

California Board of Chiropractic Examiners (CBCE) enacts regulation requiring verbal and written informed consent prior to chiropractic care

Overview

As of October 7, 2011 every California Doctor of chiropractic will be required to provide each patient they provide care to with a verbal and written informed consent related to the care they will receive. The regulation which began with the release of a notice to amend the regulations relating to the practice of chiropractic, was reviewed and approved by the Office of Administrative Law (OAL) and was noticed to the profession as a fully enacted regulation on **October 7, 2011**. In California, an appropriately adopted regulation carries the strength and force of law and as a result is binding on all persons licensed to practice chiropractic.

The Regulation

The new regulation can be found in the California Code of Regulations, Title 16, Division 4, Article 2, Section 319.1 and reads as follows:

Informed Consent.

(a) A licensed doctor of chiropractic shall verbally and in writing inform each patient of the material risks of proposed care. "Material" shall be defined as a procedure inherently involving known risk of serious bodily harm. The chiropractor shall obtain the patient's written informed consent prior to initiating clinical care. The signed written consent shall become part of the patient's record.

(b) A violation of this section constitutes unprofessional conduct and may subject the licensee to disciplinary action.

The Disclaimer

I am not an attorney. I am not offering legal advice. If you need legal advice about this regulation or any other matter you should contact a duly qualified legal adviser.

The goal of this information is to educate the California chiropractor about the existence of the regulation, to offer perspective about the regulation itself and the context in which it has been established.

Where Did This Regulation Come From?

The regulation was conceived, developed and implemented by the CBCE. An initial public hearing was held on May 19, 2011. The CBCE released an “Initial Statement of Reasons” (ISR) associated with the regulation. The ISR included the following statement:

“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).”

The ISR, from my viewpoint, is an accurate statement of fact with one important exception. The comment: “...informed consent is considered a standard of care that should be utilized in the chiropractic profession.” is an opinion offered by the Board as opposed to a statement of fact. At this point the issue is mute. With the enactment of the regulations and with the regulation carrying the force of law it is now factual to say that in California informed consent is the standard of care in the practice of chiropractic.

It has been speculated that this regulation was brought about as a result of the involvement of members of the CBCE as expert witnesses in litigation related to

the practice of chiropractic who wish to clarify any ambiguity with respect to **the** requirement for informed consent by Doctors of chiropractic in California resolved.

Agree or disagree, like it or not, informed consent for chiropractors becomes the law in California as of October 7, 2011.

Getting Your Head Around It!

The mechanics of including an informed consent discussion with patients and the inclusion of a written statement of informed consent are not complex and they can be implemented with minimal disruption to your current office procedures. That being said, the biggest problem getting this regulation implemented resides in the heart and mind of the chiropractor who views this requirement as an over-the-top and unnecessary requirement of practice or a requirement that will inappropriately deter patients from seeking chiropractic care. Proponents of the informed consent process view the experience as strengthening the doctor-patient relationship as well as helping to insulate any risk which may result from an allegation of “failure” to provide informed consent which has become commonplace.

Chiropractors appropriately consider chiropractic care to be a very safe and effective form of care. We often think of the limited types and numbers of problems associated with our care and contrast that with the type and number of problems associated with medical care for the cases we see. The data regarding injury associated with the use of medicines as common as acetaminophen and as extreme as spinal fusion are extensive and stunning. The difference in professional liability costs between chiropractors and medical providers is significant and dramatic. These data cause us as chiropractors to take a “give me a break” perspective. While the contrast is striking the individual patient is really the key in the patient-centered world of healthcare that chiropractors have adopted long before it became common expectation in health care delivery.

This regulation isn't primarily about the chiropractor. It is, at its core, a regulation about patient's rights—regardless of provider. The perspective is that the patient has a right to know as much as possible about the suggested care and alternative options including the right to informed refusal they are about to receive from any

and every provider. The ISR stated: “This process ensures that patient’s rights to self-determination regarding their health care are paramount.”

