

#### **California State Board of Pharmacy**

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

#### a. Summary of Annual Presentation on the Board's Inspection Program

#### 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.

#### Summary of Committee Discussion

During the meeting, the Committee received a presentation on the Board's inspection program from Julie Ansel, Deputy Executive Officer. The presentation focused 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.

Committee members expressed appreciation for the efforts undertaken by staff to meet the policy goal of inspecting each pharmacy every four years. Members requested that next year's inspection presentation data be broken down by license category. Members also discussed that it may be helpful to add a reference section on the inspection report, and/or draft a fact sheet or *Script* article, to clarify specific terminology for licensees to define terms such as orders of correction, violations, and written notice. The Committee suggested that this issue be referred to and discussed by the Communication and Public Education Committee. Providing some education to licensees may help inform licensees to better understand the inspection process, terminology, and outcomes.

**Attachment 1** includes a copy of the presentation slides. Data reflects inspection data from July 1, 2024, through May 15, 2025.

#### b. Summary of Annual Presentation on the Board's Citation Program

#### 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.

#### **Background**

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<br>Complete   | 426        | 341         | 325         | 359          | 406         |
| Order of Abatements<br>Issued | 245        | 269         | 196         | 97           | 52          |
| Amount of Fines<br>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 |

<sup>\*</sup>July 1, 2024, through May 31, 2025

#### Summary of Committee Discussion

During the meeting, members received a presentation providing updated information on the Board's citation and fine program from Executive Officer Anne Sodergren.

The Committee appreciated that staff reported the citation data by license type. Members noted the decrease in the overall citations issued in fiscal year 24/25, noting staff's focus on internal norming of case investigations and inspector education of licensees.

**Attachment 2** includes a copy of the presentation slides. Data reflects July 1, 2024, through May 30, 2025.

# c. <u>Summary of 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>

#### 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.

California Code of Regulations, 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.

#### Summary of Committee Discussion

During the meeting, Chief of Enforcement Janice Dang provided a presentation describing updated information related to quality assurance reports received pursuant to CCR section 1711(f). Members noted there may still be an issue with underreporting QA records for ADDS and confusion amongst the regulated public on reporting requirements, making it challenging to evaluate the error reports provided. Over the

next year, the Board will continue with its outreach and education efforts. Members suggested staff review the ADDS FAQs and offer recommendations for possible updates. In addition, members suggested staff develop a standardized template for reporting of ADDS QA reports under CCR section 1711(f), to aid with compliance and consistency in data elements.

**Attachment 3** includes a copy of the presentation slides.

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

#### Background

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.

#### Summary of Committee Discussion and Action

During the meeting, members reviewed the updated FAQs and provided feedback to staff. FAQs #1-13 are existing FAQs from 2021 that have been updated. Questions #14-18 are new FAQs that are proposed to be added. Members spoke in support of the updates to the FAQs.

Members asked for clarification on questions #1, #6, and #18. Based on the Committee's discussion, staff made further updates to the responses to questions #1 and #6 after the meeting. For #18, members discussed developing regulations in this area addressing the wearing of identification, as interpretive questions with the word "name" in BPC section 680 were noted. The Committee will continue its discussion on #18 at a future meeting.

Committee Motion: Recommend approval of the updated FAQs related to the Board's Ask An Inspector Program consistent with the Committee's discussion.

Attachment 4 includes a copy of the updated FAQs.

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

#### 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.

#### Summary of Committee Discussion and Action

During the meeting, members reviewed the edits to the FAQs and provided feedback to staff. The updates to the FAQs pertain to medication errors and CAMER (California Medication Error Reporting), including registration and fee information for licensees.

**Committee Motion**: Recommend approval of the updated FAQs related to Assembly Bill 1286 as presented.

**Attachment 5** includes a copy of the updated FAQs.

f. <u>Discussion, Consideration, and Possible Action on Proposal to Add New Section 1707.51</u>
Related to Accessible Prescription Drug Labels to Article 2 of Division 17 of Title 16 of the
California Code of Regulations

#### 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.)

#### Summary of Committee Discussion and Action

During the March 2025 Committee meeting, members discussed and considered various policy questions related to Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024), the measure that added section 4076.8 to the BPC. 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.

During the June Committee meeting, members reviewed and discussed draft regulatory language developed by staff. Members were in support of the draft language. Members suggested that drafting FAQs on the topic in the future may also be appropriate. Members received public comment suggesting that section (b) of the

proposed regulation, which requires pharmacy personnel to sign a copy of the policies and procedures, should be removed. After discussion, members did not reach a consensus on whether to keep or remove section (b). Accordingly, section (b) was left in to allow the full Board to consider the issue.

**Committee Motion**: Recommend initiation of a rulemaking to add California Code of Regulations, title 16, section 1707.51 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.

#### Should the Board agree to move the regulation forward the following motion may be used:

Initiate a rulemaking to add California Code of Regulations, Title 16, section 1707.51 [either "as presented" or "consistent with the Board's discussion"]. Authorize the executive officer to further refine the language consistent with the Board's discussion. Direct Board staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review, and if no adverse comments are received, authorize the executive officer to take all steps necessary to initiate the rulemaking process, 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 the action, and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking process and adopt the proposed regulation at Section 1707.51. Finally, delegate to the Executive Officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

