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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
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Enforcement and Compounding Committee Report

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a. Summary of Discussion Regarding and Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1711 Related to 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 the collective system review concept.

During 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.

The proposed amendments recommended by staff include requirements to analyze and trend medication errors to assess causes, contributing factors and actions necessary to prevent or mitigate future errors. Additionally, proposed amendments require that the pharmacy establish policies and procedures that define the pharmacy's overall quality assurance program and aligns the definition of medication error with the definition provided in BPC 4113.1.

Summary of Committee Discussion

During the meeting, members considered staff-proposed amendments to CCR section 1711. Overall, members spoke in support of the amended language which addresses both individual and aggregate medication errors analysis to minimize medication errors and improve patient safety. Members noted there are differences in pharmacy practices and that facilities should define the details of their quality assurance program in their policies and procedures. Members recommended the possible development of an FAQ for licensees.

Members also mentioned that facilities under common ownership may want the flexibility to evaluate medication errors collectively, across facilities. Members noted that the current language allows for facilities to use additional resources to satisfy the requirements including use of corporate administrative offices or third party.

Members discussed excluding errors related to unlicensed ADDS, such as robots and counting machines in pharmacies, from the facilities' annual medication error report sent to the Board. There was concern that these type of automation errors continue to be a problem in high volume pharmacies and in mail orders. A consensus was not reached on this topic.

Public comment expressed support of the proposed regulation, including an aggregate analysis of medication errors. Public comment agreed with the proposed three-year retention period of error reports and further agreed that the analysis of medication errors be shared with all pharmacy staff.

After discussion of the proposed amendments, the Committee referred the draft regulation as discussed to the full Board for consideration and possible action.

Attachment 1 includes the proposed amendments to CCR section 1711 that incorporates the changes based on the Committee's discussion. Should the Board agree with the Committee's recommendation, the following motion could be used:

> **Suggested Motion:** Move to initiate rulemaking to amend California Code of Regulations, Title 16, Section 1711 [either "as presented" or "consistent with the Board's discussion"] and direct staff to submit the text to the Director of the Département of Consumers Affairs and the Business, Consumer Services and Housing Agency for review and authorize the executive officer to take all steps necessary to initiate the rulemaking process, make any technical or nonsubtantive changes to the package, and set the matter for hearing, if requested. If during the 45-day comment period, the board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting certain action, and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at section 1711.

b. Summary of Discussion and Possible Action Regarding Frequently Asked Questions Related to Medication Error Reporting Requirements Pursuant to Business and Professions Code Section 4113.1

Relevant Law
Business and Professions Code (BPC) section 4113.1 provides that a community pharmacy, as defined, shall report medication errors to an entity approved by the Board. A community pharmacy shall submit the report no later than 14 days following the discovery of the error.

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. Based on questions raised by the regulated public, FAQs are periodically updated. As a reminder, the Board is also in the processing of reorganizing and reformatting how the Board delivers FAQs on the website. As part of this reformatting, the FAQs will be categorized by topic/subject matter, e.g., medication error reporting, inventory reconciliation, etc. Currently some FAQs are presented and grouped together based on specific pieces of legislation (e.g. AB 1286) with multiple topics comingled in one document, which can make it challenging for the regulated public to locate topics of interest.

Summary of Committee Discussion
During the meeting, members reviewed staff-recommended updates to the current FAQs related to medication error reporting under BPC 4113.1. Specifically, new question #9 was added related to infusion center pharmacies to clarify CAMER reporting requirements. Members noted agreement with the new FAQ as presented.

Further, members also suggested making some technical edits throughout the FAQs to reflect that provisions being discussed in the FAQs are presently (rather than prospectively) effective.

Public comment expressed support of the updated FAQs, and suggested that FAQ updates be communicated to the inspectors to ensure that provisions covered in FAQs are interpreted consistently.

The Committee is referring the updated FAQs related to medication error reporting to the full Board for consideration and possible approval.

Recent Update
Following the meeting, staff incorporated changes consistent with the Committee's discussion, including the technical changes to the FAQs related to medication error reporting requirements. An example of a technical change made is question 6, where the answer was updated to include the specific timeframes for the ISMP contract years.

Staff recommend the Board delegate authority to the Committee Chair to finalize technical changes that will facilitate the transition to the new FAQ formatting and organizational structure discussed under the background discussion above.

Should the Board agree with the updated FAQs and the recommended delegation of authority to the Committee Chair, the following motion could be used :

> **Recommended Motion**: Approve the updated FAQs [either as presented or consistent with the Board's discussion.] Delegate to the Committee Chair to finalize technical/nonsubstantive changes that will facilitate the transition to the new FAQ formatting and organizational structure.

Attachment 2 includes the updated FAQs on Medication Error Reporting incorporating changes made based on the Committee's discussion.

c. <u>Summary of Discussion and Possible Action Regarding Frequently Asked Questions Related to Automated Drug Delivery Systems</u>

<u>Relevant Law</u>
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.

<u>Background</u>
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 suggest 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.

