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Loree V. Kessler, MPA
Executive Director

Memo

To: Missouri Licensed Chiropractors

From: Missouri State Board of Chiropractic Examiners

Date: August 22, 2012

Re: Injectable Nutrition in Missouri

For some time, the Missouri State Board of Chiropractic Examiners has received inquiries and information regarding the injectable and intravenous delivery of dietary nutritional supplements to chiropractic patients ("injectable nutrition"). The growing availability of such products to alternative health care practitioners, and their patients, has prompted the Missouri Board of Pharmacy to examine the sale and distribution of injectable nutrition within Missouri, and the applicability of state and federal statutory limitations placed on the sale and distribution of these products. This examination by the Missouri Board of Pharmacy, combined with an increasing number of inquiries to the State Board by and relating to the vendors and distributors of injectable nutrition, has brought this topic to the forefront once again. Based upon the State Board of Chiropractic Examiners' recent consultation with the Missouri Board of Pharmacy for clarification of this issue, the following information is being provided in order to assist Missouri chiropractors in evaluating the contemplated utilization of injectable nutrients within a licensee's practice.

First, that portion of the licensure law commonly referred to as the "scope of practice" does not include the authority to "prescribe" any "drug or medicine", nor does the law authorize the state board to approve a type of treatment that is not within the scope of practice. Specifically, Section 331.010.1 RSMo of the licensure law for chiropractors states, "[t]he "practice of chiropractic" is defined as the science and art of examination, diagnosis, adjustment, manipulation and treatment both in inpatient and outpatient settings, by those methods commonly taught in any chiropractic college or chiropractic program in a university which has been accredited by the Council on Chiropractic Education, its successor entity or approved by the board. It shall not include the use of operative surgery, obstetrics, osteopathy, podiatry, *nor the administration or prescribing of any drug or medicine* nor the practice of medicine. The practice of chiropractic is declared not to be the practice of medicine and operative surgery or osteopathy within the meaning of chapter 334 and not subject to the provisions of the chapter". Section 331.010.1, RSMo. Supp. (emphasis added).

Secondly, Missouri law regulates the prescribing and dispensing of "legend drugs", which may also be referr to as "Rx Only" drugs. The following definition of "Legend drug" appears in section 338.330, RSMo relating to pharmacies and wholesale drug distributors:

(1) "Legend drug":
(a) Any drug or biological product:
a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such Section 503(b); or
b. Required under federal law to be labeled with one of the following statements prior to being dispensed o delivered:
(i) "Caution: Federal law prohibits dispensing without prescription";
(ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or
(iii) "Rx Only"[.]
(Emphasis added).

Third, pursuant to the definition of "legend drug" in the statutes administered by the Board of Pharmacy, which includes all products required by federal law to be marked as "Rx Only", no such "legend drug" can be *sold to, or purchased and administered by, any health professional(s) that do not have statutory authority to "prescribe" legend drugs.* The U.S. Food and Drug Administration, ("FDA"), has informed the chiropractic board that nutritional supplements, in essence, *become legend drugs when they are manufactured, packaged, and sold for administration via the route of injection or IV.* This includes both unaltered supplements which are packaged and sold for injection/IV administration, as well as blended, mixed, or compounded products.

The FDA's position derives from the Dietary Supplement Health and Education Act of 1994, which act i administered by the FDA. This act defines the term "dietary supplement" to mean "a product (other tha tobacco) intended to supplement the diet that bears or contains one or more of the following dietar ingredients:

- a vitamin;
- a mineral;
- an herb or other botanical;
- an amino acid;
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- a concentrate metabolite, constituent, extract, or combination of any ingredient described in [the above]."

This act further defines "dietary supplement" to mean a product that "**is intended for ingestion in a form described in Section 411 C1 (B)(i)"**. Section 411 C1(B)(i) clarifies that "ingestion" means *oral* intake of the supplement. This provision specifically requires that, in order to be a "dietary supplement", rather than a "legend drug", the supplement must be one that:

"(i) [I]s intended for ingestion in *tablet, capsule, powder, softgel, gelcap, or liquid form. . .*"

Products, such as those coming from other countries or from other states within the United States, may not be in compliance with federal law when the "Rx Only" designation is omitted from the labeling of these products. However, such omission does *not* change the character of such products or their legal status as "legend drugs".

A Missouri licensed chiropractor considering the utilization of injectable nutrition, needs to first consult with their own legal counsel to discuss the legality and implications of such practice by examining the scope of practice for chiropractors, the laws relating to legend drugs, and corresponding regulations promulgated by the Missouri Board of Pharmacy and federal Food and Drug Administration.