

**Board of Chiropractic Examiners**  
**INITIAL STATEMENT OF REASONS**

**Hearing Date:** None

**Subject Matter of Proposed Regulations:** Informed Consent

**Sections Affected:**

The proposed regulations would add Section 319.1, which is contained in Article 2 in Division 4 of Title 16 of the California Code of Regulations (CCR).

**Introduction:**

The Chiropractic Initiative Act Section 1000 – 4(b) authorizes the Board of Chiropractic Examiners (Board) to adopt regulations as they may deem proper and necessary for the performance of its work, the effective enforcement and administration of this act, the establishment of educational requirements for license renewal, and the protection of the public.

Additionally, Section 1000-10(a) of The Chiropractic Initiative Act authorizes the Board to adopt, amend or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of professional service and the protection of the public.

Although there are no laws or regulations which currently require Doctors of Chiropractic in California to obtain informed consent from their patients prior to providing chiropractic care, informed consent is considered a standard of care that should be utilized in the chiropractic profession. Informed consent is a two-part process, which includes verbal discussion between the Doctor of Chiropractic and a patient regarding the material risks of a procedure followed by documentation signed by the patient acknowledging that the material risks of the recommended treatment have been disclosed and that the patient understands the risks and agrees to the recommended treatment based on the information provided by the doctor. This process ensures that patient's rights to self-determination regarding their health care are paramount. The informed consent standard regarding disclosure of material risks of a medical procedure are also specified in publications such as the California Civil Jury Instructions (CACI No. 532) and the Book of Approved Jury Instructions (BAJI 6.11).

A power poll conducted by the Federation of Chiropractic Licensing Boards in November of 2008 and repeated in March of 2011 revealed that nine (9) states currently have rules, regulations or statutes that specifically mention informed consent for the practice of chiropractic. Although the other states do not have formal requirements for informed consent in rules, regulations or statute, seven of these state licensing boards recommend the use of informed consent for the practice of chiropractic.

The American Chiropractic Association (ACA) adopted a policy supporting the use of informed consent for chiropractic care. The policy recommends that the process of informed consent include an ongoing discussion throughout the patient's course of care that includes the Doctor of Chiropractic's recommended course of action and the nature of any recommended examination procedure, diagnostic test or treatment intervention, a discussion of reasonable alternatives to the proposed course of action, a discussion of the benefits and material risks and options related to the proposed course of action, the patient's voluntary acceptance of the proposed course of action and appropriate documentation in the patient's file indicating that this process took place. Although the ACA has adopted this informed consent policy, it does not have the force of law; therefore, the ACA cautions the Doctor of Chiropractic to consult with their personal attorney, malpractice carrier, state licensing board and case law to determine the legal standards that are required in each state.

The Association of Chiropractic Colleges (ACC), whose members consist of numerous chiropractic colleges throughout the world, and include those approved by the Board, adopted an Informed Consent Guideline to encourage each of its programs to conduct their practice in accordance with the guidelines for greater safety and understanding for patients. In the Informed Consent Guideline, the ACC recommends that prior to performing diagnostic testing and prior to implementing chiropractic procedures, the patient should be informed about the material and inherent risks and common options to the recommended care and the associated risks, including the risk of refusing care. The ACC recommends that a program be incorporated at all member institutions to ensure students learn the concept(s) regarding informed consent by incorporating in the classroom and clinics a process allowing for compliance and educational instruction at every level of the educational encounter.

While chiropractic students who apply for licensure in California are trained in the use of informed consent, not all choose to incorporate this practice in their business once licensed. This proposal will enhance consumer protection by requiring chiropractors and their patients to be active participants in the patient's chiropractic treatment plan. The Board does not choose to require informed consent for every chiropractic examination or procedure as the risks involved with most chiropractic procedures are minor or unlikely to occur. Nor does the Board wish to prescribe the type of informed consent form or specific material contained therein which should be used. Rather, this proposal would require the use of informed consent when there is a risk of serious bodily harm that may result from the proposed care to ensure patients are aware of the risks associated with some chiropractic treatments and are able to make an informed choice of whether the proposed treatment is in their best interest. This proposal would not create a new standard. Instead, the proposed regulation would reinforce an existing standard of care by providing licensees with a written regulation to ensure that they follow the standard of care regarding informed consent when a proposed treatment presents a material risk to the patient, as well as provide the Board with additional authority to enforce this requirement.

**Specific Purpose and Factual Basis of each adoption, amendment, or repeal:**

Section 319.1(a) is added:

The purpose of this proposed regulation is to protect consumers of chiropractic care by ensuring that each patient is informed both orally and in writing of any known risk of serious bodily harm that may result from the proposed care so that the patient can make an educated decision regarding their chiropractic care.

Specifically, the proposed regulation would require all licensed doctors of chiropractic in California to inform each patient verbally and in writing of the material risks of proposed care and obtain their written informed consent prior to initiating clinical care. The proposed regulation would define “material” as a procedure inherently involving known risk of serious bodily harm and would require the patient’s signed written consent to become part of the patient’s record.

This proposal is necessary for protection of patients of chiropractic services and would ensure that all doctors of chiropractic in California incorporate informed consent in their practice when the proposed treatment presents a known risk of serious bodily harm to their patient which would afford chiropractic patients autonomy in making an informed decision regarding their care.

Section 319.1(b) is added:

The proposed regulation would define a violation of this section as unprofessional conduct and would give the Board authority to take disciplinary action against a licensee for violation of this section.

This proposal is needed to provide the Board with authority to discipline licensees who fail to comply with this requirement.

#### Underlying Data:

- Board Meeting Minutes – December 2, 2010 (Proposal approved)
- Association of Chiropractic Colleges – Informed Consent Guideline
- American Chiropractic Association: Chiropractic Profession Supports Patients’ Right to Know Benefits, Risks Of all Treatments – The Stree, January 1, 2010
- Informed Consent – The Chiropractic Report - July 2006, Vol. 20, No. 4
- Informed Consent – Encyclopedia of Everyday Law
- Communication Central to Informed Consent by William Moreau, DC, DACBSP and William Stoos, JD – Journal of the American Chiropractic Association, May/June 2006
- Informed Choice and Consent for Cervical Spine Manipulation by Kate Haswell – Australian Physiotherapy Professional Issues, Vol. 42, No. 2 1996
- Informed Consent – American Cancer Society (Rev. 8/10/2010)
- Torts – Civil Procedure, Bronneke v. Rutherford, 89 P.3d 40, 42 (Nev. 2004) by Ronda Heilig– Nevada Law Journal
- Informed Consent – Definition – California Civil Jury Instructions (CACI No. 532)
- Reality of Consent – Physician’s Duty of Disclosure [Informed Consent] – Book of Approved Jury Instructions (BAJI 6.11)
- Federation of Chiropractic Licensing Boards (FCLB) Power Polls – Informed Consent (March 11, 2011)

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts or evidence/documents/testimony:

This proposal would impact licensees who do not currently obtain informed consent from patients, for which the overall cost is minimal to non-existent. The proposal allows the chiropractor the freedom to create their own informed consent form or use existing informed consent forms available through professional associations, colleges, etc. Although the numbers of malpractice cases against licensees are unknown to the board, it is estimated that the proposed regulation may result in a decrease in malpractice suits against chiropractors, resulting in a savings to the chiropractor.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation.