an earlier paper by Holder et al, in which they describe the Brain Reward Cascade in relationship to vertebral subluxation and its role in resolving Reward Deficiency Syndrome (RDS).[38]

A study where chiropractors collaborated with researchers at the University of Lund found that chiropractic care could influence basic physiological processes affecting oxidative stress and DNA repair. The study examined serum thiols in patients under short-term and long-term chiropractic care. Serum thiols are primary antioxidants, and serve as a measure of human health status. The test provides a surrogate estimate of DNA repair enzyme activity, which has been shown to correlate with lifespan and aging.[39]

Comparing serum thiol levels in nearly 50 patients receiving short- or long-term chiropractic care with controls, researchers found that independent of age, sex or taking nutritional supplements, long-term chiropractic care of two or more years re-established a normal physiological state in patients. Ability to repair damaged DNA is an important factor in health and longevity. Oxidative stress is now a broadly accepted theory of how persons age and develop disease. Oxidative stress results in DNA damage, and inhibits DNA repair.[40]

Another study looked at the degree to which chiropractic intervention affected a change in a healthy lifestyle. The study found that chiropractic care users do tend towards the practice of a positive health lifestyle, which also has a direct effect on reported improvements in wellness. These empirical links are relative to the sociodemographic characteristics of this population and show that use of chiropractic care is an aspect of a wellness lifestyle.[41, 42]

In a review of literature related to objective physiological changes following chiropractic care, Hannon discussed more than twenty studies documenting objective health benefits in subjects who were specifically described as "asymptomatic," "healthy," "normal," or "free from physical injury." Nearly an equal number of studies were found documenting objectively measured health benefits in subjects in which no symptomatic presentation was described.[43]

Appendix B

Example of an LCD (Local Coverage Determination)

Connecticut

ICD-9-CM Codes that Support Medical Necessity

Code	Description
346.00-346.91	Migraine
350.1-350.9	Trigeminal nerve disorders (Neuralgia)
352.0-352.9	Disorders of other cranial nerves
353.0	Brachial plexus lesions
353.1	Lumbosacral plexus lesions
353.2	Cervical root lesions, not elsewhere classified
353.3	Thoracic root lesions, not elsewhere classified
353.4	Lumbosacral root lesions, not elsewhere classified
353.8	Other nerve root and plexus disorders
355.0	Lesion of sciatic nerve
355.1	Meralgia paresthetica
356.0	Hereditary peripheral neuropathy
356.1	Peroneal muscular atrophy
356.4	Idiopathic progressive polyneuropathy
356.8	Other specified idiopathic peripheral neuropathy
715.00	Osteoarthrosis, generalized, site unspecified
715.09	Osteoarthrosis, generalized, multiple sites
715.10	Osteoarthrosis, localized, primary, site unspecified
715.18	Osteoarthrosis, localized, primary, other specified sites
715.20	Osteoarthrosis, localized, secondary, site unspecified
715.28	Osteoarthrosis, localized, secondary, other specified sites
715.30	Osteoarthrosis, localized, not specified whether primary or secondary, site unspecified
715.38	Osteoarthrosis, localized, not specified whether primary or secondary, other specified sites
715.80	Osteoarthrosis involving, or with mention of more than one site, but not specified as generalized, site unspecified
715.89	Osteoarthrosis involving, or with mention of more than one site, but not specified as generalized, multiple sites
715.90	Osteoarthrosis, unspecified whether generalized or localized, site unspecified
716.10	Traumatic arthropathy, site unspecified
716.90	Arthropathy, unspecified, site unspecified
719.48	Pain in joint, other specified sites
720.0	Ankylosing spondylitis
720.1	Spinal enthesopathy
720.2	Sacroiliitis, not elsewhere classified
720.81	Inflammatory spondylopathies in diseases classified elsewhere
720.9	Unspecified inflammatory spondylopathy
721.0-721.91	Spondylosis and allied disorders
722.0	Displacement of cervical intervertebral disc without myelopathy
722.10-722.11	Displacement of thoracic or lumbar intervertebral disc without myelopathy

