

California State Board of Pharmacy

2720 Gateway Oaks Drive, Suite 100

Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov





Enforcement and Compounding Committee Report June 11, 2025

Maria Serpa, Licensee Member, Chair Renee Barker, Licensee Member, Vice-Chair Jeff Hughes, Public Member Seung Oh, Licensee Member, President Ricardo Sanchez, Public Member 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 March 27, 2025 Enforcement and Compounding Committee Meeting

Attachment 1 includes a copy of the draft minutes.

IV. <u>Annual Presentation on the Board's Inspection Program</u> – Cheryl Jenkins, Chief of Enforcement

Background

Pharmacy inspections are conducted by Board inspectors (licensed pharmacists) and are triggered for a variety of reasons, including receipt of a consumer complaint, required annual inspections for specific license categories (e.g., sterile compounding pharmacies, outsourcing facilities, etc.), or routine inspections to determine a pharmacy's compliance with state and federal laws and regulations. This process also involves an educational component, wherein licensees have an opportunity to meet and speak with Board inspectors, ask questions and receive guidance, and obtain pharmacy law updates. The Board's policy is to have all pharmacies inspected at least once every four years.

For Committee Consideration and Discussion

During the meeting, the Committee will receive a presentation on the Board's

inspection program, focusing primarily on routine inspections conducted during the last fiscal year. In fiscal year 2024/25, through May 15, 2025, staff conducted 2,833 in-person inspections including 1,135 routine inspections of pharmacies where the sole purpose of the inspection was triggered for routine evaluation. Of the routine inspections completed, 580 inspections resulted in correction(s) being issued and 75 pharmacies were issued a notice of violation(s). Further, 160 routine inspections revealed violations of the Board's patient consultation requirements, either failure to provide consultation, failure to provide written notice of consultation on delivered or mail order prescriptions, or failure of written notice of consultation to meet all required elements. The Committee will be looking further into barriers to consultation as one of its strategic objectives. The Board remains committed to its goal to inspect each licensed pharmacy every four years.

V. <u>Annual Presentation on the Board's Citation Program</u> – Anne Sodergren, Executive Officer

Relevant Law

<u>Business and Professions Code (BPC) section 4314</u> establishes authority for the Board to issue citations which may include fines and/or orders of abatement. This section provides that the order of abatement may include a requirement that up to six hours of continuing education courses be completed and specifies that any such continuing education courses shall be in addition to those required for license renewal.

California Code of Regulations, title 16, sections 1775-1775.4 are the Board's regulations governing its citation and fine program. More specifically, section 1775 includes the authority of the executive officer or designee to issue citations which may contain either or both an administrative fine and an order of abatement and details the types of violations for which a citation may be issued.

<u>Section 1775.2</u> establishes the factors to be considered in assessing the amount of an administrative fine, as follows:

- 1. The gravity of the violation.
- 2. The good or bad faith of the cited person or entity.
- 3. The history of previous violations.
- 4. Evidence that the violation was or was not willful.
- 5. The extent to which the cited person or entity has cooperated with the Board's investigation.
- 6. The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- 7. Other matters as may be appropriate.
- 8. The number of violations found in the investigation.

<u>Section 1775.3</u> establishes the order of abatement (OOA) compliance requirements.

<u>BPC section 4317.5</u> establishes authority for the Board to bring an action for fines of up to \$100,000 per violation for repeated violations under specified conditions. This section further provides authority for the Board to bring an action against a chain community pharmacy operating under common ownership or management for fines not to exceed \$150,000 for any violation demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager.

<u>Background</u>

Provided below is summary information providing comparisons for the past five fiscal years.

Citation and Fine	FY 2020/21	FY 2021/22	FY 2022/23	FY 2023/24	FY 2024/25*
Citations Issued	934	1,274	1.053	843	609
Average Days to Complete	426	341	325	359	406
Order of Abatements Issued	245	269	196	97	52
Amount of Fines Assessed	\$787,100	\$2,029,012	\$3,418,500	\$ 3,363,265	\$1,887,050
Amount Collected	\$711,729	\$1,093,911	\$1,713,100	\$1,813,951	\$1,627,523

^{*}July 1, 2024, through May 31, 2025

For Committee Consideration and Discussion

During the meeting, members will receive a presentation providing updated information on the Board's citation and fine program.

VI. <u>Presentation on Quality Assurance Reports Received Pursuant to California Code of Regulations, Title 16, Section 1711(f) Related to the Use of Automated Drug Delivery Systems</u> – Janice Dang, Chief of Enforcement

Relevant Law

<u>BPC section 4427.8</u> required the Board, on or before January 1, 2025, to report to the Legislature on the regulation of automated drug delivery system (ADDS) units as part of the sunset evaluation process. This report was submitted as part of the Board's 2025 Sunset Oversight Review Report (see <u>Attachment I</u>).

California Code of Regulation, title 16, <u>section 1711(f)</u> establishes an ongoing reporting requirement for any quality assurance record related to the use of an ADDS as specified in the section.

For Committee Consideration and Discussion

During the meeting, Supervising Inspector Janice Dang will provide a presentation describing updated information related to quality assurance reports received pursuant to CCR section 1711(f).

VII. <u>Discussion and Consideration of Updates to Frequently Asked Questions Related to the Board's Ask An Inspector Program</u>

<u>Background</u>

As part of its licensee education efforts, the Board offers a service whereby a Board inspector and Board staff are available to respond to verbal and written inquiries from Board licensees. The Board has compiled a list of Frequently Asked Questions (FAQs) that it has received through this program.

The Board's Ask An Inspector FAQs were originally drafted in 2021. Board staff believe it is important to share updated FAQs with licensees.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review the updated FAQs and provide feedback to staff.

Note: The previous version of the FAQs was not numbered. For ease of reference, staff numbered the questions. FAQs #1-13 are existing FAQs from 2021 that have been updated. Questions #14-17 are new FAQs that are proposed to be added.

After discussion of the updates, should the Committee believe the updated FAQs are ready for consideration and approval by the Board, the following motion may be appropriate.

Suggested Motion: Recommend approval of the updated FAQs related to the Board's Ask An Inspector Program [either as presented or consistent with the Committee's discussion].

Attachment 2 includes a copy of the updated FAQs.

VIII. <u>Discussion and Consideration of Updates to Frequently Asked Questions Related to</u> Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Background

Assembly Bill 1286 included several significant patient safety measures. As part of the Committee's prior discussions on implementation of <u>Assembly Bill 1286</u>, staff prepared a list of Frequently Asked Questions (FAQs) to assist stakeholders in gaining an understanding of the bill's requirements. The most recent version of the FAQs was approved by the Board during its November 2024 meeting. More recently, new

questions were submitted for inclusion by Board staff.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review the edits to the FAQs and provide feedback to staff. The updates to the FAQs pertain to medication errors and CAMER (California Medication Error Reporting). Updated responses and new questions are highlighted in yellow.

After discussion of the updates, should the Committee believe the FAQs are ready for consideration and approval by the Board, the following motion may be appropriate.

Suggested Motion: Recommend approval of the updated FAQs related to Assembly Bill 1286 [either as presented or consistent with the Committee's discussion].

Attachment 3 includes a copy of the updated FAQs.

IX. <u>Discussion and Consideration of the Committee's Strategic Objectives</u>

Background

The Board's <u>Strategic Plan 2022-2026</u> includes strategic objectives to guide the work of the Enforcement and Compounding Committee.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to review the strategic objectives and actions taken related to the objectives where applicable. It may be appropriate for the Committee to confirm if the strategic objectives remain appropriate and determine if there is a priority for the remaining objectives and additional actions it wishes to take related to objectives.

2.1 Evaluate, and take necessary actions, regarding the causes and effects of medication errors to reduce errors.

<u>July 2022 Status</u>: Medication Error Reduction and Workforce Ad Hoc Committee established and has begun convening public meetings.

<u>July 2023 Status</u>: Board sponsors Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023), a patient safety measure that includes provisions to establish mandatory reporting of medication errors.

<u>July 2024 Status</u>: Assembly Bill 1286 is signed by the governor in October 2023. Board releases educational materials and FAQs on implementation. Board delegates to the Chair of the Enforcement and Compounding Committee authority to participate in the development and evaluation of responses to the Request for Proposal for the medication error reporting entity.

June 2025 Status: Board approved the Institute for Safe Medication Practices (ISMP) as the entity to receive medication error reports in September 2024 and entered into a contract with ISMP effective February 1, 2025. In May 2025 Board advised licensees that medication errors that occur on or after September 1, 2025, must be reported to the California Medication Error Reporting (CAMER) system consistent with legal requirements established.

2.2 Analyze enforcement outcomes to identify trends to educate licensees of common violations and improve patient outcomes.

<u>July 2022 Status</u>: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided and top violations published in the Board's newsletter.

<u>July 2023 Status</u>: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided. Top violations and corrections discussed with information published in the Board's newsletter.

<u>July 2024 Status</u>: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided. Top violations and corrections discussed with information published in the Board's newsletter.

<u>June 2025 Status</u>: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided. Top violations and corrections discussed with information to be published in the Board's next newsletter.

2.3 Complete routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees.

<u>July 2022 Status</u>: In FY 2021/22, Board staff conducted 1,598 routine inspections. <u>July 2023 Status</u>: In FY 2022/23, Board conducted 1,316 routine inspections. This is an increase to 69.3% of licensed pharmacies from 37.7% two years ago. Staff will continue to prioritize pharmacies that have not been inspected for more than four years. <u>July 2024 Status</u>: In FY 2023/24, Board staff conducted 1,431 routine inspections; 79.7% of pharmacies inspected within 4-year period.

<u>June 2025 Status</u>: In FY 2024/25, Board staff conducted 1,464 routine inspections. The Board is committed to the goal of inspecting each pharmacy every four years.

2.4 Determine and reduce barriers to timely case resolution to improve consumer protection.

<u>July 2023 Status</u>: Board votes to propose amendments to Business and Professions Code (BPC) sections 4081 and 4105, related to providing records for the Board. <u>June 2025 Status</u>: The Board's proposed amendments to BPC sections 4081 and 4105 are included in the Board's sunset measure, Assembly Bill 1503 (Berman, 2025). In addition, the Board implemented a new digital process to streamline the investigative process and reduce investigation time frames.

2.5 Assess, and pursue where appropriate, further use of a Standard of Care Enforcement Model to protect consumers. (Completed)

<u>July 2022 Status</u>: Standard of Care Ad Hoc Committee established and has begun convening public meetings.

<u>July 2023 Status</u>: Board submits report to the Legislature as required in BPC section 4301.3 related to the Board's assessment of Standard of Care Enforcement Model in the regulation of pharmacy.

<u>July 2024 Status</u>: The Board's Licensing Committee reviewed a potential statutory proposal to transition pharmacist practice to a more robust standard of care practice model.

<u>June 2025 Status</u>: Standard of care provisions are included in the Board's sunset measure, Assembly Bill 1503 (Berman, 2025).

2.6 Establish greater consistency in how inspectors interpret the law and carry out inspections to improve compliance, support licensees, and further patient care.

<u>July 2023 Status</u>: Post-inspection surveys are performed as a means to receive feedback from licensees. Management staff review cases together to achieve consistency where appropriate.

<u>July 2024 Status</u>: Staff established a norming process to evaluate issues related to compounding compliance.

<u>June 2025 Status</u>: Staff continues to review cases together to achieve consistency. Supervising Inspectors conduct ride-along inspections with inspection staff. Post-inspection surveys of pharmacies resumed as a means to receive feedback from licensees.

2.7 Write a Budget Change Proposal to increase the number of enforcement staff to ensure more regular inspections and investigations, and to improve case processing times.

<u>July 2022 Status</u>: New inspector position received to perform inspections and related investigations stemming from new legislative mandates.

<u>July 2023 Status</u>: Board secures one inspector position related to new legislative requirements.

<u>July 2024 Status</u>: Board secures additional inspector staff to perform sterile compounding inspections and improve oversight of sterile compounding pharmacies on probation. <u>June 2025 Status</u>: Three new compounding inspectors hired and onboarded. Two enforcement positions were included in the governor's May revised budget.

2.8 Educate licensees about enforcement responsibilities to improve compliance and build relationships.

<u>July 2023 Status</u>: Board staff provide live and recorded presentations via WebEx to licensees and in person presentations to various pharmacist groups. The Board has released FAQs and newsletter articles. The Board is developing a training for pharmacist-in-charge.

<u>July 2024 Status</u>: Board develops FAQs on newly enacted legislation including Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023). Board publishes a special edition newsletter focusing on compliance with the provisions of the measure. Board continues

to evaluate existing FAQs to incorporate changes and respond to questions from stakeholders. Also developed a self-assessment process for surgical clinics. <u>June 2025 Status</u>: The Board implemented a new Learning Management System for licensees to complete Board-provided continuing education (CE), including the newly required PIC training course. The Enforcement and Compounding Committee will consider further updates to the AB 1286 FAQs and the Ask an Inspector FAQs at its June meeting.

2.9 Assess pharmacist involvement in medication handling at locations not regulated by the Board of Pharmacy to increase patient safety and standardize care.

<u>July 2024 Status</u>: Board staff begin conducting inspections at IV hydration clinics. **Note**: Discussion of pharmacy technicians compounding outside of a licensed pharmacy and with or without the direct supervision and control of a pharmacist was referred to and is under consideration of the Licensing Committee.

June 2025 Status: The Board's sunset report included statutory proposals on certain IV hydration clinics (where sterile compounding is occurring without appropriate supervision) and pharmacy technicians compounding outside of a licensed pharmacy. Provisions authorizing pharmacy technicians to perform certain activities outside of a licensed pharmacy under specified conditions are included in the Board's sunset measure, Assembly Bill 1503 (Berman, 2025).

2.10 Evaluate if regulations align with federal regulations and standards governing the practice of compounding and pursue changes, if appropriate, to ensure patient safety and assist licensees with education about standards.

<u>July 2023 Status</u>: The Board approves draft regulations related to USP General Chapters 795, 797, 800 and 825.

<u>July 2024 Status:</u> Forty-five-day comment period completed, and regulation hearing convened. Members to consider information during the July 31-August 1, 2024, Board Meeting for potential changes.

<u>June 2025 Status</u>: After five formal comment periods, a regulation hearing, and extensive review and discussion over the course of multiple public meetings, the Board approved final regulatory text and submitted the final rulemaking file to OAL.

