

BOARD OF CHIROPRACTIC EXAMINERS
FINAL STATEMENT OF REASONS

Hearing Date: N/A

Subject Matter of Proposed Regulations: Informed Consent

Section Affected: Article 2, Division 4, Title 16 of the California Code of Regulations, Section 319.1.

Updated Information: The Initial Statement of Reasons is included in the file. There were no comments received which warranted changes to the proposed language.

Updated Specific Purpose and Factual Basis of Each Adoption, Amendment or Repeal:

Adopt Section 319.1

There were no changes made during the rulemaking process which affect the purpose or rationale stated in the Initial Statement of Reasons for adoption of Section 319.1.

Written Comments Received During the 45-Day Comment Period

Comment 1.1:

Dr. Kenneth Martin, D.C. asserts that the proposed regulation will not protect the public.

Response 1.1:

The Board disagrees and rejects this comment. The proposed regulation would require doctors of chiropractic to discuss the material risks of chiropractic treatment as well as obtain their written consent prior to providing the treatment. This process will ensure that patients are aware of the risks of the proposed treatment so that they can make an educated decision regarding their health care. Further, informed consent is considered a standard of care that should be utilized in the chiropractic profession.

Comment 1.2:

Dr. Martin, D.C., believes that the wording on this proposal is so vague as to ‘choke’ all conversations between doctors of chiropractic and their patients into a fear of the care that can be provided.

Response 1.2:

The board disagrees and rejects this comment. The purpose of the proposed regulation is not to instill fear of chiropractic services in patients; rather, this proposal will require chiropractors to inform patients of the material risks of procedures involving a known risk of serious bodily harm. The board agrees that chiropractic is a safe modality of treatment; however, there are some chiropractic procedures and/or medical conditions

which may put the patient at risk of serious bodily harm. The board believes that, under these circumstances, it should be a requirement to inform the patient of the serious risk(s) of the proposed treatment so that the patient can decide whether the benefits outweigh the risks that may result from the treatment.

Comment 1.3:

Dr. Martin, D.C., states, “Given the number of iatrogenic illnesses caused by medical physicians, I could not imagine them having to discuss with patients each and every side effect of every medication or procedure.” Dr. Martin wants to know why the chiropractic profession would be required to do more than any other health profession.

Response 1.3:

The board rejects this comment. This proposal does not require chiropractors to disclose each and every side effect of the proposed treatment. This proposal requires chiropractors to use their professional expertise determine the risks of a treatment and to disclose only those risks which may cause serious bodily harm to the patient. Informed consent is considered a standard of care in the health care profession and is taught in chiropractic colleges. Further, our judicial system requires health care professionals to use informed consent, pursuant to the Book of Approved Jury Instructions 6.11(BAJI), subdivisions (a) and (e). Subdivision (a) states, in part, “It is the duty of the physician to disclose to the patient all material information to enable the patient to make an informed decision regarding the proposed treatment.” Subdivision (e) states, in part, “However, when a procedure inherently involves a known risk of death or serious bodily harm it is the physician’s duty to disclose to the patient the possibility of such outcome and to explain in lay terms the complications that might possibly occur.” As such, jurors would expect to see the use of informed consent in such cases.

Comment 1.4:

Dr. Martin, D.C., believes that the proposed language opens up too many areas where DC’s could be persecuted for not providing “something” that a legal person would otherwise consider as “serious bodily harm”. He also stated that he would support this proposal if specific language were presented for adoption such as the copy of the informed consent form provided with his comments.

Response 1.4:

The board rejects this comment. The board is unable to adopt specific informed consent language as the risks of a treatment vary from one patient to another based on age, physical health, medications, surgeries, etc. The board believes that chiropractors, as diagnosticians, should be able to use their expertise to determine whether a recommended treatment may pose a risk of serious bodily harm to their patient, and under such circumstances, disclose the risk(s) to the patient so that the patient has adequate knowledge to make decisions regarding their health care. Conversely, if a patient were harmed by a chiropractic treatment without having been warned of the risks, nor provided informed consent for the treatment, an expert witness for the profession would likely determine this as a deviation from the chiropractic standard of

care which could result in administrative or disciplinary action against the chiropractic license as well as result in a malpractice suit. Further, the type of disclosure would depend on the proposed treatment and factors described above; therefore, licensees may want to seek legal guidance regarding the language to use on different informed consent forms.

Comment 2.1:

Joseph Homesley, D.C., questions the frequency of which chiropractic patients incur “serious bodily harm” and would like the board to provide statistics confirming the frequency and type of “procedure” involved.

