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MEMORANDUM

Tuesday, February 3, 2009



TO: Diana Protopapa
Director of Legislative Affairs
Colorado Medical Society

FROM: Kevin D. Heupel
Attorney for Bob Nelson, D.C.

RE: Proposed Amendment to Chiropractic Practice Act

The Colorado Chiropractic Practice Act and Board of Chiropractic Examiners are undergoing a sunset review this year. As part of the process, the Department of Regulatory Agencies ("DORA") has issued some recommendations and amendments to the practice act. Unfortunately, however, the amendments do not go far enough to reflect current chiropractic practice. There is one central area that the sunset review fails to address, which is the administration and prescription of nutritional remedial measures.

Background on Nutritional Remedial Measures

Over the last couple of years, the Chiropractic Board has adopted rules allowing chiropractors to administer and prescribe nutritional remedial measures. However, due to some wording in the current practice act, chiropractors are not able to prescribe or obtain nutritional remedial measures that fall within the FDA's legend drug category.

The practice act at section 12-33-102(1), C.R.S., provides that a licensed chiropractor can use "nutritional remedial measures" necessary to his/her practice. This Chiropractic Board further defined "nutritional remedial measures" by implementing Rule 7(C), which states:

"Nutritional remedial measures as referenced in § 12-33-102(1), C.R.S., means that a doctor of chiropractic may administer, prescribe, recommend, compound, sell and distribute homeopathic and botanic medicines, vitamins, minerals phytonutrients, antioxidants, enzymes, glandular extracts, non-prescriptive drugs, durable and non-durable medical goods and devices."

3 Colo. Code Regs. 707-1

Exhibit B to Supplemental
Submission

However, the practice act at section 12-33-118, C.R.S., prohibits a chiropractor from prescribing and administering drugs related to the practice of medicine as defined in § 12-36-106, C.R.S. As a result, some pharmacies will not dispense "legend drugs" falling within the definition of nutritional remedial measures to a chiropractor even though Rule 7 and § 12-33-102(1), C.R.S., provide for such authority within the scope of chiropractic practice. "Legend drug" means any drug intended for use by humans that carries on its label any of the following: "Caution: Federal law prohibits dispensing without a prescription", "Rx", or "Rx Only". Recently, my client contacted Brown's Pharmacy in Parker, Colorado, and Key Company in St. Louis, Missouri, for vitamin B-12 (30 cc vial), which is a legend drug. Both pharmacies would not fill the order for B-12 because it was their understanding that Colorado chiropractors do not have prescription authority.

In hopes to get assistance on this issue, my client contacted the Department of Justice, Drug Enforcement Agency (DEA) about obtaining a DEA Registration in order to access those nutritional that are considered to be legend drugs by the FDA. The U.S. Department of Justice responded to his inquiry and suggested that he contact the Colorado State Board of Chiropractors for clarification of their regulations.

With the DEA recommendation, my client and I then filed a declaratory order with the Colorado State Board of Chiropractic Examiners to clarify this ruling. However, DORA refused to issue any order and merely stated that the issue needed to be resolved through statutory amendments. It was our hope that DORA would address the issue in the sunset review, but again, DORA did not and referred it back to the profession for resolution.

As a result of these road blocks over the last year, we believe it is important to amend the chiropractic practice act to ensure that chiropractors can practice within their full scope of authority by being able to prescribe, administer, inject, and dispense nutritional remedial measures that fall within the legend drug category. My client has no interest in seeking full prescription authority for legend drugs that are beyond the scope of his chiropractic practice and training; and certainly has no interest in prescribing controlled substances. Instead, the goal is to clarify the scope of practice within the context of the state chiropractic statute and rules to reflect the current practice and training of Colorado doctors of chiropractic.

Proposed Amendments

In order to resolve some of these issues and ensure that the practice act is broad enough to represent the current practice of science and art of chiropractic medicine, my client would like to see two amendments added to the current practice act sunset language.

The first amendment is to add "administration", "injection" and "prescription" to the definition of chiropractic at 12-33-102(1), C.R.S., as proposed to be amended by DORA in the Sunset Review (DORA's amendments are in **bold** and my client's recommendations are in ***bold italics***):

- (1) "Chiropractic" means that branch of the healing arts which is based on the premise that disease is attributable to the abnormal functioning of the

human nervous system. It includes the diagnosing and analyzing of human ailments, and seeks the elimination of the abnormal functioning of the human nervous system by the adjustment or manipulation, by hand, instrument, **administration, injection or prescription**, of the articulations and adjacent tissue of the human body, particularly the spinal column, and the usage as indicated of procedures which facilitate and make the adjustment or manipulation more effective, and the use of sanitary, hygienic, nutritional, and physical remedial measures **for the promotion, maintenance, and restoration of health, the prevention of disease and the treatment of human ailments.** "Chiropractic" includes the use of venipuncture for diagnostic purposes. "Chiropractic" includes treatment by acupuncture when performed by an appropriately trained chiropractor as determined by the Colorado state board of chiropractic examiners. Nothing in this section shall apply to persons using acupuncture not licensed by the board.

