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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report
April 16, 2026

Maria Serpa, PharmD, Licensee Member, Chair
Renee Barker, PharmD, Licensee Member, Vice Chair
Jeff Hughes, Public Member
Seung Oh, PharmD, Licensee Member, President
Ricardo Sanchez, Public Member
Nicole Thibeau, PharmD, 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. Discussion and Possible Action to Approve Minutes of the January 7, 2026, Enforcement and Compounding Committee Meeting

Attachment 1 includes a copy of the draft minutes.

IV. Discussion and Possible Action to Make a Recommendation to the Board Regarding Proposed Amendment to Title 16, California Code of Regulations, Section 1711, Regarding Quality Assurance Programs

Relevant Law

Business and Professions Code (BPC) section 4125 provides that every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

California Code of Regulations (CCR), title 16, section 1711 further specifies the

requirements that apply to quality assurance programs, and provides that each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy services and prevent errors.

Background

At the February 7, 2024, Board meeting, the Board approved proposed regulation text to amend section 1711 related to quality assurance (QA) programs. Board staff released the proposed text for the 45-day comment period on August 9, 2024, which ended on September 23, 2024. Several comments were received during the comment period. The Board reviewed the comments at the November 2024 Board meeting and voted to amend the text in response to the comments received. Board staff released the revised text for a 15-day comment period on November 15, 2024, which ended on December 2, 2024. One comment was received during this comment period. The Board reviewed the comment at the January 2025 Board meeting and voted to amend the text in response to the comment received. Board staff released a revised text for a second 15-day comment period on January 27, 2025, which ended on February 11, 2025. Three comments were received during this comment period.

At the March 6, 2025, Board meeting, Board members considered the comments received and the regulation text. During the meeting, members discussed the value of having a QA program that requires a systematic review of medication errors. Additionally, the discussion continued regarding the current QA regulation's purpose to advance error prevention by analyzing, both individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause(s) and any contributing factors, such as system or process failures. Members noted that most of the regulation, as written, focused on reporting individual errors, and discussed the need to emphasize a collective system review approach further, potentially by requiring periodic system reviews in regulation. The Board deferred a decision on the QA regulation to allow staff to develop possible language to include an emphasis on collective system review concept.

At the June 2025 Board meeting, Board staff advised that the one-year timeframe to complete the QA rulemaking would end on August 25, 2025, and recommended the rulemaking be withdrawn. The Board voted to withdraw the QA rulemaking. This approach would enable the Board to continue its policy discussion on a collective review process and initiate a subsequent rulemaking with clear regulatory language and policy.

For Committee Consideration and Discussion

During the meeting, the Committee will have the opportunity to review staff recommended amendments to section 1711 and provide feedback. The proposed language addresses documentation and assessment of medication errors to mitigate future errors. In addition, the proposed language adds requirements to analyze and

trend medication error reports to assess causes, contributing factors, and actions necessary to prevent or mitigate future errors.

After discussion of the proposed amendments, should the Committee believe the draft amendments are ready for consideration by the Board, the Committee may refer the draft language to the full Board for discussion and possible action.

Attachment 2 includes a copy of the draft amendments.

V. Discussion and Possible Action to Make a Recommendation to the Board Regarding Updates to Frequently Asked Questions (FAQs) Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023) – Including Updates to FAQs Regarding Medication Error Reporting

Background
As part of its licensee education efforts, the Board has a series of Frequently Asked Questions (FAQs) available on its website to assist licensees in understanding pharmacy law and regulations.

Assembly Bill 1286 included several significant patient safety measures. Based on questions raised by the regulated public, FAQs are periodically updated. Staff suggest additional updates to the current FAQs related to AB 1286.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to review updates to the AB 1286 FAQs and provide feedback to staff. The updates to the FAQs pertain to medication error reporting. Specifically, question number nine related to infusion center pharmacies was updated to provide clarification.

After discussion of the updates, should the Committee believe the FAQs are ready for consideration by the Board, the Committee may refer the FAQs to the full Board for discussion and possible action.

Attachment 3 includes a copy of the updated AB 1286 FAQs.

VI. Discussion and Possible Action to Make a Recommendation to the Board Regarding Updates to Frequently Asked Questions (FAQs) Related to Automated Drug Delivery Systems

Relevant Law
BPC section 4017.3 defines the term "automated drug delivery system" (ADDS) and related terms. Provisions outlining the Board's licensing and operational requirements related to ADDS appear throughout the Pharmacy Law, including in BPC sections 4119.01, 4119.11, and 4427-4427.8.

Background
As part of its licensee education efforts, the Board has a series of Frequently Asked Questions (FAQs) available on its website to assist licensees in understanding pharmacy law and regulations.

Staff are suggesting updates to the current FAQs related to ADDS based on questions raised by licensees and changes to law enacted by the Board's sunset bill, Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025) and Assembly Bill 447 (Gonzalez, Chapter 363, Statutes of 2025). Additionally, staff reorganized and categorized the questions to help the regulated public more easily find topics of interest.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to review the updates to the ADDS FAQs and provide feedback to staff.

