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Enforcement and Compounding Committee Report

Maria Serpa, Licensee Member, Chair
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Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member

a. Presentation and Discussion on Board's Inspection Program

Background

Pharmacy inspections are conducted by board inspectors and are triggered for a variety of reasons including receipt of consumer complaints, required annual inspections for specific license types or routine inspections to determine if a pharmacy complies with all 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 pharmacy law updates. The board's policy is to have all pharmacies inspected at least once every four years.

Committee Discussion and Action

During the meeting the Committee received presentation detailing inspection information focusing primarily on routine inspections. In fiscal year 2020/21, staff conducted 2,963 in person inspections including 1,174 routine inspection of pharmacies. Of the routine inspections completed 487 inspections resulted in correction(s) being issued and 23 pharmacies were issued a notice of violation(s). Further, 44 routine inspections revealed violations of the Board's patient consultation requirements.

The Committee was advised that about 25% of its licensed pharmacies received a routine inspection during the last fiscal year. Members expressed appreciation to staff for their efforts to focus on pharmacies that have never had a routine inspection and noted the progress made in the past year toward meeting is goal.

Members were also reminded about the educational information available to licensees to prepare for inspections including a pharmacy inspections brochure and online presentation, How to Prepare for a California State Board of Pharmacy Inspection.

The Committee did not take action on this item.

Attachment 1 includes a copy of the presentation slides.

b. Presentation and Discussion on Board's Citation and Fine Program

Relevant Law

Business and Professions Code section 4314 establishes the authority for the board to issue citations which may include fines and/or orders of abatement. As included in this section, the order of abatement may include completion of continuing education courses and specifies that any such continuing education courses shall be in addition to those required for license renewal.

Title 16, California Code of Regulations 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 violation for which a citation may be issued.

Section 1775.2 establishes the factors to be considered in assessing an administrative fine. Such factors include:

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 violations.
7. Other matters as may be appropriate.
8. The number of violations found in the investigation.

Section 1775.3 establishes the order of abatement (OOA) compliance requirements.

Background

As part of the May 2018 Board Meeting, members suggested that staff consider using the abatement provisions, especially in cases where the violations involved a medication error. Since that time, board staff have been ordering abatements with much greater frequency. Further, as part of the Board's October 2018 Board Meeting, the Board updated its Strategic Plan to include additional strategic goals. Related to this agenda item, Goal 2.10, Evaluation of the Board's Citation and Fine Program, was added. Since that time, the Committee has received annual reports on the program. During the meeting, members will receive an annual report on the program.

Citation and Fine	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20	FY 2020/21*
Citations Issued	1,936	2,168	1,144	1,426	926
Average Days to Complete	363	381	381	400	426
Order of Abatements Issued	29	30	224	415	245
Amount of Fines Assessed	$2,355,150	$2,268,600	$1,176,450	$1,462,300	$778,850
Amount Collected	$2,032,745	$2,027,656	$1,210,086	$963,446	$701,479

*Data through June 18, 2021

Committee Discussion and Action

During the meeting members received a presentation providing updated information on the Board's citation and fine program that included information on the most frequent violation for pharmacies and pharmacists and other licensees.

The Committee did not take action on this item.

Attachment 2 includes a copy of the presentation slides.

c. Discussion and Consideration of Pre-filing Settlement Conference

Relevant Law

BPC Section 4001.1 provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Further, the section states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Article 19 (BPC sections 4300 – 4313), and other various provisions of Pharmacy Law and its regulations, define the provisions for disciplinary proceedings and other enforcement actions, acts that constitute unprofessional conduct and other violations of law, mitigating factors, and other authorizing and notification requirements.

CCR section 1760 requires the Board, when reaching a decision on a disciplinary matter, to consider the Disciplinary Guidelines, which are incorporated by reference into this regulation.

The Administrative Procedure Act (Government Code section 1140, et seq.,) defines the administrative case process developed to ensure due process.

Background

The Committee and Board have previously contemplated what, if any, changes could be made to its disciplinary process to reduce the time and cost associated with resolving a disciplinary matter which must be balanced with also continuing to provide due process to licensees, as well as consumer protection. Several proposals were considering including a model used by the Physical Therapy Board. The Committee and Board has dedicated a significant amount of time over many meetings to consider various proposals to determine on how best to achieve its goals - - to reduce costs and case resolution time. Ultimately the Committee and Board directed staff to identify possible solutions to meet the overall policy goal that would NOT require legislative changes.

Most recently, as part of its April 2021 Committee Meeting, members considered a pre-accusation conference model used by the California Board of Accountancy, a brief description of which is provided below:

THE PRE-ACCUSATION REVIEW/CONFERENCE

> Before an accusation is filed, unless public safety requires immediate action, you may be offered an opportunity to review a draft accusation and comment on its factual content. The accusation will be available for review only at a scheduled pre-filing review conference. No copies will be released to you until the actual filing of the accusation.

As part of the April Board Meeting, members expressed support for establishing a similar process for the Board and requested that staff work with the AG's Office on further refinement of the proposal for a pre-accusation conference.

Subsequent to the meeting, staff and representatives of the AG's Office have worked to further refine the process and develop a general implementation plan. Specifically, it is recommended that the Board initially pilot this process at the recommendation of the assigned Deputy Attorney General (DAGs). In the pilot period, the process will be used primarily through the Board's two assigned liaison DAGs for the first 6 months to year to assess the process. It was also recommended that this process would most likely not be appropriate for extremely egregious cases, including those described as Category 4 in the Board's Disciplinary Guidelines.

Committee Discussion and Action

During the meeting members discussed the pre-filling conference and had substantial conversation about the proposed process detailed in the provide flow charts. Members noted that, when applicable, respondents will have additional opportunity to provide supplemental information and mitigation prior to the filing of the pleading (accusation) by the Attorney General's office. Members noted that through the pre-filing conference process outcomes could include amending the draft pleading before filing or potential withdrawal of the matter from the Office of the Attorney General. Further, members discussed the potential for future

settlement agreement could be discussed.

Members reminded stakeholders present that the Committee's discussion was limited to the development of pre-filing settlement conference as previously approved by the Board. The Board has approved moving forward on a pre-filing settlement approach suggested in the proposed flowchart to meet the goals of the disciplinary process within the current legislative authority. Public comment should be limited to this agenda item and not to rediscuss other Alternative Enforcement Models. Members received public comment that the concept and flowchart for pre-filing settlement does not go far enough. Consistent with prior public comments received on this topic, stakeholders again stated the process should avoid matters going to the Office of the Attorney General and that Board Members should be involved in an earlier conference.

Committee Recommendation: Approve the finalized flow chart and allow staff and the Office of the Attorney General to implement the process.

Attachment 3 includes a flowchart that demonstrates conceptually how a pre-filing settlement process could work as well as the general case process.

d. Discussion and Consideration of Board's Disciplinary Guidelines

Relevant Law
Title 16, California Code of Regulations section 1760 provides that the board, in reaching a decision on a disciplinary matter, shall consider the Disciplinary Guidelines (Rev. 2/2017), which are incorporated by reference.

Background
During the March 2019 Enforcement Committee Meeting, members received a presentation from Supervising Deputy Attorney General Joshua Room on the Disciplinary Guidelines and how the Guidelines are used by attorneys, judges, board staff and members. As part of the presentation, a review of the structure and purpose of the Guidelines was provided as well as the related, but separate Uniform Standards which establish standards for substance-using licensees. No action was taken at that time.

More recently, as part of its April 2021 Board Meeting, it was recommended that the Board consider the current provisions contained with the Disciplinary Guidelines (Guidelines) as it relates to underlying actions involving Driving Under the Influence convictions. As the guidelines were previously adopted in February 2017, it may also be appropriate to determine if a broader review would be appropriate.

Committee Discussion and Action
During the meeting members considered several questions including:

1. Is it the Committee's preference to limit the review to specific areas? If so, are

there specific areas, e.g. penalty ranges for various categories of violations, types of violations and current category classifications, nature and type of mitigation or rehabilitation the Board would like to review, etc.