- 2.11 Enhance patient consultation compliance by evaluating barriers to consultation to provide patient education and reduce medication errors. [NOTE: The Board approved the addition of this new strategic objective in November 2024]

 June 2025 Status: The Enforcement and Compounding Committee will be considering this issue at a future meeting.
- X. <u>Discussion, Consideration, and Possible Action on Proposal to Add New Section 1707.51</u>
 <u>Related to Accessible Prescription Drug Labels to Article 2 of Division 17 of Title 16 of the California Code of Regulations</u>

Relevant Law

BPC section 4076.8 establishes requirements for a pharmacy to provide to a patient who identifies as a person who is blind, has low-vision, or is otherwise print disabled, or their authorized representative, an accessible prescription label affixed to the container, 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: Section 4076.8 does not apply to prescription drugs dispensed and administered by an institutional pharmacy, correctional institution, or licensed correctional pharmacy. However, the section does apply to an institutional pharmacy when providing prescription drugs to a person with a disability for use by the individual upon their release from the health care facility.)

For Committee Consideration and Discussion

During the March 2025 Committee meeting, members discussed and considered various policy questions related to the measure. The Committee agreed that Board regulations in this area should focus on the creation of policies and procedures to define how compliance with the legislation will be achieved. Following the Committee discussion and subsequent Board discussion during the April 2025 meeting, the Board directed staff to develop proposed regulation text for consideration. Included in the meeting materials is draft regulatory language developed by staff for the Committee's review and consideration.

Should the Committee believe the draft regulatory language is ready for consideration and approval by the Board, the following motion may be appropriate:

Suggested Motion: Recommend initiation of a rulemaking to add California Code of Regulations, title 16, section 1707.51 [either as presented or consistent with the Committee's discussion]. Authorize the executive officer to further refine the language consistent with the Committee's discussion and make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

Attachment 4 includes a copy of the draft regulatory text.

XI. Discussion and Consideration of Enforcement Statistics

During the first eleven months of the fiscal year, July 1, 2024, through May 31, 2025, the Board initiated 2,850 complaints and closed 2,597 investigations. The Board has issued 144 letters of admonishment and 609 citations and referred 141 cases to the Office of the Attorney General. The Board has revoked 82 licenses, accepted the disciplinary surrender of 33 licenses, formally denied 5 applications, and imposed other levels of discipline against 105 licensees and/or applicants.

As of May 31, 2025, the Board had 1,582 field investigations pending. Following is a

breakdown providing more detail in the various investigation processes:

	July 1	, 2024	Oct. 1	, 2024	Jan. 1	, 2025	Apr. 1,	2025	Jun.	1, 2025
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	44	6	63	14	31	10	71	14	107	10
Cases Under Investigation	1,005	136	908	146	978	141	1,021	143	957	137
Pending Supervisor Review	223	74	147	74	173	62	295	70	322	65
Pending Second Level Review	99	22	229	26	116	64	93	68	161	41
Awaiting Final Closure	56	8	34	14	49	34	29	52	35	42

Attachment 5 includes the enforcement statistics for fiscal year 2024-25, through May 31, 2025.

XII. <u>Future Committee Meeting Dates</u>

• October 16, 2025

XIII. Adjournment

Attachment 1



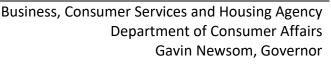
California State Board of Pharmacy

2720 Gateway Oaks Drive, Suite 100

Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov





California State Board of Pharmacy Department of Consumer Affairs DRAFT Enforcement and Compounding Committee Meeting Minutes

Date: March 27, 2025

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:

California State Board of Pharmacy

2720 Gateway Oaks Drive, First Floor Hearing Room

Sacramento, CA 95833

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM

REMOTE LOCATIONS VIA WEBEX

Board Members

Present: Maria Serpa, PharmD, Licensee Member, Chair

Renee Barker, PharmD, Licensee Member, Vice Chair

Seung Oh, PharmD, Licensee Member Ricardo Sanchez, Public Member

Nicole Thibeau, PharmD, Licensee Member

Board Members Not

Present: Jeff Hughes, Public Member

Staff Present: Anne Sodergren, Executive Officer (WebEx)

Corinne Gartner, DCA Counsel Jennifer Robbins, DCA Counsel

Debbie Damoth, Executive Specialist Manager

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

Chairperson Serpa called the meeting to order at approximately 9:01 a.m. As part of the opening announcements, Dr. Serpa welcomed Board Member Ricardo Sanchez back to the Board. Dr. Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

Dr. Serpa reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Serpa advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their non-appearance when the camera was turned off.

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

Members of the public in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public participating via WebEx were provided the opportunity to comment.

A registered nurse thanked the Board for sharing information about how to increase thresholds and requested an audit on the process asking pharmacists if they knew they could ask for the increase and if they tried to request an increase, how the process went. The registered nurse also asked the Committee to follow up with other healing arts board on the policy statement.

Dr. Serpa advised the policy statement with other health care professional boards was still being developed.

Members were provided the opportunity to comment. A member requested the thresholds discussion be added as a periodic reminder for the Communication and Public Education Committee.

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

The draft minutes of the October 16, 2024 Enforcement and Compounding Committee meeting were presented for review and approval. Members were provided the opportunity to comment.

Motion: Approve October 16, 2024 Enforcement and Compounding

Committee meeting minutes as presented.

M/S: Oh/Barker

Members of the public participating in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public participating via WebEx were provided the opportunity to comment.

A registered nurse commented that Ms. Lindhal's statement about the injunctive terms on page 4 of the draft minutes should be clarified.

Amended Motion: Approve October 16, 2024 Enforcement and

Compounding Committee meeting minutes with any necessary amendments after staff confirm whether Ms. Lindahl's statement is accurate.

M/S: Oh/Barker

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Hughes	Not Present
Oh	Support
Sanchez	Support
Serpa	Support
Thibeau	Support

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

Dr. Serpa recalled during the October 2024 Committee meeting, the Committee discussed possible implementation activities for a number of measures signed by the governor, including Assembly Bill 1902, a measure

related to prescription drug label accessibility. During the initial discussion there was discussion about the need to develop regulations to implement the requirements. Dr. Serpa noted that today the Committee had the opportunity to continue this discussion, and that the meeting materials included questions intended to assist the Committee.

Policy Question #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.

Dr. Serpa agreed with the information from staff that if the Committee determined a definition was appropriate, the Committee may need to provide different provisions for the various types of pharmacy business models.

Members were provided the opportunity to comment. Members appreciated the intent of the measure. There was consensus that due to the different pharmacy practice settings (e.g., independent, community chain, etc.), "timely manner" should be determined by the pharmacy's policies and procedures, so each specific facility could define how it can best meet the requirements. Members expressed concerns about being overly prescriptive in regulations, and also discussed these labels possibly becoming a barrier to access.

Members of the public participating in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public participating via WebEx were provided the opportunity to comment. The Committee heard comments from representatives of Kaiser Permanente and CPhA. Comments were received agreeing with the approach to meet the requirements through policies and procedures; suggesting the Committee recommend changes to the statute to resolve the tension between directions from the statute and pharmacy operations; and asking the Committee to consider an exemption for non-chain community pharmacies.

Members were provided the opportunity to comment having heard public comment. Members inquired if the Board had the authority to provide exemptions. Counsel noted this was probably not within the Board's authority. Members discussed exploring agreements between pharmacies. Members noted compliance with the statute would require interaction and discussion with the patients.

Policy Question #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?

Dr. Serpa noted it may be appropriate to consider a requirement for the pharmacy to develop a policy defining how it meets the requirements. Such an approach would allow each pharmacy to develop the process that works best for their business model.