Response 2.1:

The board rejects this comment. The frequency with which chiropractic patients incur “serious bodily harm” is irrelevant. Informed consent is a tool to ensure that chiropractic patients are provided with relevant information regarding the risks of a proposed treatment so that they can make an informed decision on whether or not to proceed with the treatment. This proposal will not prevent all cases of serious bodily harm to chiropractic patients, but rather ensure that the patient is aware of the risks prior to consenting to proceed with the treatment. Further, there are too many variables affecting chiropractic treatments and their corresponding risks based on a patient’s age, physical health, medications, etc., for the board to provide statistics. As a consumer protection board, we believe that the patient is entitled to know the benefits as well as the risks of a proposed treatment. As mentioned in Comment 1.2, chiropractic is a relatively safe modality; however, numerous factors such as age, surgeries, medications, health, etc. may increase the risks associated with an otherwise safe or routine procedure. The board believes that chiropractors, as diagnosticians, should be able to use their professional expertise to determine whether a recommended treatment, combined with the variables mentioned above, may pose a risk of serious bodily harm to their patient, and under such circumstances, disclose the risk(s) to the patient so that the patient has adequate knowledge to make decisions regarding their health care.

Comment 2.2:

Joseph Homesley, D.C., argues that the statement included in the board’s Initial Statement of Reasons which states, “Nine states mention informed consent” does not constitute support for “a standard of care that should be utilized in the chiropractic profession”.

Response 2.2:

The board disagrees and rejects this comment. The board chose to include a poll conducted by the Federation of Chiropractic Licensing Boards, as **one part** of its underlying data, to show that other states have laws or regulations regarding informed consent for the practice of chiropractic. This poll, which is included as Underlying Data, provides information on how other states address informed consent for the practice of chiropractic. Specifically, this poll asks the following questions: 1) Do you regulations, rules, or statutes mention informed consent? 2) If not, is your board planning on

addressing informed consent in the near future? 3) Is informed consent suggested or required? 4) If your regulations do require informed consent, do they dictate whether the consent is to be verbal or written? 5) If informed consent is required, does it apply to all aspects of chiropractic care or is it limited to select areas such as the use of unproven treatment procedures? 6) If limited, please specify. This data was provided to show trends regarding adoption of informed consent laws or regulations by other chiropractic state licensing boards. Further, informed consent is considered a standard of care in the chiropractic profession in this state, which is further evidenced by the curriculum and policies adopted by chiropractic colleges, and are included as Underlying Data in this rulemaking package. Therefore, the board's proposal is not unprecedented.

Comment 2.3:

Joseph Homesley, D.C. asserts that "disciplinary action" is not outlined. He also believes this proposal would only serve to increase the board's revenue with no increased "protection of patients of chiropractic services" and no change in authority to oversee and discipline care outside of the accepted arena of treatment.

Response 2.3:

The board rejects this comment. Disciplinary action is outlined in the board's Disciplinary Guidelines which are incorporated by reference in California Code of Regulations Section 384. One of the purposes of this proposal is to define a violation of this proposed section as unprofessional conduct, which provides the board with authority to take disciplinary action for violations of this section in accordance with the Disciplinary Guidelines.

Comment 2.4:

Joseph Homesley, D.C. claims that the board estimates that the proposed regulation may result in a decrease of malpractice suits with no statistics to support such a claim.

Response: 2.4:

The board rejects this comment. The board believes that it is logical to predict that if a patient knows about the potential risks associated with a proposed treatment, and agrees to have the procedure nonetheless, the patient will be less likely to sue if there is an adverse outcome. Further, even if the consumer decides to sue the chiropractor, they will be less likely to prevail in court if the proposed informed consent procedures were followed.

Comment 2.5:

Joseph Homesley, D.C. states that he does not engage in procedures which could "inherently involve known risks of serious bodily harm" and wants to know if he would be violating this proposed regulation if he chose not to provide informed consent.

Response 2.5:

The board has considered this question. The board cannot provide legal advice on this matter. The proposed language clearly states that if there is a known material risk,

disclosure of the risk(s) must be given verbally and in writing to the patient prior to performing the proposed treatment. If a procedure does not pose a material risk to the patient, the chiropractor is not required to provide disclosure to the patient. The board believes that chiropractors, as diagnosticians, should be able to use their professional expertise to determine whether a recommended treatment may pose a risk of serious bodily harm to their patient, and under such circumstances, disclose the risk(s) to the patient so that the patient has adequate knowledge to make decisions regarding their health care. Violations will be considered on a case by case basis by the board based on consumer complaints.