The fact that this process is performed in a lax and virtually meaningless manner throughout health care is not a justification for the chiropractor to approach the process with the same attitude. There is no doubt that informed consent and its adequate delivery to the patient is a big deal and is becoming a bigger deal across all of health care. This situation has been the subject of major articles by major professional publications and many consumer, general population oriented articles.

The Silver Lining

While this process is fundamentally a consumer/patient protection mechanism it is also a provider protective measure as well.

As a result of teaching in the area of cervical spine adjusting and vertebral artery issues I have become involved in a good bit of litigation and pre-litigation activity. When chiropractors provide care absent a statement of informed consent the issue of a lack of informed consent almost always becomes a “cause of action” in any related litigation. The process of appropriately providing a patient with informed consent is informative for the patient and it is protective of the chiropractor. There is an upside to this for the patient and the practitioner.

Informed Consent in General

The Association of Chiropractic Colleges (ACC) developed and published a guideline on informed consent in 2008. It was my pleasure to serve as a member of the task force that developed the informed consent guideline adopted by the member institutions of the ACC. The other members of the task force were Clay McDonald, D.C., J.D., (Texas Chiropractic College) Jean Moss, D.C., M.B.A. (Canadian Memorial Chiropractic College). At the time this guideline was developed I was president of Life Chiropractic College West.

The guideline of the ACC outlined four elements that are parts of an appropriate statement of informed consent. The four components of informed consent in general are:

- (1) the proposed procedure;
- (2) the potential benefits;
- (3) risks of the procedure;
- (4) common alternatives to the procedure, including refusing care and the associated risks of that refusal.

The ACC offered additional guidance to help the chiropractor understand when informed consent is appropriate the key issues underlying the “when” and “why” of informed consent.

Consider the perspectives offered by the ACC:

“(1) the potential severity of the injury or adverse consequences which may result; and

(2) the likelihood that the injury or consequence will occur.

No Doctor is required to disclose every single conceivable risk of a proposed procedure, regardless of how remote that risk of injury might be. However, if a certain risk is a mere possibility which ordinarily need not be disclosed, yet if its occurrence carries serious consequences, as for example paralysis or even death, it should be regarded as a “material risk” requiring disclosure. When in doubt, the Doctor is urged to err on the side of disclosure, rather than non-disclosure, because by erring on the side of disclosure, the Doctor eliminates the frequently surfacing legal/factual question of whether the risk was material.”

Informed Consent in California

With the enactment of the CBCE’s new Informed Consent regulation the California chiropractor has received some basic guidance on the subject from the CBCE.

The central statement of the regulation is:

“A licensed doctor of chiropractic shall verbally and in writing inform each patient of the material risks of proposed care”

The key word in this regulation is “material”. If a risk is not considered “material” the regulation does not require that information about the risk be disclosed. The

regulation itself offers the definition of “material” to be used in the context of this regulation:

““Material” shall be defined as a procedure inherently involving known risk of serious bodily harm.” (Emphasis added)

I must admit that I do not understand the word “inherently” in this regulatory statement. I do not know what it adds or implies. The term that is more understandable in this clause of the regulation is “known risk”. This is an important and critical distinction.

The regulation calls for disclosure of “known risks”, not perceived risks, not suspected risks, not theorized risks, not possible risks. The term used is “known risks”.

In the context of vertebral artery injury that some associate with cervical spine adjusting there are several known details. For example the “known” rate of occurrence of vertebral artery dissection in the population is 0.75 per 100,000 per year or 1 occurrence per 133,000 persons per year.¹ This number has nothing to do with chiropractic care it is the “natural” occurrence of this phenomenon.

The largest, most detailed and most powerful research on the subject of chiropractic care and vertebral artery dissection involving almost 110 million person years indicates that the risk of this condition occurring under chiropractic care is no greater than the “background” risk of this occurring under medical (presumably without cervical spine adjusting). If the risk under chiropractic care is less than the background risk then one can confidently say there is no known risk under chiropractic care.

