State of California
Office of Administrative Law

In re:
Board of Pharmacy

Regulatory Action:

Title 16, California Code of Regulations

Adopt sections: 1730, 1730.1
Amend section: 1749
Repeal sections:

DECISION OF DISAPPROVAL OF REGULATORY ACTION

Government Code Section 11349.3

OAL Matter Number: 2016-0603-02

OAL Matter Type: Regular (S)

SUMMARY OF REGULATORY ACTION

This rulemaking action by the Board of Pharmacy (Board) sets forth requirements and fees for a licensed pharmacist to obtain Board recognition as an Advanced Practice Pharmacist.

DECISION

On July 18, 2016, the Office of Administrative Law (OAL) notified the Board of the disapproval of this regulatory action. The reason for the disapproval was failure to comply with the "clarity" and "necessity" standards of Government Code section 11349.1.

DISCUSSION

Regulations adopted by the Board must generally be adopted pursuant to the rulemaking provisions of the California Administrative Procedure Act (APA), Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code (sections 11340-11361). Pursuant to section 11346 of the Government Code, any regulatory action a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the requirements of the APA, unless a statute expressly exempts or excludes the regulation from compliance with the APA. No exemption or exclusion applies to the present regulatory action under review. Consequently, before these regulations may become effective, the regulations and rulemaking record must be reviewed by OAL for compliance with the substantive standards and procedural requirements of the APA, in accordance with Government Code section 11349.1.

A. CLARITY

OAL must review regulations for compliance with the "clarity" standard of the APA, as required by Government Code section 11349.1. Government Code section 11349, subdivision (c), defines "clarity" as meaning "...written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

The "clarity" standard is further defined in section 16 of title 1 of the California Code of Regulations (CCR), OAL's regulation on "clarity," which provides the following:

> In examining a regulation for compliance with the "clarity" requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:
>
> (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; or
>
> (4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
>
> (5) the regulation presents information in a format that is not readily understandable by persons "directly affected;" or
>
> (6) the regulation does not use citation styles which clearly identify published material cited in the regulation.
>
> (b) Persons shall be presumed to be "directly affected" if they:
>
> (1) are legally required to comply with the regulation; or
>
> (2) are legally required to enforce the regulation; or
>
> (3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or
>
> (4) incur from the enforcement of the regulation a detriment that is not common to the public in general.

In this "Advanced Practice Pharmacist" rulemaking, proposed section 1730.1 fails to comply with the "clarity" standard. Section 1730.1, "Application Requirements for Advanced Practice Pharmacist Licensure," reads:

> For purposes of Business and Professions Code section 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.
>
> (a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and the date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and the area(s) of specialty. For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:

(A) Earned the clinical experience within the required time frame;

(B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210(a)(2)(C), which includes initiating, adjusting, modifying or discontinuing drug therapy of patients; and

(i) The applicant shall provide a copy of the collaborative practice agreement or protocol.

(ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients. For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).

Business and Professions Code section 4210 reads, in pertinent part:

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) [...]

(2) Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) [cont.]

Pursuant to section 16 of title 1 of the CCR, *supra*, proposed regulatory language must be patently clear and unambiguous to a reasonable, directly affected reader, and must be consistent with the effect of the proposed regulatory language as described by the rulemaking agency.

A plain reading of proposed section 1730.1 informs the reader that an applicant must provide to the Board documented proof of compliance with two of the three criteria presented in subdivisions (a) through (c). These subdivisions contain the Board's documentation requirements; the criteria are actually established in Business and Professions Code section 4210, subdivisions (a)(2)(A) through (a)(2)(C). The rulemaking record demonstrates that throughout the one-year APA rulemaking period, members of the interested public were confused as to whether the proposed text allows for Board approval of the application of a person who completed two of the criteria concurrently.

The record contains many comments made during meetings of the Board's Senate Bill 493 Implementation Committee (hereafter, "SB 493 Committee"). The SB 493 Committee, comprised of four members of the Board, was formed to implement multiple components of

Senate Bill 493 (Stats. 2013, ch. 469), which included the enactment of Business and Professions Code section 4210. The following are excerpts from the minutes of these meetings concerning the adoption of proposed section 1730.1 (all references are to section 1730.1):

