

Legal Concerns of Nutritional Counseling

The State of Wisconsin offers a unique ability for licensed chiropractors to provide "nutritional counseling". The provision of this service is largely regulated by Chapter 12 of the Wisconsin Administrative Code relating to chiropractors. These regulations, combined with various disciplinary proceedings, have resulted in important legal parameters on the doctor's ability to provide nutritional counseling. This article provides a general overview of those legal concerns relating to the practice of nutritional counseling in the State of Wisconsin.

A. What can be promoted or sold by Wisconsin Chiropractors

There are legal parameters on the type of product which can be the subject of nutritional counseling by a chiropractor. Wisconsin Administrative Code CHIR 12.01(4) provides the definition of a "nutritional supplement". It should be noted that the product "must contain one or more" of certain ingredients or have labeling as "a nutritional or dietary supplement". In addition, CHIR 4.05(1)(d) prohibits the "prescribing, dispensing, delivery or administration of drugs". Wisconsin's legal definition of a "drug" is defined at Wis. Stats. §450.01(10).

This statute references an official US publication of both "pharmacopoeia and homeopathic pharmacopoeia". This distinction has been the subject of prior notices to state doctors indicating that a chiropractor may not sell "homeopathic supplements". There may be a fine distinction between the broad reference to these types of products and the specific products identified under US guidelines. It is likely that the true composition of any product a chiropractor is promoting would be the subject of careful scrutiny by the Chiropractic Examining Board. There are prior examples of Board Investigations in which the Chiropractor was disciplined based solely upon the distinction between promoting a product which was only approved by the FDA for "market clearance" as compared to "FDA approved".

There are two other legal issues associated with the nature of the product sold by a chiropractor which should be given attention. First, a chiropractor may need to charge sales tax on certain types of recommended products. The rules relating to sales tax charges can be obtained from the Wisconsin Department of Revenue. In general, the following items may be subject to sales tax:

- Supplements that are sold in tablet or capsule form.
- Powdered or liquid supplements that do not have higher concentrated values of proteins and carbohydrates and is **not** intended to be a substitute, in whole or in part, for the ordinary diet.
- Nutrition or energy bar that is candy or yogurt coded.
- Nutrition or energy bar that is not of cereal consistency.
- Most sports drinks.
- Many vitamins.

The actual manufacturer of any product promoted by the chiropractor should be familiar with sales tax responsibilities or liability in each individual state.

Second, the Wisconsin Administrative Code contains some unique provisions regarding the labeling on nutritional supplements. Wisconsin Administrative Code CHIR 12.06(3) provides that a chiropractor cannot "deliver, dispense, administer, transfer or sell a product unless the product is prepackage for use by consumers and labeled in accordance with state and federal law." Chiropractors may consider adding their own name and identifying information on the label of products within their office. Although this marketing approach should be acceptable, the chiropractor should confirm that the manufacturer of the product has properly complied with all state and federal labeling laws.

Summary of Concerns:

1. Obtain written report from manufacturer and/or its legal counsel that the product promoted does not contain portions of the federally defined "drug" or homeopathic drug.
2. Determine whether a sales tax permit is required. If so, the sellers permit must be prominently displayed within the office.
3. Obtain written opinion from manufacturer and/or its legal counsel that any products sold are properly labeled in accordance with federal and state law.

B. Who can provide nutritional counsel and acceptable manner of promotion

Any doctor providing nutritional counseling pursuant to Wisconsin Administrative Code CHIR 12, must insure that all of the continuing education requirements are met as required by the Chiropractic Examining Board. After obtaining the initial educational requirements, a doctor is required to renew their application during each two (2) year licensure period with additional,

approved CE courses. The Examining Board's investigators perform random and periodic evaluations of doctor's CE courses to insure that the necessary classes have been obtained for renewal of the nutritional certificate.

A major debate developed over the issue of whether chiropractors can participate in "multi-level marketing" (MLM) of nutritional products manufactured and promoted by third party companies or individuals. This was a major issue for debate before the Examining Board in the summer of 2007. The Board was primarily relying upon the language of CHIR 12.06(1). At that time, the Board appeared to be concerned that the chiropractor would not exercise appropriate judgment in relation to the monetary incentive of an MLM "scheme" and that "down the line" sellers of products, originally recommended by a chiropractor, may be inappropriately acting only in their own best financial interest as agents in a sales scheme for a doctor.

The author of this article had the privilege of representing the interests of individual chiropractors who preferred an expanded ability to aggressively sell nutritional supplements. With the subsequent involvement of three (3) national multi-level marketing trade associations, the examining board in 2007 ultimately limited its aggressive restrictions on the ability of a chiropractor to actively promote nutritional supplements. The examining board ultimately decided to take no action on the issue after formal legal proceedings were filed in Dane County seeking an injunction against the examining board. Instead, the board indicated that it would place a "FAQ" on the examining board website addressing this issue.

As a consequence of this debate, there are two (2) issues which appear to be resolved from a legal perspective. First, it was recognized that Chiropractic Assistants (now, "C.T.'s") have the ability to provide administrative services in connection with the sale of products recommended by the doctor. As such, a CT should be able to inventory products, engage in the actual sale of the products, and monitor the actual distribution of the products following the recommendation of the chiropractor.