2. As changes in the law have occurred since the Guidelines were most recently adopted, would it be helpful to the Committee for staff to recommend changes to incorporate new licensing programs, e.g., Automated Drug Delivery Systems, Outsourcing Facilities, etc., as well as recommended solutions to resolve conflicts between the Guidelines and other areas of Pharmacy Law and its regulation.
3. The Board on occasion resolves a disciplinary matter with the issuance of a Letter of Public Reproval. Should the Guidelines be updated to incorporate this potential outcome?

After consideration of the questions, members determined the next step will be for staff to review the issues discussed and identify recommended changes to Disciplinary Guidelines and coordinate with Chairperson Serpa on the scheduling of a meeting to discuss recommended changes. The Committee stated its preference for an in-person meeting should conditions be appropriate but noted the meeting can proceed via WebEx if necessary.

e. Discussion and Consideration of Authority for Pharmacists to Furnish Naloxone, including California Code of Regulations Section 1746.3, Protocol for Pharmacists Furnishing Naloxone Hydrochloride

Relevant Law

BPC Section 4052.01 provides the authority for a pharmacist to furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by the Board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities.

CCR Section 1746.3 establishes the protocol a pharmacist must follow when furnishing naloxone as required in statute.

Background

Subsequent to enactment of the authorizing legislation, in April 2015, emergency regulations became effective followed by the permanent regulations. Since that time several subsequent measures have passed to ensure broad availability to naloxone as a key life saving measure to mitigate potential opioid overdose.

During its last meeting, members considered the current labeling requirements for naloxone. At that time the committee determined that current labeling requirements are appropriate. Further members noted that pharmacists providing appropriate consultation would be providing education on naloxone where appropriate.

During that meeting members also received public comment suggesting there may

be barriers to access to consumers receiving naloxone. There may be a variety of reasons including perhaps a lack of education about the availability of the product by consumers or an understanding of how to request the product. It has been suggested that the Board's current protocol could also impede access.

Committee Discussion and Action

During the meeting members discussed the provisions for pharmacist provided naloxone. Members considered several policy questions including:

1. Included in Assembly Bill 1533, the Board will be convening a workgroup force to consider if a transition to a standard of care enforcement model would be feasible and appropriate. Should evaluation of this issue be incorporated into the work of the workgroup?
2. If discussion is appropriate now, does the Committee believe the current requirements in statute are appropriate?
3. Does the Committee believe the protocol established in regulation is still appropriate? **Note**: Should the Committee and Board determine changes to the regulation are appropriate, the Board and Committee can instruct the Executive Officer to contact the Medical Board of California and consult with California Society of Addiction Medicine and other appropriate entities to determine next steps and if amendments to the protocol are warranted.
4. Is there any other action the Committee believes is appropriate?

As part of its discussion members heard public comment from stakeholders. Members considered if the protocol was a barrier to pharmacist-provided naloxone as suggested by public comment. Members also received comments from an expert in the field, Dr. Gaspar. Dr. Gaspar is a psychiatric pharmacist by training with subspecialties in addiction medicine and has been a part of naloxone distribution and opioid use disorder treatment for almost 20 years. Dr. Gaspar advised members that he started some of the early co-prescribing and naloxone distribution programs. Dr. Gaspar suggested that in his opinion other issues such a stigma within the profession may prevent for pharmacists from participating. The Committee noted that it may be appropriate to request that the Communication and Public Education Committee develop educational materials to help focus on steps that can be done to increase pharmacist participation within the current statutory language.

The Committee determined that evaluation of the protocol should be considered as part of the standard of care workgroup.

f. Discussion and Consideration of draft FAQs related to Regulations Governing Automated Drug Delivery Systems

Background

The Board's regulations related to Automated Drug Delivery System take effective July 1, 2021. To assist licensees with compliance with these regulations, staff are recommending updated Frequently Asked Questions.

Committee Discussion and Action

The Committee reviewed the draft Frequently Asked Questions related to Automated Drug Delivery Systems. The Committee agreed with the questions and answers. They requested revision to question 21 related to the use of an ADDS used to dispense drugs up to a 72-hour supply of drugs to a patient discharged from the emergency room. This should be to clarified that such use of the ADDS may only be done when the pharmacy is closed and the each ADDS is used for such a function has a separate license.

Members received public comment indicating concern with the ADDS registration requirement for discharge medications when a pharmacy is closed and requested that the Committee reevaluate the responses provided in questions 18 & 20 of the FAQs.

Committee Recommendation: Recommend approval of the FAQs incorporating the changes made during the meeting discussion.

Attachment 4 includes revised Automated Drug Delivery System FAQs.

g. Review and Discussion of Enforcement Statistics

Since July 1, 2020, the board received 2533 complaints and has closed 2819 investigations. The board has issued 452 Letters of Admonishment, 936 Citations and referred 188 cases to the Office of the Attorney General. The board has secured 13 interim suspension orders and granted two Penal Code 23 suspensions. Further, the board has revoked 92 licenses, accepted the disciplinary surrender of 86 licenses, denied 6 applications, and imposed other levels of discipline against 217 licensees and/or applicants.

As of July 3, 2021. The board currently has 1,253 field investigation pending. Below is a breakdown providing more detail in the various investigation process:

	June 15, 2020 (FY 19/20)		July 3, 2021 (FY 2020/21)	
	Volume	Average Days	Volume	Average Days
Cases Under Review for Assignment	42	8	41	18
Cases Under Investigation	756	170	631	150
Investigation Pending Supervisor Review	266	41	141	40
Investigations Pending Second Level Review	180	42	30	16
Investigations Awaiting Final Closure	127	26	410	70

Attachment 5 includes the annual and three-year comparison enforcement statistics.

Attachment 1

CA State Board of Pharmacy

Enforcement Committee Meeting

Inspection Presentation

July 15, 2021

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 being 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, ORDERLINESS
- EXPIRATION DATES, INCLUDING ON LABELS

EDUCATION

- Questions from Licensee
- Standard education Topics

TOTAL INSPECTIONS COMPLETED

- FY 17/18 2,366
- FY 18/19 3,462
- FY 19/20 2,545
- FY 20/21* 2,963
  - IN PERSON INSPECTIONS 2817
  - DESK AUDITS 146

*FY20/21 data is as of 6/18/21

INSPECTIONS BY VISIT TYPE – FY20/21

- Routine Pharmacy Inspections (PHY-PHE): 1,174
- Complaint Inspections: 343
- Pharmacist Recovery Program/Probation: 318
- Automated Drug Delivery Systems: 150
- Compounding Inspections: 931
  - New 54
    - In Person Inspections 29
    - Desk Audits 25
  - Renewal 877
    - In Person Inspections 777
    - Desk Audit 100

INSPECTIONS, BY VISIT TYPE, FY20/21 CONTINUED

- Outsourcing Renewal Inspections: 25
  - In Person Inspection 5
  - Desk Audits 20

- Other Routine Inspections, by License Type: 22
  - Wholesaler 11
  - Third Party Logistics Provider 2
  - Drug Room 1
  - Clinic 1
  - Hospital 5
  - Licensed Correctional Facility 1
  - Unlicensed Inspection 1

- **Total Inspections Completed: 2,963**

July 1, 2020 through June 18, 2021

ROUTINE PHARMACY INSPECTIONS COMPLETED FY 20/21

- TOTAL NUMBER OF LICENSED PHARMACIES: 6,462
- TOTAL NUMBER OF ROUTINE PHARMACY INSPECTIONS: 1,654
  - 1,174 ROUTINE PHARMACY INSPECTIONS COMPLETED
  - 83 ROUTINE PHARMACY INSPECTIONS COMPLETED PROBATION VISIT
  - 226 ROUTINE PHARMACY INSPECTIONS COMPLETED ON COMPLAINT INVESTIGATION
  - 171 ROUTINE PHARMACY INSPECTIONS COMPLETED DURING STERILE COMPOUNDING VISIT

JULY 1,2020 THROUGH JUNE 18, 2021

ROUTINE INSPECTION OUTCOMES FY20/21

- ASSIGNED ROUTINE INSPECTIONS COMPLETED: 1174
  - 676 PHARMACIES WERE ISSUED NO VIOLATIONS
  - 487 PHARMACIES WERE ISSUED 1092 CORRECTIONS
  - 23 PHARMACIES ISSUED 46 VIOLATION NOTICES

(A PHARMACY MAY RECEIVE BOTH CORRECTIONS AND VIOLATION NOTICES DURING ONE INSPECTION.)

