STATE OF WISCONSIN CHIROPRACTIC EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE	: ORDER OF THE : CHIROPRACTIC EXAMINING BOARD
CHIROPRACTIC EXAMINING BOARD	: ADOPTING RULES
	: (CLEARINGHOUSE RULE 06-051)

ORDER

An order of the Chiropractic Examining Board to amend Chir 4.05 (1) (d); and to create Chir 5.01 (1) (f) and (g), 6.02 (31) and chapter Chir 12, relating to nutritional counseling certification.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes interpreted:

Section 446.02 (2) (b), Stats., and s. 446.02 (2) (c) and (6m), Stats., as created by 2005 Wisconsin Act 25.

Statutory authority:

Sections 15.08 (5), 227.11 (2) and 446.02 (2) (b), Stats.

Explanation of agency authority:

2005 Wisconsin Act 25 created s. 446.02 (2) (c) and (6m), Stats, which expand the scope of practice for chiropractors. The legislature has directed that the Chiropractic Examining Board establish the educational requirements for this area of practice. Pursuant to s. 446.02 (2) (b), Stats., the Chiropractic Examining Board has the ability to set educational standards for licensure. This rule establishes the educational requirements for the new certificate as well as incorporating changes to prohibited practices, professional conduct and continuing education to make the rules consistent with the addition of nutritional counseling as a practice area.

Related statute or rule:

Wisconsin Administrative Code Chapters Chir 4, 5 and 6; Chapter 446, Wis. Stats.

Plain language analysis:

The Chiropractic Examining Board is proposing changes to s. Chir 4.05, prohibited practice, s. Chir 5.01, continuing education requirements for license renewal, and the creation of ch. Chir 12, relating to the certification process for nutritional counseling. These changes are in response to 2005 Wisconsin Act 25, that went into effect on January 1, 2006, specifying that chiropractors

will be able to expand their scope of practice to provide nutritional counseling once they have completed 48 hours of board-approved postgraduate study in nutrition and paying a one-time certification fee of \$25.

This proposed rule-making is required to define the substance and requirements of what constitutes a board-approved 48 hour post graduate program in nutrition. Rule-making is also required to develop additional continuing education requirements, possible exemptions for advanced nutritional education, and scope of nutritional counseling.

SECTION 1 amends the existing exception under s. Chir 4.05 Prohibited Practice which allows a chiropractor to sell vitamins, herbs or nutritional supplements to include the provisions under ch. Chir 12 Nutritional Counseling Certification.

Prior to the changes directed by 2005 Wisconsin Act 25, it was considered a prohibited practice for a chiropractor to engage in some types of nutritional counseling. This section makes changes to the prohibited practice language to allow counseling in compliance with the provisions of Act 25.

SECTION 2 defines the educational hours of coursework required under ch. Chir 12 and establishes that chiropractors who hold a nutritional counseling certificate shall complete at least 4 hours of study in nutrition as a part of their biennial 40 hours of continuing education requirement.

SECTION 3 expands the language of the unprofessional conduct provisions to recognize that a chiropractor who makes unsubstantiated claims about the effectiveness of nutritional counseling can be disciplined.

SECTION 4 sets out the minimum standards for the nutritional counseling coursework that is required to obtain the additional certificate. This section also sets out the procedure for course sponsors to obtain board approval. This section identifies the subject matter which must be covered and sets the standards for determination of successful completion. This section requires that the course contain at least 4 tests and that a score of 75% or higher is necessary to successfully complete the course.

This section also contains a sunset provision requiring that chiropractors must either obtain this education and certification or cease selling nutritional supplements within 24 months of the effective date of this rule.

Summary of, and comparison with, existing or proposed federal regulation:

None.

Comparison with rules in adjacent states:

Illinois:

A "chiropractic physician" licensed under Illinois's Medical Practice Act: 225 ILCS 60 may treat human ailments without the use of drugs or surgery [225 ILCS 60/2 (10)]. The statutes and rules appear to be silent regarding the provision of nutritional advice or counseling as well as the dispensation or prescription of nutritional supplements.

Michigan:

Pursuant to Michigan's Public Health Code Action 368 Section 333.16401 (1) (b) (iii), providing "nutritional advice" is within the chiropractic scope of practice; however, the prescribing or dispensing of drugs or medicine is not within their scope of practice.

Section 333.16401 (1) (b) (iii):

The use of analytical instruments, *nutritional advice*, rehabilitative exercise and adjustment apparatus regulated by rules promulgated by the board pursuant to section 16423, and the use of x-ray machines in the examination of patients for the purpose of locating spinal subluxations or misaligned vertebrae of the human spine. The practice of chiropractic does not include the performance of incisive surgical procedures, the performance of an invasive procedure requiring instrumentation, or the *dispensing or prescribing of drugs or medicine*.