722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.30-722.32	Schmorl's nodes
722.4	Degeneration of cervical intervertebral disc
722.51-722.52	Degeneration of thoracic or lumbar intervertebral disc
722.70-722.73	Intervertebral disc disorder with myelopathy
722.80-722.83	Postlaminectomy syndrome
722.90-722.93	Other and unspecified disc disorder
723.0-723.9	Other disorders of cervical region
724.00-724.09	Spinal stenosis, other than cervical
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.71	Hypermobility of coccyx
724.79	Other disorders of coccyx
724.8	Other symptoms referable to back
726.5	Enthesopathy of hip region
726.90	Enthesopathy of unspecified site
728.10	Calcification and ossification, unspecified
728.11	Progressive myositis ossificans
728.12	Traumatic myositis ossificans
728.2	Muscular wasting and disuse atrophy, not elsewhere classified
728.3	Other specific muscle disorders
728.4	Laxity of ligament
728.5	Hypermobility syndrome
728.81	Interstitial myositis
728.85	Spasm of muscle
729.0	Rheumatism, unspecified, and fibrositis
729.1	Myalgia and myositis, unspecified
729.2	Neuralgia, neuritis, and radiculitis, unspecified
733.00-733.09	Osteoporosis
737.0	Adolescent postural kyphosis
737.10	Kyphosis (acquired) (postural)
737.12	Kyphosis, postlaminectomy
737.20-737.22	Lordosis (acquired)
737.30	Scoliosis [and kyphoscoliosis], idiopathic
737.31	Resolving infantile idiopathic scoliosis
737.32	Progressive infantile idiopathic scoliosis
737.34	Thoracogenic scoliosis
737.8	Other curvatures of spine
738.2	Acquired deformity of neck
738.4	Acquired spondylolisthesis
738.6	Acquired deformity of pelvis
756.11-756.17	Anomalies of spine
756.2	Other congenital musculoskeletal anomalies, cervical rib
784.0	Headache

847.0-847.4	Sprains and strains of other parts of back
848.3	Other and ill-defined sprains and strains, ribs
848.41	Other and ill-defined sprains and strains, sternoclavicular (joint)(ligament)
848.42	Other and ill-defined sprains and strains, chondrosternal (joint)
848.5	Other and ill-defined sprains and strains, pelvis
905.1	Late effect of fracture of spine and trunk without mention of spinal cord lesion
905.6	Late effect of dislocation
907.3	Late effect of injury to nerve root(s), spinal plexus(es), and other nerves of trunk
953.0-953.5	Injury to nerve root and spinal plexus
954.0	Injury to cervical sympathetic nerve
954.1	Injury to other sympathetic nerve(s)
956.0	Injury to sciatic nerve

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108TH CONGRESS
1ST SESSION

H. R. 2560

To amend title XVIII of the Social Security Act to clarify the scope of chiropractic services that may be furnished under the Medicare Program and that chiropractors are the only health care professionals qualified under that program to furnish those services.

IN THE HOUSE OF REPRESENTATIVES

JUNE 23, 2003

Mr. MANZULLO introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to clarify the scope of chiropractic services that may be furnished under the Medicare Program and that chiropractors are the only health care professionals qualified under that program to furnish those services.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. SHORT TITLE.**
4 This Act may be cited as the "Chiropractic Medicare
5 Freedom and Benefit Protection Act".

1 **SEC. 2. MEDICARE CHIROPRACTIC SERVICES.**

2 (a) SEPARATE TREATMENT OF CHIROPRACTORS.—
3 Section 1861(r) of the Social Security Act (42 U.S.C.
4 1395x(r)) is amended—

5 (1) by striking ‘‘, or (5)’’ and all that follows
6 and inserting a period; and

7 (2) by inserting ‘‘or’’ before ‘‘(4)’’.