The second amendment is to distinguish chiropractic authority to prescribe and administer nutritional remedial measures in the statute at 12-33-118, C.R.S., which is the primary source of the current problem. The proposed amendment would allow a chiropractor to prescribe nutritional remedial measures in all forms, including those that fall within the "legend drug" category, and certain anesthetics, but not an ability to perform anesthesia. This would allow for the continued use of ethyl chloride, an anesthetic used for spray and stretch and the treatment of musculoskeletal injuries. At the same time, the proposed amendment would require the Colorado Chiropractic Board of Examiners to develop a formulary through open rulemaking so that it is clear to all practitioners and pharmacies as to the intended scope of what constitutes a nutritional remedial measure.

My client would propose the following amendment and is certainly open to suggestions in order for the intent and scope to be clear:

12-33-118. A license to practice chiropractic entitles the holder to use the title "Doctor" or "Dr." when accompanied by the word "Chiropractor" or the letters "D.C.", and to use the title of "Doctor of Chiropractic". Such license shall not confer upon the licensee the right to practice surgery or obstetrics or to prescribe, compound, or administer drugs, or to administer ~~anesthetics~~ **anesthesia**. Nothing in this article shall be construed to prohibit **the use of nutritional remedial measures in all forms, including those formulated as legend drugs**, nor to require a license for bona fide chiropractic students or interns in attendance upon a regular course of instruction in a lawfully operated chiropractic school or hospital with respect to performing chiropractic services within such school or hospital while under the direct supervision of a licensed chiropractor. **A formulary that includes all substances constituting nutritional remedial measures shall be developed and approved by the board.**

allows the FDA is able to assess the true benefit of such substances and require manufacturers to perform studies and have documented evidence supporting their marketing claims.

There is the possibility of harm if legend drugs are used irresponsibly or incorrectly. However, chiropractors have the training and skills necessary to use legend drugs that fall under the category of nutritional remedial measures. Nutrition has been a deeply rooted and robust part of the chiropractic curriculum and practice act since the 1950s.

I have attached a copy of the Council on Chiropractic Education Standards for Doctor of Chiropractic Programs and Requirements for Institutional Status 2007 Report. On page 22, you will see that 90 credit hours of undergraduate education is an admission requirement before entering chiropractic school. Page 18 states that all chiropractic students are required to complete 4,200 hours of minimum of classroom time prior to clinical. The curriculum required for the must include the following subjects (not necessarily in individual courses for each subject): anatomy; biochemistry; physiology; microbiology, pathology; public health; physical, clinical and laboratory diagnosis; gynecology; obstetrics; pediatrics; geriatrics; dermatology; otolaryngology; diagnostic imaging procedures; psychology; **nutrition/dietetics**; biomechanics; orthopedics; neurology; first aid and emergency procedures; spinal analysis; principles and practice of chiropractic; clinical decision making; adjustive techniques; research methods and procedures; and professional practice ethics. The clinical competencies are detailed on pages 29-39 and page 38 clearly states that chiropractors must have the skills to identify and initiate the appropriate nutritional supplements or supplementation as part of their health care regimen. Thus, despite the refinements of some nutritionals, chiropractors have adequate training to use those constituting legend drugs.

Conclusion

As noted in the Sunset Review, the definition of chiropractic has not been updated since the late 1950s and the word nutritional existed at that time. The proposed amendments are brought forward to resolve a current problem in regards to nutritionals.

In the interest of public safety and welfare, chiropractors should have access to the growing emergence of high quality, by prescription only nutritional legend drugs. This growth has been fueled by the general inconsistency in nutritional products, the FDA focus towards employing good manufacturing practices (GMP), requiring product claims to be supported by research and the product to be efficacious and support any claims made. Chiropractors, who have had a long history of training and use of nutritional remedial measures should have access to legitimate, scientifically formulated high quality nutritionals that have had the benefit of scientific studies so they can provide their patients with care that is both safe and effective.

Regardless of one's medical or healthcare philosophy, the definition of chiropractic needs to be updated to allow chiropractors to practice to the extent of their training and expertise. It is our opinion that these amendments will permit chiropractors to use nutritional remedial measures safely, responsibly, and within their scope of training and practice.

cc Bob Nelson, D.C.
Colorado Chiropractic Association