Michigan's administrative rules are silent regarding provision of nutritional advice or counseling as well as the dispensation or prescription of nutritional supplements.

Minnesota:

Minnesota's statutes are mostly silent with regards to the provision, recommendation or dispensation of nutritional supplements. Minnesota statutes do mention that nutrition is a part of the required written chiropractic examination.

A chiropractor in Minnesota may provide nutritional therapy and counseling on a dietary regimen as part of Rehabilitative Therapy for their patients.

Minnesota Administrative Rules state:

2500.0100 Subp.11 Rehabilitative Therapy.

"Rehabilitative therapy" means therapy that restores an ill or injured patient to the maximum functional improvement by employing within the practice of chiropractic those methods, procedures, modalities, devices, and measures which include mobilization; thermotherapy; cyrotherapy; hydrotherapy; exercise therapies; *nutritional therapy*; meridian therapy; vibratory therapy; traction; stretching; bracing and supports; trigger point therapy; massage and the use of forces associated with low voltage myostimulation, high voltage myostimulation, ultraviolet light, diathermy, and ultrasound; and *counseling on dietary regimen*, sanitary measures,

occupational health, lifestyle factors, posture, rest, work, and recreational activities that may enhance or complement the chiropractic adjustment.

2500.4000 Rehabilitative Treatment.

Rehabilitative therapy, within the context of the practice of chiropractic, may be done to prepare a patient for chiropractic adjustment or to complement the chiropractic adjustment, provided the treating chiropractor initiates the development and authorization of the rehabilitative therapy. The administration of the rehabilitative therapy is the responsibility of the treating chiropractor. The rehabilitative therapy must be rendered under the direct supervision of qualified staff.

Iowa:

Iowa Statutes allow chiropractors to provide *nutritional advice* under Iowa Stats section 151.1 (3) Chiropractic Defined which states:

Persons utilizing differential diagnosis and procedures related thereto, withdrawing or ordering withdrawal of the patient's blood for diagnostic purposes, performing or utilizing routine laboratory tests, performing physical examinations, *rendering nutritional advice*, utilizing chiropractic physiotherapy procedures, all of which are subject to and authorized by section 151.8.

Iowa Statutes also provide that licensed chiropractors may not administer or prescribe drugs or medicine. Iowa Stats Section 151.5 Operative surgery – drugs.

A license to practice chiropractic shall not authorize the licensee to practice operative surgery, osteopathy, nor administer or prescribe any drug or medicine included in materia medica.

Iowa's administrative rules are silent regarding provision of nutritional advice or counseling as well as the dispensation or prescription of nutritional supplements.

Summary of factual data and analytical methodologies:

The Chiropractic Examining Board, in an effort to create an adequate curriculum of 48 hours of board-approved postgraduate study in nutrition, which was called for in the enactment of the statutes under 2005 Wisconsin Act 25, consulted with the following educational bodies and professional associations: Palmer College of Chiropractic; Northwestern Chiropractic College; Wisconsin Chiropractic Association; Wisconsin Dieticians Association.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report:

The proposed rules for the provisions of nutritional counseling will affect the practice of small business as defined by a company, clinic or chiropractic practice is defined a business with 25 employees or less than \$5 million in annual receipt (billings).

Chiropractic Small Business Market Analysis:

as per the Department of Commerce, the 2002 Economic Census Report for Health professions that are Employers who are chiropractors is:

1. 898 offices of Chiropractic with receipts (\$1000s) 255,518 for average receipts of \$284,541 per office with 3,477 paid employees (ave. of 4 per office).

as per the Department of Commerce, the 2003 Economic Census Status report for NonEmployers, which are establishments consisting of one licensed Chiropractor engaged in the independent practice of Chiropractic indicates:

1. 303 offices with receipts (\$1,000s) of 15,706 for average receipts of \$51,835 per office.

The Department of Regulation and Licensing's March of 2006 licensee count indicates that there are 1,708 chiropractors with active licenses (up to date and eligible to practice).

The effect of the rules on the practice of small business may be as follows:

1. Prior to the enactment of the new statutes and the pending proposed rules, licensed chiropractors were able to sell vitamins, herbs or nutritional supplements for the general health and well-being of their patients, however the practice of recommending, counseling or directing patients to take vitamins, herbs or nutritional supplements were prohibited by their scope of practice, and administrative rules governing conduct.

