

by statute is subject to the APA unless a statute expressly exempts or excludes the act from the requirements of the APA. (Gov. Code, sec. 11346.) No exemption or exclusion applies to the regulatory action under review. Thus, before it may become effective, OAL must review this regulatory action for compliance with both the procedural requirements of the APA and certain substantive standards. (Gov. Code, sec. 11349.1.)

Please note that there were numerous provisions of the proposed regulation that failed to meet the consistency, clarity, and necessity standards. Examples of some of the issues are contained in this disapproval. These examples and all of the problems with the regulation must be resolved before the regulation can be approved by OAL. All of the issues have been discussed with Board staff. OAL reserves the right to conduct a complete APA review when the regulation is resubmitted.

As adopted, Title 16 California Code of Regulations section 4152.1 states:

- (a) An occupational therapist who is approved by the Board to perform advanced practices in physical agent modalities may administer topical medications to a patient via iontophoresis and phonophoresis.
- (b) As used in this article “topical medications” means medications for use with iontophoresis or phonophoresis applied locally to the skin or underlying tissue where such medications require a prescription or order under federal or state law.
- (c) Topical medications administered via iontophoresis or phonophoresis shall be applied or administered by an occupational therapist in accordance with this section.
 - (1) Any topical medication applied or administered via iontophoresis or phonophoresis shall be ordered on a specific or standing basis by a practitioner legally authorized to order or prescribe such medication pursuant to Business and Professions Code section 2571(a).
 - (2) Written protocols shall be prepared for the administration or application of medications utilized for iontophoresis or phonophoresis for which a prescription is required under federal or state law, which shall include a description of the medication, its actions, its indications and contraindications, and the proper procedure and technique for the application or administration of medication.
 - (3) Supervision by an occupational therapist of the administration of topical medications under this section shall be in accordance with Article 9.

A. *Clarity*

OAL reviews regulations for clarity, as defined in Government Code section 11349, subdivision (c):

“‘Clarity’ means written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.”

Title 1 California Code of Regulations section 16 provides further guidance on the meaning of “clarity”, stating:

“(a) A regulation shall be presumed not to comply with the ‘clarity’ standard if any of the following conditions exists:

- (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
- (2) The language of the regulation conflicts with the agency’s description of the effect of the regulation; or
- (3) the regulation uses terms which do not have meanings generally familiar to those ‘directly affected’ by the regulation, and those terms are defined neither in the regulation nor in the governing statute....”

Two provisions of the Board’s proposed section 4152.1 fail to meet the clarity standard.

1. *Section 4152.1 (c) (2)*

As noted above, adopted section 4152.1(c)(2) indicates that “Written protocols shall be prepared for the administration or application of medications utilized for iontophoresis or phonophoresis for which a prescription is required under federal or state law, which shall include a description of the medication, its actions, its indications and contraindications, and the proper procedure and technique for the application or administration of medication.”

An occupational therapist reading this section cannot reasonably determine the person or entity responsible for preparing the topical medication protocols required. The rulemaking record seems to indicate members of the Board believed the protocols referred to both the equipment used to administer the medications and the medications themselves. Notably, the sole commenter in the rulemaking record made the same observation as OAL.

The commenter noted the protocols could conceivably be prepared by the Board, a physician, an occupational therapist, an administrator or some other third party. The Board, in its Final Statement of Reasons, rejected this comment “because protocols are usually developed

by the manufacturer of the iontophoresis/phonophoresis equipment. The statute does not require that any specific individual or entity prepare the protocols as long as they are in place.” (Final Statement of Reasons, page 1) This response is misplaced to the commenter’s concern. The protocols required by Business and Professions Code section 2571, as cited in the Reference section of the regulation, apply to the topical medications, not the equipment. Additionally, as explained *infra*, the medication protocols are required to be specified by the Board.

Similarly, the statement in the Initial Statement of Reasons regarding the protocols adds further confusion to this issue: “The proposed regulations require that written protocols be prepared for the administration of the topical medications. *The industry standard is for each facility to establish protocols for equipment use.* Typically these protocols are based on instructions which are included by the manufacturer of the iontophoresis and phonophoresis equipment. The regulation requires that the protocols include a description of the medication, its actions, its indications and contraindications, and the proper procedure and technique for the application or administration of medication.” (Emphasis added.) (Initial Statement of Reasons, page 1.) The Initial Statement of Reasons, as written, confuses the protocols required for the equipment used to administer the topical medications with the protocols the Board is required to specify for the medications themselves. The same is true for the Final Statement of Reasons.

The Initial Statement of Reasons and Final Statement of Reasons fail to adequately address the issue of protocol preparation. This failure, combined with the lack of specificity in the regulation itself, makes the proposed regulation unclear for purposes of Title 1 California Code of Regulations section 16 (a)(1).

2. *Clarity of Definition of “Topical Medications.”*

Section 4152.1 (b), when paraphrased, appears to mean that topical medications are any and all prescription topical medications for use with physical modality equipment. This definition appears to be circular in nature, in that defining topical medications as topical medications is unclear. If the definition of “topical medications” is set by statute, the Board should simply refer to the definition contained in the statute. Because of its circular reasoning, this provision of the regulation is unclear for purposes of Title 1 California Code of Regulations section 16(a)(1).

B. Consistency

OAL must review regulations for compliance with the “Consistency” standard of the APA, in accordance with Government Code section 11349.1. Government Code section 11349, subdivision (d), defines “Consistency” as “being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.”