8 (b) INCLUSION OF CHIROPRACTIC SERVICES AS MED-
9 ICAL AND OTHER HEALTH SERVICES.—Section
10 1861(s)(2) of such Act (42 U.S.C. 1395x(s)(2)) is amend-
11 ed—

12 (1) in subparagraph (U), by striking ‘‘and’’ at
13 the end;

14 (2) in subparagraph (V)(iii), by inserting ‘‘and’’
15 at the end; and

16 (3) by adding at the end the following new sub-
17 paragraph:

18 ‘‘(W) chiropractic services (as defined in sub-
19 section (ww)(1));’’.

20 (c) SERVICES DESCRIBED.—Section 1861 of such
21 Act (42 U.S.C. 1395x) is amended by adding at the end
22 the following new subsection:

23 ‘‘CHIROPRACTIC SERVICES; CHIROPRACTOR

24 ‘‘(ww)(1)(A) The term ‘chiropractic services’ means
25 only for the purpose of subsections (s)(1) and (s)(2)(A)
26 clinically necessary care by means of adjustment of the

1 spine (to correct a subluxation) performed by a chiro-
2 practor legally authorized to perform such adjustment by
3 the State or jurisdiction in which such care is provided.
4 ''(B) For purposes of subparagraph (A), care is clini-
5 cally necessary when examination by a chiropractor dem-
6 onstrates objective evidence of a subluxation. Such exam-
7 ination may include—
8 ''(i) physical examination;
9 ''(ii) radiological examination; and
10 ''(iii) specialized diagnostic instruments used in
11 the practice of chiropractic.
12 ''(C) For purposes of subparagraph (A), the term
13 'subluxation' means a complex of any or all of the fol-
14 lowing articular changes that compromise neural integrity
15 and may influence organ system function and general
16 health:
17 ''(i) Functional.
18 ''(ii) Structural.
19 ''(iii) Pathological.
20 ''(2) The term 'chiropractor' means an individual who
21 is licensed as a chiropractor by the State (or in a State
22 which does not license chiropractors as such, is legally au-
23 thorized to perform the services of a chiropractor in the
24 jurisdiction in which he performs such services), and who

1 meets uniform minimum standards promulgated by the
2 Secretary.''.
3 (d) PAYMENT AS PHYSICIANS' SERVICES.—Section
4 1848(j)(3) of such Act (42 U.S.C. 1395w–4(j)(3)) is
5 amended by inserting ''(2)(W),'' after ''(2)(S),''.
6 (e) CONFORMING AMENDMENTS.—(1) Section
7 1834(m) of such Act (42 U.S.C. 1395m(m)) is amended
8 by inserting '', a chiropractor (as defined in section
9 1861(ww)(2))'' after ''a physician (as defined in section
10 1861(r))''.
11 (2) Section 1852(j)(3)(D) of such Act (42 U.S.C.
12 1395w–22(j)(3)(D)) is amended by inserting '', a chiro-
13 practor (as defined in section 1861(ww)(2))'' after ''a phy-
14 sician (as defined in section 1861(r))''.
15 (3) Section 1802(b)(5)(C) of such Act (42 U.S.C.
16 1395a(b)(5)(C) is amended to read as follows:
17 ''(C) PRACTITIONER.—The term 'practi-
18 tioner' has the meaning given such term by sec-
19 tion 1842(b)(18)(C), and includes 'chiropractor'
20 as that term is defined in continuing care re-
21 tirement community 1861(ww)(2).''.
22 (4) Section 1832(a)(2)(C) of such Act (42 U.S.C.
23 1395k(a)(2)(C)) is amended by inserting before the term
24 ''outpatient physical therapy services'' the following:
25 ''chiropractic services as defined in section 1861(ww)(1)''.