2. The proposed rules will allow chiropractors, who elect to take the prescribed 48 hour program under the rules and pay the \$25 fee to the Department of Regulation and Licensing will be able to expand their scope of practice by providing nutritional counseling, guidance and recommendations for vitamins, herbs or nutritional supplements. This is seen as a substantial business benefit through the generation of additional revenues and enhanced patient care.

3. The proposed rules will prohibit chiropractors whom have not taken the prescribed 48hour program and received their certificate from selling vitamins, herbs or nutritional supplements. This practice is being eliminated as it prevents confusion to the consumer who may have difficulty discerning those chiropractors whom are allowed to provide counseling and guidance in addition to selling, and those chiropractors whom are only allowed to sell vitamins, herbs or nutritional supplements. This is seen by the board as an enhancement to public safety and protection. Chiropractors who are currently selling these products, but wish not to obtain their certificate must discontinue selling these products which will have an effect on their business.

4. The board notes that in addition to the \$25 fee, the 48-hour program will have additional fiscal effect of time away from the office and subsequent lost billings, and the

program may cost approximately \$1,000 or more based on the provider of the program. This cost to small business will be substantially offset and may be entirely eliminated by existing continuing education costs. Chiropractors are required by law to complete 40 hours of continuing education in the biennium. The 48-hour program may be counted toward their ongoing CE requirement in the biennium in which it is completed. This will offset the cost of the program by having it count towards their continuing education requirement, and offsetting additional cost in terms of educational dollars and time away from their practice.

Section 227.137, Stats., requires an "agency" to prepare an economic impact report before submitting the proposed rule-making order to the Wisconsin Legislative Council. The Department of Regulation and Licensing is not included as an "agency" in this section.

Fiscal estimate:

The Department of Regulation and Licensing estimates that this rule will require staff time in the Division of Professional Credentialing, Division of Enforcement, and the Division of Management Services. The total staff salary and fringe is estimated at \$13,807.

Anticipated costs incurred by private sector:

\$25 fee for the certificate, educational costs for the required 48 hour program.

Effect on small business:

These proposed rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at <u>larry.martin@drl.state.wi.us</u>, or by calling (608) 266-8608.

Agency contact person:

Pamela Haack, Paralegal, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708-8935. Telephone: (608) 266-0495. Email: pamela.haack@drl.state.wi.us.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Pamela Haack, Paralegal, Department of Regulation and Licensing, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708-8935, or by email at <u>pamela.haack@drl.state.wi.us</u>. Comments must be received on or before July 3, 2006, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chir 4.05 (1) (d) is amended to read:

Chir 4.05 (1) (d) The prescribing, dispensing, delivery or administration of drugs as defined in s. 450.01 (10), Stats., except nothing in this paragraph may be construed to prevent the sale of vitamins, herbs or nutritional supplements <u>consistent with the provisions of ch. Chir 12</u>.

SECTION 2. Chir 5.01 (1) (f) and (g) are created to read:

Chir 5.01(1)(f) Course work completed in pursuit of the educational requirements of ch. Chir 12 may be counted on an hour-for-hour basis.

(g) Of the 40 continuing education credit hours in par. (a), a chiropractor holding a nutritional counseling certificate issued under ch. Chir 12 shall complete at least 4 continuing education credit hours in nutrition.

SECTION 3. Chir 6.02 (31) is created to read:

Chir 6.02 (31) Making a representation likely to create an unjustified expectation about the results of a nutritional counseling service or procedure.

SECTION 4. Chapter Chir 12 is created to read:

CHAPTER CHIR 12

NUTRITIONAL COUNSELING CERTIFICATION

Chir 12.01 Definitions. In this chapter:

(1) "Administering" means the direct application of a product, whether by ingestion or any other means, to the body of a patient or research subject by any of the following:

(a) A chiropractor.

(b) A patient or research subject at the direction of the chiropractor.

(2) "Dispensing" means delivering a product to an ultimate user or research subject by a chiropractor.

(3) "Nutritional counseling" means providing counsel, direction, guidance, advice or a recommendation to a patient regarding the health effects of vitamins, herbs or nutritional supplements.

(4) "Nutritional supplement" means a product, other than tobacco, that is intended to supplement the diet that contains one or more of the following dietary 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 daily intake, or concentrate, metabolics, constituent, extract or combination of these ingredients; or is labeled as a nutritional or dietary supplement. **Chir 12.02 Requirements for nutritional counseling certification**. (1) The board shall grant a certificate for nutritional counseling to a licensed chiropractor who does all of the following:

(a) Submits an application for a certificate to the department on a form provided by the department.