I may be wrong but I am assuming that one of the key areas this regulation is attempting to address is the perceived relationship between cervical spine adjusting and vertebral artery problems. In light of the discussion above one could conclude (perhaps erroneously) that the regulation does not require disclosure of a perceived or suspected relationship between cervical spine adjusting and vertebral artery injury. That being said I do not believe that was the intent of the regulation, the exacting language of the regulation notwithstanding.

If the requirement of the CBCE expressed in 319.1 is compared to the perspectives offered by the ACC a different conclusion regarding the need for disclosure in this clinical area can easily be reached.

The CBCE calls for a “hard” standard of “material risks” which are defined as “known risks” while the ACC applies a “softer” standard as follows:

“... if a certain risk is a mere possibility which ordinarily need not be disclosed, yet if its occurrence carries serious consequences, as for example paralysis or even death, it should be regarded as a material risk requiring disclosure”

In the world of “standard of care” many people think this is a defined term. In reality it is a variable circumstance that is informed by:

- (1) law and regulation
- (2) the published literature
- (3) the educational community
- (4) the behavior of peers
- (5) Expert witnesses in litigation

While there isn't a great deal published in chiropractic on informed consent what has been published, especially in relation to cervical spine adjusting and vertebral artery issues leans toward disclosure being required. The literature from the medical community exploring this area as it relates to chiropractic care offers a stronger call for disclosure in this environment.

This leaves the California DC with two areas of concern, (1) the fulfillment of the requirements of 319.1 and (2) legal defense of a cause of action related to informed consent. The approach to providing the best protection in both environments is to disclose perceived risks as well as known risks.

Generic Informed Consent Statements

Responding to the expectations of the CBCE's regulation 319.1 should not be difficult, but it will take some time, some thought and some research.

Undoubtedly there will be generic informed consent statements offered by some

in the profession to address the requirements of the new informed consent regulation. While a generic response may be better than no response it may not fulfill the expectation of the regulation. This would not be the case if every DC practiced in the same manner, applied the same evaluation and the same care approaches. We know this is not the case. When a generic form is suggested it is important for the DC to evaluate whether the form addresses all that happens in his/her office.

For example, let's say you provide full spine adjusting without any adjunctive therapies as the form of care provided in your office. In this environment the informed consent statement is relatively simple and straightforward. If a DC also provides traction, electrical stimulation and ultrasound therapy to patients then the informed consent statement for the office above will be deficient. Traction, electrical stimulation and ultrasound each has known risks that need to be disclosed. Add acupuncture to the care provided and another layer of known risks will be encountered.

Detailed Informed Consent Statements

For an informed consent to be meaningful it must address the specifics of the clinical situation and the care to be provided to that specific patient for the specific immediate condition(s). As noted above a generic form is likely better than no form but it does not rise to the level of being an adequate informed consent.

Think about your practice, list the range of services you provide in your office and then consider the risks associated with each intervention (it is easier than it sounds!). Then think about how you would convey this to a patient in an informative and engaging manner.

You can take an approach that while you may not provide every form of care to every patient you will provide a blanket comprehensive informed consent about everything you do to every patient. You can also take an approach that provides informed consent on the specifics of the care you will be providing a patient in the presence of a given problem.

Once you have decided how you are going to approach the written side of the informed consent you need to remember that this is likely the less important part of the process. The key to the process is the **focused** dialogue with the patient. You need to have a conversation with the patient about the care you are going to provide, the benefits and risk of the care, the alternatives to the care you recommend and the effect of doing nothing about the problem the patient is presenting. The patient must have the ability to ask questions about the information you are providing-remember a dialogue, not a monologue!

Perfecting the Delivery

The dialogue noted above together with an accurate written statement is referred to as “perfecting the delivery of the informed consent”. A spectacular form, absent the dialogue does not constitute an informed consent process. A detailed conversation absent the delivery of a written statement of benefits and risks likewise does not perfect the delivery.

When a cause of action related to informed consent is raised the matter will hang on the question of whether the delivery of the informed consent was complete. If so the cause of action will fail, if not it will linger to complicate matters.