July 1, 2020 through June 18, 2021

TOP CORRECTIONS ON ROUTINE PHARMACY INSPECTIONS FY20/21

Law Code	Description
CCR 1714(c)	Pharmacy Clean and Orderly
CCR 1707.5(a)(1)	Prescription Label Requirements - Patient Centered Labeling 12 pt Font
CCR 1715.65	Inventory Reconciliation Report of Controlled Substances and Reporting Losses
CCR 1714(b)	Safe and Secure Pharmacy - Maintain it facility
BPC 4058	License Display
CCR 1715(a)	Self Assessment
CCR 1707.5(d)	Policies and Procedures - Provide Interpretive Services
CCR 1707.2(b)(1)	Written Notice of Right to Consultation when Patient or Agent is not Present (including drugs shipped by mail)
BPC 4076.6(a)	Provide Translated Directions for Use if Requested by the Patient
CCR 1707.6(c)	Notice to Consumers - Requirements

*July 1, 2020 Through June 18, 2021

TOP VIOLATION NOTICES ON ROUTINE PHARMACY INSPECTIONS FY20/21

CCR 1714(d)	Security of Prescription Department
CCR 1714(b)	Safe and Secure Pharmacy - Maintain its Facility
CCR 1735.3(a)(2)	Recordkeeping for Compounded Drug - Log Requirements
CCR 1776	Prescription Drug Take-Back - Authorization
CCR 1716	Variation from Prescription

July 1, 2020 Through June 18, 2021

CCR 1707.2 – Duty to Consult
Pharmacy Routine Inspections

In FY 20/21 44 routine inspections revealed issues with patient consultation

- In 7 of the 44 inspections the inspector observed that consultation was not provided to the patient

- In 37 of the 44 inspections the inspector found that the site was not providing written notice of consultation on delivered or mail order prescriptions

July 1, 2020 through June 18, 2021

CURRENT PHARMACY LICENSEES YEAR OF LAST ROUTINE INSPECTION

Year of Last Inspection	As of FY 19/20	As of FY 20/21
Inspected Within 1 Year	507	1078
Inspeted Within 2 Years	1233	1479
Inspected Within 3 Years	1512	2093
Inspected Within 4 Years	1698	2310
Inspected Within 5 Years	1807	2440
Inspected Within 6 Years	1970	2518
Inspected Within 7 Years	2134	2637
Inspected Within 8.5 Years	**N/A**	**2702**
Inspected or Visited for Other Reasons After January 1, 2013 (COMPLAINT OR PROBATION VISIT)	**1986**	**2292**
Inspected Before January 1, 2013 OR Never Inspected	**2080**	**1193**
Total Pharmacies (DOES NOT INCLUDE NEW PHY-PPHE LICENSES ISSUED IN CURRENT FY)	**6200**	**6187**

QUESTIONS?

Attachment 2

Board of Pharmacy

Enforcement Committee Meeting

Citation Presentation

July 15, 2021

CITATION PROGRAM RELEVANT LAW

- Business and Professions Code Section 4314 establishes the authority for the board to issue citations, which may include fines and/or orders of abatement.
- Orders of abatement may include completion of continuing education courses and specifies that any such continuing education courses shall be in addition to those required for license renewal.
- 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
- A citation may contain no fine, an administrative fine or a fine and an order of abatement

CITATION PROGRAM OVERVIEW

- The board uses its authority to issue citations to deal with important violations that warrant the licensee's attention, thought and correction, but do not rise to the level where sanctions such as probation, suspension or revocation are appropriate.
- Consistent with the board's direction, the highest fines for the most serious violations
- In most cases, The board has the authority to issue citations of up to $5,000 per license (BPC 125.9).
- The board has specific statutory authority to issue fines of $25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred (BPC 4067).

FACTORS TO CONSIDER IN ASSESSING ADMINISTRATIVE FINES – CCR 1775.2

- 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 the cited person or entity has 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

Citation Process

1. Investigation is completed
2. Supervising Inspector Review
3. Second level review
4. Citation issued w/out fine & w/wo abatement
5. Citation completed with fine or abatement accepted
6. Appeal - - Office Conference and/or AG's Office

CITATIONS ISSUED

	FY2015/16	FY2016/17	FY2017/18	FY2018/19	FY2019/20	FY2020/21*
CITATIONS ISSUED	1,975	1,936	2,168	1,134	1,426	926
CITATIONS ISSUED WITHOUT FINE	376	439	504	339	535	399
CITATIONS ISSUED WITH FINE	1,599	1,497	1,664	795	891	527
FINES ASSESSED	$2,264,650	$2,354,525	$2,268,625	$1,166,700	$1,462,300	$778, 850
FINES COLLECTED	$2,145,398	$2,071,478	$2,079,806	$1,212,077	$963,446	$701,479

* July 1, 2020 Through June 18, 2021

CITATION PROCESSING TIMES FROM RECEIPT TO ISSUANCE

FISCAL YEAR	AVERAGE DAYS
2015/16	280
2016/17	319
2017/18	354
2018/19	333
2019/20	400
2020/21*	426

* July 1, 2020 Through June 18, 2021

CITATION ORDER OF ABATEMENTS

- THE BOARD MAY ISSUE CITATIONS WITH ORDERS OF ABATEMENT
- THE BOARD HAS BEEN USING ORDER 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
- COMPLIANCE WITH THE ORDER OF ABATEMENT TYPICALLY RESULTS IN EITHER A REDUCTION OR FORGIVENESS OF THE FINE