> "[A committee member] asked if the committee wanted to address the issue of earning their postgraduate experience (b) and clinical experience (c) concurrently. The committee decided not to amend the language as they felt that the experience could be gained concurrently." (February 25, 2015)
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> "The committee discussed whether the postgraduate residency experience (b) and clinical experience (c) could be gained concurrently. The committee felt that the experience could be earned concurrently and asked [DCA counsel] to conduct a legal review to ensure that this was permissible." (April 13, 2015)
>
> "[A member of the public] expressed support for allowing the postgraduate residency experience (b) and clinical experience (c) to be gained concurrently." (April 13, 2015)
>
> "[A member of the public] stated that the experience in (b) and (c) should be gained separately." (April 13, 2015)
>
> "The committee asked [a member of the public] if the intent of the legislation was to allow the postgraduate residency experience (b) and clinical experience (c) to be gained concurrently. [The member of the public] responded that the original language only required pharmacists to fulfill one of the three requirements; so allowing (b) and (c) to be earned concurrently would not be contradictory to the intent of the legislation." (April 13, 2015)

Further comments relevant to this issue were made during APA public comment periods:

> "[1730.1(c)] eliminates any collaborative practice experience that occurred more than 10 years prior to the date of application for licensure as an advanced practice pharmacist from the qualifying criteria, while accepting collaborative practice experience gained during the one-year period of a postgraduate residency without regard to when it occurred prior to the application." (D. Barcon, 1st 15-day comment period)
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> "Further, as currently written, there is nothing to prevent a pharmacist with a one-year residency, assuming 1500 hours working in collaborative practice environments from meeting 1730.1(b) and 1730.1(c). Therefore, 1730.1(c) should specifically preclude any experiential hours earned during a residency that qualifies under 1730.1(b). Such hours should not be able to be 'double dipped' to meet two criteria that were clearly intended to be mutually exclusive." (R. Stein, 2nd 15-day comment period)

The inherent ambiguity in proposed section 1730.1 is apparent from the above excerpts and comments. The rulemaking record shows that prior to and throughout the APA rulemaking period, Board members and interested parties alike interpreted the language of section 1730.1 differently – some reasoning for "double dipping," and others arguing against it. This debate over the meaning and application of the proposed text continues because section 1730.1 does not clearly effectuate the Board's intent.

The Board's current position regarding the meaning of section 1730.1 can be determined based on responses to comments in the rulemaking record. Essentially, the Board maintains that Business and Professions Code section 4210, subdivisions (a)(2)(A)-(C), are clear and unambiguous, and since the proposed text of section 1730.1 either closely aligns with or specifically cross-references the underlying statute, the regulation itself is clear. The Board's statements include:

> "The second comment refers to the practice of double-dipping of hours from a residency program and a collaborative practice agreement. After consideration, the board believes the regulation to be written so that double dipping of experience in one requirement is not allowed or accepted as proof for documentation for the other requirement."
>
> "The statute requires the applicant to meet two of three criteria: earn certification, complete postgraduate residency, and provide clinical services to patients for at least a year under a collaborative practice agreement or protocol. Allowing experience to be used in lieu of a residency so as to count experience twice would undermine the intent of the legislation and statute."

Yet, these statements by the Board are weakened by evidence in the record of the Board's struggle to interpret the Business and Professions Code. If the statute was facially clear, the record would be devoid of all Board analysis of the meaning of section 4210. Instead, the record includes the following statements (emphasis added):

> "[A Board member] asked if the residency program director could sign the letter of completion of a postgraduate residency (required in (b)(2)) and have it also count towards the one year of clinical experience in (c)(2). [Another Board member] commented that the committee previously discussed this and wanted them to be two separate requirements. [The Executive Officer] noted that <u>there is nothing in the statute that separates them, so the board would have to build it in</u>." (February 25, 2015)
>
> "The board discussed whether the experience in 1730.1(b) and (c) could be gained simultaneously. [The Executive Officer] stated that <u>the statute requires that the experience be earned separately</u>." (April 21-22, 2015)

The goal of this discussion is not to question the Board's analysis of a statute it is legislatively mandated to implement and enforce. As stated above, a regulation is clear if the text is consistent with the regulatory effect described in the record. In this case, the record ultimately demonstrates that the Board's intent is to enforce section 1730.1 by not allowing an applicant to use one collection of practical experience to satisfy two separate criteria. However, this effect is not clearly translated to the proposed regulatory text. As written, the text neither definitively allows nor disallows "double-dipping." Due to the fact that the record reflects a plain intent to disallow "double-dipping," the text is inconsistent with the Board's description of the text and thus, fails to meet the "clarity" standard pursuant to section 16, subdivision (a), of title 1 of the CCR.

