

Board of Chiropractic Examiners

INITIAL STATEMENT OF REASONS

Hearing Date: March 13, 2012

Subject Matter of Proposed Regulations: Use of Lasers

Section Affected:

The proposed regulation would add Section 302.5, which is contained in Article 1 in Division 4 of Title 16 of the California Code of Regulations (CCR).

Introduction:

Business and Professions Code (BPC) section 1000-4(b), (Chiropractic Initiative Act of California Stats. 1923 p. 1xxxviii), hereinafter Initiative Act, 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, BPC section 1000-10(a) of the 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.

The scope of chiropractic, as described in BPC section 1000-7 of the Initiative Act, authorizes licensed chiropractors to use all necessary mechanical, and hygienic and sanitary measures incident to the care of the body, but does not authorize the practice of medicine, surgery, osteopathy, dentistry or optometry, nor the use of any drug or medicine now or hereafter included in materia medica.

CCR section 302 clarifies that the measures that duly licensed chiropractors are authorized to use in their practice include, but are not limited to, air, cold, diet, exercise, heat, light, massage, physical culture, rest, ultrasound, water and physical therapy techniques in the course of chiropractic manipulations and/or adjustments. Lastly, CCR section 302(a)(3) specifies, in part, that a duly licensed chiropractor may treat any condition, disease, or injury in any patient so long as the methods and treatment do not constitute the practice of medicine by exceeding the scope of chiropractic practice.

The use of lasers in the practice of chiropractic is an emerging technology which is rapidly becoming more commonplace, and the purpose for which they are used within the chiropractic profession is diverse. In January of 2011, the Board received correspondence from California State Senator Bob Huff, 29th Senate District, relating to a public safety issue regarding advertisements by chiropractors claiming they can cure food allergies through laser therapy. Specifically, Senator Huff expressed concern

regarding whether this treatment was within the scope of chiropractic and patient safety. His correspondence included a letter from a parent whose children suffer from severe food allergies resulting in anaphylactic reactions and were forced to seek emergency medical treatment following a laser treatment and exposure for food allergies, numerous advertisements from chiropractors marketing treatment of allergies through laser therapy, as well as a letter from Physicians from the Capital Allergy & Respiratory Disease Center who assert, "There is no known cure for allergies at this time other than avoidance, and any claims to the contrary are deeply troubling to us."

As a result of this correspondence, the Board held public meetings to discuss these concerns and heard testimony from laser manufacturers, other regulatory agencies charged with the regulation of laser manufacturers, lasers, and/or their use, experts in the field, and professional associations. Consequently, it was determined that the lasers specified in the advertisements have not been approved or cleared by the United States Food and Drug Administration (FDA), which ensures the safety and efficacy of such devices.

Accordingly, the Board developed the proposed laser device safety regulations to protect chiropractic consumers and the person administering laser treatments from harm.

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

Section 302.5(a)(1) is added:

The purpose of this proposed regulation is to prohibit chiropractors and any person under their direct or indirect supervision from using lasers in their practice which have not been approved or cleared by the FDA. Currently, the Board does not have any regulations specifically regarding the use of lasers by chiropractors. Furthermore, the chiropractic scope of practice indicates that the use of heat and light (as used in laser therapy) are accepted modalities of treatment within chiropractic. As technology in new modalities emerge, the chiropractor is forced to interpret their scope of practice as it relates to new technology, which can result in the improper, unsafe or fraudulent uses of new modalities in treatment of chiropractic patients. Approval and clearance with the FDA ensures that clinical studies have been conducted to validate the safety and efficacy of the use of a particular laser or a substantially equivalent laser device under specific conditions and for prescribed purposes.

This proposal is necessary to protect chiropractic patients from fraud or physical harm caused by treatments using lasers which have not been proven to be safe and/or effective by the FDA for the specific purpose in which it is used.