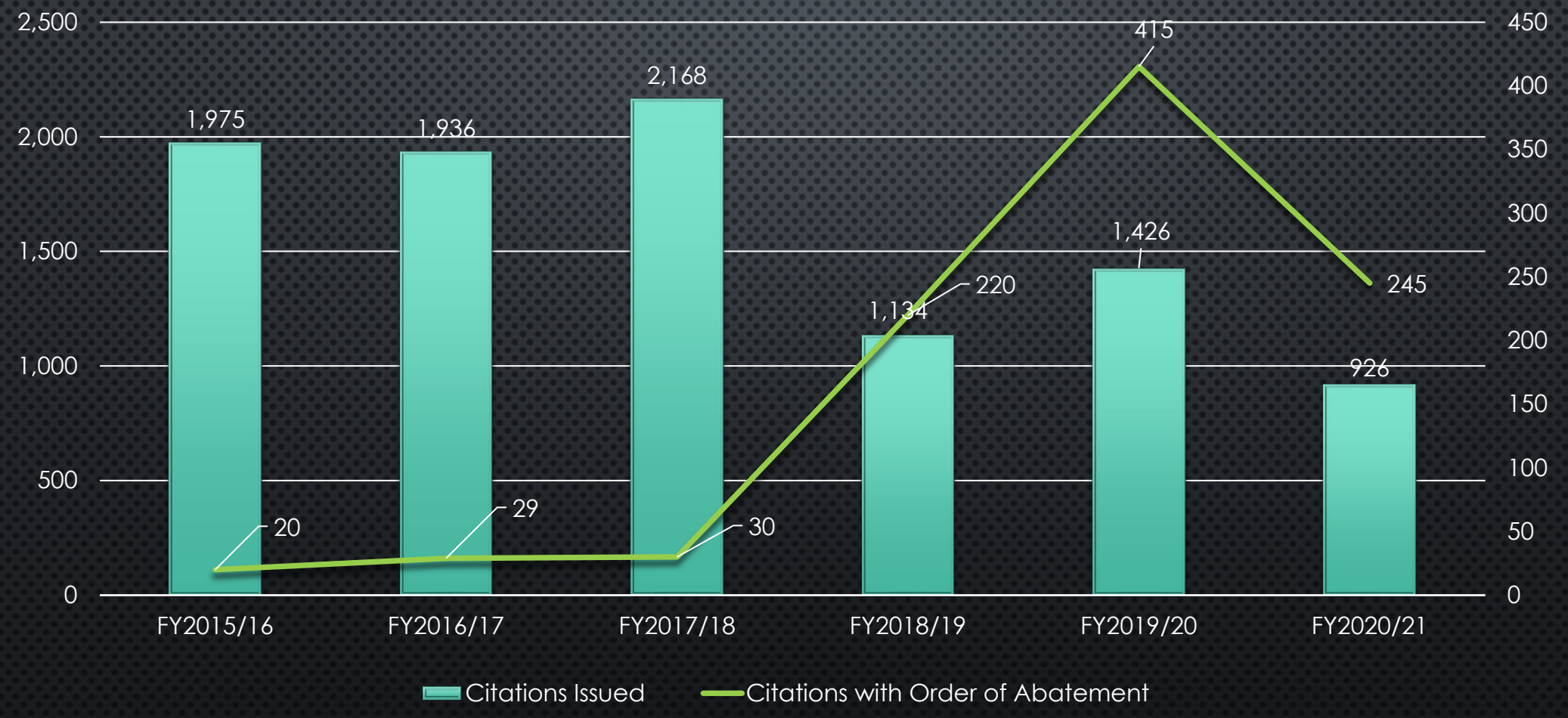
ABATEMENT TYPES

- Requested Continuing Education (CE) to be Completed by Licensee (Typically 2-6 hours)
  - Medication error reduction strategies
  - Role of the Pharmacist in Charge (PIC)
  - Pharmacy Operations
  - Pharmacy Law & Ethics
  - Compounding Training
  - Immunization Training
  - Ethics Course (Pursuant to CCR 1773.5)
  - Board Provided Rx Drug Abuse Course

ABATEMENT TYPES

- Other abatements that may be requested by the board:
  - Updated Self Assessment
  - Updated policies and procedures
  - Internal policy training for pharmacy staff
  - In service trainings for staff

CITATIONS ISSUED/ ORDERS OF ABATEMENT



* July 1, 2020 Through June 18 2021

PROOF OF CITATION ABATEMENTS FY20/21

- TOTAL ABATEMENTS ISSUED: 245
  - ABATEMENTS SATISFIED: 170

* July 1, 2020 Through June 18, 2021

VIOLATIONS THAT LEND THEMSELVES TO ABATEMENTS

- 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 (MAJORITY OF ABATEMENTS FALL INTO THIS CATEGORY)
- 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

APPEAL PROCESS

- LICENSEES WHO ARE ISSUED A FINE MAY REQUEST AN INFORMAL OFFICE CONFERENCE
- OFFICE CONFERENCE ALLOWS THE LICENSEE THE OPPORTUNITY TO PRESENT ADDITIONAL OR MITIGATING INFORMATION TO THE BOARD'S EXECUTIVE OFFICER OR DESIGNEE AND A SUPERVISING INSPECTOR
- IN ADDITION, A LICENSEE MAY SUBMIT A FORMAL APPEAL TO THE BOARD WITHIN 30 DAYS OF ISSUANCE OF THE CITATION
  - 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

CITATIONS COMPLETED OR CONTESTED

	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20	FY 2020/21*
CITATIONS COMPLETED	1,753	1,855	2,112	1,116	1,210	992
CITATIONS CONTESTED AT OFFICE CONFERENCE	201	191	140	148	216	154
CITATIONS CONTESTED AT THE ATTORNEY GENERAL'S OFFICE	54	61	50	29	20	29

* July 1, 2020 Through June 18, 2021

CITATION APPEAL OUTCOMES FY20/21*

- Total Office Conferences (OC) requested 173
- Office conference outcomes
  - Withdrawn 3
  - Modified 180
  - Reduced to Letter of Admonishment 14
  - Dismissed 19
  - Upheld 74
- Total Appeals Requested 97
  - Total Referred 29
  - Withdrawn 1
  - Settled by Stipulation 1

* July 1, 2020 Through June 18, 2021

PHARMACIES TOP TEN VIOLATIONS FY20/21*

Violation Code	Description	Number of Violations
CCR 1716	Medication Error	146
CCR 1761(a)	Erroneous or Uncertain Prescription	41
CCR 1764/56.10	Unauthorized Disclosure of Prescriptions and Medical Information	35
CCR 1714(b)	Safe and Secure Pharmacy- Maintain its Facility	35
BPC 4081(a)/ CCR1718	Records Kept Open for Inspection 3 years and Current Inventory Defined	32
BPC 4113	Notify Board within 30 Days of Change in Pharmacist in Charge	27
CCR 1707.2	Duty to Consult	27
CCR 1707.3	Duty to Review Drug Therapy	15
CCR 1711(d)	Quality Assurance Program	9
HSC 11165(d)	Report Controlled Substance Dispensing to CURES	6

* July 1, 2020 Through June 18, 2021

PHARMACISTS TOP TEN VIOLATIONS FY20/21*

Violation Code	Description	Total
CCR 1716	Medication Error	147
CCR 1761	Erroneous or Uncertain Prescription	56
CCR 1707.2	Duty to Consult	37
BPC 4081	Records Kept Open for Inspection for 3 Years	30
CCR 1764/56.10	Unauthorized Disclosure of Prescription and Medical Information	28
CCR 1714	Operational Standards and Security	28
BPC 4301(h)	Unprofessional Conduct - Self Administer Drugs or Alcohol	18
CCR 1707.3	Duty to Review Drug Therapy	16
BPC 4301(l)	Unprofessional Conduct - Conviction of a Crime Substantially Related to Pharmacy	14
CCR 1711(d)	Quality Assurance Program	8

* July 1, 2020 Through June 18, 2021

INTERN TOP VIOLATIONS FY20/21*

Violation Code	Description	Number of Violations
BPC 4301(h)	Self-Use	6
BPC 4301(l)	Conviction of a Crime Substantially Related to Pharmacy	6
BPC 4301(o)	Violating or Attempting to Violate Applicable Federal and State Laws or Regulations Governing Pharmacy	1

* July 1, 2020 Through June 18, 2021

TECHNICIAN TOP VIOLATIONS FY20-21*

Violation Code	Description	Number of Violations
BPC 4301(l)	Conviction of a Crime Substantially Related to Pharmacy	58
BPC 4301(h)	Self Use	54
BPC 4301(f)	Commission of an act involving moral turpitude, dishonesty, fraud, deceit or corruption	14
BPC 4301(k)	Commission of more than one misdemeanor or felony involving self-use	6
BPC 4301(g)	Knowingly Making or Signing Any Document that Falsely Represents the Facts	2
BPC 4115(e)	Unlicensed Technician	6