Members were provided the opportunity to comment. Members agreed that the Board should not define how pharmacy personnel were to determine what was appropriate as it should be determined through policies and procedures and the pharmacist would need to interact with the patient to determine what would be appropriate for the patient.

b. Should the Board establish a minimum font size to define "large print?"

Dr. Serpa noted it may be appropriate for the Board to establish a minimum large print size.

Members were provided the opportunity to comment. Members discussed referring to an organization that defines this, but the consensus was to keep the regulation flexible and simple to allow for changes in standards.

c. Should the Board specify that the accessible prescription label needs to be in the patient centered format?

Dr. Serpa noted that she was leaning towards providing flexibility for pharmacies to determine how best to meet the individual patient's needs, especially if the Board's patient-centered label requirements would ultimately make it more difficult for the patient.

Members were provided the opportunity to comment. Members continued to support a flexible approach over a prescriptive approach and agreed the pharmacy's policies and procedures should determine what was appropriate for patients.

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.

Dr. Serpa agreed with the staff recommendation that at a minimum the Board should require pharmacies to develop policies and procedures that provide guidance to pharmacists on how to identify the appropriate accessible prescription labels.

Members were provided the opportunity to comment; however, no additional comments were made.

Members of the public participating in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public participating via WebEx were provided the opportunity to comment. The Committee heard comments from representatives of Kaiser Permanente and CPhA. Comments were received in support of adopting a national standard where available; asking if a regulation was required at all; and focusing on a standard of care approach.

Policy Question #3 - The law requires that accessible prescription labels must conform to the format specific best practices established by the United States 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.

Members were provided the opportunity to comment. Members continued to support a regulatory approach that required each pharmacy to develop policies and procedures to provide guidance to pharmacists on how to

evaluate for compliance with these standards. Members also discussed the possibility of developing an FAQ to assist with education.

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

Dr. Serpa advised the topic would be brought to the full Board as a part of the Committee report. Following discussion by the full Board, if there appeared to be general agreement, Dr. Serpa would work with staff on developing proposed regulation text that could be considered at a future Committee 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)
 - 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

Dr. Serpa advised as indicated in the meeting materials, the Board previously approved a number of changes to the self-assessment forms based on changes that became effective in 2024. Regrettably, many of these changes were not yet final through the rulemaking process. Dr. Serpa recommended that the Committee focus today's discussion on the proposed updated drafts that include changes effective in 2025. If the Committee and Board agreed the proposed updates were appropriate, staff could post the updated versions on the Board's website and work with counsel on the best path forward to facilitate the rulemaking process for those forms that require update through regulation.

Dr. Serpa recalled the Board included in its sunset report a proposal to pursue a statutory change to establish the self-assessment process in statute. Should that occur, the Board would be in a position to implement updated versions of the self-assessment forms in a more streamlined manner.

Dr. Serpa provided an overview of proposed changes to the community pharmacy and hospital outpatient pharmacy self-assessment.

Members were provided the opportunity to comment. Member discussed the proposed changes and next steps.

Dr. Serpa advised she would work with staff to refine the form for consideration by the Board at the next Board meeting.

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

Dr. Serpa then provided an overview of proposed changes to the inpatient hospital self-assessment.

Members were provided the opportunity to comment. Members discussed where the regulations were in the process and what forms could be updated.

Members of the public participating in Sacramento were provided the opportunity to comment; however, no comments were made.

Members of the public participating via WebEx were provided the opportunity to comment. A pharmacist comment on the three-day rule discussed in the proposed changes.

Dr. Serpa next reviewed the changes to the wholesaler/3PL self-assessment form. The only proposed changes were nonsubstantive.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

Dr. Serpa then reviewed the changes to the ADDS self-assessment form, noting that if the Board was successful in securing the statutory change to establish the self-assessment process in statute, some of the challenges with displaying changes over various versions of forms would be addressed.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

Finally, Dr. Serpa reviewed the proposed changes to the surgical clinic self-assessment form.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

The Committee took a break from 10:27 a.m. to 10:45 a.m. Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

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

Dr. Serpa advised the meeting materials provided background information on this item, including the relevant sections of the law that establish the general parameters for petitioning the Board for changes in a penalty or seeking reinstatement of a license. As the meeting materials noted, in 2023 staff made changes to the petition forms. Following implementation of the revised forms, it appeared there was an opportunity to evaluate the information requested and determine if additional changes were appropriate. Dr. Serpa discussed some concepts with staff in advance of the meeting, noting one potential change was to consolidate the forms into a single petition. Dr. Serpa believed such an approach may make it easier for petitioners and ensure the Board receives consistent information. Dr. Serpa believed the proposed new consolidated form was a good starting place for the Committee discussion. She noted that question 15 might need to be updated to require petitioners to provide proof of required continuing education related to pharmacy law, ethics, and cultural competency.

Member Sanchez re-joined the meeting at 10:48 a.m.

Members were provided the opportunity to comment. Members appreciated the new form. Discussion noted question 16 should be updated to include minimum requirements for licensee written letters of recommendation.

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

Dr. Serpa agreed to work with staff to further refine the proposed form to present to the Board in April 2025.

VII. Discussion and Consideration of Enforcement Statistics

Dr. Serpa advised the meeting materials included a summary of the enforcement statistics for the first eight months of fiscal year 2024/25. The Board initiated 2,099 complaints and closed 1,971 investigations. As of March 1, 2025, the Board had 1,495 field investigations pending. The meeting materials provided a breakdown of the average timeframe for the various stages of the field investigation process.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public participating in Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

VIII. Future Committee Meeting Dates

Dr. Serpa advised the next meeting was scheduled for June 11, 2025.

IX. Adjournment

The meeting adjourned at 10:55 a.m.

Attachment 2

Frequently Asked Questions from ask.inspector@dca.ca.gov

As part of its licensee education efforts, the California State Board of Pharmacy (Board) offers a service whereby a Board inspector and Board staff are available to respond to verbal and written inquiries from Board licensees. The Board believes it is important to share frequently asked questions with licensees.

Question #1: Does a pharmacist have to perform a final verification by physically inspecting the patient's medication if it was filled by a pharmacy technician or an intern?

Answer: There are multiple provisions of law that address this question, and the answer varies based on various factors. Relevant legal references include:

- 1. With respect to interns, section 1726 of title 16 of the California Code of Regulations states that a pharmacist supervising an intern shall be responsible for all professional activities performed by the intern under his or her supervision.
- 2. With respect to pharmacy technicians, section 1793.7 of title 16 of the California Code of Regulations states that any function performed by a pharmacy technician in connection with dispensing of a prescription, including repackaging from bulk, must be verified and documented in writing by a pharmacist. Except for certain situations outlined in the regulation, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.¹ (See also Business and Professions Code section 4115.5(b)(3) for similar provisions with respect to pharmacy technician trainees.)

Question #2: What is the pharmacist to intern pharmacist ratio?

Answer: Business and Professions Code section 4114(b) provides that a pharmacist may not supervise more than two interns at one time.

Question #3: What is the pharmacist to pharmacy technician ratio in a community pharmacy?

Answer: Business and Professions Code section 4115(g) specifies as follows:

1. A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a) of Business and Professions Code section 4115 (i.e., packaging, manipulative, repetitive, or other nondiscretionary tasks).

¹ Pursuant to section 1712 of title 16 of the California Code of Regulations, section 1793.7's requirement for the pharmacist to initial the prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made, and the record of the reviewing pharmacist's identity made in the computer system must be immediately retrievable in the pharmacy.