Section 302.5(a)(2) is added:

The purpose of this section is to prohibit a licensed chiropractor and any person under their direct or indirect supervision from marketing or advertising the use of a laser or

using a laser for purposes other than treatment consistent with section 302 and the device's FDA approval or clearance. In addition to the laser treatment of allergies, the Board has seen advertisements by chiropractors for laser treatments and the use of laser devices which are either not approved or cleared by the FDA and/or are used for purposes outside of the scope of chiropractic as defined in section 302, as well as outside the FDA's intended purpose for that device. The FDA's approval and clearance processes ensure that the safety and efficacy of a laser device or its substantial equivalent has been proven through clinical trials for which the results are reviewed and undisputed by the FDA. This proposal is necessary to protect chiropractic patients from the false or misleading advertising of laser treatments or use of lasers that have not been proven safe and effective for the purpose in which it is advertised.

Section 302.5(a)(3) is added:

The purpose of this section is to require the licensed chiropractor and any person under their direct or indirect supervision to follow the manufacturer's specified guidelines for the safe use of the laser device. A laser device's potential to cause harm varies from one laser device to another; therefore, the manufacturer's guidelines specify the specific type of safety goggles and other precautionary measures relevant to the specific laser device to prevent harm to the patient and the person administering the laser treatment. This section is necessary to protect chiropractic patients and the chiropractor or person administering the laser treatment from physical harm to the eyes or skin caused by the failure to adhere to the manufacturer's specified guidelines for use of laser device.

Section 302.5(a)(4) is added:

The purpose of this section is to require a duly licensed chiropractor and any person under their direct or indirect supervision to comply with all state and federal laws governing the use of lasers in clinical settings. As laser technology advances, state and federal laws may change to ensure the safe use of laser devices. This regulation is necessary to ensure protection of the patient and the person administering the laser treatments.

Section 302.5 (b) is added:

The purpose of this section is to ensure that laser treatments provided by chiropractors do not exceed the chiropractic scope of practice. Laser treatments that exceed the scope of chiropractic include, but are not limited to, laser ablation or surgical procedures and laser treatment of allergies in cases where there is a known risk of anaphylactic reaction to the individual being treated. There are no restrictions to ensure that laser manufacturers or distributors sell laser devices only to licensees whose scope of practice allows them to provide treatments for that particular laser device. This has led to the use of lasers in chiropractic outside the scope of practice. This provision is necessary to protect chiropractic patients from physical harm caused by laser treatments provided by chiropractors which fall outside their scope and expertise.

Section 302.5(c) is added:

The proposed provision would define a violation of this section as unprofessional conduct which could subject the licensee to discipline by the Board. This section is necessary to provide the Board with authority to discipline licensees who fail to comply with the proposed laser requirements.

Underlying Data:

- Correspondence from Senator Bob Huff dated January 10, 2011
- Draft Minutes of the February 24, 2011 Scope of Practice Meeting
- Minutes of the March 17, 2011 Board Meeting
- Minutes of the July 21, 2011 Board Meeting
- Draft Minutes of the November 17, 2011 Board Meeting (Proposal Approved)

Economic Impact Assessment:

Impact on Jobs:

The Board has determined that the proposed regulation would not affect the creation or elimination of jobs within the State of California. This proposal specifically sets safety standards for the use of laser devices within the practice of chiropractic.

Business Impact:

This regulation would not have a significant adverse impact on the creation of new businesses or the elimination of existing businesses within California or the expansion of businesses currently doing business in California. This initial determination is based on the following facts or evidence/documents/testimony:

This proposal would impact only those chiropractic licensees who choose to use laser devices in their practice for which the overall cost for compliance would be minimal to non-existent. The proposal would provide greater protection to the public and workers who administer laser treatments in chiropractic by establishing safety standards for laser devices used in chiropractic.

Benefits:

Section 1000 – 4(b) of the Business and Professions Code (Chiropractic Initiative Act of California Stats. 1923 p.1xxxviii) authorizes the 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. Further, BPC 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. The specific benefits

anticipated by this proposal include greater protection of public health and safety, as well as improved worker safety by setting standards for the advertising and safe use of laser devices within the practice of chiropractic.

The Board does not anticipate that this proposed regulation will impact ~~the~~ the prevention of discrimination, the promotion of fairness or social equity, or an increase in openness and transparency in business and government.

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.