* July 1, 2020 Through June 18, 2021

DUTY TO CONSULT CCR 1707.2 FY20/21

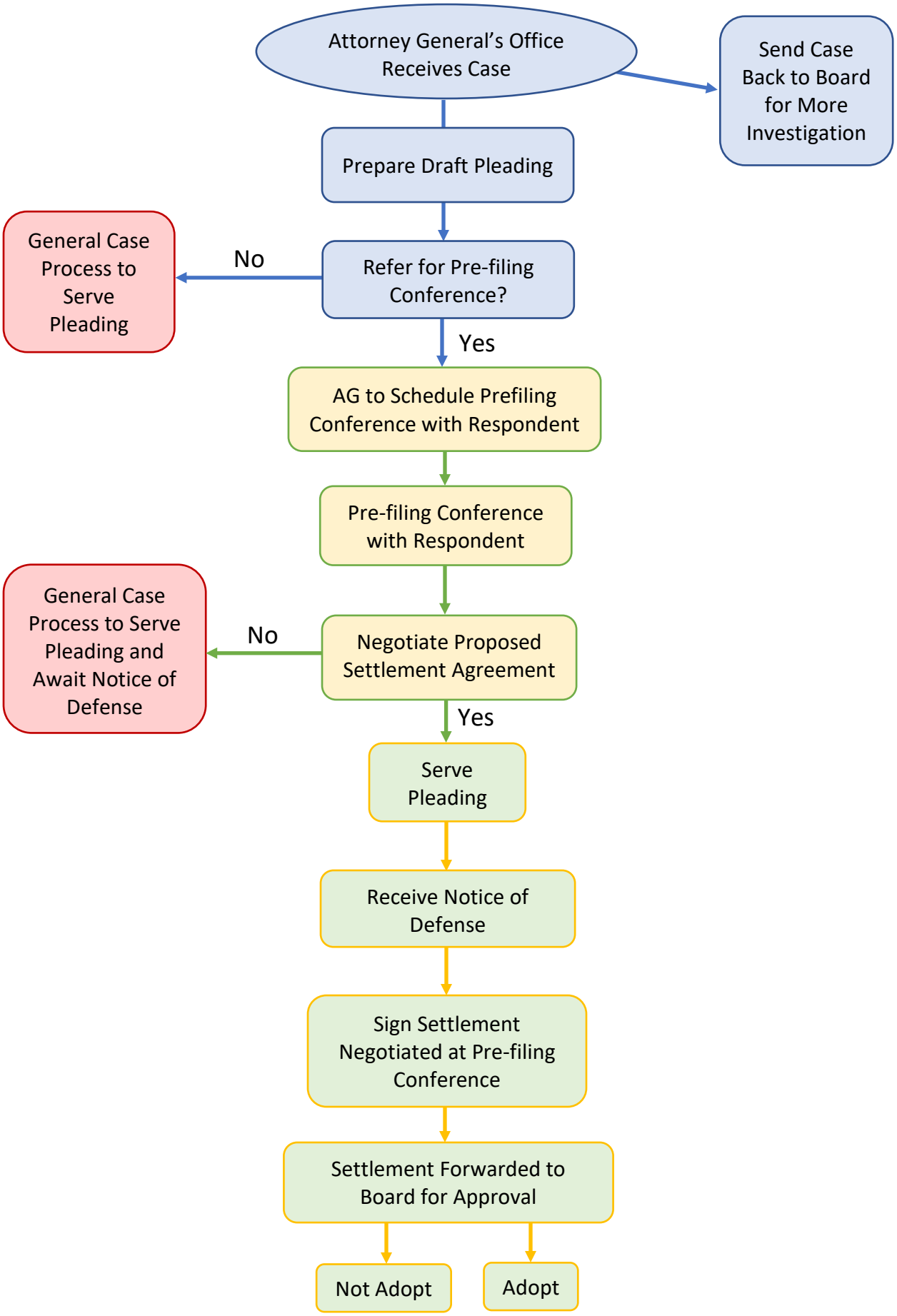
	FY 19/20	FY 20/21
Total Duty to Consult Citations (Includes Pharmacists and Pharmacies)	64	60
Pharmacy Citations	30 (23 with fine, 7 without)	28 (21 with fine, 7 without)
Average Citation Amount for Pharmacies	$3,117	$3,798
Pharmacist Citations	34 (12 with fine, 22 without)	32 (19 with fine, 13 without)
Average Citation Amount for Pharmacists	$654	$974

THANK YOU

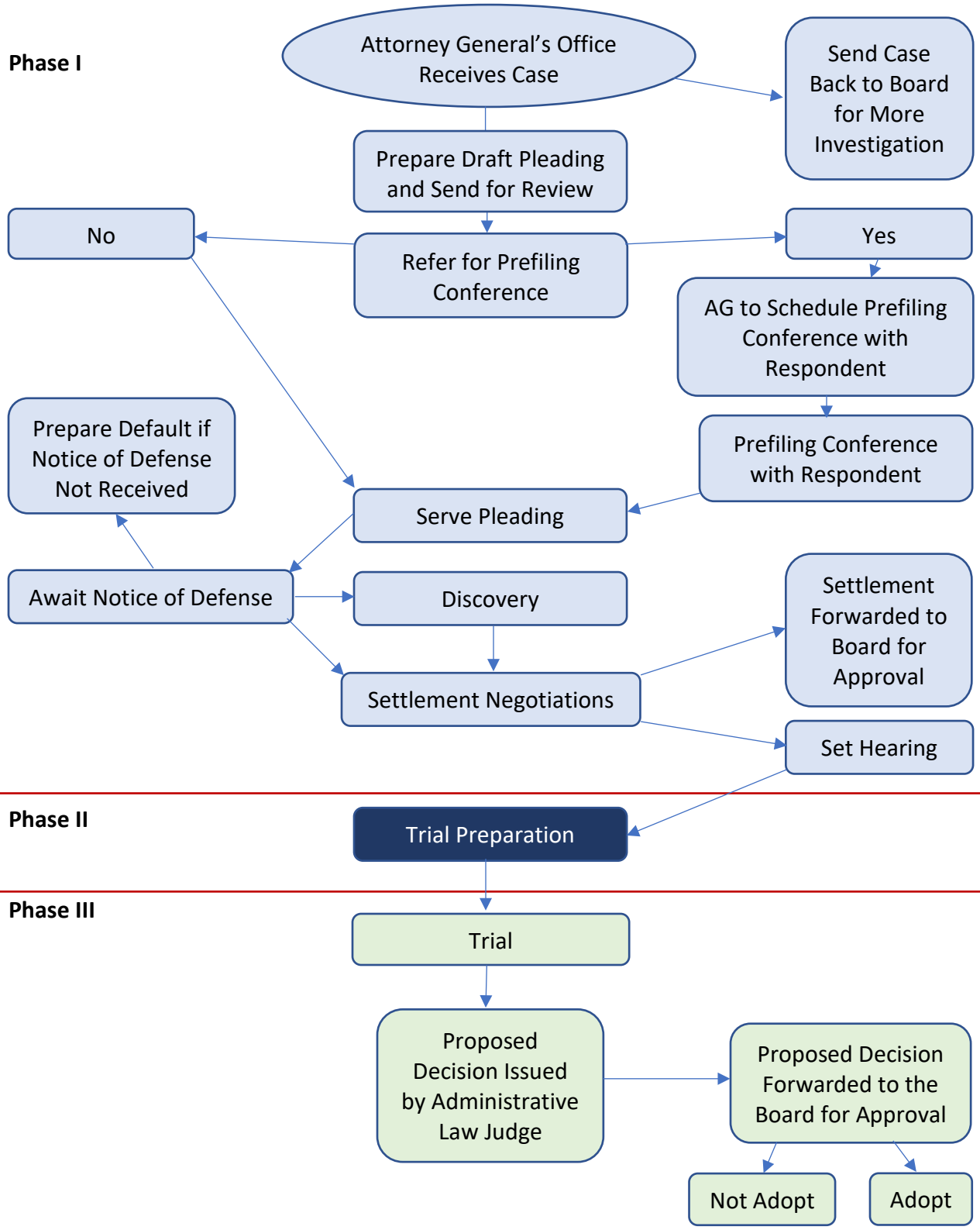
QUESTIONS?

Attachment 3

Pre-Filing Case Flow



GENERAL CASE PROCESS



Attachment 4

ADDS FREQUENTLY ASKED QUESTIONS

Question #1: My pharmacy has multiple licensed ADDS, do I have to complete a self-assessment for each licensed ADDS?

Answer: Yes, per BPC section 4427.2(c), a separate application and license is required for each ADDS. Also, per BPC section 4427.7(a), a pharmacy holding an ADDS license shall complete an annual self-assessment. The pharmacy shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

References: Business and Professions Code (BPC) 4427.7(a), 4427.2(c), California Code of Regulations (CCR) 1715

Question #2: Do I have to complete a new self-assessment for each ADDS if my pharmacy received a new permit, had a change in pharmacist-in-charge, or the pharmacy had a change in address?

Answer: Yes, per CCR section 1715(b), the pharmacist-in-charge of the pharmacy shall complete a self-assessment within 30 days whenever a new pharmacy permit has been issued, or change in PIC, or change in the licensed location of the pharmacy to a new address.

References: Business and Professions Code (BPC) 4427.7, California Code of Regulations (CCR) 1715(b)

Question #3: A medication error was made, and a quality assurance review was completed related to the licensed ADDS, do I have to report to the Board?

Answer: Yes, per CCR 1711(f), any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review. A "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

References: California Code of Regulations (CCR) 1711(f), 1716, Business and Professions Code (BPC) 4427.8,

Question #4: My pharmacy is in an acute care hospital and exempt from the licensing requirements for an ADDS, do I have to report all quality assurance records of medication errors related to the use of the ADDS to the Board at the time of renewal?

Answer: Yes, per CCR 1711(f), any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal. A "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

References: California Code of Regulations (CCR) 1711(f), 1716, Business and Professions Code (BPC) 4427.8, Final Statement of Reasons for CCR sections 1711 and 1716

Question #5: My pharmacy is located in an acute care hospital and exempt from the licensing requirements for ADDS, do I have to report ALL quality assurance record related to the use of the ADDS to the Board at the time of renewal, including quality assurance records related to near-misses, or errors caught by nursing staff?