- 2. A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (b) of Business and Professions Code section 4115 (these include preparation and administration of certain vaccines and/or epinephrine, performing specimen collection for CLIA-waived tests, receiving prescription transfers, and accepting clarification on prescriptions, subject to specified conditions). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a).
- 3. The ratio of pharmacy technicians increases for each additional pharmacist to a ratio not to exceed 2 technicians to 1 pharmacist for pharmacy technicians performing the tasks specified in subdivision (a).
- 4. A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under Pharmacy Law. (See paragraph (3) of subdivision (g) of Business and Professions Code section 4115 for specific conditions that apply in such situations.)

Question #4: How do I identify the dates of the renewal period within which I must earn 30 units of continuing education (CE) to renew my pharmacist license?

Answer: Pharmacists must earn 30 units of continuing education each two-year renewal cycle. (See Business and Professions Code section 4231; see also section 1732.5 of title 16 of the California Code of Regulations.)

Example: A pharmacist's license expires October 31, 2025. The current renewal period runs November 1, 2023, through October 31, 2025, within which the pharmacist must have earned 30 units of CE to renew the license in an active status. The next renewal period will be November 1, 2025, through October 31, 2027. Please note that California law requires pharmacists to keep CE certificates for four years following completion of the CE course.

Question #5: Is it possible to purchase pen needles over-the-counter in California?

Answer: Yes, but with a few restrictions and requirements. Please see Business and Professions Code sections 4144.5, 4145.5, and 4146 for the complete requirements.

A pharmacist or physician MAY (but is not mandated to) furnish hypodermic needles and syringes for human use without a prescription, if the furnisher has previously been provided with a prescription or other proof of legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

Additionally, until January 1, 2026, as a public health measure, the pharmacist or physician MAY (but is not mandated to), without a prescription, furnish hypodermic needles and syringes for human use to a person 18 years or older solely for personal use. A pharmacy that furnishes nonprescription hypodermic needles and syringes must counsel the consumer on the safe disposal of syringes or needles and provide

the consumer with one or more of the following disposal options:

- Onsite disposal that meets applicable state and federal standards for collection and disposal of medical sharps waste.
- 2. Mail-back sharps containers authorized by the USPS that meet applicable state and federal requirements for the transport of medical sharps waste, with tracking forms to verify destruction at a certified disposal facility.
- 3. A sharps container that meets applicable state and federal standards for collection and disposal of medical sharps waste.

Until January 1, 2026, the pharmacy must also provide written information or verbal counseling to the consumer at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to (1) access to drug treatment, (2) access testing and treatment for HIV and hepatitis C, and (3) safely dispose of sharps waste.

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container, as defined in section 117750 of the Health and Safety Code.

Business and Professions Code section 4144.5 allows a pharmacy to sell hypodermic needles and syringes without a prescription for uses that the Board determines are industrial. In addition, Business and Professions Code section 4145.5(c) allows a pharmacist to furnish hypodermic needles and syringes without a prescription for use on animals.

Question #6: Can a Schedule II controlled substance prescription be refilled?

Answer: Health & Safety Code section 11200(c) prohibits the refilling of a prescription for a Schedule II controlled substance.

Question #7: How long is a controlled substance prescription valid?

Answer: Health & Safety Code section 11200(a) specifies that no person shall dispense or refill a controlled substance prescription more than six months after the date thereof. See also Health & Safety Code section 11166, providing: "No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber."

Question #8: How many times can a Schedule III or IV controlled substance prescription be filled?

Answer: Health & Safety Code section 11200(b) specifies that no prescription for a Schedule III or IV controlled substance may be refilled more than five times. Further, this section also creates a limit of a 120-day total supply for refills of a Schedule III or IV controlled substance prescription.

Example: A prescription is written for temazepam 15mg QHS (a Schedule IV controlled substance), quantity #30 with 5 refills. The prescription is dispensed on 7/1/2016 for a quantity of 30. The pharmacy refills the prescription on 8/1/2016, 9/1/2016, 10/1/2016, and 11/1/2016, a 30-day supply for each refill and a total of a 120-day supply between the four refills. Although the prescriber wrote for 5 refills, the pharmacy cannot dispense the remaining refill because the 120-day limit was reached after dispensing the refill on 11/1/2016. A new prescription is required for any additional dispenses.

Question #9: Where is the law that establishes the requirement for a pharmacist to exercise corresponding responsibility?

Answer: Health & Safety Code section 11153(a) states that a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Health & Safety Code section 11153(a) further provides that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a *corresponding responsibility* rests with the pharmacist who fills the prescription. In addition, subdivision (b) of section 1761 of title 16 of the California Code of Regulations states: "Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

NOTE: Additional information about corresponding responsibility can be found using the following link - - http://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf. Information on the Board's precedential decision on corresponding responsibility can be found at http://www.pharmacy.ca.gov/enforcement/precedential.shtml. The DEA Pharmacist's Manual, available at https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1) Pharmacist's Manual DEA.pdf, includes an overview of a pharmacist's duty of corresponding responsibility under federal law.

Question #10: Am I required to apply for registration to California's prescription drug monitoring program, CURES?

Answer: Health & Safety Code section 11165.1(a)(1)(A)(ii) requires that a pharmacist shall, upon licensure, submit an application to the California Department of Justice to obtain approval to electronically access the CURES system. The California Department of Justice website to register for CURES is: https://cures.doj.ca.gov/register/pre-registration

Question #11: How often does a pharmacy need to report controlled substances dispensing information to CURES?

Answer: Health & Safety Code Section 11165(d) specifies that a dispensing pharmacy must report information to the Department of Justice as soon as reasonably possible, but not more than one working day after the controlled substance is dispensed.

Question #12: How do I get on the Board's email distribution list?

Answer: You may sign up for the Board's email distribution list by visiting the following website and signing up: https://www.dca.ca.gov/webapps/pharmacy/subscribe.php

Question #13: Where can I find prescription drug take back locations?

Answer: Go to the Board's website, <u>www.pharmacy.ca.gov</u>; click on the "Consumers" menu, then select "Information for Consumers"; and click on "Drug Takeback Search and Information."

Question #14: Can a Board-licensed pharmacy or pharmacist remotely verify medication chart orders?

Answer: There are two provisions in the law that allow for remote verification of chart orders.

Business and Professions Code section 4071.1(d)(1) states that a pharmacist located and licensed in California may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with section 1250) of Division 2 of the Health and Safety Code, from a location outside of the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures.

In addition, a pharmacy can process prescriptions for another pharmacy sharing a common electronic file pursuant to section 1717.1 of title 16 of the California Code of Regulations.

<u>For dangerous drugs other than controlled substances</u>: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.

<u>For controlled substances</u>: To the extent permitted by federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.

(Refer to section 1717.1 of title 16 of the California Code of Regulations for complete requirements.)

Question #15: Can a QR Code be provided to the patient, instead of the medication guide in paper format?

Answer: According to FDA's Patient Labeling Resources for Industry, available at https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#medication-guides (accessed May 21, 2025): The medication guide shall be dispensed to the patient (or to the patient's agent) in paper form when the product is dispensed; however, the patient may also request electronic delivery of the Medication Guide in lieu of the printed form.

Question #16: What are the staffing requirements in a retail chain community pharmacy?

Answer: Business and Professions Code section 4113.5(a) states that a community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times. See section 1714.3 of title 16 of the California Code of Regulations for additional requirements that apply to community pharmacies that are required to comply with Business and Professions Code section 4113.5.