**Attachment 6** includes a copy of the draft regulatory text.

#### g. <u>Discussion and Consideration of Enforcement Statistics</u>

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, 202                       |       | , 2024       | Oct. 1, 2024 |              | Jan. 1, 2025 |              | Apr. 1, 2025 |              | Jun. 1, 2025 |              |
|-----------------------------------|-------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
|                                   | Vol.  | Avg.<br>Days | Vol.         | Avg.<br>Days | Vol.         | Avg.<br>Days | Vol.         | Avg.<br>Days | Vol.         | Avg.<br>Days |
| Awaiting<br>Assignment            | 44    | 6            | 63           | 14           | 31           | 10           | 71           | 14           | 107          | 10           |
| Cases Under<br>Investigation      | 1,005 | 136          | 908          | 146          | 978          | 141          | 1,021        | 143          | 957          | 137          |
| Pending<br>Supervisor<br>Review   | 223   | 74           | 147          | 74           | 173          | 62           | 295          | 70           | 322          | 65           |
| Pending<br>Second<br>Level Review | 99    | 22           | 229          | 26           | 116          | 64           | 93           | 68           | 161          | 41           |
| Awaiting<br>Final Closure         | 56    | 8            | 34           | 14           | 49           | 34           | 29           | 52           | 35           | 42           |

**Attachment 7** includes the enforcement statistics for fiscal year 2024-25, through May 31, 2025.

# Attachment 1

California State Board of Pharmacy

**Enforcement Committee Meeting** 

**Inspection Presentation** 

**June 2025** 



# Mandate

**Consumer Protection** 



# Inspection Process - Observations

- Consultation Procedure
- Notice to Consumer Poster, Language Sign, Pharmacy Permit
- Security Features
- Name Tags
- Privacy (audio and visual)
- Staffing Ratio and Duties Performed
- Professional Interactions



# Inspection Process - Items Reviewed

- > Self-Assessment
- > Transmitting to CURES
- Enrollment in the Subscriber Alert System
- Quality Assurance Policy AND Medication Errors Reports
- Policies and Procedures



# What is Inspected

- Physical Facility
- Security
- Cleanliness and Orderliness
- Expiration Dates, including on Labels



#### Education

- Questions from Licensee
- Standard Education Topics
- > Tools for Licensees



# **Total Inspections Completed**

- >FY 20/21 2,963
- >FY 21/22 2,938
- >FY 22/23 3,045
- >FY 23/24 2,969
- >FY 24/25 2,833\*



# Inspections by Visit Type - FY 24/25

- Routine-Only Pharmacy Inspections (PHY-PHE): 1,135
- Complaint Inspections:
- Pharmacist Recovery Program/Probation: 251
- Compounding Inspections:
  812
  - New 53
  - > Renewal 759
- Outsourcing:
  - New 8
  - Renewal 22
- Change of Location/Ownership:



# Inspections by Visit Type - FY 24/25

> Other Inspections by License Type: 213

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> ADDS 159
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- > CLN 1
- > HSP 10
- > LCF 1
- > NPL 5
- > OSD 2
- > TPL 2
- > WLS 15
- > UNL 18

> Total Inspections Completed: 2,833\*

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# Routine Pharmacy Inspections

Total Number of Licensed Pharmacies: 6,080

Total Number of Routine Inspections (PHY/PHE): 1,464

- > 1,135 Routine-Only Pharmacy Inspections Completed
- > 241 Routine Pharmacy Inspections Completed on a Complaint Visit
- > 75 Routine Pharmacy Inspections Completed on a Probation Visit
- > 13 Routine Pharmacy Inspections Completed on a Compounding Visit



## Routine Inspection Outcomes

Routine-Only Inspections Completed: 1,135

- > 527 Pharmacies Were Issued No Violations
- > 580 Pharmacies Were Issued 1,590 Corrections
- > 75 Pharmacies Were Issued 183 Written Notices

Routine Inspections Completed during Complaint Visit: 241

- > 109 Pharmacies Were Issued No Violations
- > 106 Pharmacies Were Issued 256 Corrections
- > 47 Pharmacies Were Issued 103 Written Notices



## Routine Inspection Outcomes

Routine Inspections Completed during Probation Visit: 75

- > 59 Pharmacies Were Issued No Violations
- > 17 Pharmacies Were Issued 40 Corrections
- > 1 Pharmacy Was Issued 2 Written Notices

Routine Inspections Completed during Compounding Visit: 13

- > 13 Pharmacies Were Issued No Violations
- > 0 Pharmacies Were Issued Corrections
- > 0 Pharmacies Were Issued Written Notices



# Top Corrections on Routine Inspections

|            | Chain Pharmacies                   | Non-Chain Pharmacies |   |  |  |
|------------|------------------------------------|----------------------|---|--|--|
| Violation  | Description                        | Violation            | Description   |  |  |
| CCR 1714   | Operational Standards and Security | CCR 1715.65          | Inventory Reconciliation Reports of Controlled Substances |  |  |
| BPC 4058   | License Display                    | CCR 1707.2           | Duty to Consult   |  |  |
| CCR 1746.4 | Pharmacists Administering Vaccines | CCR 1714             | Operational Standards and Security                        |  |  |
| CCR 1715   | Self-Assessment of PHY by PIC      | CCR 1707.5           | Patient-Centered Labels                                   |  |  |
| CCR 1707.2 | Duty to Consult                    | CFR 1304.11          | Inventory Requirements                                    |  |  |



# Top Written Notices on Routine Inspections

|            | Chain Pharmacies                                | Non-Chain Pharmacies |   |  |
|------------|---|----------------------|---|--|
| Violation  | Description                                     | Violation            | Description   |  |
| CCR 1714   | Operational Standards and Security              | CCR 1715.65          | Inventory Reconciliation Reports of Controlled Substances |  |
| CCR 1707.2 | Duty to Consult                                 | CCR 1714             | Operational Standards and Security                        |  |
| CCR 1715   | Self-Assessment of PHY by PIC                   | BPC 4301             | Unprofessional Conduct                                    |  |
| CCR 1776.1 | Prescription Take-Back                          | HSC 111330           | Labeling  |  |
| BPC 4115   | Pharmacy Technician; Tasks, Ratios, Supervision | BPC 4312             | Voiding of License  |  |