Answer: CCR 1711(b) defines "medication error" as any variation from a prescription or drug order not authorized by the prescriber, as described in; Section 1716. Section 1711(b), however, expressly excludes from the definition of a medication error any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

NOTE: Only, quality assurance records related to the use of the ADDS that caused the medication error, as defined by the section, are required to be reported to the Board at the time of renewal.

References: California Code of Regulations (CCR) 1711(b), 1716, Business and Professions Code (BPC) 4427.8

Question #6: What information is required to be reported as part of the Quality Assurance Review?

Answer: CCR 1711(e) states, the record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and
4. recommended changes to pharmacy policy, procedure, systems, or processes, if any.

References: California Code of Regulations (CCR) 1711(e), 1716, Business and Professions Code (BPC) 4427.8

Question #7: What personnel are authorized to restock the ADDS (e.g., nurses and other personnel)?

Answer: This depends on the location of the ADDS. The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

Pursuant to Health and Safety Code section 1261.6 (g) if the ADDS utilizes removable pockets, cards, drawers, or similar technology, or unit of use, or single dose containers, and the facility, in conjunction with the pharmacy, has developed policies and procedures to ensure the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS, then the facility and contracted personnel authorized by law to administer drugs may also restock the ADDS.

References: June 2017 Script Newsletter, , Business and Professions Code (BPC) 4427.3, 4427.4, 4186, 4187.5, 4119.11, Health and Safety Code (HSC) 1261.6 (g)

Question #8: Are drugs required to be restocked immediately into the ADDS?

Answer: Per BPC section 4427.4(f), if drugs are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs may be stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs from secured storage, an inventory must be taken to detect any losses or overages.

References: Business and Professions Code (BPC) 4427.4

Question #9: The pharmacy uses an ADDS device with an open-matrix design allowing the user to access multiple drugs, what are the requirements for the facility?

Answer: Facilities using automated drug delivery system with an open-matrix design shall contact the California Department of Public Health for a clear understanding of the requirements for such use.

References: Health and Safety Code (HSC) 1261.6

Question #10: Does my pharmacy have to review the ADDS on a monthly basis?

Answer: Yes, a review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system

References: Health and Safety Code (HSC) 1261.6(h), Business and Professions Code (BPC) 4186(d), 4119.11(h)

Question #11: Can an ADDS be licensed in other locations such as psychiatric health facilities, jails, etc.?

Answer: No, ADDS may only be placed in locations listed under BPC section 4427.3:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of the BPC.

(4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

There is currently pending legislation (Assembly Bill 1533), that if enacted which will expand the permissible locations for ADDs.

References: Business and Professions Code (BPC) 4427.3

Question #12: Is the pharmacy required to obtain a separate Drug Enforcement Administration (DEA) registration for each licensed ADDS if the device contains controlled substances?

Answer: Pharmacies should consult the federal regulations to ensure compliance with DEA requirements and contact the DEA for any necessary clarifications regarding federal rules regarding controlled substances. Cited below are some authorities from the DEA regarding ADDS.

Reference: Code of Federal Regulations (CFR) 1301.27, ADDS FAQ, Dispensing of Controlled Substances to Residents at Long Term Care Facilities

Question #13: Our pharmacy offers an APDS to dispense to patients, what is required for patient consultation?

Answer: The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive drugs from an APDS and the APDS has a means to identify each patient and only release the drugs to the patient or the patient's agent.

All prescribed drugs and devices dispensed from the APDS ***for the first time*** must be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: Business and Professions Code (BPC) 4119.11(d)(6), 4427.6(f)

Question #14: Can the pharmacist provide consultation via telephone for new prescriptions prior to placing the medication in the APDS?

Answer: No, all prescribed drugs and devices dispensed from the APDS ***for the first time*** shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

References: Business and Professions Code (BPC) 4427.6(f)

Question #15: Who can provide the consultation for patients using the APDS?

Answer: A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

References: Business and Professions Code (BPC) 4427.6(d)

Question #16: What drugs can be placed in the APDS?

Answer: The pharmacy should have policies and procedures to determine which drugs and devices are appropriate for placement in the automated patient dispensing system.

References: Business and Professions Code (BPC) 4119.11(d)((1)(B), 4427.6(a)(2)

Question #17: What shall a pharmacy do if a patient cannot use the APDS due to the drug not being in stock or the APDS is not in service?

Answer: The pharmacy must develop policies and procedures orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices. The pharmacy shall ensure the delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

References: Business and Professions Code (BPC) 4427.6(a)

Question #18: We are a hospital with less than 100-beds and have a licensed drug room. When patients are discharged from the hospital, the physician sometimes writes an order for the patient to be discharged with a 72-hour supply which is taken from the ADDS. The physician will remove the drugs from the ADDS and dispense the drugs to the patient that is properly labeled and meets the patient centered labeling requirements. Is the drug room exempt from licensing the ADDS located at the nursing station if the ADDS is primarily used to administer doses to patients in the hospital, but occasionally used for dispensing no more than a 72-hour supply of discharge medications to the patient?

Answer: No, the drug room is not exempt from licensing the ADDS if the location is dispensing medications to discharge patients. The drug room will be required to license the ADDS location. The drug room is only exempt if the drugs in the ADDS are solely used for administration to patient while in the acute care hospital. When drugs from the ADDS is used for dispensing, not solely for administration, the exemption no longer applies.

Should your hospital provide discharge medication from the drug stock contained within an ADDS, the board respectfully requests that your facility secure licensure to be compliant with these requirements.

References: Business and Professions Code (BPC) 4427.2(i), BPC 4056

Question #19: Can the facility start using the ADDS device as soon as the ADDS application is submitted or do I need to wait until the Board issues the ADDS permit?

Answer: The ADDS device cannot be used until the Board issues the ADDS permit.

Reference: Business and Professions Code (BPC) 4427.1, 4427.2(a), 4119.11(a)(1)

Question #20: We are a hospital with a 24-hour pharmacy. Can we utilize an ADDS to dispense a 72-hour supply of medication from our ER, if we request a license from the board for the ADDS.

Answer: No. A prescriber may only dispense a prescription medication to an emergency room patient, if the pharmacy is closed and there is no pharmacist available.

Reference: Business and Professions Code (BPC) 4068 (a)(1)

21. In the emergency room, when the pharmacy is not open, the physician will remove from the ADDS and dispense no more than a 72-hour supply of drugs to a patient to ensure a drug regimen is immediately commenced and continued pursuant to Business and Professions Code section 4068. Is the hospital pharmacy required to license the ADDS in the emergency room if the ADDS is primarily used for the administration of doses to patients in the emergency room but occasionally used to dispense a 72-hour supply of drugs to a patient discharged from the emergency room for doses removed from the ADDS by the physician?

Answer: Yes, the ADDS will be required to be licensed. The hospital pharmacy is only exempt from licensing the ADDS when the acute care hospital pharmacy solely uses the ADDS to administer drugs. When an ADDS is used to dispense drugs to a patient, the exemption no longer applies. While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered to be an APDS and need not follow the APDS requirements found in BPC 4427.6. Reference: BPC 4017.3, 4068, 4427.2(i), 4427.6.

Should your hospital provide discharge medication from the drug stock contained within an ADDS when the pharmacy is closed, the board respectfully requests that your facility secure licensure for each ADDS used for such a function to be compliant with these requirements. **Note**: As a reminder, under provisions of BPC 4068, medications can only be dispensed from the emergency room if the hospital pharmacy is closed and there is no pharmacist available in the hospital.