Documentation of the Informed Consent

Under 319.1 a chiropractor is required to provide written informed consent to the patient as well as to maintain a copy of the same for the patient record. While the regulations doesn't specifically say that a patient's acknowledgement of the informed consent by way of a signature from the patient must be obtained common sense would seem to argue that this would be the case. Some method to memorialize the fact that the process took place is essential.

Resources to Help You with this Requirement

1. California Board of Chiropractic Examiners
<http://www.chiro.ca.gov/res/docs/pdf/Regulations/Informed%20Consent2.pdf>
2. Association of Chiropractic Colleges
http://www.chirocolleges.org/informed_consent.html

3. Dr. Gerry Clum, PowerPoint presentation entitled: "Informed Consent"
<http://www.drgerryclum.com/>
4. The American Journal of Law and Medicine: Rethinking Informed Consent, 2006
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1284511
5. MedicalMalpractice.com Informed Consent and Patients
<http://www.medicalmalpractice.com/Informed-Consent.cfm>
6. "Come Again? Good Medicine Requires Clarity, New York Times, January 24, 2006
<http://www.nytimes.com/2006/01/24/health/24cons.html?scp=4&sq=Consent+forms+patients+can+understand&st=nyt>

Some Additional Thoughts for Your Consideration...

1. Can I have a CA handle this for me?

A CA, or another DC in the office can provide the patient with the written statement of informed consent. The person providing the care, or directing the care, should have the conversation about the consent with the patient. Having more than one person in this chain of events opens the door for he-said, she-said problems as well as for things to fall through the cracks. The "process" must be a consistent, reliable and uniform part of the practice for every patient.

2. I use a Terms of Care statement, do I need to bother with this?

Yes, yes, and hell yes. I would ask everyone that uses a terms of care statement to go read it and ask yourself one question: "who does it protect?" Terms of care statements are designed to protect the DC, not to inform the patient about the specifics of their problem and the care proposed to address it. Frankly I think terms of care statements as used in most offices are meaningless and a waste of time. They are certainly no substitute for a properly delivered informed consent.

3. Is there a grace period after October 7, 2011 for me to ramp up this process?

No. The regulation and its attendant requirements go into effect on October 7, 2011.

4. Can this be done electronically?

I suppose it could be done with an online delivery system. That would not eliminate the need for the dialogue with the patient. Make sure a system such as this documents receipt by the party to which it was directed and then make all of that part of the patient record.

5. Can I just add this to my HIPAA notice and get one signature and be done with it?

No. A HIPAA disclosure of privacy rights cannot be combined with any other document. HIPAA privacy rights are generic and apply to all patients. The details of an informed consent are generally more personalized to the specific patient and circumstance.

6. Can I charge a patient for this?

No.

7. How will this help or harm my practice?

In today's world of internet searches one only has to "Google" the terms 'chiropractic informed consent' and literally dozens and dozens of forms, articles and other information will appear. This is information you can access as well as your patient. A word of caution, if you obtain an informed consent form over the internet, please be certain your attorney reviews it for completeness. Just as Terms of Acceptance and other similar forms and concepts have appeared in the chiropractic world there are many which have not been properly vetted and are merely opinions of the author(s) who crafted them. Using any form or literature which you have not personally reviewed and agreed to as representative of your practice style is simply a poor practice procedure.

How informed consent can help is a very interesting question, many practitioners who have utilized an informed consent process for decades have not only

reinforced the perception of a better doctor-patient relationship, but have also suggested that the patient's confidence in the doctor and the suggested care intervention has been fortified. Patients who feel empowered by the ability to refuse care, participate in the care determination and be a participant in the care program have been shown to be more compliant with the recommendations for care and more inclined to feel involved in their care plan.

Since the law is established and informed consent in California is now required it would behoove doctors of chiropractic to take this new requirement and turn what some may perceive as an obstacle into a positive patient experience.

ⁱ Cassidy 2008