Second, a doctor must be aware of prohibitions on the delegation of "adjunctive services" to third-party individuals or other entities. The prohibition against delegation of adjunctive services is defined in CHIR 10.02. Generally, the Board wants to insure that any third-parties delegated to provide services adjunctive to chiropractic care have appropriate training or licensure. The enforcement of this concern is best exemplified in a recent disciplinary action taken by the

Board against a Wisconsin chiropractor. In that decision, a chiropractor was working with an "unlicensed employee" who was given responsibilities for "adjunctive services" in the area of nutritional testing, counseling, and sales. Apparently, the chiropractor was actually referring patients to this third-party individual rather than personally providing nutritional advice and suggested to patients that the third-party can provide appropriate nutritional counseling. The Board ultimately disciplined this doctor under other provisions of the Administrative Code which were unrelated to those provisions in CHIR Chap 12.

Summary of Concerns:

1. Supplement the patient's "informed consent form" to indicate that any patient receiving counseling for nutritional services or purchasing actual products recommended by the chiropractor cannot make any representations (either in written, verbal or other form) that they are acting for or on behalf of the chiropractor with respect to the nutritional counseling services or needs of other parties who have not directly consulted with the doctor.
2. Have regular and routine training sessions with employees to insure that they are not engaging in any type of adjunctive services as it relates to nutritional counseling and that their services are limited merely to administrative functions.
3. Carefully examine any "pyramid type schemes" of nutritional manufacturers to insure that patients the chiropractor counsels for nutritional needs are not subsequently selling products utilizing the doctor as a referral source for the specific product and that the doctor is not receiving any type of direct "fee" for these sales by prior patients to other third-parties.

C. How must supplements be promoted to the patients

The issue of the manner by which supplements are promoted has legal ramifications from three (3) perspectives. First, legal attention has been given to the manner by which the doctor advertises their training in the area of nutritional counseling. Although there have been a few examples of discipline in this area, the WCA has notified chiropractors that the completion of the training does not permit a chiropractor to refer to themselves as a "nutritionist" in any advertising. Nutritionists are separately regulated in this state and it is generally acknowledged that an individual must have a degree in nutrition or have graduated from an accredited university with a nutritional program before referring to themselves as a "nutritionist". In addition, Wisconsin Administrative Code's 6.02(15) places specific limitations on a doctor's ability to refer to themselves as any type of "specialist". Given the interpretation of this

Administrative Code provisions, it has been noted that a chiropractor cannot imply that they "specialize" unless they have completed the applicable ACA courses. A chiropractor should still be permitted to accurately indicate that they completed training approved by the Chiropractic Examining Board to provide nutritional counseling as a chiropractor. Moreover, a chiropractor can indicate that their office provides chiropractic counseling with regard to the use of "nutritional supplements", "vitamins", and "herbs".

As it relates to advertising or promotion, a chiropractor cannot promote products in a manner which violates CHIR 6.02(31). Consistent with this provision, a chiropractor must insure that information provided about a product is truthful and not misleading to a patient, as evaluated from an "objective" patient perspective. In making any recommendation for a nutritional product, the doctor must insure that the underlying condition for which the product is advanced fits within the overall health needs and conditions which are within the "practice of chiropractic" as defined in CHIR 4.03. Given this perspective, chiropractors should be prepared to provide information from authoritative and recognized scientific sources on the adverse side effects, risks, and dangers of any nutritional products offered to the patient. It is not clear whether the doctor needs to provide the specific information to the patient or merely inform the patient, from a general perspective, that there are two (2) "schools of thought" with respect to the value or efficacy of certain nutritional products and that the patient may want to consult with other sources of information.

Finally, a chiropractor should insure that any product recommended to a patient is specifically advisable given the patient's specific health needs. In this regard, the doctor should be aware of the obligations of CHIR 6.03 to evaluate each specific patient's condition before rendering treatment. One of those "means" of treatment would include the nutritional counseling of CHIR 12 so as to provide information to the patient on the "health effects" and benefits of vitamins, herbs, or nutritional supplements. See CHIR 12.01(3). When speaking with the patient regarding a particular supplement, the doctor's should be able to document the reason for recommending a particular supplemental product. Consequently, a chiropractor can only recommend a product as potentially beneficial for the specific health need of a patient which can be treatable through chiropractic means.

Summary of Concerns:

1. Supplement informed consent to advise patients that there may be contrary or different opinions regarding the efficacy of nutritional

supplements. The informed consent could also reference sources of general information on the values, risks, dangers, and side effects of nutritional supplements.

2. Insure that all written and oral promotion does not infer that the doctor is a "specialist" or "nutritionist".
3. Do not "prescribe" generalize use of any supplements, but merely "recommend" the use of the nutritional supplement to address the patient's specific health need, as analyzed to be within the scope of a chiropractic.
4. Maintain written patient records which not only (1) establish a chiropractic need for any nutritional supplement, but (2) reference information regarding the patient's progress/on-going need for continued use of nutritional supplements.

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