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Use of Informed Consent with "Experimental" Therapies/Protocols

Chiropractors, like other professionals within the broad profession of public healthcare, may consider adopting treatment therapies or protocols which are not commonly used by other doctors and could be regarded as "experimental" in nature. While chiropractors have the broad education and training which logically justifies their use and implementation of these "alternative and complimentary healthcare practices," the chiropractor, as a profession licensed by a governmental body, must take reasonable steps before implementing such a new therapy or protocol into their practice. A chiropractor should carefully consider all applicable statutory and regulatory requirements within their state of licensure in order to maintain those basic requirements of their licensed privileges when utilizing the new protocol or therapy. A review of the statutes and regulations should involve an analysis of the State's definition of the practice of chiropractic, description of the scope of chiropractic, and consideration of other regulated standards and marketing practices. As it relates to the practice of chiropractic in Wisconsin, several of these important considerations are described below:

A. Meeting the Definition of Chiropractic

The broad definition of the science of chiropractic in Wisconsin is presented in CHIR 4.02(1). Within that definition of "chiropractic science", Wisconsin recognizes that "disease or abnormal function" may be caused by many factors, including "biochemical factors". A doctor utilizing a new therapy or protocol should insure that the technique seeks to reduce, detect, or eliminate any of the various factors which produce "disease or abnormal function". The doctor should be prepared to produce reliable studies or research on how the new therapy or protocol contributes to the overall objective of chiropractic in eliminating such disease or abnormal function.

B. Meeting the Scope of Chiropractic

Although many new techniques can arguably be designed to fit within Wisconsin's definition of chiropractic science, greater attention often must be given to whether the therapy or protocol fits within the scope of chiropractic as commonly practiced by other doctors in this state. Specifically, CHIR 4.03 addresses the actual practice of chiropractic in this State by placing a more specific emphasis upon the "adjustment" and "the use of procedures and instruments preparatory and complimentary" to such treatment.

A determination of whether a new practice or protocol fits within the scope of practice of chiropractic often depends upon the interpretation of the "preparatory and complimentary" language as contained within the administrative code in Wisconsin. A "narrow" interpretation of this language might conclude that a new protocol or therapy is not specifically developed as a procedure for the treatment of the spinal column or articulations, and adjacent tissue. However, under a "broad" interpretation, a new therapy or protocol may not be prohibited unless it fits within one of the "prohibited chiropractic practices" defined in CHIR 4.05 and could arguably be interpreted as "preparatory" in nature through its overall objective of improving healthy organ or spinal function. Of particular concern with this "broad" interpretation is the determination as to whether the new therapy or protocol appears to be more of a "practice system" or "protocol" which operates largely or on its own without extensive involvement of "adjustments" to the spine in potential violation of prohibitive practices defined in CHIR 4.05(2)(f),(g). These sections of the Administrative Code include the following prohibitive practices:

> (f) Any practice system, analysis, method or protocol which does not include the competent assessment, evaluation or diagnosis of the condition to be treated before beginning treatment of the patient.
>
> (g) Any practice system, analysis, method or protocol which relies upon diagnostic methods that are not generally recognized or accepted within the profession or which do not have scientific validity.

C. Other Practice Standards and Marketing Practices

Another consideration when analyzing complimentary therapies is whether the activity may result in "unprofessional conduct" prohibited under Chapter 6 of CHIR. As it relates to a new therapy or protocol, particular attention should be given to the following practice standards of CHIR 6.02:

> 6.02(3) – must insure that the protocol improper the standard "SOAP" process.
> 6.02(9) – important to maintain a complimentary exam justifying use of this protocol.
> 6.02(10) – insure that disclosure of analysis to third parties does not expose confidential patient information.
> 6.02(14) – billing arrangements must be considered.
> 6.02(15) – must not "over promise" results of any therapy.
> 6.02(15f) – avoid false promotion.
> 6.02(31) – nutritional counseling implications.

It should be noted that after December 1, 2008, CHIR 12.06 mandates that a Wisconsin Chiropractor cannot sell "nutritional supplements" unless the doctor holds a certificate in nutritional counseling. "Nutritional supplements" are defined under CHIR 12.01(4). Many new therapies or protocols involve the sale of devices or container which utilize "nutritional supplements."

Informed Consent

When utilizing an experimental therapy or protocol, it is prudent for a doctor to obtain the express, informed consent of the patient. Wisconsin's statutory informed consent language for chiropractors is stated in Wis. Stat. §446.08. **(Further information on this statute is available at other white papers on this website.)** A patient's written informed consent is regarded as a ongoing process by which a patient consents to ongoing examination and treatment as the doctor evaluates substantially changing conditions necessitating chiropractic care. Although the informed consent does not need to be in writing, the patient's healthcare records should clearly reflect that the doctor received the informed consent of the patient or patient's legal guardian

before the examination, diagnosis, testing and resulting treatment. (See CHIR 11.02, enclosed.) It is normally recommended that the daily notes of a chiropractor reflect that there was discussion resulting in the patient's consent to ongoing treatment; if there is not already in existence a separate informed consent form within the patient's file.

From a general perspective, the patient's informed consent should include the following features when the doctor is utilizing a new or exploratory protocol/therapy:

1. Accurate and clear description of the key aspects of a new protocol or therapy, to including:
    a. Indicate that a new protocol/therapy is regarded as a form of complementary and alternative healthcare.
    b. Indicate that a new protocol/therapy is an unregulated complementary and alternative health care protocol.
    c. Describe the "theory" behind the treatment.
    d. Briefly indicate nature of a new protocol/therapy treatment; with description of the initial examination, follow up care, and means of revaluation.
    e. Indicate the duration of care and physical experiences which the patient may undergo through protocol or therapy.

2. Accurate and complete the description of and clearly describe what the new protocol or therapy does <u>not</u> consist of, including:
    a. Indicate that a protocol may not be recognized or otherwise approved by the federal drug administration; or other similar federal and state regulatory bodies.
    b. Indicate that this protocol is not commonly recognized or utilized as part of common chiropractic procedure in the State and throughout other areas of the world.
    c. Indicate that the protocol does not constitute homeopathy or homeopathic medicine.
    d. Indicate that you are not a licensed holistic physician and that the State of Wisconsin does not regulate such discipline.

3. Address the issue of charges and insurance. Clearly indicate that there are charges for the service (consider attaching a schedule of fees) and state that those fees will not be paid by insurance or Medicare.

4. Clearly describe the potential risks of receiving such therapy. Specific reference to studies can be offered to the patient and patient should be advised of their right to refuse this form of therapy; as well as resort to alternative forms of treatment.

5. Explicitly state that the protocol is not subject to any educational and training standards either in this State or in a national basis and that it is part of a therapy which is unregulated, and unmonitored.

6. Explicitly indicate that a new protocol/therapy should not be regarded as a protocol for the care and treatment of any specific disease and that this it should not be regarded as a substitute or replacement for the care a patient has or may receive from a medical doctor or other form of licensed physician/healthcare provider. Patient should be reminded that a new protocol/therapy should not be regarded as an alternative to medical treatment and that the patient is free to consult with a physician for any reason, including the administration of medications.

7. Patient should be clearly advised that no representations, warranties, guarantees, or promises have been made regarding the effectiveness, safety, or efficacy of a new protocol/therapy as a means of improving a patient's health condition.

It is strongly recommended that any chiropractor developing an informed consent for a new or exploratory therapy or protocol should have the informed consent document clearly reviewed by a qualified legal professional.