Note: Application forms are available on request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708, or from the department's website at: <u>http://drl.wi.gov</u>.

(b) Pays the fee specified in s. 446.02 (2) (c), Stats.

(c) Submits evidence satisfactory to the board that he or she has completed any of the following:

1. Received a postgraduate degree in human nutrition, nutrition education, food and nutrition or dietetics conferred by a college or university that is accredited by an accrediting body listed as nationally recognized by the secretary of the federal department of education.

2. Received diplomate status in human nutrition conferred by a college of chiropractic accredited by the Council on Chiropractic Education (CCE) or approved by the board or by an agency approved by the United States office of education or its successor.

3. Received a postgraduate degree in human nutrition conferred by a foreign school determined to be equivalent to an accredited college of chiropractic by the CCE or approved by the board or another board approved accrediting agency, indicating that the applicant has graduated from a program that is substantially equivalent to a postgraduate or diplomate program under subd. 1. or 2.

4. Received a degree from or otherwise successfully completed a postgraduate program after (revisor insert effective date) consisting of a minimum of 48 hours in human nutrition that is approved by the board as provided in s. Chir 12.03, after (revisor insert effective date).

Chir 12.03 Approval of nutritional counseling education programs. (1) To qualify for board approval as a nutritional counseling education program under s. Chir 12.02 (1) (c) 4., a program shall meet all of the following minimum requirements:

(a) The program is sponsored by the Wisconsin Chiropractic Association, the American Chiropractic Association, the International Chiropractors Association, a college of chiropractic approved by the board, or a college of medicine or osteopathy accredited by an agency recognized by the United States department of education. (b) The program subject matter includes core curriculum education in each of the following areas:

physical examination.	1. Nutrition counseling and initial screening to include nutrition
	2. Diet history taking.
blood samples.	3. Analysis of laboratory data including hair, saliva, urine and
the toxicity of excess vitamin supplements.	4. Symptoms of severe vitamin and nutritional deficiencies, and and mineral supplementation, herbals or other nutritional
symptoms of deficiencies of a	5. Protein, carbohydrates, and fat macronutrient needs and any of these nutrients.
intakes.	6. Vitamin recommended daily allowances and dietary reference
biochemistry of essential and	7. Mineral and metals needs of the human body and the non-essential nutritional supplements.
	8. Fiber needs.
	9. Codex Alimentarius Commission.
103-417 and related regulation	10. Dietary supplement health and education act of 1994, P.L. ns.
diseases and conditions.	11. Etiology of organ system dysfunction, internal medicine
	12. Supplements and nutrition.
chelation therapy and therape	13. The efficacy, safety, risks and benefits of glandular products, utic enzymes.
	14. Food composition and foods as a source of vitamins.
physiology.	15. Sports nutrition, endurance, body building and exercise
	16. Weight management and control.

17. Contraindications, side effects, and toxic effects of botanicals, nutritional supplements and diet products.

18. Nutrition across the life cycle.

- 19. Nutrition relating to infants, pregnancy and lactation.
- 20. Geriatric nutritional needs.
- 21. Adolescent nutrition needs.
- 22. Male and female nutrition needs.
- 23. Therapeutic use of botanical medicine.
- 24. Food, drug, and nutritional supplements interactions.
- 25. Safety and efficacy risks and benefits of nutritional

supplements.

(c) The program sponsor agrees to provide a responsible person to monitor and verify the attendance of each registered chiropractor at the program, and the program sponsor agrees to keep the records of attendance for 3 years from the date of the program and to furnish each participant with evidence of having attended the program.

(d) The program sponsor shall not assign or delegate its responsibilities to monitor or record attendance, provide evidence of attendance, compare course content with subject matter content required under sub. (1) (b), or provide information on instructors or other aspects of the program unless the assignment or delegation is specifically identified in the application for approval and approved by the board.

(e) The program sponsor has reviewed and validated the program's content to insure its compliance with par. (b).

(f) When a course instructor of the program is on the undergraduate or postgraduate faculty of a chiropractic college, the program sponsor has provided written verification that the course instructor has been appointed in accordance with the accreditation standards of the Council on Chiropractic Education.

(g) The program offers significant professional educational benefit for participants, as determined by the board.

(h) The instructor is qualified to present the course.

(i) The program shall include a written assessment instrument, designed to ensure that the chiropractor actively participated in the presentation of material and derived a measurable benefit from participation. There shall be an assessment or test at the conclusion of each 12 hours of education. A score of 75% or higher shall be considered a passing score.

