

# California State Board of Pharmacy

## Enforcement Committee Meeting

### Citation Presentation

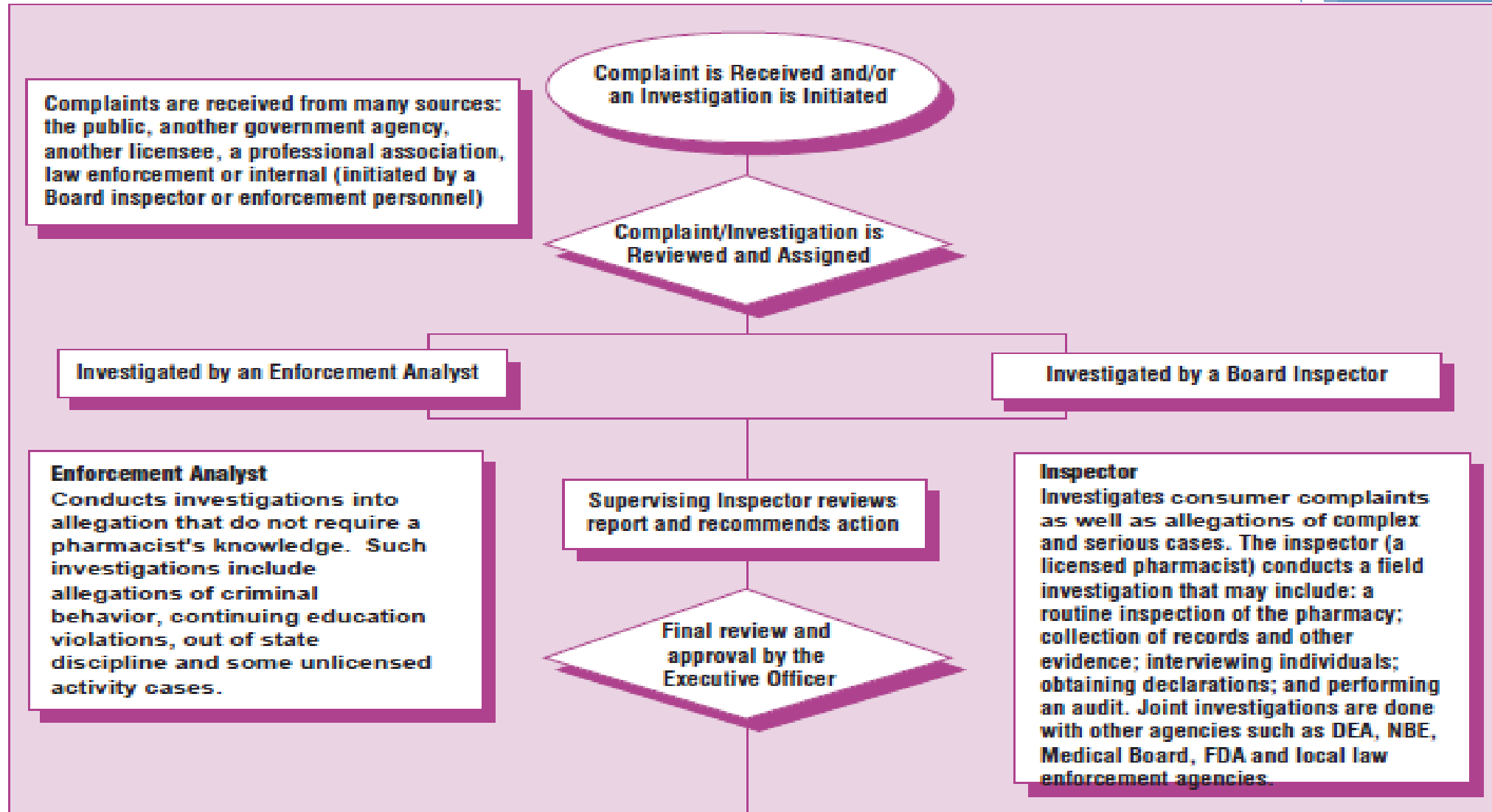
#### June 2025



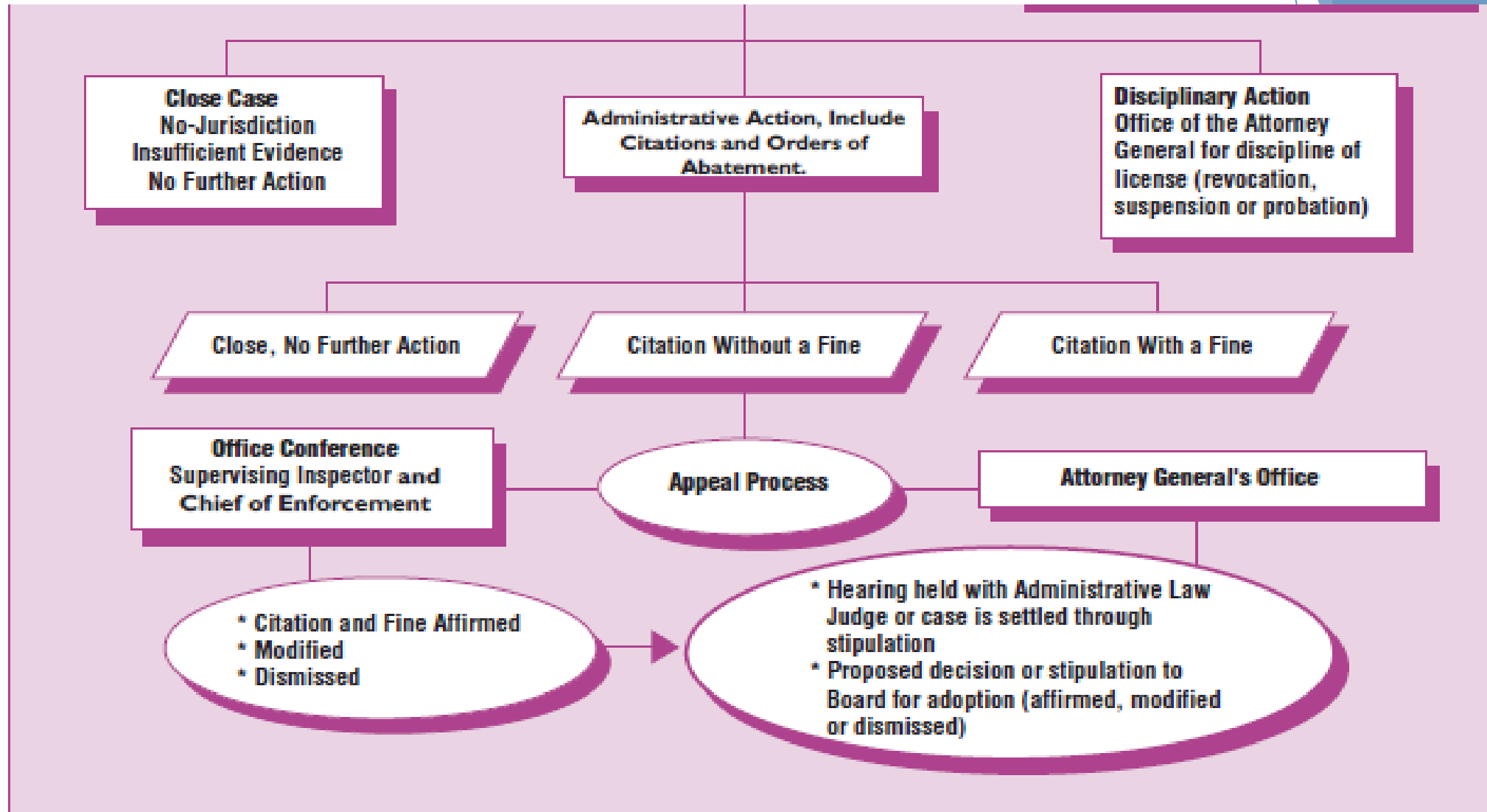
CALIFORNIA STATE BOARD OF PHARMACY  
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# Complaint/Citation Process



# Complaint/Citation Process



# Relevant Law

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.

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



# Average Time from Complaint Receipt to Citation Issuance

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





## Citations Issued by License Type

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 Compounder	19	12	4
Non-Resident Sterile 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 - 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 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, 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/Federal Law

BPC 4301(l) Conviction of a Crime Substantially 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 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/ CCC 56.10/ CCR 1714	Security of Records Storage	4	\$10,000
CCR 1711	Quality Assurance	2	\$5,000
CCR 1764/ CCC 56.10	Disclosure of Medical Information	2	\$10,000
CCR 1715.65	Controlled Substances Reconciliation Report	1	\$2,500
BPC 4125(a)/ 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 Amount
BPC 4113.7(a)/ 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 18 with fine 3 no fine	26 Total 23 with fine 3 no fine	15 Total 13 with fine 2 no fine	15 Total 15 with fine 0 no fine
Average Violation Amount (PHY)	\$3,416	\$3,462	\$3,025	\$4,267
Pharmacist Violations	28 Total 11 with fine 17 no fine	32 Total 8 with fine 24 no fine	15 Total 2 with fine 13 no fine	5 Total 0 with fine 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.

<b>Total Appeals Referred to AG in FY 24/25:</b>	<b>121</b>
➤ 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?