1 (5) Section 1835(a)(2) of such Act (42 U.S.C.
2 1395n(a)(2)) is amended by inserting after ‘‘physician’’
3 the first place it appears the following: ‘‘or for purposes
4 of chiropractic services (as defined in section
5 1861(ww)(1)), a chiropractor,’’.

6 (6) Section 1842(a) of such Act (42 U.S.C.
7 1395u(a)) is amended by inserting ‘‘chiropractic services
8 (as defined in section 1861(ww)(1)’’ after ‘‘physician’s
9 services’’.

10 (7) Section 1842(h) of such Act (42 U.S.C.
11 1395u(h)) is amended by inserting ‘‘or chiropractor (as
12 defined in section 1861(ww)(2))’’ after ‘‘physician’’ each
13 place it appears.

14 (8) Section 1842(r) of such Act (42 U.S.C. 1395u(r))
15 is amended by inserting ‘‘chiropractor (as defined in sec-
16 tion 1861(ww)(2))’’ after ‘‘physician’’.

17 (9) Section 1847(d) of such Act (42 U.S.C. 1395w–
18 3(d)) is amended by inserting ‘‘chiropractic services (as
19 defined in section 1861(ww)(1))’’ after ‘‘physicians’ serv-
20 ices’’.

21 (10) Section 1852 of such Act (42 U.S.C. 1395w–
22 22) is amended by inserting ‘‘or chiropractor (as defined
23 in section 1861(ww)(2))’’ after ‘‘physician’’ each place it
24 appears.

1 (11) Section 1862(a)(20) of such Act (42 U.S.C.
2 1395y(a)(20)) is amended by inserting ''or chiropractic
3 services (as defined in section 1861(ww)(1))'' after ''physi-
4 cian's professional services''.

5 (12) Section 1866(a)(1)(N)(ii) of such Act (42
6 U.S.C. 1395cc(a)(1)(N)(ii)) is amended by inserting ''or
7 chiropractor (as defined in section 1861(ww)(2))'' after
8 ''physician'' each place it appears.

9 (13) Section 1868(a) of such Act (42 U.S.C.
10 1395ee(a)) is amended by inserting ''and chiropractor (as
11 defined in section 1861(ww)(2))'' after ''physician''.

12 (14) Section 1869(b)(1)(F) of such Act (42 U.S.C.
13 1395ff(b)(1)(F)) is amended by inserting ''or chiropractor
14 (as defined in section 1861(ww)(2))'' after ''physician''.

15 (15) Section 1876(b)(2)(i) of such Act (42 U.S.C.
16 1395mm(b)(2)(i)) is amended by inserting ''or chiro-
17 practic services (as defined in section 1861(ww)(1))'' after
18 ''physicians' services''.

19 (16) Section 1877 of such Act (42 U.S.C. 1395nn)
20 is amended—

21 (1) in subsection (a)(1)(A) by inserting ''or chi-
22 ropractor (as defined in section 1861(ww)(2))'' after
23 ''physician''; and

24 (2) in subsection (b)(1)—

1 (A) in the heading to read as follows:
2 "PHYSICIANS' AND CHIROPRACTIC SERVICES";
3 and
4 (B) by inserting "or chiropractic services
5 (as defined in section 1861(ww)(1))" after "in
6 section 1861(q))".
7 (17) Section 1887(a)(1)(A) of such Act (42 U.S.C.
8 1395xx(a)(1)(A)) is amended by inserting "or chiropractic
9 services (as defined in section 1861(ww)(1))" after "which
10 constitute professional medical".
11 (18) Section 1888(e)(2)(A)(ii) of such Act (42 U.S.C.
12 1395yy(e)(2)(A)(ii)) is amended by inserting "chiropractic
13 services (as defined in section 1861(ww)(1))," after "phy-
14 sicians' services".
15 (19) Section 1891(a)(2)(F) of such Act (42 U.S.C.
16 1395bbb(a)(2)(F)) is amended by inserting before the pe-
17 riod at the end the following: "or chiropractor (as defined
18 in section 1861(ww)(2))".