Comment 2.6:

Joseph Homesley, D.C. is concerned that the emphasis is the violation from not signing a form rather than the emphasis being to not cause “serious bodily harm”.

Response 2.6:

The board rejects this comment. The cause of “serious bodily harm” and informed consent are two separate issues. The board’s highest priority is protection of chiropractic consumers. As such, the board’s has authority to take disciplinary action against licensees who cause serious bodily harm to their patients through gross negligence or incompetence. This proposal, however, is a proactive approach to ensure that the patient of chiropractic services is made aware of the serious risks that may result from a chiropractic treatment prior to consenting and receiving the treatment and there is documentation of informed consent in the patient’s file. A patient who is educated on the serious risks of a proposed treatment is provided pertinent information which allows them to make informed decisions on whether or not to proceed with the treatment.

Comment 2.7:

Joseph Homesley, D.C. wants the board to define “serious bodily harm”.

Response 2.7:

The board rejects this comment. It is not necessary to define “serious bodily harm”. Doctors of chiropractic are educated and trained to know when a patient may be placed at risk by undergoing specific, chiropractic procedures. It is implied in the proposed language that a chiropractor must reflect on his or her education and training in order to identify the risks associated with chiropractic procedures. If, based on that education and training, it is determined that the procedure involves a known risk of serious bodily injury to a patient, informed consent is required. If a determination is made that a procedure does not involve such risk, the proposed regulation would not apply.

Comment 2.8

Joseph Homesley, D.C. would like the board to explain why informed consent should be a standard of care in the chiropractic profession without the offense outlined in far more specificity.

Response 2.8:

The board has considered this comment and is unclear what Dr. Homesley, D.C is referring to regarding the term “offense”. This proposal is not designed to address an “offense”, but rather protect consumers by ensuring they are aware of material risks associated with a proposed treatment before consenting, thereby allowing a fully informed decision regarding their health care. Informed consent is considered a standard of care in the chiropractic profession in this state as evidenced by the inclusion of this topic in chiropractic college curriculum as well as inclusion in BAJI 6.11.

Comment 2.9:

Joseph Homesley, D.C. wants to know why it makes a difference to a patient or a physician whether an informed consent is signed or not if “serious bodily harm” occurs doing (sic) treatment. He further states that signing a form does not release liability if there is misconduct.

Response 2.9:

The board has considered this comment. Informed consent is not considered a means to prevent misconduct; rather, informed consent is a tool to ensure that chiropractic patients are provided with relevant information regarding the risks of a proposed treatment so that they can make an informed decision on whether or not to proceed with the proposed treatment. The board believes that it is logical to predict that if a patient knows about the potential risks associated with a proposed treatment, and agrees to have the procedure nonetheless, the patient will be less likely to sue if there is an adverse outcome. Further, even if the consumer decides to sue the chiropractor, they will be less likely to prevail in court if the proposed informed consent procedures were followed.

Oral Comments Received at the Public Hearing**Comment 1:**

Dr. Charles C. Davis, D.C., International Chiropractic Association of California supports the use of informed consent; however, he argues that the procedure (relating to a known risk of serious bodily harm) outlined in the proposed regulation conflicts with a ruling of the Supreme Court (*Canterbury v. Spence*, 464 F.2d 772 [D.C. Cir. 1972]) and recommends that the procedure be redefined. He further states that the case, *Cobbs v. Grant*, indicates that taking a blood pressure can cause serious bodily harm.

Response 1:

The board disagrees and rejects this comment. As a consumer protection agency, the board has an obligation to protect consumers from chiropractors who are aware that certain procedures carry with them risks of serious bodily harm to patients and, nevertheless, fail to disclose such risks. A patient’s right of self-decision can only be effectively exercised when patients are informed of dangers associated with certain chiropractic procedures. It is implied in the proposed language that a chiropractor must reflect on his or her education and training in order to identify the risks associated with chiropractic procedures. If, based on that education and training, it is determined that

the procedure involves a known risk of serious bodily injury to a patient, informed consent is required. The proposed language does not require the disclosure of information that is not known to a chiropractor, nor does it require a chiropractor to obtain a patient's consent prior to performing all chiropractic procedures; it merely prohibits a chiropractor from intentionally keeping specific information (material risks) from a patient that, if revealed, could have an impact on a patient's decision regarding proposed care. The board believes that the proposed language is the best approach to address a patient's right to specific information that is needed to make an informed decision when a procedure has the potential to expose the patient to serious harm.

ALTERNATIVES DETERMINATION:

The board has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulations.

LOCAL MANDATE DETERMINATION: The proposed regulations do not impose any mandate on local agencies or school districts.