<u>Summary of Committee Discussion</u>
During the meeting, members reviewed the updates to the ADDS FAQs and noted general agreement and support of the proposed FAQs. Members discussed whether to keep question #13, related to whether an ADDS used to select, count, package and label dangerous drugs is required to report errors under 16 CCR section 1711. The Committee consensus was to keep FAQ #13 to provide guidance to licensees on this topic. Members also suggested adding a table of

contents listing the new categories to the FAQ for ease of use by licensees.

Public comment expressed support for the proposed FAQs.

After discussion, the Committee referred the updated FAQs as discussed to the full Board for consideration and possible action.

Should the Board agree with the updated FAQs, the following motion could be used to formally approve the updated FAQs:

> **Recommended Motion**: Approve the updated FAQs [either as presented or consistent with the Board's discussion.]

Attachment 3 includes the updated FAQs incorporating changes made based on the Committee's discussion.

d. <u>Summary of Discussion and Possible Action Regarding Wholesaler/Third-Party Logistics Provider Self-Assessment (Form 17M-26)</u>

<u>Relevant Law</u>
BPC section 4102 requires the designated representative in charge of a 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.

<u>Background</u>
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.

<u>Summary of Committee Discussion</u>
During the meeting, members reviewed the updated Wholesaler/Third-Party Logistics Provider Self-Assessment form. Members spoke in support of the new format, specifically that the links to applicable laws are helpful. Members also suggested a subscriber alert be sent to designated representatives to solicit feedback and written comments from them before the Board meeting.

Public comment expressed support for the updated self-assessment and agreed that sending the updated form to licensees for feedback was appropriate.

After discussion of the updates to the Wholesaler/Third-Party Logistics Provider Self-Assessment, the Committee referred the updated form as discussed to the full Board for consideration and possible action.

Recent Update
Consistent with the Committee's direction, a subscriber alert was released to designated representatives soliciting comments on the Wholesaler/Third Party Logistics Provider Self-Assessment form. Comments received will be provided to members and posted on the Board's website.

Should the Board agree with the updated self-assessment, the following motion could be used to formally approve the form:

> **Recommended Motion**: Approve the updated Wholesaler/Third-Party Logistics Provider Self-Assessment form [either as presented or consistent with the Board's discussion.]

Attachment 4 includes the updated Wholesaler/Third Party Logistics Provider Self-Assessment.

e. **Summary of Discussion and Possible Action Regarding 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 (d) above for background information on this item.

Summary of Committee Discussion
During the meeting, members reviewed the updated Surgical Clinic Self-Assessment form.

Members spoke in support of the new format and suggested a subscriber alert be sent to pharmacists to solicit feedback and written comments before the Board meeting.
Members also suggested some formatting changes to the licensee section on page 2 and that in section 8.1 the phrase"(if applicable)" be added after "Sterile Compounding License #."

Public comment expressed support for the self-assessment and suggested that surgery centers should have a PIC instead of a consulting pharmacist.

After discussion of the updates to the Surgical Clinic Self-Assessment, the Committee referred the updated form as discussed to the full Board for consideration and possible action.

Recent Update
Consistent with the Committee's direction, a subscriber alert was released to pharmacists soliciting comments on the Surgical Clinic Self-Assessment form. Comments received will be provided to members and posted on the Board's website.

Should the Board agree with the updated self-assessment, the following motion could be used to formally approve the form:

Recommended Motion: Approve the updated Surgical Clinic Self-Assessment [either as presented or consistent with the Board's discussion.]

Attachment 5 includes the updated Surgical Clinic Self-Assessment incorporating changes made based on the Committee's discussion.

f. Summary of Discussion and Possible Action Regarding 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 (d) above for background information on this item.

Summary of Committee Discussion
During the meeting, members reviewed the updated Hospital Self-Assessment form. Members spoke in support of the new format and suggested a subscriber alert be sent to pharmacists to solicit feedback and written comments before the Board meeting. Members also suggested some technical edits to the licensee section/other services section on page 2 and asked that parts of section 8 regarding policies and procedures be rephrased.

Members also discussed whether the words "if applicable" should be added to all sections or even to each question to impress upon licensees to mark N/A if the question is not applicable. Other members thought the existing instructions in the introduction to the self-assessment regarding when to mark N/A were sufficient. The Committee did not reach a consensus on the issue.

Public comment suggested support for the self-assessment and raised questions about sections 12.22 and 12.23.

After discussion of the updates to the Hospital Self-Assessment, the Committee referred the updated form as discussed to the full Board for consideration and possible action.

Recent Update
Consistent with the Committee's direction, a subscriber alert was released to pharmacists soliciting comments on the Hospital Pharmacy Self-Assessment form. Comments received will be provided to members and posted on the Board's website.

Should the Board agree with the updated self-assessment, the following motion could be used to formally approve the form:

Recommended Motion: Approve the updated Hospital Self-Assessment [either as presented or consistent with the Board's discussion.]

Attachment 6 includes the updated Hospital Pharmacy Self-Assessment incorporating changes made based on the Committee's discussion.

g. <u>Summary of Discussion of Enforcement Statistics</u>

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

There were no member comments on this agenda item. Members of the public were provided with the opportunity to comment; however, no comments were made.

Attachment 7 includes the enforcement statistics.