Rev 7.2021

Attachment 5

Enforcement Workload Statistics FY 2020/21

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	609	501	546	637	2,293
Closed	565	635	658	691	2,549
Pending	1,649	1,776	1,642	1,582	1,582
Average Days for Investigation	226	260	224	221	233

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	820	661	524	514	514
Drug Diversion / Fraud	175	160	141	144	144
Prescription Drug Abuse	62	68	74	126	126
Compounding	67	75	64	42	42
Outsourcing	24	20	5	11	11
Probation / PRP	28	24	9	14	14
Enforcement	187	469	532	449	449
Criminal Conviction	286	299	294	282	282

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	58	64	62	56	240
Closed					
Approved	47	49	46	66	208
Denied	8	9	10	5	32
Total Closed (includes withdrawn)	***74***	***69***	***58***	***74***	275
Pending	89	85	89	72	89

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	123	167	178	176	644
Non-Jurisdictional	69	85	95	120	369
No Violation	72	94	86	94	346
No Further Action	47	47	48	71	213
Other - Non-Substantiated	6	7	10	11	34
Subject Educated	34	13	10	32	89

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	48	72	66	266	452
Citations Issued	226	262	248	200	936
Proof of Abatement Requested	53	64	88	43	248
Appeals Received	17	31	22	23	93
Dismissed	0	6	10	6	22
Total Fines Collected	***$204,815***	***$207,140***	***$199,225***	***$174,575***	***$785,755***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	48	36	49	55	188
Pleadings Filed	56	42	45	51	194
Pending					Quarter Ending
Pre-Accusation	117	105	108	96	108
Post-Accusation	205	180	153	144	153
Total Pending	**322**	**285**	**261**	**243**	**261**
Total Closed	50	71	80	90	291

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	1	2	5	4	12
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	9	15	16	26	66
Designated Representative	0	1	0	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	1	3	1	7	12
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***22***	***22***	***37***	***92***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	0	0	0	1	1
Intern Pharmacist	0	0	1	0	1
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***	***1***	***1***	***2***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	12	13	20	18	63
Intern Pharmacist	1	0	1	1	3
Pharmacy Technician	5	4	2	4	15
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	1	1
Clinic	0	0	0	0	0
Pharmacy	4	0	7	8	19
Sterile Compounding	0	0	2	3	5
Outsourcing	0	0	0	0	0
Total	***22***	***17***	***32***	***35***	***106***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	10	2	5	3	20
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	2	3	7	6	18
Designated Representative	0	0	0	3	3
Wholesaler	0	0	0	2	2
Clinic	0	0	0	0	0
Pharmacy	13	9	7	9	38
Sterile Compounding	0	0	1	1	2
Outsourcing	0	0	2	0	2
Total	***25***	***15***	***22***	***24***	***86***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	5	8	12	13	38
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	2	3	6
Designated Representative	1	0	0	0	1
Wholesaler	1	0	0	0	1
Clinic	0	0	1	1	2
Pharmacy	1	12	15	16	44
Sterile Compounding	0	0	2	3	5
Outsourcing	2	0	0	0	2
Total	***10***	***21***	***32***	***36***	***99***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	0	2	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	1	1	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	***0***	***3***	***1***	***1***	***5***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	1	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	2	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	1	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	1	0	0	1
Total	***1***	***3***	***2***	***0***	***6***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$448,360***	***$439,165***	***$676,662***	***$910,851***	***$2,475,038***
Cost Recovery Collected	***$380,388***	***$405,001***	***$364,386***	***$428,653***	***$1,578,428***

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

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	236	239	236	232	232
Intern Pharmacist	13	9	7	5	5
Pharmacy Technician	29	30	31	28	28
Designated Representative	2	2	2	2	2
Wholesaler	3	3	3	3	3
Pharmacy	73	70	70	69	69
Sterile Compounding	2	2	3	8	8
Total	***358***	***355***	***352***	***347***	***347***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	2	25	32	20	79
Probation Site Inspections	121	139	55	218	533
Probation Terminated / Completed	7	29	26	34	96
Referred to AG for Non-Compliance	0	2	1	0	3

As of 6/30/2021

Board of Pharmacy

Citation and Fine Statistics FY20/21

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	***Total***
Pharmacist with Fine	60	66	66	47	239
Pharmacist no Fine	38	77	43	35	193
Pharmacy with Fine	42	54	41	31	168
Pharmacy no Fine	47	65	59	43	214
Pharmacist-in-Charge with Fine*	29	35	25	22	111
Pharmacist-in-Charge no Fine	31	62	44	135	272
Pharmacy Technician with Fine	17	14	16	23	70
Pharmacy Technician no Fine	1	1	0	0	2
Wholesalers	3	1	0	0	4
Designated Representative	2	0	0	1	3
Clinics	0	0	0	1	1
Drug Room	0	0	0	0	0
Exempt Hospital	0	0	1	1	2
Hospital Pharmacy	6	2	1	1	10
Miscellaneous**	12	14	15	13	54
Unlicensed Premises	1	7	5	4	17
Unlicensed Person	0	0	0	1	1
Total Issued	289	398	316	358	1361

*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

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	33%	1716 - Variation from prescription	33%	4126.5(a)(3) - A licensed wholesaler acting as a reverse distributor	71%
1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously	13%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	18%	1716 - Variation from prescription	7%
1707.3 - Duty to review drug therapy	9%	1707.3 - Duty to review drug therapy	10%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%
4301(h) - Unprofessional Conduct – The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	9%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	8%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	4%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	7%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously	8%	1707.3 - Duty to review drug therapy	3%
4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	6%	1715.6 - Reporting drug loss	7%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	3%
1714(b)(c) - Operational Standards and Security; pharmacy responsible for pharmacy security; the pharmacy must be maintained in a sanitary condition	6%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	7%	1735.5(a) - Compounding Policies and Procedures- Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding…	2%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%	1716/1761(a) - Variation from prescription/Erroneous or uncertain prescription; no pharmacist shall compound or dispense any prescription which contains any significant error or omission…	3%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	2%
1761 - Erroneous or uncertain prescriptions	6%	4076(a)(11)(A) - Prescription Container - Requirements for Labeling/The physical description of the dispensed medication, including its color, shape, and any identification code that appears…	3%	1735.2(d)(3) - Compounding commercially available products	2%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%	1714(b)(c) - Operational Standards and Security; pharmacy responsible for pharmacy security; the pharmacy must be maintained in a sanitary condition	3%	1714(b)(c) - Operational Standards and Security; pharmacy responsible for pharmacy security; the pharmacy must be maintained in a sanitary condition	2%

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 20/21
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	2		2	2	6
PRP Under Investigation		1	1		2
PRP In Lieu Of (investigation conducted)			1		1
Total Number of PRP Intakes	2	1	4	2	9
New Probationers					
Pharmacists	3		3	1	7
Intern Pharmacists	1		2		3
Pharmacy Technicians	2	3	1	2	8
Total New Probationers	6	3	6	3	18
PRP Participants and Recovery Agreements					
Total PRP Participants	58	55	56	51	N/A
Recovery Agreements Reviewed	56	53	48	50	207
Probationers and Inspections					
Total Probationers	80	76	75	73	N/A
Inspections Completed	53	62	58	63	236
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1		3	2	6
Drug Tests					
Drug Test Ordered (PRP and Probationers)	744	761	699	708	2912
Drug Tests Conducted (PRP and Probationers)	721	694	683	682	2780
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	1	2	1		4
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3	7	10	5	25
Termination from PRP	2	1	1	6	10
Probationers Referred for Discipline			1	3	4
Closure					
Successful Completion (PRP and Probationers)	1	5	5	1	12
Termination (Probation)			1		1
Voluntary Surrender (Probation)	4		2	5	11
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)		1			1
Non-compliance (PRP and Probationers)	23	14	14	31	82
Other (PRP)	2	1	1		4
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 20/21
Alcohol		1	2	1	
Ambien					
Opiates	1				
Hydrocodone					
Oxycodone				1	
Morphine	1				
Benzodiazepines			1		
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Alcohol	1		1		
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine			1		
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Alcohol	2	2	1	2	
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine		1			
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Workload Statistics	Total FY 18/19	Total FY 19/20	Total FY 20/21	% Change
Complaint Investigations				
Received	2,872	2,647	2,293	-20%
Closed	2,892	2,910	2,549	-12%
Pending	1,969	1,600	1,582	-20%
Average Days for Investigation	257	232	233	-9%
Cases Under Investigation (By Team)				
Compliance/Routine	941	837	514	-45%
Drug Diversion/Fraud	304	191	144	-53%
Rx Abuse	107	78	126	18%
Compounding	68	67	42	-38%
Outsourcing	13	23	11	-15%
Probation/PRP	50	26	14	-72%
Enforcement	224	115	449	100%
Criminal Conviction	261	262	282	8%
Complaint Closure Outcomes Not Resulting in Further Action				
Insufficient Evidence	601	635	644	7%
Non-Jurisdictional	390	402	369	-5%
No Violation	388	365	346	-11%
No Further Action	344	253	213	-38%
Other - Non-Substantiated	65	32	34	-48%
Subject Educated	61	151	89	46%
Application Investigations				
Received	381	374	240	-37%
Closed				
Approved	272	247	208	-24%
Denied	63	48	33	-48%
Total Closed (includes withdrawn	***409***	***341***	***271***	***-34%***
Pending	72	78	72	0%
Letter of Admonmishment / Citations				
LOA Issued	285	327	452	59%
Citations Issued*	1,144	1,428	936	-18%
Proof of Abatement Requested	187	414	248	33%
Appeals Received	135	103	93	-31%
Dismissed	24	21	22	-8%
Total Fines Collected	***$811,724***	***$963,445***	***$785,755***	***-3%***
Administrative Cases				
Referred to the AG's Office	264	230	188	-29%
Pleadings Filed	277	248	194	-30%
Pending				
Pre Accusation	165	128	108	-35%
Post Accusation	233	192	153	-34%
Total Pending	***398***	***322***	***261***	***-34%***
Total Closed	***326***	***320***	***291***	***-11%***
Revocation				
Pharmacist	23	19	12	-48%
Intern Pharmacist	2	2	1	-50%
Pharmacy Technician	96	77	66	-31%
Designated Representative	1	1	1	0%
Wholesaler	0	2	0	0%
Clinic	0	0	0	0%
Pharmacy	16	9	12	-25%
Sterile Compounding	0	1	0	0%
Outsourcing	0	0	0	0%
Total	***138***	***111***	***92***	***-33%***

