

**State of California
Office of Administrative Law**

In re:
Board of Pharmacy

Regulatory Action:

Title 16, California Code of Regulations

Adopt section: 1746.5

**DECISION OF DISAPPROVAL OF
REGULATORY ACTION**

Government Code Section 11349.3

OAL Matter Number: 2016-1109-02

OAL Matter Type: Regular (S)

SUMMARY OF REGULATORY ACTION

This rulemaking action by the Board of Pharmacy (Board) proposed the adoption of section 1746.5 of title 16 of the California Code of Regulations, which would set forth the standards and procedures pharmacists must follow in order to furnish prescription medications to individuals traveling outside the United States.

DECISION

On November 9, 2016, the Board submitted the above-referenced regulatory action to the Office of Administrative Law (OAL) for review. On December 27, 2016, OAL notified the Board of the disapproval of this regulatory action. The reasons for the disapproval were failure to comply with the “consistency,” “clarity,” and “necessity” standards of Government Code section 11349.1. The Board also failed to follow all required procedures under the California Administrative Procedure Act (APA). This Decision of Disapproval of Regulatory Action explains the reasons for OAL’s action.

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 (secs. 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.

I. 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.

As discussed below, two provisions of proposed section 1746.5 fail to comply with the clarity standard of the APA.

Issue 1. Section 1746.5, subdivision (c), provides, in pertinent part:

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) [...]

(2) Completion of an [sic] travel medicine training program, which must consist of at least 10 hours of training and cover each medication related element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012), [Emphasis added.]

(3) [cont.]

According to the introduction of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine, revised 2012 (Body of Knowledge), the document defines the "scope and extent of knowledge required for professionals working in the field of travel medicine. Major content areas include the global epidemiology of health risks to the traveler, vaccinology, malaria prevention, and pre-travel counseling designed to maintain the health of the traveling public." These major content areas are further broken down into more detailed subtopics and lists of recommended curricula. For example, the major content area entitled "Pretravel Assessment/Consultation" contains the subtopics "Patient Evaluation," "Special Populations," "Special Itineraries," "Prevention and Self-Treatment," and "Risk Communications Regarding."

What the Body of Knowledge does not do is specifically isolate which content areas, subtopics, or curricula are "medication-related" elements that must be included in a training program pursuant to proposed section 1746.5, subdivision (c)(2). Further, the text of section 1746.5, subdivision (c)(2), does not provide or otherwise identify the elements of the Body of Knowledge that the Board believes to be "medication-related." This lack of distinct guidance leaves "medication-related" open to more than one reasonable and logical interpretation by each directly affected person, which is a violation of the clarity standard of the APA and section 16, subdivision (a)(1), of title 1 of the CCR.

Issue 2. Proposed section 1746.5, subdivision (c)(1), requires each pharmacist who furnishes travel medications in the form of vaccines to retain documentation of "[c]ompletion of an immunization certificate program that meets the requirements of Business and Professions Code section 4052.8(b)(1)." (Emphasis added.)

However, Business and Professions Code section 4052.8, subdivision (b)(1), requires only the completion of an immunization training program endorsed by the Centers for Disease Control and Prevention (CDC) or Accreditation Council for Pharmacy Education (ACIP). Further,

section 1764.4 of title 16 of the CCR specifies, in subdivision (b)(1), that each pharmacist who initiates and/or administers any vaccine must complete a Board-approved immunization training program. Neither of these existing laws refers to a certificate program. In order to meet the clarity standard of the APA, the Board must clarify that the proposed text is referring to the training programs authorized by existing laws, rather than a separate certificate program.

II. CONSISTENCY

OAL is mandated by Government Code section 11349.1, subdivision (a)(4), to review each regulation adopted pursuant to the APA to determine whether the regulation complies with the “consistency” standard. Government Code section 11349, subdivision (d), defines “consistency” to mean “being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.”

Business and Professions Code section 4052, subdivision (a)(10), permits a pharmacist to “[f]urnish the medications described in subparagraph (A) in accordance with subparagraph (B).” Subparagraph (A)(3) allows furnishing of “[p]rescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.” Subparagraph (B) requires pharmacists furnishing these prescription medications (i.e., “travel medications”) to “notify the patient’s primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider.”

