



Enforcement and Compounding Committee Report January 9, 2025

Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member, Vice-Chair
Indira Cameron-Banks, Public Member
Jeff Hughes, Public Member
Seung Oh, Licensee Member, President
Nicole Thibeau, Licensee Member

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The Committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Approval of Draft Minutes from the October 16, 2024 Enforcement and Compounding Committee Meeting

Attachment 1 includes a copy of the draft minutes.

IV. Discussion and Consideration of Implementation of Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility

Background

Assembly Bill 1902 establishes requirements for a pharmacy to provide an accessible prescription label affixed to the container to a patient that is blind, has low-vision, or is otherwise print disabled, under specified conditions. This law further provides that if the accessible prescription label cannot be affixed to the container, the dispenser must provide the patient or their authorized representative with a supplemental document that meets the requirements of this section. (Note: Exempt from these requirements are drugs dispensed and administered by an institutional pharmacy (unless the medication is provided upon release from the health care facility), correctional institution, or licensed correctional pharmacy.)

For Committee Consideration and Discussion

During the meeting, it is recommended that members consider the measure and seek

input from interested stakeholders on proposed regulations to assist consumers and licensees with an understanding of the requirements of the legislation. To help guide the discussion, it may be appropriate for the Committee to consider the following questions.

1. The law specifies that the accessible prescription label be made available in a timely manner comparable to other patient wait times and lasting for at least the duration of the prescription.

Should the Board further define through regulation the phrase, “in a timely manner comparable to other patient wait times?” Staff note that depending on the type of pharmacy, e.g. mail order, community pharmacy, closed door pharmacy, etc., the parameters for “timely manner” could require different provisions.

2. The law specifies that the accessible prescription label must be appropriate to the disability and language of the person making the request through the use of audible, large print, Braille, or translated directions.

- a. Should the Board further define through regulation how a pharmacy will determine what is appropriate to the disability?
- b. Should the Board establish a minimum font size to define “large print?”
- c. Should the Board specify that the accessible prescription label needs to be in the patient centered format?
- d. Staff note that it may be appropriate to establish requirements for pharmacies to develop policies and procedures to provide guidance to pharmacists on how to identify the appropriate accessible prescription label.

3. The law requires that accessible prescription labels must conform to the format-specific best practices established by the United State Access Board and the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (also referred to as the National CLAS Standards).

Should the Board further define through regulation how a pharmacy will educate pharmacists about these standards? Staff note that it may be appropriate to establish requirements for pharmacies to develop policies and procedures to provide guidance to pharmacists on how to evaluate for compliance with these standards.

Following the Committee and subsequent Board discussion, staff will develop proposed regulation text for consideration at a future meeting.

V. Discussion, Consideration and Possible Action on Updates to Self-Assessment Forms Incorporated by Reference

- a. Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13, California Code of Regulations (CCR), Title 16, Section 1715(c)
- b. Hospital Pharmacy Self-Assessment Form 17M-14, CCR, Title 16, Section 1715(c)
- c. Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26, CCR, Title 16, Section 1784(c)

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- d. Automated Drug Delivery System Self-Assessment Form 17M-112, CCR, Title 16, Section 1715.1
- e. Surgical Clinic Self-Assessment Form 17M-118, Business and Professions Code Section 4192

Relevant Law

California Code of Regulations, title 16, section 1715(c) establishes the self-assessment requirements for the pharmacist-in-charge of a community pharmacy to complete a “Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment.” Section 1715 (c) further establishes a similar requirement for the pharmacist-in-charge of a hospital pharmacy serving inpatient consumers to complete a “Hospital Pharmacy Self-Assessment.” Both forms are incorporated by reference in this section of the regulation.

California Code of Regulations, title 16, section 1784(c) establishes the self-assessment requirements for a wholesaler or third-party logistics provider (3PL), through its designated representative-in-charge or responsible manager, to complete a “Wholesaler/Third Party Logistics Provider Self-Assessment.” The form is incorporated by reference in the regulation.

California Code of Regulations, title 16, section 1715.1(c) establishes the self-assessment requirements for the pharmacist-in-charge of an automated drug delivery system (ADDs) to complete an “Automated Drug Delivery System Self-Assessment.” The form is incorporated by reference in this section of the regulation.

Business and Professions Code section 4192 establishes a self-assessment requirement for the consulting pharmacist of a surgical clinic to complete a Surgical Clinic Self-Assessment Form.

Background

As pharmacy law is very dynamic, on an annual basis, the self-assessment forms must be updated to reflect the most current law. During discussions on the proposed updates to the self-assessment forms in February 2023, given that the forms restate law and do not create requirements not already established in statute and regulation, the Board determined updates to the forms could best be facilitated through a streamlined Section 100 regulation process. Regrettably, staff was recently advised by the Office of Administrative Law (OAL) that updates to these forms cannot be made via this streamlined process.