Revocation; stayed suspension/probation				
Pharmacist	3	0	1	-67%
Intern Pharmacist	0	0	1	0%
Pharmacy Technician	1	0	0	-100%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	1	0	0	-100%
Sterile Compounding	0	0	0	0%
Outsourcing	3	0	0	-100%
Total	***8***	***0***	***2***	***-75%***
Revocation; stayed; probation				
Pharmacist	62	60	63	2%
Intern Pharmacist	0	5	3	0%
Pharmacy Technician	15	14	15	0%
Designated Representative	0	1	0	0%
Wholesaler	0	1	1	0%
Clinic	0	0	0	0%
Pharmacy	22	15	19	-14%
Sterile Compounding	3	2	5	67%
Outsourcing	0	1	0	0%
Total	***102***	***99***	***106***	***4%***
Surrender/Voluntary Surrender				
Pharmacist	21	28	20	-5%
Intern Pharmacist	4	1	1	-75%
Pharmacy Technician	24	35	18	-25%
Designated Representative	3	4	3	0%
Wholesaler	1	1	2	100%
Clinic	0	0	0	0%
Pharmacy	25	31	38	52%
Sterile Compounding	3	1	2	-33%
Outsourcing	0	0	2	0%
Total	***81***	***101***	***86***	***6%***
Public Reproval/Reprimand				
Pharmacist	19	4	38	100%
Intern Pharmacist	1	0	0	-100%
Pharmacy Technician	4	1	6	50%
Designated Representative	0	0	1	0%
Wholesaler	1	0	1	0%
Clinic	0	0	2	0%
Pharmacy	13	6	44	238%
Sterile Compounding	1	0	5	400%
Outsourcing	0	0	2	0%
Total	***39***	***11***	***99***	***154%***
Licenses Granted				
Pharmacist	6	2	2	-67%
Intern Pharmacist	2	1	0	-100%
Pharmacy Technician	5	6	3	-40%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	2	0	0	-100%
Sterile Compounding	1	0	0	-100%
Outsourcing	0	1	0	0%
Total	***16***	***10***	***5***	***-69%***
Licenses Denied				
Pharmacist	0	4	1	0%
Intern Pharmacist	0	2	0	0%
Pharmacy Technician	10	5	3	-70%
Designated Representative	0	0	0	0%
Wholesaler	0	0	0	0%
Clinic	0	0	0	0%
Pharmacy	1	0	1	0%

Sterile Compounding	0	0	0	0%
Outsourcing	1	0	1	0%
Total	***12***	***11***	***6***	***-50%***
Cost Recovery Requested	***$1,640,135***	***$2,184,365***	***$2,475,038***	***51%***
Cost Recovery Collected	***$811,724***	***$1,072,751***	***$1,578,428***	***94%***

Immediate Public Protection Sanctions				
Interim Suspension Order	3	8	13	333%
Automatic Suspensions	2	2	0	-100%
Penal Code 23 Restrictions	9	5	2	-78%
Cease and Desist - Unlicensed	2	1	0	-100%
Cease and Desist - Sterile Compounding	1	0	0	-100%
Probation Statistics				
Licenses on Probation				
Pharmacist	223	229	232	4%
Intern Pharmacist	8	12	5	-38%
Pharmacy Technician	21	26	28	33%
Designated Representative	1	2	2	100%
Wholesaler	3	3	3	0%
Pharmacy	78	72	69	-12%
Sterile Compounding	1	2	8	700%
Outsourcing	0	0	0	0%
Total Probationers	***335***	***346***	***347***	***4%***
Probation Office Conferences	88	115	79	-10%
Probation Site Inspections	425	442	533	25%
Probation Terminated / Completed	85	99	96	13%
Referred to AG for Non-Compliance	8	6	3	-63%

California State Board of Pharmacy
SB 1441 Uniform Standards
Three Year Comparison

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	FY18/19	FY19/20	FY20/21
PRP Intakes			
PRP Self-Referrals	2	1	0
PRP Probation Referrals	15	10	6
PRP Under Investigation	8	6	2
PRP In Lieu Of (investigation conducted)	1	0	1
Total Number of PRP Intakes	26	17	9
New Probationers			
Pharmacists	12	9	7
Interns	0	2	3
Pharmacy Technicians	15	10	8
Total New Probationers	27	21	18
PRP Participants and Recovery Agreements			
Total PRP Participants	57	59	51
Total Participant Recovery Agreements Reviewed	228	221	207
Probationers and Inspections			
Total Probationers	92	95	
Inspections Completed (This information is not available)	n/a	226	236
Referrals to Treatment			
Referrals to Treatment (PRP and Probationers)	16	16	6
Drug Tests			
Drug Test Ordered (PRP and Probationers)	3128	2947	2912
Drug Tests Conducted (PRP and Probationers)	3069	2884	2780
Relapses			
Relapsed (PRP and Probationers)	14	11	4
Major Violation Actions			
Cease Practice/Suspension (PRP and Probationers)	38	34	25
Terminated from PRP	9	3	10
Probationers Referred for Discipline	1	0	4
Closure			
Successful Completion (PRP and Probationers)	12	13	12
Termination (Probation)	3	0	1
Voluntary Surrender (Probation)	7	7	11
Surrender as a result of PTR (Probation)	0	0	0
Closed Public Risk (PRP)	9	3	1
Non-compliance (PRP and Probationers)	45	23	82
Other (PRP)	7	4	4
Patients Harmed			
Number of Patients Harmed (PRP and Probationers)	None	None	None

Drug of Choice at PRP Intake or Probation			
Pharmacists	**FY18/19**	**FY19/20**	**FY20/21**
Alcohol	21	13	4
Ambien			
Opiates	2	2	1
Hydrocodone	1	2	
Oxycodone	1	2	1
Morphine			1
Benzodiazepines			
Barbiturates			
Marijuana		1	
Heroin			
Cocaine		1	
Methamphetamine			
Pharmaceutical Amphetamine	1		
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol	1		
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine	2		
Intern Pharmacists	**FY18/19**	**FY19/20**	**FY20/21**
Alcohol	2	4	2
Opiates			
Hydrocodone			
Oxycodone			
Benzodiazepines			
Barbiturates			
Marijuana			
Heroin			
Cocaine		1	1
Methamphetamine			
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone		1	
Clonazepam			
Tramadol		1	
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			
Pharmacy Technicians	**FY18/19**	**FY19/20**	**FY20/21**
Alcohol	8	6	7
Opiates			
Hydrocodone			
Oxycodone			
Benzodiazepines		1	
Barbiturates			
Marijuana			
Heroin			
Cocaine		1	
Methamphetamine	1	2	1
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			