(j) The program shall contain a reasonable security procedure to assure that the chiropractor enrolled is the actual participant.

(k) Programs shall be approved for one hour of education credit for every 50 minutes of instruction. The time used for testing and assessment purposes shall not be included in the computation of educational credit.

(2) (a) An application for approval of a nutritional counseling education program shall meet all of the following requirements:

1. Be on a form provided by the board.

Note: Application forms are available on request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708, or from the department's website at: <u>http://drl.wi.gov</u>.

2. Identify the name and address of the program sponsor and describe how the program sponsor qualifies under s. Chir 12.03(1)(a).

3. Describe the time and place of the program.

4. Be complete as prescribed in this subsection and filed with the board no later than 75 days prior to the program date. An application is not considered complete until such time as all information required to be submitted with the application, and any supplementary information requested by the board, is received by the board.

5. Include evidence of the program sponsor's verification showing to the satisfaction of the board that the subject matter is generally taught at the undergraduate or postgraduate level of a chiropractic college and relates to improving the clinical skills of a chiropractor. A detailed course outline or syllabus describing the subject matter of the program, and the amount of time devoted to each section of the outline or syllabus shall be attached to the application.

6. Describe the names and qualifications of all instructors, and if applicable, whether an instructor of the program who is an undergraduate or postgraduate faculty member of a sponsoring college was appointed in accordance with accreditation standards of the Council on Chiropractic Education.

7. Identify whether the program sponsor intends to assign or delegate any of its responsibilities to another person or entity, and if so, include all of the following:

a. A specific description of the assignment or delegation.

b. The person or entity who is assigned or delegated to perform the responsibility, including name, address and qualification to perform the responsibility.

c. The method by which the program sponsor intends to assure that the delegated or assigned responsibility is performed.

8. Include a written assessment instrument, designed to ensure that the chiropractor actively participated in the presentation of material and derived a measurable benefit from participation.

9. Include a reasonable security procedure to assure that the chiropractor enrolled is the actual participant.

(b) If necessary, in order to determine whether an applicant meets the requirements of this chapter, the board may require that the applicant submit information in addition to that described in this section.

(3) Continuing education credit may not be awarded for meals, breaks, testing or assessment periods.

(4) The sponsor of an approved program shall ensure that the program is carried out and presented as represented to and approved by the board, and that all responsibilities of the program sponsor, an instructor, and any person or entity delegated or assigned a responsibility relating to a program approved by the board are fulfilled.

(5) The approval of a course shall be effective only for the biennium in which it is approved.

Chir 12.04 Application denials. The board may deny approval of an application submitted under s. Chir 12.03 for any of the following reasons:

(1) The program or program sponsor does not meet requirements established in this chapter.

(2) The emphasis of the program is on the business, management, or insurance aspects of a chiropractic practice rather than on improving the clinical skills of the chiropractor.

(3) The board determines that the program sponsor has not provided adequate assurance that responsibilities delegated or assigned to others will be satisfactorily performed.

(4) Any presentation, program content, materials or displays for the advertising, promotion, sale or marketing of equipment, devices, instruments or other material of any kind or purpose is not kept separate from the program content and presentation for which approval is applied and granted.

Chir 12.05 Revocation of approval. The board may revoke approval of a program for any of the following reasons:

(1) The program sponsor, an instructor, or a person delegated or assigned a responsibility has a financial, personal or professional interest which conflicts directly with the performance of responsibilities in this chapter.

(2) Failure on the part of a program sponsor, an instructor, or a person delegated or assigned a responsibility to carry out a program as represented to and approved by the board or as provided in this chapter.

Chir 12.06 Prohibited practices. (1) A chiropractor shall not delegate to any chiropractic assistant or other person any recommendations, analysis, advice, consultation or dispensing with respect to vitamins, herbs, or nutritional supplements. Nothing in this subsection may be construed to prevent chiropractic assistants or administrative employees from processing sales of vitamins, herbs, or nutritional supplements.

(2) After (revisor insert date 24 months after the effective date) a chiropractor shall not sell, barter, trade or give away vitamins, herbs or nutritional supplements unless the chiropractor holds a certificate for nutritional counseling and except as consistent with the provisions of this chapter.

(3) A chiropractor shall not deliver, dispense, administer, transfer or sell a product unless that product is prepackaged for use by consumers and labeled in accordance with the requirements of state and federal law.

(END OF TEXT OF RULE)

The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated _____ Agency _____

Chairperson Chiropractic Examining Board

Ch Chir 12 CR06-051 (Nutritional counseling) Draft for Final Adoption 9-22-06