# CCR 1707.2 - Duty to Consult Pharmacy Routine Inspections

In FY 24/25 160 routine inspections revealed issues with patient consultation

- In 9 of the 160 inspections the inspector observed that consultation was not provided to the patient or pharmacy staff was observed screening for consultation
- ➤ In 68 of the 160 inspections the inspector found that the site was not providing written notice of consultation on delivered or mail order prescriptions
- In 83 of the 160 inspections the inspector found that the written notice of consultation did not meet All the requirements of the regulation (lacked one or more required elements)



# **Inspection Summary**

Every pharmacy licensed for more than 4 years has received a routine inspection.



# Questions?

# Attachment 2

California State Board of Pharmacy

**Enforcement Committee Meeting** 

**Citation Presentation** 

**June 2025** 



# **Complaint/Citation Process**

Complaints are received from many sources: the public, another government agency, another licensee, a professional association, law enforcement or internal (initiated by a Board inspector or enforcement personnel) Complaint is Received and/or an Investigation is Initiated

Complaint/Investigation is Reviewed and Assigned

**Investigated by an Enforcement Analyst** 

Investigated by a Board Inspector

#### **Enforcement Analyst**

Conducts investigations into allegation that do not require a pharmacist's knowledge. Such investigations include allegations of criminal behavior, continuing education violations, out of state discipline and some unlicensed activity cases. Supervising Inspector reviews report and recommends action

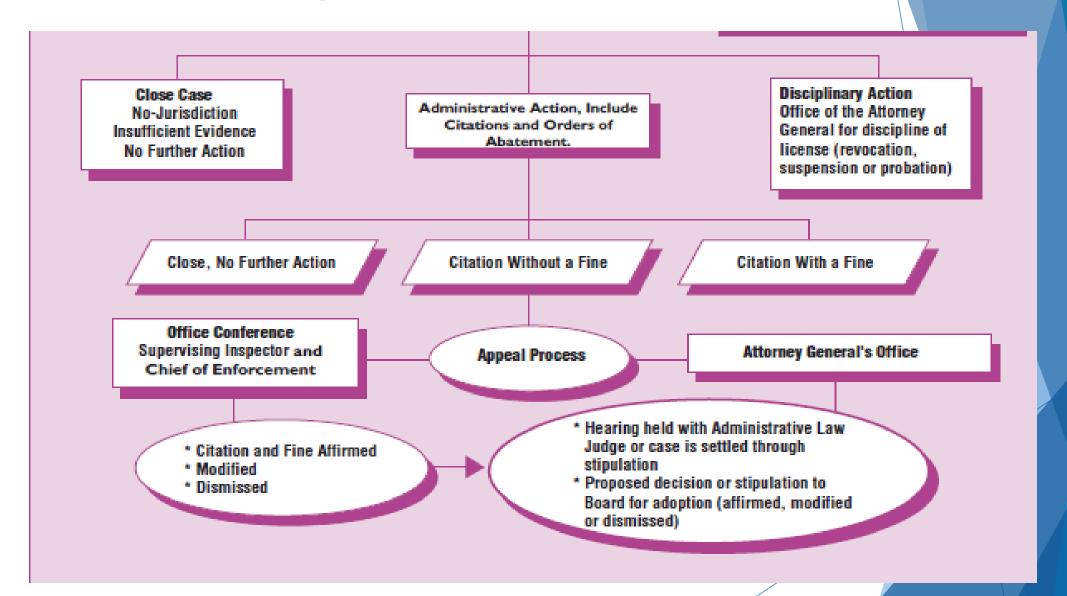
> Final review and approval by the Executive Officer

#### Inspector

Investigates consumer complaints as well as allegations of complex and serious cases. The inspector (a licensed pharmacist) conducts a field investigation that may include: a routine inspection of the pharmacy; collection of records and other evidence; interviewing individuals; obtaining declarations; and performing an audit. Joint investigations are done with other agencies such as DEA, NBE, Medical Board, FDA and local law enforcement agencies.



# **Complaint/Citation Process**





Business and Professions Code (BPC) Section 4314 establishes the authority for the board to issue citations

BPC Section 4317.5(a) establishes the authority for the board to issue citations for similar repeat violations occurring within five years by three or more pharmacies within a chain pharmacy.

# Relevant Law

BPC Section 4317.5(b) establishes the authority for the board to issue citations for violations demonstrated to be the result of a written policy or which was expressly encouraged by a common owner or manager of a chain pharmacy.

Title 16, California Code of Regulations (CCR) Sections 1775-1775.4, provide the board's regulations governing its citation and fine program.

