California State Board of Pharmacy

Enforcement Committee Meeting

Inspection Presentation

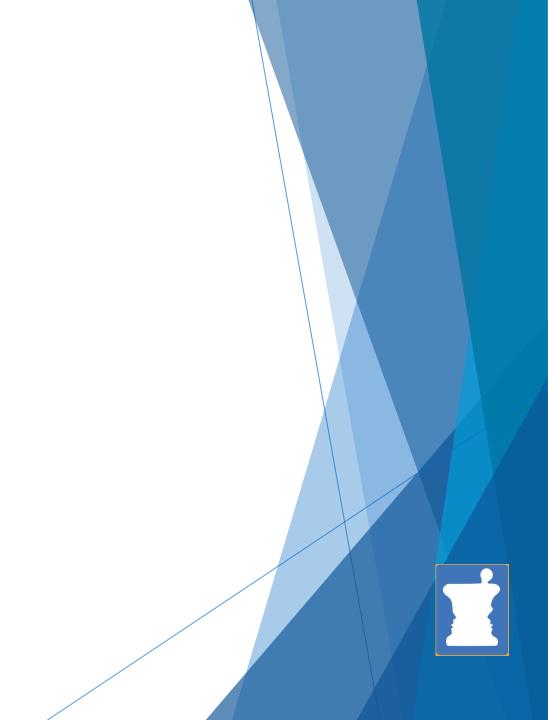
June 2025



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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
- Fools 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*

*FYTD through May 15, 2025



Inspections by Visit Type - FY 24/25

- Routine-Only Pharmacy Inspections (PHY-PHE): 1,135
- Complaint Inspections: 389

251

812

30

3

- Pharmacist Recovery Program/Probation:
- Compounding Inspections:
 - > 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
 - > ADDS 159
 - > CLN 1
 - ➤ HSP 10
 - > LCF 1
 - > NPL

5

2

- > OSD
- > TPL 2
- > WLS 15
- > UNL 18

> Total Inspections Completed: 2,833*

*FYTD through May 15, 2025

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

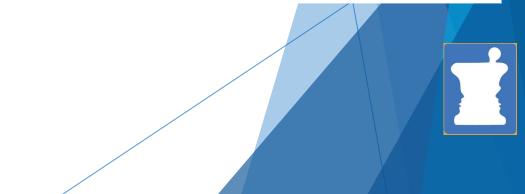
- > 13 Pharmacies Were Issued No Violations
- > 0 Pharmacies Were Issued Corrections
- > 0 Pharmacies Were Issued Written Notices

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

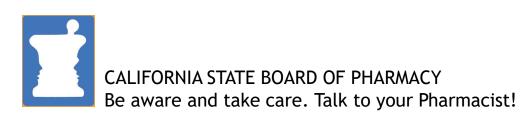
In FY 24/25 160 routine inspections revealed issues with patient consultation

- 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?



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