Proposed section 1746.5, subdivision (f), provides, in part:

Notifications: The pharmacist shall notify the patient’s primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. [Emphasis added.]

Subdivision (f) clearly implements the Business and Professions Code provisions above by making specific that pharmacists must comply with the statutory notification requirements within 30 days of furnishing travel medications. Notably, the Board did not distinguish between different types of travel medications, or include different reporting timeframes for furnished vaccines, pills, etc.

Yet, the Board’s existing “Vaccinations” regulation, section 1746.4 of title 16 of the CCR, provides, in part:

(d) Notifications: A pharmacist shall notify each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. [Emphasis added.]

Subdivision (d) of section 1746.4 plainly states that all vaccines – including vaccines furnished to international travelers – must be reported by the administering pharmacist within 14 days. Therefore, the proposed 30-day reporting requirement in subdivision (f) of section 1746.5 directly conflicts with existing law and violates the consistency standard of the APA.

III. 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:

- (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.

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 minutes taken during Board meetings and several of the Board’s Senate Bill 493 Implementation Committee (hereafter, “Committee”) meetings spanning the time between June of 2014 and June of 2015. The 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 amendment of Business and Professions Code section 4052.

Proposed section 1746.5, subdivision (g), includes the following provision:

A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan.

The ISR simply restates the above provision without offering any evidence to explain why a progress note is required to be provided directly to the patient. Further, the Board and Committee discussions captured in the documents relied upon never touch on the progress note requirement. The complete absence of evidentiary support for the adoption of this provision is a violation of the necessity standard of the APA.

IV. INCORRECT PROCEDURE

A. Incorporation by Reference

Section 20 of title 1 of the CCR, cited below in pertinent part, is OAL's regulation on "Incorporation by Reference," and sets forth a number of requirements that apply when a rulemaking agency proposes to incorporate documents by reference in its regulations.

(c) An agency may "incorporate by reference" only if the following conditions are met:

(1) The agency demonstrates in the final statement of reasons that it would be cumbersome, unduly expensive, or otherwise impractical to publish the document in the California Code of Regulations.

(2) The agency demonstrates in the final statement of reasons that the document was made available upon request directly from the agency, or was reasonably available to the affected public from a commonly known or specified source. In cases where the document was not available from a commonly known source and could not be obtained from the agency, the regulation shall specify how a copy of the document may be obtained.

(3) The informative digest in the notice of proposed action clearly identifies the document to be incorporated by title and date of publication or issuance. If, in accordance with Government Code section 11346.8(c), the agency changes the originally proposed regulatory action or informative digest to include the incorporation of a document by reference, the document shall be clearly identified by title and date of publication or issuance in the notice required by section 44 of these regulations.

(4) The regulation text states that the document is incorporated by reference and identifies the document by title and date of publication or issuance. Where an authorizing California statute or other applicable law requires the adoption or enforcement of the incorporated provisions of the document as well as any subsequent amendments thereto, no specific date is required.

(5) The regulation text specifies which portions of the document are being incorporated by reference.

Much of the rulemaking record evinces the Board's intent to incorporate the Body of Knowledge by reference in proposed section 1746.5, subdivision (c)(2). For example, the Informative Digest in the Notice of Proposed Action clearly identifies the Body of Knowledge by title and date, and the document was made available for public viewing during the 45-day APA notice period. The text of section 1746.5, subdivision (c)(2), includes the document title and date of publication,

which are required to fix an incorporated document in time and clearly identify the incorporated document to a directly affected person in accordance with section 20, subdivision (c)(4).

Additionally, the Board rejected a public comment that suggested removal of the 2012 publication date from the proposed regulation text in an effort to prospectively incorporate the most current version of the Body of Knowledge. In the Final Statement of Reasons (FSR), the Board responded that in order “[t]o comply with the spirit of Cal. Code Reg Title 1 § 20, the Board believes it is necessary to reference a specific version (2012) of the ISTM’s Body of Knowledge for the Practice of Travel Medicine.”