CCR Section 1775 includes the authority of the executive officer or designee to issue citations



# Fine Authority

- ▶ BPC 125.9 Fine of up to \$5,000 per investigation
- ▶ BPC 4067 Fine of \$25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred
- ▶ BPC 4126.5 Fine of up to \$5,000 per occurrence
- BPC 4317.5 (a) Fine for up to \$100,000 for repeated violations for pharmacies operating under common ownership or management within a chain community pharmacy
- ▶ BPC 4317.5(b) Fine for up to \$150,000 for violations that are a result of a written policy or which was expressly encouraged by a common manager or owner



# Factors Considered in Assessing Administrative Fines

Gravity of the violation

Good or bad faith of the cited person or entity

History of previous violations

Evidence that the violation was or was not willful

Extent to which the cited person or entity has cooperated with the board's investigation

Extent to which they have mitigated or attempted to mitigate any damage or injury caused by the violations

Other matters as may be appropriate

Number of violations found in the investigation



#### **Overall Citation Data**

|  | FY 20/21  | FY 21/22    | FY 22/23    | FY 23/24    | FY 24/25    |
|--|-----------|-------------|-------------|-------------|-------------|
| Citations Issued   | 934       | 1,274       | 1,053       | 843         | 609         |
| Average Time from Complaint Receipt to Citation Issuance | 426       | 341         | 325         | 359         | 406         |
| Citations Issued <u>without</u> a Fine                   | 401       | 451         | 390         | 305         | 239         |
| Citations Issued <u>with</u> a Fine                      | 533       | 823         | 663         | 538         | 370         |
| Fines Assessed   | \$787,100 | \$2,029,012 | \$3,418,500 | \$3,363,265 | \$1,887,050 |
| Total Fines after Modification                           | \$612,200 | \$1,313,075 | \$2,516,750 | \$3,141,515 | \$1,795,800 |
| Fines Collected  | \$711,729 | \$1,093,911 | \$1,713,100 | \$1,813,951 | \$1,627,523 |



| Fiscal Year | Average Days |
|-------------|--------------|
| FY 20/21    | 426          |
| FY 21/22    | 341          |
| FY 22/23    | 325          |
| FY 23/24    | 359          |
| FY 24/25    | 406          |

# Average Time from Complaint Receipt to Citation Issuance

| License Type                       | FY 22/23 | FY 23/24 | FY 24/25 |
|------------------------------------|----------|----------|----------|
| Pharmacy                           | 524      | 464      | 337      |
| Hospital Pharmacy                  | 23       | 10       | 9        |
| Nonresident Pharmacy               | 13       | 14       | 28       |
| Resident Sterile<br>Compounder     | 19       | 12       | 4        |
| Non-Resident Sterile<br>Compounder | 0        | 0        | 3        |
| Wholesaler                         | 12       | 5        | 3        |
| Out of State Distributor           | 13       | 9        | 13       |
| Nonresident Outsourcer             | 11       | 6        | 2        |
| Pharmacist                         | 378      | 248      | 141      |
| Pharmacy Technician                | 33       | 53       | 36       |
| Miscellaneous                      | 19       | 14       | 9        |
| Unlicensed                         | 8        | 8        | 24       |

# Citations Issued by License Type



# Citations Issued - BPC 4314

|                                 | FY 20/21  | FY 21/22    | FY 22/23    | FY 23/24    | FY 24/25    |
|---------------------------------|-----------|-------------|-------------|-------------|-------------|
| Citations Issued                | 934       | 1,273       | 974         | 721         | 571         |
| Citations Issued without a Fine | 401       | 451         | 390         | 305         | 216         |
| Citations Issued with a Fine    | 533       | 822         | 584         | 372         | 332         |
| Fines Assessed                  | \$787,100 | \$1,954,012 | \$1,790,500 | \$1,705,015 | \$1,255,550 |
| Fines Collected                 | \$711,729 | \$1,093,911 | \$1,643,100 | \$1,154,951 | \$1,067,273 |



#### Citations Issued - BPC 4317.5 (a) and (b) Combined

|                  | FY 21/22  | FY 22/23    | FY 23/24    | FY 24/25  |
|------------------|-----------|-------------|-------------|-----------|
| Citations Issued | 2         | 78          | 132         | 38        |
| Fines Assessed   | \$225,000 | \$1,627,500 | \$2,145,750 | \$631,500 |
| Fines Collected  | \$0       | \$81,500    | \$659,000   | \$560,250 |



### Citations Issued - BPC 4317.5

| Fine Amounts          | FY 22/23 | FY 23/24 | FY 24/25 |
|-----------------------|----------|----------|----------|
| \$1 - \$10,000        | 42       | 77       | 19       |
| \$10,000 - \$15,000   | 14       | 31       | 10       |
| \$15,001 - \$25,000   | 11       | 16       | 4        |
| \$25,001 - \$50,000   | 3        | 1        | 5        |
| \$50,001 - \$75,000   | 5        | 3        | 0        |
| \$75,001 - \$100,000  | 2        | 3        | 0        |
| \$100,001 - \$125,000 | 0        | 1        | 0        |
| \$125,001 - \$150,000 | 1        | 0        | 0        |



## Pharmacies (PHY) Top Ten Violations

|                       | Chain Pharmacies                                   | Non-Chain Pharmacies |   |
|-----------------------|--|----------------------|---|
| Violation             | Description  | Violation            | Description                               |
| CCR 1716              | Medication Error                                   | CCR 1714             | Operational Standards and Security        |
| CCR 1714              | Operational Standards and Security                 | BPC 4301             | Unprofessional Conduct                    |
| BPC 4113              | Notify Board Regarding PIC                         | BPC 4113             | Notify Board Regarding PIC                |
| BPC 4301              | Unprofessional Conduct                             | CCR 1735             | Compounding-Related                       |
| CCR 1764<br>CCC 56.10 | Disclosure of Medical Information                  | CCR 1761             | Erroneous or Uncertain Prescription       |
| CCR 1707.2            | Duty to Consult                                    | CCR 1715             | PIC Self-Assessment                       |
| BPC 733               | Obstruction/Delay in Therapy                       | BPC 4305             | Operate for More than 30 Days without PIC |
| BPC 4115              | Pharmacy Technician; Tasks, Ratios,<br>Supervision | CCR 1716             | Medication Error                          |
| BPC 1711              | Quality Assurance                                  | BPC 4059             | Rx Requirements                           |
| CCR 1707              | Offsite Storage Requirements                       | BPC 4081             | Records Maintenance                       |