Section 4152.1 purports to govern who may apply medications by iontophoresis and phonophoresis. In adopting the regulation, the Board cited its desire to implement Business and Professions Code section 2571, which states:

“Section 2571. Licensed occupational therapists; application of prescription topical medications; adoption of and compliance with regulations.

(a) An occupational therapist licensed pursuant to this chapter and certified by the Board in the use of physical agent modalities may apply topical medications prescribed by the patient’s physician and surgeon, certified nurse-midwife pursuant to Section 2746.51, nurse practitioner pursuant to Section 2836.1, or physician assistant pursuant to Section 3502.1, if the licensee complies with regulations adopted by the board pursuant to this section.

(b) The board shall adopt regulations implementing this section, after meeting and conferring with the Medical Board of California, the California State Board of Pharmacy, and the Physical Therapy Board of California, *specifying those topical medications applicable to the practice of occupational therapy and protocols for their use.*

(c) Nothing in this section shall be construed to authorize an occupational therapist to prescribe medications.”

(Emphasis added.)

As drafted, section 4152.1 fails to specify the protocols for the use of the topical medications applicable to the practice of occupational therapy as required by Business and Professions Code section 2571 (b). The regulation only provides that the occupational therapist may administer the topical medications as long as the prescription medication is one of those listed in section 2571(a). Section 4152.1(c)(2) only indicates that written protocols shall be prepared, not who will prepare them. It does not include protocols to be followed, nor does it direct occupational therapists to the location where such protocols may be found. A clear reading of Business and Professions Code section 2571 mandates the Board specify the protocols for the use of topical medications. (See *Clarity, supra*, for additional discussion.) Because the Board has not fulfilled the directive of Business and Professions Code section 2571, the proposed regulation does not meet the consistency standard set forth in Government Code section 11349(d).

C. Necessity.

OAL’s review also requires evaluation of compliance with the Necessity standard stated in Government Code section 11349 (a):

“‘Necessity’ means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality

of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion.”

Title 1 California Code of Regulations section 10 (b) provides instruction regarding what must be included in the rulemaking record to meet the Necessity standard:

“In order to meet the ‘necessity’ standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:

- (1) A statement of the specific purpose of *each* adoption, amendment, or repeal; and
- (2) information explaining why *each provision* of the adopted regulation is required to carry out the described purpose of the provision. Such information *shall include*, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An ‘expert’ within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.”

The necessity stated in the file consists of the following passage from the Initial Statement of Reasons:

“Section 4152.1: The application of topical medications (used for pain management) through iontophoresis (electricity) and phonophoresis (ultrasound) is a practice that has been engaged in by occupational therapists (OT) for many years. Iontophoresis and phonophoresis are physical agent modalities as defined by [Business and Professions Code] Section 2570.2(m) of the OTPA. The proposed regulations will limit the application of topical medications to administration via iontophoresis and phonophoresis. Any medication applied must be ordered on a specific or standing basis by a practitioner legally authorized to order or prescribe such medication.

The proposed regulations require that written protocols be prepared for the administration of the topical medications. The industry standard is for each facility to establish protocols for equipment use. Typically these protocols are based on instructions which are included by the manufacturer of the iontophoresis and phonophoresis equipment. The regulation requires that the protocols include a description of the medication, its actions, its indications and contraindications, and the proper procedure and technique for the application or administration of medication.

The regulations allow for supervision of the administration of topical medications by an OT in accordance with Title 16, Division 9, California Code of Regulations,

Article 9. This will allow occupational therapy assistants, limited permit holders, Level II students, and occupational therapy aides who are under the supervision of OT approved to use physical agent modalities to apply topical medications via iontophoresis and phonophoresis pursuant to the OTPA.

Existing law requires that the Board meet and confer with the Medical Board of California, the California State Board of Pharmacy, and the Physical Therapy Board of California to specify those topical medications applicable to the practice of occupational therapy and protocols for their use. Representatives from each of these boards attended the Advanced Practice Regulatory Committee meeting held August 25, 2005, and testified in support of OTs applying topical medication. Representatives of each board were provided a copy of draft language prior to approval by the California Board of Occupational Therapy at its November 4, 2005 meeting.”

While this statement provides an overview of the applicable law and the goals of the regulation and shows the support of the required consulting agencies, it does not address the statutory basis for the Board to implement protocols for topical *medication* use. Business and Professions Code section 2571 (b) directs the Board to adopt regulations “specifying those topical medications applicable to the practice of occupational therapy and protocols for their use.” The statement of reasons provided in the present rulemaking record addresses protocols for use of the *equipment* (see Clarity and Consistency, *supra*), not topical medications. Since the purpose of the regulation is to implement Business and Professions Code section 2571 which specifically applies to topical medications, the requirements of Title 1 California Code of Regulations section 10(b) have not been met for the provisions of the regulation addressing protocols. Upon resubmission, the Board must explain how the regulation implements Business and Professions Code section 2571.

D. Non APA issue.

Additionally, although not an APA issue, the regulation states that protocols for the application of topical medication must be prepared but does not specify that occupational therapists must follow these protocols once prepared. This may be an issue the Board wishes to address while correcting the issues identified by OAL.

CONCLUSION

For the reasons described above, OAL disapproved this regulatory action because it did not comply with the clarity, consistency, and necessity standards as required by Government Code section 11349.1.

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