B. NECESSITY

OAL must review regulations for compliance with the "necessity" standard of Government Code section 11349.1. Government Code section 11349, subdivision (a), defines "necessity" as meaning "...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."

To further explain the meaning of substantial evidence in the context of the "necessity" standard, subdivision (b) of section 10 of title 1 of the CCR provides:

> In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
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> (1) a statement of the specific purpose of each adoption, amendment, or repeal; and
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> (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.

In order to provide the public with an opportunity to review and comment upon an agency's need for a regulation, the APA requires a rulemaking agency to describe the need for the regulation and identify documents relied upon in proposing the regulation in the Initial Statement of Reasons (ISR), pursuant to Government Code section 11346.2, subdivision (b). In the instant case, the Board's rulemaking record includes an ISR, which in turn identifies eleven documents relied upon in support of the proposed regulation text. These documents are a series of SB 493 Committee meeting and Board meeting minutes spanning the time between June of 2014 and June of 2015.

Proposed section 1730.1, *supra*, includes three regulatory provisions that are not supported by substantial evidence in the rulemaking record. These provisions are excerpted below.

> "Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients." (1730.1(c))
>
> "[The Board shall be provided a] written statement from the applicant attesting under penalty of perjury that he or she has [completed required tasks]." (1730.1(c)(1))
>
> "[The Board shall be provided a] written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients." (1730.1(c)(2))

The ISR contains broad, general statements of necessity, providing the reader only with background information and an overview of the action. Still, the documents relied upon supply adequate purpose and rationale for most of the proposed text. Memorialized discussions between Board members, Board staff, legal counsel, and the interested public can be reasonably regarded as a collection of facts and expert opinions proffered to satisfy the substantial evidence standard. Yet, neither the ISR nor the documents relied upon explain the specific purpose and rationale for the proposed regulatory provisions excerpted above.

Regarding the 1,500 hour requirement in section 1730.1, subdivision (c), the ISR is silent and the documents relied upon barely acknowledge its presence in the text. The exchange below is found in minutes of a Board meeting held during January 27-28 of 2015:

> "[A Board member] commented that she would change [1730.1](c) to say 'at least 1,500 hours' instead of one year. [The Executive Officer] recommended keeping in the term 'one year' in order to be compliant with statue [sic]. [The Board member] proposed amending the language to 'at least one year with no less than 1,500 hours....' The Board agreed with this amendment."

This exchange evidences that the 1,500 hour requirement was proposed and included in the text, but identifies no specific purpose for the requirement or reasonable justification for the chosen number of hours. Business and Professions Code section 4210, subdivision (a)(2)(C) does not define "one year" as a certain number of hours, or even an acceptable range of hours from which the Board may choose. Accordingly, when the Board settled on 1,500 hours, it was proposing a discretionary, substantive regulatory change that the APA requires to be explained in the rulemaking record.

Similarly, inclusion of the "under penalty of perjury" requirements in section 1730.1, subdivisions (c)(1) and (c)(2) was a discretionary choice made by the Board. Business and Professions Code section 4210, subdivision (c) mandates: "The board shall adopt regulations establishing the means of documenting completion of the requirements in this section." No further direction regarding acceptable documentation, such as whether to require attestation under penalty of perjury, is present in the statute. The APA requires that the adoption be adequately justified in the rulemaking record before the "necessity" standard is satisfied. Concerning these statements, the totality of the record reveals no reason for their adoption. The reader is left to wonder why, and for what purpose, the Board is requiring these actions.

In sum, the rulemaking record is bereft of purpose and lacks evidentiary support for the provisions of proposed section 1730.1 excerpted above, and therefore fails to meet the "necessity" standard of the APA.

CONCLUSION

For the reasons set forth above, OAL has disapproved this regulatory action. Pursuant to Government Code section 11349.4, subdivision (a), the Board may resubmit this rulemaking action within 120 days of its receipt of this Decision of Disapproval.

Any changes made to the regulation text to address the clarity issues discussed above must be made available for at least 15 days for public comment pursuant to Government Code section 11346.8 and section 44 of title 1 of the CCR prior to adoption by the Board. The Board must document in the rulemaking file its approval of the final text after consideration of all public comments and relevant information, as well as resolve all other issues raised in this Decision of Disapproval, before resubmitting to OAL.

If you have any questions, please contact me at (916) 322-3761.

Date: July 25, 2016

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