### Nonresident Pharmacy (NRP) Top Violations

#### Violation Description

BPC 733 Unlawful Dispensing of Dangerous Drugs and Devices/Obstruction

BPC 4301 Unprofessional Conduct

### Nonresident Wholesaler (OSD) Top Violations

| Violation Description                 |                                |
|---------------------------------------|--------------------------------|
| BPC 4161(j) DRIC Requirements         |                                |
| BPC 4301(j) Controlled Substances and | Dangerous Drug Violations      |
| BPC 4301(o) Violation of State/Federa | Law                            |
| BPC 4301(l) Conviction of a Crime Sub | stantially Related to Pharmacy |



#### Pharmacist (RPH) Top Violations

#### **Violation Description**

BPC 4301 Unprofessional Conduct

CCR 1714 Operational Standards and Security

CCR 1761 Erroneous or Uncertain Prescription

CCR 1715 PIC Self-Assessment

CCR 1716 Medication Error

BPC 4306.5 Misuse of Education

**CCR 1735 Compounding Requirements** 

BPC 4059 Rx Requirements

BPC 4081 Record Maintenance and Inventory

BPC 4115 Pharmacy Technician; Tasks, Ratios, Supervision



### Pharmacy Technician (TCH) Top Violations

#### **Violation Description**

BPC 4301(l) Conviction of a Crime Substantially Related to Pharmacy

BPC 4301(h) Self Administer Drugs or Alcohol

BPC 4301(f) Moral Turpitude, Dishonesty, Fraud, Deceit or Corruption

BPC 4115 Pharmacy Technician; Tasks, Ratios, Supervision



### Hospital Pharmacy (HSP/HPE) Top Violations

| Violation Description                        |
|--|
| BPC 4301 Unprofessional Conduct              |
| CCR 1714 Maintain Facilities                 |
| BPC 4113 Notify Board Regarding PIC          |
| CCR 1761 Erroneous or Uncertain Prescription |



### Violations Issued Under Authority of 4317.5(a)

| Violation                           | Description  | Count | Average Fine<br>Amount |
|-------------------------------------|--|-------|------------------------|
| CCR 1716                            | Medication Error   | 14    | \$7,500                |
| BPC 4113                            | Notify Board Regarding PIC                                     | 11    | \$2,250                |
| BPC 4305                            | Operate More Than 30 Days Without PIC                          | 10    | \$12,250               |
| CCR 1707.2                          | Duty to Consult  | 10    | \$8,000                |
| BPC 4301                            | Unprofessional Conduct   | 7     | \$15,714               |
| CCR 1714                            | Operational Standards and Security                             | 5     | \$2,200                |
| CCR 1707/<br>CCC 56.10/<br>CCR 1714 | Security of Records Storage                                    | 4     | \$10,000               |
| CCR 1711                            | Quality Assurance  | 2     | \$5,000                |
| CCR 1764/<br>CCC 56.10              | Disclosure of Medical Information                              | 2     | \$10,000               |
| CCR 1715.65                         | Controlled Substances Reconciliation Report                    | 1     | \$2,500                |
| BPC 4125(a)/<br>CCR 1711(a)(d)      | Quality Assurance  | 1     | \$5,000                |
| BPC 733                             | Unlawful Dispensing of Dangerous Drugs and Devices/Obstruction | 1     | \$7,500                |
| BPC 4115(g)                         | Pharmacy Technician Ratio                                      | 1     | \$1,000                |

### Violations Issued Under Authority of 4317.5(b)

| Violation                   | Description  | Count | Average Fine<br>Amount |
|-----------------------------|--|-------|------------------------|
| BPC 4113.7(a)/<br>4113.7(b) | Quota Established by Chain Pharmacy                            | 1     | \$50,000               |
| BPC 733                     | Unlawful Dispensing of Dangerous Drugs and Devices/Obstruction | 1     | \$25,000               |
| CCR 1717                    | Pharmaceutical Practice  | 1     | \$10,000               |



### Duty to Consult CCR 1707.2 - BPC 4314

|   | FY 21/22                               | FY 22/23                              | FY 23/24                              | FY 24/25                                   |
|---|--|---------------------------------------|---------------------------------------|--|
| Total Duty to Consult Violations (Pharmacists and Pharmacies) | 49                                     | 58                                    | 30                                    | 20   |
| Pharmacy Violations   | 21 Total<br>18 with fine<br>3 no fine  | 26 Total<br>23 with fine<br>3 no fine | 15 Total<br>13 with fine<br>2 no fine | 15 Total<br>15 with fine<br>0 no fine      |
| Average Violation Amount (PHY)                                | \$3,416                                | \$3,462                               | \$3,025                               | \$4,267                                    |
| Pharmacist Violations   | 28 Total<br>11 with fine<br>17 no fine | 32 Total<br>8 with fine<br>24 no fine | 15 Total<br>2 with fine<br>13 no fine | <b>5 Total</b><br>0 with fine<br>5 no fine |
| Average Violation Amount (RPH)                                | \$1,272                                | \$844                                 | \$1,000                               | \$0  |



# Duty to Consult CCR 1707.2 - BPC 4317.5

|   | FY 22/23 | FY 23/24 | FY 24/25 |
|---|----------|----------|----------|
| Total Duty to Consult Pharmacy Violations | 7        | 22       | 10       |
| Average Violation Amount                  | \$7,500  | \$9,205  | \$12,350 |



#### Orders of Abatement

- > The board may issue citations with orders of abatement
- The board has been using orders of abatement routinely since 2018
- The abatement order may require:
  - The licensee to take continuing education courses/training
  - The licensee to provide specific documentation
  - The licensee to detail a plan to comply with Pharmacy Law
- May result in either a reduction or forgiveness of the fine