Since that time, Board staff have completed the initial rulemaking package to amend sections 1715 and 1784 and self-assessment forms 17M-13, 17M-14, and 17M-26 (community pharmacy, hospital pharmacy, and wholesaler/3PL), incorporated by reference, to update the forms to include statutory and regulatory changes, which became effective on January 1, 2024 (as approved by the Board in February 2024). The amendments will be noticed for a 45-day public comment period on January 10, 2025.

Additionally, Board staff is working with the Department of Consumer Affairs on the amendment to section 1715.1 and ADDS self-assessment form 17M-112, incorporated by reference, as approved by the Board in February 2023.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review the proposed updates to the self-assessment forms. The forms incorporate the changes considered by the Committee last year and now also reflect additional changes to incorporate more recent changes in pharmacy law.

Given the various stages of promulgation for the respective forms, it is recommended that during the meeting members provide staff with feedback to finalize the draft forms. Once approved by the Board, staff will update the drafts available on the Board's website and will work with counsel on the appropriate manner to update the self-assessment forms currently undergoing the formal rulemaking process.

Attachment 2 includes copies of the updated self-assessment forms. Proposed changes to the forms are reflected in yellow highlight.

VI. Discussion and Consideration of Petition Request Forms used for Petitions for Reinstatement of a License, Petitions for Modification of Penalty, and Petitions for Early Termination of Probation

Relevant Law

Business and Professions Code section 4309 permits a person whose license has been revoked or suspended or who has been placed on probation to petition the Board for reinstatement or modification of penalty, including modification or termination of probation, after not less than the following minimum periods have elapsed from the effective date of the decision ordering disciplinary action:

- (1) At least three years for reinstatement of a revoked license.
- (2) At least two years for early termination of probation of three years or more.
- (3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

Background

Petitioners are required to answer several questions on the application, including but not limited to, questions related to personal history and current and/or prior discipline whether it occurred in California or out of state.

The Board uses different forms to reflect the different types of petitions that may be considered by the Board. Board staff recently revised the petition forms as they had not been revised since 1999.

Recently staff revised the various applications, as detailed below:

1. The petition for reinstatement application form was updated to align the personal

history questions with those used on initial applications for licensure. In addition, the application was converted to a fillable pdf to improve accessibility and ease of use.

2. The petition for early termination of probation and the petition for reduction (modification) of penalty application forms were also converted to a fillable pdf to improve accessibility and ease of use. In addition, the forms were updated to remove questions related to disclosure of arrests or disciplinary information. These questions were removed for streamlining purposes, as this information is reported as part of the renewal application process and as part of standard terms and conditions of probation.

These changes were made in consultation with prior Board counsel but were not reviewed by the Committee or the Board.

More recently, the Licensing Committee considered changes to the proposed individual applications for licensure to update questions related to impairment so that the applications are free of intrusive mental health questions and stigmatizing language.

In advance of the Committee meeting, staff consulted with the Committee chair to review the revised applications and is now proposing a new consolidated application form to be used for all types of petitions.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review updates to the petition forms and provide feedback to staff on the use of the consolidated application. In addition, members might consider delegating to staff to make changes to the application instructions and guidelines in coordination with the Committee chair.

Attachment 3 includes the following:

- Attachment 3a: Proposed New Form
- Attachment 3b: Current Forms (recently updated)
- Attachment 3c: Prior Forms

VII. Discussion and Consideration of Enforcement Statistics

During the first five months of the new fiscal year, July 2024-November 2024, the Board initiated 1,279 complaints and closed 1,250 investigations. The Board has issued 65 letters of admonishment and 295 citations and referred 69 cases to the Office of the Attorney General. The Board has revoked 41 licenses, accepted the disciplinary surrender of 17 licenses, formally denied six applications, and imposed other levels of discipline against 54 licensees and/or applicants.

As of December 1, 2024, the Board had 1,402 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Jan. 1, 2024		Mar. 1, 2024		July. 1, 2024		Oct. 1, 2024		Dec. 1, 2024	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	152	15	107	7	44	6	63	14	43	17
Cases Under Investigation	1,037	146	1,061	134	1,005	136	908	146	964	137
Pending Supervisor Review	286	77	355	85	223	74	147	74	157	60
Pending Second Level Review	81	21	115	26	99	22	229	26	180	49
Awaiting Final Closure	26	19	24	3	56	8	34	14	58	18

Attachment 4 includes the enforcement statistics. Updated statistics that include the data for December 2024 will be provided during the February 5-6, 2025 Board meeting.

VIII. Future Committee Meeting Dates

- March 27, 2025
- June 11, 2025
- October 16, 2025

IX. Adjournment