○

Appendix 1

Primary Care Physician

World Health Organization (WHO)

The definition primary health care used by the World Health Organization in the Declaration of Alma (1978) is as follows:

> Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.[1]

The document goes on to describe specific components of primary care. According to this definition, primary health care:

> includes at least: education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs.[1]

Under this definition, primary care must include a number of services, such as the provision of drugs and vaccines, which are outside the scope of chiropractic practice, and incompatible with chiropractic practice.

American Academy of Family Practice (AAFP)

The American Academy of Family Physicians defines primary care physician as follows:

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[1] Declaration of Alma-Ata. International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978. http://www.who.int/publications/almaata_declaration as a programmatic and institutional accreditor_en.pdf

> A primary care physician is a generalist physician who provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's care. Such a physician must be specifically trained to provide primary care services.
>
> Primary care physicians devote the majority of their practice to providing primary care services to a defined population of patients. The style of primary care practice is such that the personal primary care physician serves as the entry point for substantially all of the patient's medical and health care needs - not limited by problem origin, organ system, or diagnosis. Primary care physicians are advocates for the patient in coordinating the use of the entire health care system to benefit the patient.
>
> In this document, the term physician refers only to doctors of medicine (M.D.) and osteopathy (D.O.).[2]

This definition requires a primary care physician to serve "as the entry point for substantially all of the patient's medical and health care needs" and limits the term physician "only to doctors of medicine (M.D.) and osteopathy (D.O.)."

"Medical Home" Concept

Medicine.net defines primary care as:

> The "medical home" for a patient, ideally providing continuity and integration of health care. All family physicians and most pediatricians and internists are in primary care. The aims of primary care are to provide the patient with a broad spectrum of care, both preventive and curative, over a period of time and to coordinate all of the care the patient receives.[3]

The definition of primary care provider:

> In insurance parlance, a physician chosen by or assigned to a patient, who both provides primary care and acts as a gatekeeper to control access to other medical services.[4]

This definition requires a primary care physician "to control access to other medical services." Such is not the role of a doctor of chiropractic.

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[2] American Academy of Family Physicians. http://www.aafp.org/online/en/home/policy/policies/p/primarycare.html

[3] http://www.medterms.com/script/main/art.asp?articlekey=5042

[4] http://www.medterms.com/script/main/art.asp?articlekey=11897

Institute of Medicine (IOM)

The definition of primary care adopted by the IOM Committee on the Future of Primary Care follows:

> Primary care is the provision of *integrated, accessible health care services* by clinicians who are *accountable* for addressing a large *majority of personal health care needs*, developing a *sustained partnership* with *patients*, and practicing in the *context of family and community.*[5]

The Committee also defined terms used in the definition:

Integrated *is intended in this report to encompass the provision of* comprehensive, coordinated, *and* continuous *services that provide a seamless process of care. Integration combines events and information about events occurring in disparate settings, levels of care and over time, preferable throughout the life span.*
Comprehensive*. Comprehensive care addresses any health problem at any given stage of a patient's life cycle.*
Coordinated*. Coordinated ensures the provision of a combination of health services and information that meets a patient's needs. It also refers to the connection between, or the rational ordering of, those services, including the resources of the community.*
Continuous*. Continuity is a characteristic that refers to care over time by a single individual or team of health care professionals ("clinician continuity") and to effective and timely communication of health information (events, risks, advice, and patient preferences) ("record continuity").*
Accessible *refers to the ease with which a patient can initiate an interaction for any health problem with a clinician (e.g., by phone or at a treatment location) and includes efforts to eliminate barriers such as those posed by geography, administrative hurdles, financing, culture, and language.*
maintaining, or restoring health (Last, 1988). The term refers to all settings of care (such as hospitals, nursing homes, clinicians' offices, intermediate care facilities, schools, and homes).
Clinician *means an individual who uses a recognized scientific knowledge base and has the authority to direct the delivery of personal health services to patients.*
Accountable applies to primary care clinicians and the systems in which they operate. These clinicians and systems are responsible to their patients and communities for addressing a large majority of personal health needs through a sustained partnership with a patient in the context of a family and community and for (1) quality of care, (2) patient satisfaction, (3) efficient use of resources, and (4) ethical behavior.
Majority of personal health care needs *refers to the essential characteristic of primary care clinicians: that they receive all problems that patients bring—unrestricted by problem or organ system—and have the appropriate training to diagnose and manage a large majority of those problems and to involve other health care practitioners for further evaluation or treatment when appropriate.* **Personal health care needs** *include physical, mental, emotional, and social concerns that involve the functioning of an individual.*
Sustained partnership *refers to the relationship established between the patient and clinician with the mutual expectation of continuation over time. It is predicated on the development of mutual trust, respect, and responsibility.*
Patient *means an individual who interacts with a clinician either because of illness or for health promotion and disease prevention.*
Context of family and community *refers to an understanding of the patient's living conditions, family dynamics, and cultural background.* **Communities** *refers to the population served, whether they are patients or not. Community can refer to a geopolitical boundary (a city, county, or state), or*

[5] Primary Care. America's Health in a New Era. National Academies Press. http://books.nap.edu/openbook.php?record_id=5152&page=31

to neighbors who share values, experiences, language, religion, culture, or ethnic heritage.
Health care services *refers to an array of services that are performed by health care professionals or under their direction.*[6]

The IOM report also includes the following:

TABLE 4-1 Diagnosis Clusters That Make Up the Majority of Nonreferred Ambulatory Visits to U.S. Office-Based Physicians, NAMCS, 1989–1990[7]

Rank	Cluster Title	Percent	Cumulative Percent
1.	General medical examination	7.2	7.2
2.	Acute upper respiratory tract infection	6.2	13.4
3.	Hypertension	4.4	17.8
4.	Prenatal care	4.3	22.1
5.	Acute otitis media	3.5	25.6
6.	Acute lower respiratory tract infection	2.7	28.3
7.	Acute sprains and strains	2.7	31.0
8.	Depression and anxiety	2.5	33.5
9.	Diabetes mellitus	2.1	35.6
10.	Lacerations and contusions	1.9	37.5
11.	Malignant neoplasms	1.7	39.2
12.	Degenerative joint disease	1.7	40.9
13.	Acute sinusitis	1.6	42.5
14.	Fractures and dislocations	1.6	44.1
15.	Chronic rhinitis	1.5	45.6
16.	Ischemic heart disease	1.4	47.0
17.	Acne and diseases of sweat glands	1.3	48.3
18.	Low back pain	1.2	49.5
19.	Dermatitis and eczema	1.2	50.7
20.	Urinary tract infection	1.1	51.8

It should be noted that the IONM definition defines primary care as including "addressing a large *majority of personal health care needs.*" Note carefully this definition: "**Majority of personal health care needs** *refers to the essential characteristic of primary care clinicians: that they receive all problems that patients bring—unrestricted by problem or organ system—and have the appropriate training to diagnose and manage a large majority of those problems and to involve other health care practitioners for further evaluation or treatment when appropriate."*

Furthermore, CCE must ask if the treatment and management of the conditions enumerated in Table 4-1 be a mandated part of chiropractic education.

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[6] Primary Care. America's Health in a New Era. National Academies Press.
http://books.nap.edu/openbook.php?record_id=5152&page=32
http://books.nap.edu/openbook.php?record_id=5152&page=33

[7] Primary Care. America's Health in a New Era. National Academies Press.
http://books.nap.edu/openbook.php?record_id=5152&page=78#p200063749960078001