#### **Abatement Types**

Requested Continuing Education (CE) to be Completed by Licensee (Typically 2-6 hours)

- Board Provided Rx Drug Abuse Course
- Ethics Course (Pursuant to CCR 1773.5)
- Immunization Training
- Compounding Training
- Pharmacy Operations
- Pharmacy Law & Ethics
- Role of the Pharmacist in Charge (PIC)
- Medication Error reduction Strategies



#### **Abatement Types**

Other Abatements that may be requested by the Board:

- Internal policy training for Pharmacy staff
- In service trainings for staff
- Updated self assessment
- Updated policies and procedures



#### Abatement Examples

- CCR 1714(c): Pharmacy shall be clean and orderly Abate with photos of cleanliness and order.
- >CCR 1714(d): Pharmacy Security Abate with CE in pharmacy law and operations.
- >CC1716: Medication Error Abate with CE in medication error reduction strategies.
- >CCR 1746.4: Vaccines and Immunizations Abate with CE in immunization training.
- CCR 1735.1 TO 1735.8: Compounding Violations Abate with CE in compounding training.



#### **Orders of Abatement**

Total Orders of Abatement: 53

Abatements Satisfied: 58



#### Citations Contested at Office Conference

Office Conference (OC) allows the licensee the opportunity to present additional or mitigating information.

| Total OC Requested:               | 146 |   |
|-----------------------------------|-----|---|
| Office Conference Outcomes:       |     |   |
| Modified                          | 15  |   |
| Reduced to Letter of Admonishment | 6   |   |
| Dismissed                         | 22  |   |
| Affirmed                          | 69  | / |



#### Formal Citation Appeals

Formal Appeals are conducted pursuant to the Administrative Procedures Act by an administrative law judge who renders a decision for the board to adopt or reject.

| Total Appeals Referred to AG in FY 24/25: | 121 |
|---|-----|
| Total Appeals Pending                     | 131 |
| High Fine Authority Pending               | 95  |



#### Final Citation Outcomes - BPC 4314

| Status  | FY 20/21 | FY 21/22 | FY 22/23 | FY 23/24 | FY 24/25 |
|---|----------|----------|----------|----------|----------|
| Citations Closed                                    | 992      | 1,088    | 954      | 666      | 705      |
| Office Conferences Held                             | 154      | 229      | 192      | 120      | 85       |
| Citations Appealed at the Attorney General's Office | 29       | 34       | 40       | 62       | 35       |



#### Final Citation Outcomes - BPC 4317.5

| Status  | FY 22/23 | FY 23/24 | FY 24/25 |
|---|----------|----------|----------|
| Citations Closed                                    | 8        | 59       | 66       |
| Office Conferences Held                             | 58       | 75       | 27       |
| Citations Appealed at the Attorney General's Office | 9        | 74       | 86       |



# Questions?



## Attachment 3

# ADDS UPDATE Licensing and Med Error Reporting

### ADDS (BPC 4017.3)

#### ADDS = Automated Drug Delivery System

- A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs
- An ADDS collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy and accountability.

#### ADDS (continue)

AUDS = Automated Unit Dose System

For storage and retrieval of unit doses of drugs for administration to patients by person authorized to perform these functions.

APDS = Automated Patient Delivery System

For storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

# AUDS = Automated Unit Dose Systems







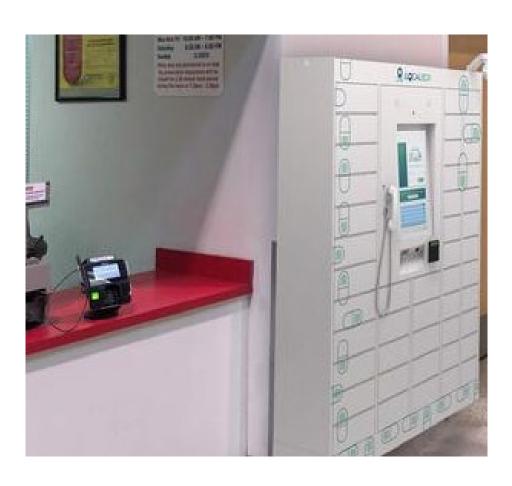
### AUDS (continue)





### APDS = Automated Patient Delivery Systems







### ADDS License Categories

ADD

ADC

ADE

### ADDS Licensing Statistics

ADD = Licensed ADDS operated by pharmacies pursuant to BPC 4427.3 and 4427.65

| ADD                                | FY 18/19 | FY 19/20<br>Operative<br>7/1/2019 | FY 20/21 | FY 21/22 | FY 22/23 | FY 23/24 | FY 24/25<br>As of 4/30/2025 |
|------------------------------------|----------|-----------------------------------|----------|----------|----------|----------|-----------------------------|
| Application received               | 595      | 325                               | 233      | 199      | 385      | 173      | 163                         |
| Application withdrawn              | NA       | 100                               | 21       | 39       | 9        | 150      | 10                          |
| Licenses issued                    | NA       | 1012                              | 150      | 172      | 293      | 205      | 154                         |
| License discontinued               | NA       | 57                                | 98       | 57       | 106      | 71       | 41                          |
| License renewed                    | NA       | 604                               | 790      | 983      | 857      | 869      | 917                         |
| Total # of licensed ADDS (current) | NA       | 910                               | 846      | 1004     | 1107     | 1149     | 1169                        |