After discussion of the updates, should the Committee believe the FAQs are ready for consideration by the Board, the Committee may refer the FAQs to the full Board for discussion and possible action.

Attachment 4 includes a copy of the updated ADDS FAQs.

VII. Discussion and Possible Action to Make a Recommendation to the Board Regarding Updates to the Wholesaler/Third-Party Logistics Provider Self-Assessment (Form #17M-26)

Relevant Law
BPC section 4102 requires the designated representative in charge of the wholesaler or responsible manager of a third party logistics provider to complete a "Wholesaler/ Third-Party Logistics Provider Self-Assessment" form by July 1 of every odd-numbered year, and within 30 days of certain triggering events.

Background
The Board requires specified licensees to periodically engage in the self-assessment process, defined as the process of self-evaluation of a facility's compliance with state and federal laws as a means to promote compliance through self-examination and education. (BPC section 4040.6.) The self-assessment forms include a compilation of relevant laws applicable to the license type. Historically, the Board's self-assessment requirements resided in various provisions of pharmacy law and regulations. The Board's sunset bill, Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025) centralized the self-assessment process into statute. New BPC section 4040.6 provides that the self-assessment process shall be performed on a form approved by the Board in consultation with stakeholders and posted on its internet website. As such, AB 1503 allows the Board to streamline the process of annually updating the forms and ensures consistency in the Board's approach to promoting licensee self-compliance. As part of the current round of updates, the Board is taking the opportunity to not only update

the substance of the forms to reflect new laws and regulations but also to update the format of these compliance tools for ease of use by the regulated public.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to review the newly drafted Wholesaler/Third-Party Logistics Provider Self-Assessment form. It is recommended that during the meeting, members provide staff with feedback to finalize the form.

After discussion of the new form, should the Committee believe the draft self-assessment is ready for consideration by the Board, the Committee may refer the draft to the full Board for discussion and possible action.

Attachment 5 includes a copy of the draft Wholesaler/Third-Party Logistics Provider Self-Assessment form.

VIII. Discussion and Possible Action to Make a Recommendation to the Board Regarding Updates to the Surgical Clinic Self-Assessment (Form #17M-118)

Relevant Law
BPC section 4102 requires the consulting pharmacist of a surgical clinic to complete a "Surgical Clinic Self-Assessment" form, and the professional director to cosign the form, by July 1 of every odd-numbered year.

Background
See item VI above for background information on this item.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to review the newly drafted Surgical Clinic Self-Assessment form. It is recommended that during the meeting, members provide staff with feedback to finalize the form.

After discussion of the new form, should the Committee believe the draft self-assessment is ready for consideration by the Board, the Committee may refer the draft to the full Board for discussion and possible action.

Attachment 6 includes a copy of the draft Surgical Clinic Self-Assessment form.

IX. Discussion and Possible Action to Make a Recommendation to the Board Regarding Updates to the Hospital Pharmacy Self-Assessment (Form #17M-14)

Relevant Law
BPC section 4102 requires the pharmacist in charge of a hospital pharmacy to complete a "Hospital Pharmacy Self-Assessment" form by July 1 of every odd-numbered year, and within 30 days of certain triggering events.

Background
See item VI above for background information on this item.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to review the newly drafted Hospital Self-Assessment form. It is recommended that during the meeting, members provide staff with feedback to finalize the form.

After discussion of the new form, should the Committee believe the draft self-assessment is ready for consideration by the Board, the Committee may refer the draft to the full Board for discussion and possible action.

Attachment 7 includes a copy of the draft Hospital Self-Assessment form.

X. Discussion of Enforcement Statistics

The Board initiated 2,863 complaints and closed 2,185 investigations through the third quarter of fiscal year 2025/26. The Board has issued 72 Letters of Admonishment and 408 citations and referred 181 cases to the Office of the Attorney General. The Board has revoked 48 licenses, accepted the disciplinary surrender of 21 licenses, formally denied 4 application(s), and imposed other levels of discipline against 57 licensees and/or applicants.

As of April 1, 2026, the Board had 2,136 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Apr. 1, 2025		Jul. 1, 2025		Oct. 1, 2025		Jan. 1, 2026		Apr. 1, 2026	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	71	14	107	10	125	7	107	9	83	8
Cases Under Investigation	1,021	143	957	137	987	110	1,189	114	1,334	124
Pending Supervisor Review	295	70	322	65	401	76	410	119	518	116
Pending Second Level Review	93	68	161	41	165	50	148	40	189	79
Awaiting Final Closure	29	52	35	42	58	29	29	45	12	19

Attachment 8 includes the enforcement statistics.

XI. Advisement of Future Committee Meeting Dates

- June 10, 2026
- October 1, 2026

XII. Adjournment