Notwithstanding the above, the Board did not properly incorporate the Body of Knowledge by reference. The Board’s FSR does not demonstrate compliance with section 20, subdivisions (c)(1) and (c)(2). The text of proposed section 1746.5, subdivision (c)(2), does not expressly incorporate the Body of Knowledge by reference as required by section 20, subdivision (c)(4). Nor is it clear from the regulation text which portions of the document are incorporated by reference in compliance with section 20, subdivision (c)(5). (OAL notes that properly incorporating by reference only the specifically identified “medication-related elements” of the Body of Knowledge would likely resolve both this procedural defect and the aforementioned clarity issue.) If the Board intends to incorporate the Body of Knowledge by reference, then it must address each of these procedural deficiencies to satisfy the letter, in addition to the spirit, of section 20 of title 1 of the CCR before resubmitting this action to OAL.

OAL notes that the FSR explains that the proposed regulation text “does not formally ‘incorporate by reference’ this body of knowledge; however, the regulation does reference that the required travel medicine training program must consist of at least 10 hours of training and that it cover each medication-related element of the ISTM’s Body of Knowledge for the Practice of Travel Medicine (2012).” This statement is inconsistent with the record. This inconsistency must be resolved before resubmittal of this action to OAL for review.

B. Incomplete Form STD. 399

Government Code section 11347.3, subdivision (b)(5), requires that the rulemaking record contain the estimate, together with the supporting data and calculations, required by Government Code section 11346.5, subdivision (a)(6). Section 11346.5, subdivision (a)(6), requires, in part, the estimate of the cost or savings to any state agency. This paragraph further defines “cost or savings” as “additional costs or savings, both direct and indirect, that a public agency necessarily incurs in reasonable compliance with regulations.” Government Code section 11357 requires that DOF adopt instructions for inclusion in the State Administrative Manual (SAM) prescribing the methods that any agency shall use in making the estimate required by section 11346.5, subdivision (a)(6).

For purposes of reporting this estimate and other information, DOF has developed, and requires regulatory agencies to use, the STD. 399 "Economic and Fiscal Impact Statement." (SAM Chapter 6600, commencing with section 6601.)

SAM section 6615 establishes when financial estimates contained in STD. 399 require the concurrence of DOF. Section 6615 provides in part:

6615 ESTIMATES WHICH REQUIRE DEPARTMENT OF FINANCE ACTION

(Revised and renumbered from 6660 on 03/09)

Subdivision (c) of Government Code Section 11357 specifically authorizes the DOF to "...review any estimate...for content including, but not limited to, the data and assumptions used in its preparation."

A state agency is not required in all instances to obtain the concurrence of the DOF in its estimate of the fiscal impact of its proposed regulation on governmental agencies. Such concurrence is required when the adoption, amendment, or repeal of a regulation results in local agency costs or savings, in state agency costs or savings, or in other nondiscretionary instances such as local/state revenue increases or decreases which must be depicted on the STD. 399 as follows:

- | | |
|----------------------------------|-------------------|
| A.1-Reimbursable Local Costs | B.1-State Costs |
| A.2-Non-Reimbursable Local Costs | B.2-State Savings |
| A.3-Local Savings | B.4-Other |
| A.6-Other | |

In addition, the DOF's approval is required for the inclusion in any such estimate of any statement to the effect that reimbursement of local costs will be requested in a subsequent Governor's Budget, Section A.1 (b) on the STD. 399....

In the rulemaking record, the Fiscal Impact Statement part of the STD. 399 indicates in section B.4, regarding the Board's proposed regulatory action's "Fiscal Effect on State Government":

Since this regulatory proposal will facilitate the expansion of pharmacy practice to include dispensing travel medications, there is the potential that enforcement costs may increase as a result of this regulation. The Board is unable to quantify the potential increase in enforcement costs; however, the Board anticipates it to be minimal.

Pursuant to SAM section 6615, when a state agency indicates that its proposed regulatory action will result in an increase in costs, then the STD. 399 is required to be submitted to DOF for review and a signature obtained from DOF indicating concurrence by DOF before submitting the

STD. 399 as part of the rulemaking record for OAL's review. This did not occur. There is no signature from DOF on the Board's STD. 399. Thus, the Board failed to follow required APA procedures. A review and signature from DOF must be obtained and indicated on the STD. 399 before resubmitting this action to OAL.


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 and consistency 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. Additionally, any supplement to the ISR or other document the Board may create or otherwise propose to add to the record in order to address the necessity issue discussed above must be made available for at least 15 days for public comment pursuant to Government Code section 11347.1 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: December 30, 2016


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