Business and Professions Code section 4113.6(a) states that a chain community pharmacy subject to Business and Professions Code section 4113.5 shall be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. Business and Professions Code section 4113.6(a) further states that the Board shall not take action against a pharmacy for violation of Business and Professions Code section 4113.6 if any of the following conditions apply:

1. The pharmacist on duty waives the requirement in writing during specified hours based on

- workload need.
- 2. The pharmacy is open beyond normal business hours, which is before 8:00 a.m. and after 7:00 p.m. During the hours before 8:00 a.m. and after 7:00 p.m., the requirement shall not apply.
- 3. The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, or any other ancillary services provided by law, paragraph (3) does not apply.

In addition, per Business and Professions Code section 4113.6(b), where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

If you believe a pharmacy is in violation of community pharmacy staffing requirements, you can notify the Board by filing a complaint here. The Board requests the following information be provided:

- Name and license number of pharmacy
- Information about how the pharmacy is non-compliant with staffing requirements.

Question #17: Is a retail pharmacy required to keep the physical prescriptions, or can the prescriptions be scanned and kept electronically?

Answer: Business and Professions Code section 4105(a) states all records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the Board shall be retained on the licensed premises in a readily retrievable form. Business and Professions Code section 4105(d)(1) states any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically. Business and Professions Code section 4105(c) states that the records required by section 4105 shall be retained on the licensed premises for a period of three years from the date of making.

Question #18: Are technicians and pharmacists required to wear identification?

Answer: Yes. According to California Code of Regulations, title 16, section 1793.7(c), a pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician. In addition, Business and Professions Code section 680(a) states, in pertinent part: "Except as otherwise provided in this section, a health care practitioner [which includes a pharmacist; see section 680(c)] shall disclose, while working, his or her name and practitioner's license status, as granted by this state, on a name tag in at least 18-point type. A health care practitioner in a practice or an office, whose license is prominently displayed, may opt to not wear a name tag."

Example: If your name is John Doe, the following formats are acceptable:

John Doe, RPh John Doe J. Doe John D. Johnny John
Pharmacist Pharmacist Pharmacist Pharmacist Pharmacist

Attachment 3

Frequently Asked Questions – Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Assembly Bill 1286, which became effective January 1, 2024, includes several patient safety provisions. Given the encompassing nature of the measure, the Board is releasing this FAQ to assist licensees with understanding the bill. To facilitate use of this document, short titles will be used to reference the various topics.

Medication Error Reporting

1. Q: What types of licensees are required to report medication errors under AB 1286?

A: A community pharmacy licensed pursuant to Article 7 of Chapter 9 of Division 2 of the Business and Professions Code (BPC) is required to report medication errors under AB 1286. For purposes of the measure, the term "community pharmacy" includes any pharmacy that dispenses medication to an outpatient, including both resident and nonresident pharmacies, but not including facilities of the California Department of Corrections and Rehabilitation.

[Reference: BPC 4113.1(a) and (c)]

2. Q: What is considered a medication error for purposes of AB 1286 reporting?

A: For purposes of AB 1286 reporting, the term "medication error" includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration, but does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

[Reference: BPC 4113.1(d)]

3. Q: AB 1286 requires a community pharmacy to report medication errors to an entity approved by the Board. What is the name of the approved entity? (Response Updated)

A: The Board approved the Institute for Safe Medication Practices (ISMP) as the entity to receive medication error reports from community pharmacies under BPC 4113.1.

[Reference: BPC 4113.1(a) and (b)]

4. Q: When do community pharmacies have to start reporting medication errors under BPC 4113.1? (Question and Response Updated)

A: The Board has announced that medication errors occurring on or after September 1, 2025, must be reported under BPC 4113.1. The Board will use a variety of means to communicate any further updates to the implementation timeframe for BPC 4113.1 medication error reporting, including through the Board's subscriber alert system and posting information on the <u>California Medication Error Reporting (CAMER) page</u> on its website.

Note: As a reminder, all licensees are required to enroll in the Board's subscriber alert system. Additional information is available here.

[Reference: BPC 4013]

5. Q: How do I register with ISMP for medication error reporting? (New Question)

A: A link to the ISMP registration portal can be found on the <u>California Medication Error</u> <u>Reporting (CAMER) page</u> on the Board's website.

6. Q: Is there a fee for medication error reporting under BPC 4113.1? (New Question)

A: Per the contract between the Board and ISMP, ISMP will charge community pharmacies an initial registration fee of \$70 for the first contract year, and a renewal fee of \$47 per year for the second and third contract years.

7. Q: I work in an outpatient hospital pharmacy. Do AB 1286's requirements for medication error reporting apply to our pharmacy?

A: Yes. However, pursuant to subdivision (e) of BPC 4113.1, an outpatient hospital pharmacy shall not be required to report to the Board-approved entity a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to section 1279.1 of the Health and Safety Code (HSC). The State Department of Public Health may share any such report with the Board.

[Reference: BPC 4113.1(e)]

8. Q: I work in an outpatient hospital pharmacy. Am I required to report all medication errors to the Board-approved entity under the provisions of AB 1286?

A: It depends. AB 1286 generally requires a community pharmacy licensed by the Board to report, either directly or through a designated third party, all medication errors to an entity approved by the Board; however, subdivision (e) of BPC 4113.1 establishes a limited exemption from the reporting requirements, and specifies that an outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to HSC 1279.1.

[Reference: BPC 4113.1]

9. Q: If I am reporting medication errors to an entity approved by the Board, am I still required to complete a quality assurance review and report?

A: Yes. The Board's quality assurance regulations remain in place and pharmacies are still required to comply with those regulations.

[Reference: 16 CCR 1711]

10. Q: Are nonresident pharmacies required to report all medication errors to the Boardapproved entity under the provisions of AB 1286? (Response Updated)

A: Yes. BPC 4113.1 states that a community pharmacy licensed pursuant to Article 7 of the Pharmacy Law (which includes nonresident pharmacies) shall report "all medication errors."

Note: The Board is pursuing a statutory change under the Board's sunset measure, Assembly Bill 1503 (Berman, 2025), to clarify BPC 4113.1 medication error reporting requirements for nonresident pharmacies.

[Reference: BPC 4113.1]

Minimum Staffing Provisions

11. Q: What minimum staffing requirements does AB 1286 establish?

A: Effective January 1, 2024, a chain community pharmacy subject to BPC 4113.5 is required to be staffed at all times during normal business hours (defined as 8:00 am to 7:00 pm) with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services, unless any of the following conditions apply:

- The pharmacist on duty waives the requirement in writing during specified hours based on workload need.
- The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm, in which case the minimum staffing requirement does not apply during the hours before 8:00 am and after 7:00 pm.
- The pharmacy's prescription volume per day on average is less than 75
 prescriptions per day based on the average daily prescription volume for the
 past calendar year. However, if the pharmacist is also expected to provide
 additional pharmacy services such as immunizations, CLIA-waived tests, or any
 other ancillary services provided by law, this exemption does not apply.

In addition, where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

Note: Additional minimum staffing requirements are detailed under "Pharmacy Technician Expanded Duties" below.

[Reference: BPC 4113.6]

12. Q. If a pharmacist is solely scheduled with an intern, does that meet the minimum staffing requirement established in BPC 4113.6(a)?

A: AB 1286 is silent about the impact to the minimum staff requirement when interns are present. As stated in the prior question, a pharmacist on duty may waive the BPC 4113.6(a) minimum staffing requirement during specified hours based on workload need.