### ADDS Licensing Statistics

ADC = Licensed ADDS operated by pharmacies located at a "covered entity" pursuant to BPC 4119.11

| ADD                      | FY 18/19 | FY 19/20<br>Operative<br>7/1/2019 | FY 20/21 | FY 21/22 | FY 22/23 | FY 23/24 | FY 24/25<br>As of 4/30/2025 |
|--------------------------|----------|-----------------------------------|----------|----------|----------|----------|-----------------------------|
| Application received     | 1        | 0                                 | 9        | 2        | 1        | 0        | 4                           |
| Application withdrawn    | 0        | 0                                 | 9        | 0        | 0        | 0        | 0                           |
| Licenses issued          | 1        | 0                                 | 9        | 0        | 1        | 0        | 2                           |
| License discontinued     | NA       | 0                                 | 1        | 0        | 0        | 0        | 0                           |
| License renewed          | NA       | 1                                 | 0        | 0        | 0        | 1        | 0                           |
| Total # of licensed ADDS | 1        | 1                                 | 0        | 0        | 1        | 1        | 3                           |

### ADDS Licensing Statistics:

ADE = ADDS operated by EMS licensed as a pharmacy or wholesaler used to restock ADDS at fire department/fire stations/EMS provider agency's location, BPC 4119.01.

| ADD                      | FY 18/19 | FY 19/20<br>Operative 7/1/2019 | FY 20/21 | FY 21/22 | FY 22/23 | FY 23/24<br>As of 3/2024 |
|--------------------------|----------|--------------------------------|----------|----------|----------|--------------------------|
| Application received     | 0        | 1                              | 0        | 0        | 0        | 0                        |
| Application<br>Withdrawn | 0        | 0                              | 0        | 0        | 0        | 0                        |
| Licenses is sued         | 0        | 1                              | 0        | 0        | 0        | 0                        |
| Licenses discontinued    | NA       | 0                              | 0        | 0        | 0        | 0                        |
| License renewed          | NA       | 0                              | 1        | 1        | 1        | 0                        |
| Total # of licensed ADDS | 0        | 1                              | 1        | 1        | 1        | 1                        |

# ADDS Medication Errors Reported

#### Number of pharmacies submitting med errors

| Type of pharmacy: | FY 18/19 | FY 19/20 | FY20/21 | FY 21/22 | FY 22/23 | FY 23/24 | FY 24/25<br>As of 4/30/25 |
|-------------------|----------|----------|---------|----------|----------|----------|---------------------------|
| PHY/PHE           | 0        | 0        | 8       | 8        | 4        | 25       | 13                        |
| HSP/HPE           | 0        | 0        | 0       | 0        | 1        | 15       | 12                        |
| DRM/DRE           | 0        | 0        | 0       | 0        | 0        | 2        | 1                         |
| LCF               | 0        | 0        | 3       | 3        | 12       | 30       | 21                        |
| Total:            | 0        | 0        | 11      | 11       | 17       | 72       | 47                        |

#### Number of medication error reported

| Type of pharmacy: | FY 18/19 | FY 19/20 | FY20/21 | FY 21/22 | FY 22/23 | FY 23/24 | FY 24/25<br>As of 4/30/25 |
|-------------------|----------|----------|---------|----------|----------|----------|---------------------------|
| PHY/PHE           | 0        | 0        | 252     | 305      | 53       | 770      | 89                        |
| HSP/HPE           | 0        | 0        | 0       | 0        | 151      | 294      | 169                       |
| DRM/DRE           | 0        | 0        | 0       | 0        | 0        | 101      | 3                         |
| LCF               | 0        | 0        | 1       | 11       | 66       | 1047     | 538                       |
| Total:            | 0        | 0        | 253     | 316      | 270      | 2212     | 799                       |

### Location of Med Errors

| Location of ADDS:              | FY 18/19 | FY 19/20 | FY 20/21 | Fy 21/22 | FY 22/23 | FY 23/24                                      | FY 24/25<br>As of 4/30/2025                       |  |
|--------------------------------|----------|----------|----------|----------|----------|---|---|--|
| Adjacent to pharmacy           | NA       | NA       | 0        | 0        | 0        | 0   | 0   |  |
| Medical Office                 | NA       | NA       | 0        | 0        | 0        | 0   | 0   |  |
| Clinic                         | NA       | NA       | 0        | 0        | 0        | 2   | 0   |  |
| Correctional<br>Clinic         | NA       | NA       | 1        | 11       | 63       | 1034 535                                      |   |  |
| Skilled<br>Nursing<br>Facility | NA       | NA       | 0        | 0        | 0        | 340   | 68  |  |
| Intermediate<br>Care Facility  | NA       | NA       | 0        | 0        | 3        | 0   | 0   |  |
| Inside the<br>Pharmacy         | NA       | NA       | 252      | 305      | 49       | 281   | 6   |  |
| Other                          | NA       | NA       | 0        | 0        | 155      | Jail 15<br>Hospital 395<br>PHF 143<br>Other 2 | Jail 5<br>Hospital 177<br>PHF 7<br>DRE 1<br>Other |  |
| TOTAL:                         | NA       | NA       | 253      | 316      | 270      | 2212  | 799   |  |