[Reference: BPC 4113.6(a)]

Staffing Decisions

13. Q: I am the pharmacist-in-charge (PIC) of a pharmacy. What changes does AB 1286 make as far as my ability to make staffing decisions?

A: Effective January 1, 2024, the law explicitly provides that the PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. The Board recommends that the PIC document their efforts to ensure sufficient staff are present.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

14. Q: I am the pharmacist on duty and the PIC is not available. Do I have the authority to adjust staffing?

A: Effective January 1, 2024, if the PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed. The Board recommends that the pharmacist on duty document their efforts to adjust staffing.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

Staffing Decisions

15. Q: I am the pharmacist-in-charge (PIC) of a pharmacy. What changes does AB 1286 make as far as my ability to make staffing decisions?

A: Effective January 1, 2024, the law explicitly provides that the PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. The Board recommends that the PIC document their efforts to ensure sufficient staff are present.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

16. Q: I am the pharmacist on duty and the PIC is not available. Do I have the authority to adjust staffing?

A: Effective January 1, 2024, if the PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed. The Board recommends that the pharmacist on duty document their efforts to adjust staffing.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

Unsafe Pharmacy Conditions

17. Q: I am concerned that the working conditions of the pharmacy are harmful. What should I do?

A: Effective January 1, 2024, the pharmacist-in-charge or pharmacist on duty is required to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:

- Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- Vermin infestation that poses a risk to the safety or efficacy of medicine.

The Board recommends that the PIC or pharmacist on duty document any such notification made by them to store management. The Board also recommends that

pharmacies establish policies and procedures for the notification process to ensure reporting personnel and store management have a common understanding of the process to be used.

[Reference: BPC 4113(d)]

18. Q: Is store management required to take action based on my report?

A: Yes. Effective January 1, 2024, store management is required to take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. The pharmacy owner may also close a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

[Reference: BPC 4113(d)]

19. Q: I made a report, but the conditions remain. What should I do?

A: Effective January 1, 2024, the law states that if the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the Board is timely notified.

[Reference: BPC 4113(d)]

20. Q: How do I make a report to the Board?

A: The Board has established a dedicated email for such reporting: — PharmacyAlert@dca.ca.gov. The Board requests that the following information be provided with the notification:

- Name and license number of pharmacy,
- Name and contact information for reporting party,
- Name and contact information for store management that received the initial notification,
- Copy of the notification provided to store management,
- Documentation of the conditions including photographs, temperature logs, etc.

[Reference: BPC 4113(d)]

21. Q: Do these requirements apply to all pharmacies?

A: No, facilities of the Department of Corrections and Rehabilitation are exempt from these requirements.

[Reference: BPC 4113(d)(6)]

Pharmacy Technician Expanded Duties

22. Q: What are the expanded duties pharmacy technicians may perform pursuant to AB 1286?

A: Effective January 1, 2024, qualified pharmacy technicians may perform the following duties <u>under specified conditions</u>:

- Prepare and administer influenza and COVID-19 vaccines via injection or intranasally
- Prepare and administer epinephrine
- Perform specimen collection for tests that are classified as waived under CLIA
- Accept clarification on prescriptions

[Reference: BPC 4115(b)]

23. Q: What are the specified conditions that must be met for a pharmacy technician to perform the expanded duties?

A: The law establishes several conditions, as follows:

- The duties are performed under the direct supervision and control of a pharmacist.
- The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in BPC 4115(a) (i.e., packaging, manipulative, repetitive, or other nondiscretionary tasks).
- The pharmacy technician is certified pursuant to the provisions of BPC 4202(a)(4) and maintains the certification.
- The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education that includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

The pharmacy technician is certified in basic life support.

[Reference: BPC 4115(b)(1)]

Unprofessional Conduct

24. Q: As a pharmacist, I know I am responsible for using professional judgment when taking care of patients. I believe my employer has implemented a policy that undermines my professional judgment. Does AB 1286 address this?

A: Yes. Effective January 1, 2024, the unprofessional conduct code was amended to expand the list of specified actions that constitute unprofessional conduct to include

actions or conduct that would subvert the efforts of a pharmacist or PIC to comply with laws and regulations, or exercise professional judgment.

[Reference: BPC 4301(v) and (w)]

25. Q: If I believe the pharmacy is violating the law, how do I file a complaint with the Board?

A: A consumer or licensee may file a complaint with the Board <u>online</u>. Fill out the boxes on the form that apply to your complaint. The Board requests that documentation or other evidence that support your allegations be retained and provided to the Board if requested.

26. Q: Can I file a complaint anonymously?

A: Yes. The Board welcomes and investigates complaints received, including anonymous complaints. However, anonymous complaints may limit the Board's ability to investigate.

Surgical Clinic Provisions

27. Q: Under new requirements established by AB 1286, our surgical clinic is required to complete a Surgical Clinic Self-Assessment Form. Where can I find that form?

A: The Surgical Clinic Self-Assessment Form is currently being developed. Upon approval, the Board will release a subscriber alert and post the form on its website. The form will be available here.

[Reference: BPC 4192(b)]

28. Q: It is my understanding that AB 1286 makes changes to the renewal requirements for surgical clinics. Please provide me with an explanation of the changes.

A: Effective January 1, 2024, as part of the renewal process for a surgical clinic, the consulting pharmacist must certify compliance with the quarterly inspections as required by BPC 4192. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in BPC 4192 must be provided to the Board.

[Reference: BPC 4204(c)]

29. Q: How does the consulting pharmacist certify compliance with the quarterly inspection requirements?

A: The renewal application form includes a statement that must be completed by the consulting pharmacist as part of the renewal process. As a reminder, the Board has a policy to accept digital signatures. The policy is available here.

[Reference: BPC 4192(b), 4204(c)]

30. Q: How do I submit a copy of the completed self-assessment form with our renewal application?

A: A copy of the completed self-assessment form can be mailed along with the renewal application form and renewal fee. It is recommended that licensees consider mailing the renewal application form, fee, and self-assessment form to the Board's office for handling, 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833.

[Reference: BPC 4204(c))

Draft Rev. June 11, 2025

Attachment 4

Department of Consumer Affairs Title 16. Pharmacy

Proposed Regulatory Language Accessible Prescription Drug Labels

Legend: Added text is indicated with an <u>underline</u>.

Add 16 CCR § 1707.51 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.51. Accessible Prescription Drug Labels.

- a) Each pharmacy subject to Business and Professions Code section 4076.8 shall establish policies and procedures for providing these accessible prescription labels. The policies and procedures shall meet the following requirements:
 - (1) Define "in a timely manner" in relation to medication dispensing time for the pharmacy's patient population, comparable to other patient wait times and based on the clinical needs of the patient.
 - (2) Describe action to take if the medication cannot be dispensed in a "timely manner" including:
 - (A) notification to the patient,
 - (B) steps to take to avoid adversely affecting the patients' medical condition based on the pharmacists' professional training and judgment, and
 - (C) steps to take to assure future access to the medication with an accessible label.
 - (3) Describe the process used to determine patient accessibility needs pursuant to Business and Professions Code section 4076.8. and list the accessibility options available in the pharmacy including any deviations from section 1707.5 of this Article that are needed to meet patient needs.
 - (4) Describes the training provided to pharmacy personnel on best practices related to prescription label accessibility.
- (b) Pharmacy personnel must read and sign a copy of the policies and procedures required in (a) of this section. All signed copies are to be maintained in the pharmacy premises in a readily retrievable format.