#### TYPE OF MED ERRORS BY LOCATION

| ADDS<br>Location                  | Wrong<br>Drug       | Wrong<br>Strength   | Wrong<br>Quantity | Wrong<br>Patient | Label<br>Error | Packaging<br>Error | Duplicate<br>Therapy | Expired<br>Drug | Not<br>enough<br>info | Unauthorize<br>Dispensing | Total: |
|-----------------------------------|---------------------|---------------------|-------------------|------------------|----------------|--------------------|----------------------|-----------------|-----------------------|---------------------------|--------|
| Pharmacy                          | 2                   | 2                   | 1                 | 1                | 0              | 0                  | 0                    | 0               | 0                     | 0                         | 6      |
| Medical<br>Office                 | 0                   | 0                   | 0                 | 0                | 0              | 0                  | 0                    | 0               | 0                     | 0                         | 0      |
| Clinic                            | 0                   | 0                   | 0                 | 0                | 0              | 0                  | 0                    | 0               | 0                     | 0                         | 0      |
| Correction al Clinic              | 37<br>+1<br>(WD/WP) | 63<br>+1<br>(WS/WP) | 99                | 97               | 1              | 0                  | 9                    | 0               | 155                   | 72                        | 535    |
| SNF                               | 24                  | 21                  | 7                 | 6                | 0              | 1                  | 0                    | 0               | 5                     | 4                         | 68     |
| ICF                               | 0                   | 0                   | 0                 | 0                | 0              | 0                  | 0                    | 0               | 0                     | 0                         | 0      |
| Adjacent<br>to<br>Pharmacy        | 0                   | 0                   | 0                 | 0                | 0              | 0                  | 0                    | 0               | 0                     | 0                         | 0      |
| Jail                              |                     | 1                   | 2                 | 0                | 0              | 0                  | 0                    | 0               | 1                     | 1                         | 5      |
| Hospital/<br>Drug Room            | 20                  | 15 + 1              | 18                | 29               | 0              | 0                  | 0                    | 9               | 56                    | 30                        | 177    |
| Psychiatric<br>Health<br>Facility | 2                   | 0                   | 1                 | 2                | 0              | 0                  | 0                    | 0               | 2                     | 0                         | 7      |
| Total:                            | 86                  | 104                 | 128               | 135              | 1              | 1                  | 9                    | 9               | 219                   | 107                       | 799    |

# Type of Med Errors Related to Type of ADDS

Type of ADDS

Type of Medication Errors

|         | Wrong<br>Drug | Wrong<br>Strength | Wrong<br>Quantity | Wrong<br>Patient | Label<br>Error | Duplicate<br>Therapy | Expired<br>Drug | Packaging<br>Error |     | Not enough information | Total: |
|---------|---------------|-------------------|-------------------|------------------|----------------|----------------------|-----------------|--------------------|-----|------------------------|--------|
| APD     | 0             | 0                 | 0                 | 1                | 0              | 0                    | 0               | 0                  | 0   | 0                      | 1      |
| AUD     | 86            | 104               | 128               | 134              | 1              | 9                    | 9               | 1                  | 107 | 219                    | 798    |
| Totals: | 86            | 104               | 128               | 135              | 1              | 9                    | 9               | 1                  | 107 | 219                    | 799    |

Thank You

# Attachment 4

### 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. (See also Business and Professions Code section 4115.5(b)(3) for similar provisions with respect to pharmacy technician trainees.)
- 3. 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.

**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).

- 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:

- 1. 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. (Also see 21 U.S.C. 829(a).) However, pursuant to Business and Professions Code section 4052.10, a pharmacist may partially fill a Schedule II controlled substance prescription as requested by the patient or prescriber. If a pharmacist dispenses a partial fill on a prescription under section 4052.10, the pharmacy must retain the original prescription, with a notation of how much of the prescription has been filled, until the prescription has been fully dispensed. The total quantity dispensed shall not exceed the total quantity prescribed. The full prescription shall be dispensed not more than 30 days after the date on which the prescriptions was written. See Business and Professions Code section 4052.10 for complete requirements regarding partial fills of Schedule II controlled substance prescriptions; see also 21 U.S.C. 829(f) and 21 CFR 1306.13.

**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 - - <a href="http://www.pharmacy.ca.gov/publications/corresponding\_responsibility.pdf">http://www.pharmacy.ca.gov/publications/corresponding\_responsibility.pdf</a>. Information on the Board's precedential decision on corresponding responsibility can be found at <a href="http://www.pharmacy.ca.gov/enforcement/precedential.shtml">http://www.pharmacy.ca.gov/enforcement/precedential.shtml</a>. The DEA Pharmacist's Manual, available at <a href="https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)">https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)</a> 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: <a href="https://cures.doj.ca.gov/register/pre-registration">https://cures.doj.ca.gov/register/pre-registration</a>

**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: <a href="https://www.dca.ca.gov/webapps/pharmacy/subscribe.php">https://www.dca.ca.gov/webapps/pharmacy/subscribe.php</a>

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 <a href="https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#medication-guides">https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#medication-guides</a> (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 <u>here.</u> 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 5

#### 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: — <a href="mailto:PharmacyAlert@dca.ca.gov">PharmacyAlert@dca.ca.gov</a>. 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 <a href="here">here</a>.

[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 6

### 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 7

### **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 |
|                                |             |           |             | - 4       | 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<br>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<br>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     |

|   |             |           |             |           | Quarter |
|---|-------------|-----------|-------------|-----------|---------|
| Probation Statistics                    | July - Sept | Oct - Dec | Jan - March | Apr - Jun | 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     |

<sup>\*</sup>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<br>oneself, of any controlled substance, or the use of any<br>dangerous drug or of aicoholic beverages to the extent or<br>in a manner as to be dangerous | 12% | 1707 2(a) - Duty to consult: A pharmacist shall provide<br>oral consultation to his or her patient or the agent of<br>patient in all care settings   | 5%  | 1715.65 - Inventory Reconciliation Report of Controlled<br>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,<br>Each permit to operate a pharmacy shall show the name<br>and address of the pharmacy, the form of ownership, the<br>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<br>Requirements, Quality reviews required at each step in<br>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;<br>purchaser must create a record of the quantity of each<br>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%  |