NOTE: Authority cited: Sections 4005 and 4076.8, Business and Professions Code. Reference: Sections 4005 and 4076.8, Business and Professions Code.

Attachment 5

Board of Pharmacy

Enforcement Workload Statistics FY 2024/25

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	757	777	816	500	2,850
Closed	750	704	673	470	2,597
					Quarter
					Ending
Pending	1,918	1,977	2,111	2,184	2,184
Average Days for Investigation	223	229	234	252	233

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	830	835	944	976	976
Drug Diversion / Fraud	242	245	255	266	266
Prescription Drug Abuse	178	113	144	162	162
Compounding	56	61	101	94	94
Outsourcing	7	5	3	5	5
Probation / PRP	36	52	33	50	50
Enforcement	59	65	49	48	48
Criminal Conviction	510	601	582	583	583

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	41	64	54	38	197
Closed					
Approved	29	20	31	38	118
Denied	17	9	12	5	43
Total Closed (includes withdrawn)	50	34	46	48	178
Pending	90	113	121	109	109

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	359	304	251	196	1,110
Non-Jurisdictional	88	86	108	73	355
No Violation	37	25	48	22	132
No Further Action	49	36	44	40	169
Other / Non-Substantiated	25	15	15	15	70
Subject Educated	19	47	45	13	124

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	44	35	51	14	144
Citations Issued	157	196	166	90	609
Proof of Abatement Requested	12	16	18	7	53
Appeals Referred to AG's Office	63	30	23	5	121
Dismissed	7	5	10	3	25
Total Fines Collected	\$612,872	\$569,232	\$356,057	\$270,162	\$1,808,32

Administrative Cases	July Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	43	38	32	28	141
Pleadings Filed	65	39	29	27	160
Total Closed	68	61	69	39	237
					Quarter
Pending					Ending
Pre-Accusation	123	118	100	83	100
Post-Accusation	181	164	148	148	148
Total Pending	304	282	248	0	248

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	4	2	3	2	11
Intern Pharmacist	0	0	0	1	1
Pharmacy Technician	20	17	20	9	66
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	1	0	2	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	25	20	23	14	82

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, suspension/probation	4				
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	0	0	0	0	0

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, probation					
Pharmacist	11	6	11	4	32
Intern Pharmacist	1	1	0	0	2
Pharmacy Technician	3	7	8	2	20
Designated Representative	0	0	1	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	5	0	2	3	10
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	20	14	22	9	65

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	0	0	3	0	3
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	5	4	4	2	15
Designated Representative	0	0	1	0	1
Wholesaler	2	0	0	0	2
Clinic	0	1	0	0	1
Pharmacy	1	4	2	1	8
Sterile Compounding	0	0	0	1	1
Outsourcing	0	1	0	0	1
Total	8	11	10	4	33

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	7	2	2	2	13
Intern Pharmacist	1	1	0	0	2
Pharmacy Technician	1	2	0	0	3
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	3	4	4	1	12
Sterile Compounding	1	0	0	1	2
Outsourcing	0	0	0	0	0
Total	14	9	6	4	33

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	1	1	0	2
Intern Pharmacist	2	0	0	0	2
Pharmacy Technician	0	1	2	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	2	2	3	0	7

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	2	0	0	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	1	2	0	3
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	2	1	2	0	5

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	\$281,598	\$297,998	\$606,714	\$112,983	\$1,299,293
Cost Recovery Collected	\$198,145	\$254,718	\$173,423	\$279,340	\$905,626

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	4	2	2	13
Automatic Suspension Orders	0	0	0	2	2
Penal Code 23 Restrictions	1	0	2	0	3
Cease and Desist - Immediate Risk	0	0	0	2	2
Cease and Desist - Outsourcing	0	0	0	0	0
Cease and Desist - Unlicensed Activity	0	0	0	0	0
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	166	153	149	139	149
Advanced Practice Pharmacist	0	0	2	2	2
Intern Pharmacist	4	4	4	4	4
Pharmacy Technician	29	37	37	33	37
Designated Representative	1	0	1	1	1
Wholesaler / 3PL	3	1	1	0	1
Pharmacy	54	49	46	47	46
Sterile Compounding	9	9	9	8	9
Outsourcing	0	0	0	0	0
Total	266	253	249	234	249
Probation Compliance Measures					Total
Probation Office Conferences	21	23	20	7	. 71
Probation Interviews / Site Inspections	183	109	127	100	519
Probation Terminated / Completed	16	28	27	19	90
Referred to AG for Non-Compliance	0	1	4	0	5

As of 5/31/2025

Board of Pharmacy

Citation and Fine Statistics FY 2024/25

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	15	15	6	4	40
Pharmacist-in-Charge with Fine*	9	12	5	2	28
Pharmacist no Fine	24	32	25	11	92
Pharmacist-in-Charge no Fine*	24	23	19	7	73
Pharmacy with Fine	56	98	32	30	216
Pharmacy no Fine	29	23	25	20	97
Pharmacy Technician with Fine	9	7	5	1	22
Pharmacy Technician no Fine	11	10	14	1	36
Wholesalers	0	2	0	0	2
Designated Representative	1	1	3	0	5
Clinics	0	0	0	0	0
Drug Room	0	0	1	0	1
Exempt Hospital	0	0	0	0	0
Hospital Pharmacy	2	3	1	1	7
Miscellaneous**	20	14	9	9	52
Unlicensed Premises	1	4	6	13	24
Unlicensed Person	0	0	0	0	0

^{*}These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs **Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

As o 3/31/2025

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	24%	1716 - Variation from prescription	45%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	25%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	12%	4113(e) - Every Pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall	16%	1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	8%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	12%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	7%	1715.65(b) - The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconcilitation reports taken, and establish and maintain secure meth	8%
4301(h) - Unprofessional Conduct - The administering to oneself, of any controlled substance, or the use of any dangerous drug or of aicoholic beverages to the extent or in a manner as to be dangerous	12%	1707 2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	5%	1715.65 - Inventory Reconciliation Report of Controlled Substances	8%
4301(I) - Unprofessional Conduct - Conviction of a cnme substantially related to the practice of pharmacy	12%	1709(a) - Names of Owners and Pharmacist in Charge, Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership, the pharmacist in charge and the names of	5%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	8%
1735.2(e)(3) - Compounding limitations and requirements; written master formula	6%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	8%
1735.2(e)(6) - Compounding Limitations and Requirements, Quality reviews required at each step in preparation of the drug	6%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	1707.2(b)(1)(A) - In addition to the obligation to consulta pharmacist shall provide oral consultation to his or her patientswhenever the prescription drug has not previously been dispensed to a pat	8%
1735.2(e)(8) - Compounding Limitations and Requirements; Instructions for storage and handling of the compounded drug preparation	6%	1717.5(a) - (a) A pharmacy may offer a program to automatically refill prescriptions provided the pharmacy complies with this section	5%	1311.30(a) - Requirements for storing and using a private key for digitally signing orders; Only the certificate holder may access or use his or her digital certificate and private key	8%
1735.3(a)(2)(c) - For each compounded drug preparation, pharmacy records shall include a compounding log consisting of a single document containing the identity of any pharmacy personnel engaged in co	6%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	5%	1305.22(g) - Procedure for filling electronic orders; purchaser must create a record of the quantity of each item received and the date received	8%
1735 3(a)(2)(D) - For each compounded drug preparation, pharmacy records shall include a compounding log consisting of a single document containing the identity of the pharmacist reviewing the final d	6%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	1793.2 - Duties of a pharmacy technician	8%