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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report
July 15, 2021

Maria Serpa, Licensee Member, Chair
Jignesh Patel, Licensee Member, Vice-Chair
Seung Oh, Licensee Member, President
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member

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

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

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Approval of April 22, 2021, Enforcement and Compounding Committee Meeting Minutes

A draft version of the minutes is provided in **Attachment 1.**

IV. Discussion and Consideration of Committee's Strategic Goals

Background

During its October 26-27, 2016, meeting, the Board approved its current strategic plan. Historically, the Board has conducted an annual review of its plan. The strategic plan is intended to be living document and updated to reflect changes in Board priorities that may result from changes in the marketplace, legislation, etc. Strategic plans are typically a five-year plan. It is anticipated that later this year the board will engage in the strategic planning process, most likely during the September 2021 Board Meeting. Provided below are updates to the strategic goals of the Committee. **UPDATE - Enforcement Committee Strategic Goals**

2.1 Implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.

Status May 2020:

- Investigation processing times are reported at meetings. Case priorities are reviewed and a team approach to case assignments and case outcomes has been implemented.

- The Committee is considering parameters for an alternative enforcement model.

Status July 2021:

- Committee and Board approve development of a pre-filing conference to achieve policy goal of reducing case resolution time and cost.

2.2 Strengthen patient consultation outcomes for Californians and increase medication safety.

Status May 2020:

- Inspectors continue to include in their routine inspections, pharmacy staff's compliance with consultation laws. Where noncompliance is noted, inspectors provide education as part of the inspection process and findings are included in investigation reports. As part of investigations into allegations of medication errors, consumers are contacted to determine if consultation was provided.
- Annual reporting on compliance observed through inspections will be provided.

Status July 2021:

- Inspectors continue to include as part of the inspection process, assessment of compliance for patient consultation requirements. Forty-four violations of failure to provide consultation were identified during inspections conducted in FY 2020/21. In addition, 60 citations were issued.
- Effective October 1, 2021, the Board updated Duty to Consult regulations. Updated regulations establish minimum consultation requirements for prescriptions mailed or otherwise delivered to patients.
- In response to COVID-19, the Board's waiver to provide for alternative method of consultation remained in effect during FY 2020/21.

2.3 Collect data and report to board members about enforcement trends that are presented at case closures, so the board can better educate licensees about board priorities.

Status May 2020: Multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action. Presentations are provided regarding the citation and fine program and the common violations resulting in the issuance of citations. Further, information on top violations are reported in *The Script* and were reported in the Board's Sunset Report.

Status July 2021: Multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action. Presentations are provided regarding the citation and fine program and the common violations resulting in the issuance of citations and common violations identified through inspections. Further, information on the most frequent violations are reported in *The Script*.

2.4 Evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety.

Status 2020: The board convened a technology summit on the use of automated drug delivery systems (ADDS) and evaluated the findings of a pilot project to expand the use of ADDS. The board secured statutory changes to expand the use of ADDS in Senate Bill 1447 (Hernandez, Chapter 666, Statutes of 2018.)

Status 2021:

- In response to COVID-19 pandemic, the Board approved a waiver to expand conditions for

remote order entry as well as remote supervision that expired in June 2021. The Board is now considering only site-specific waivers in this area.

- Committee considered provisions of Assembly Bill 2789 (Wood, Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission and recommends development of Frequently Asked Questions to assist licensees with compliance.
- Committee received presentation by the National Association of Boards of Pharmacy on the development of a Compounding Pharmacy Information-Sharing Project to help implement the FDA MOU on interstate compounding pharmacies.

2.5 Evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.

Status May 2020:

- In coordination with the Office of the Attorney General, the board initiated a review to improve the efficiency of the disciplinary process. The overall goal with the cooperation of the Attorney General's Office is to process all cases through the office of the Attorney General within one year.
- The Committee continued its consideration of an alternative enforcement model.

Status 2021:

- Committee approved educational materials intended to assist respondents with an understanding of the administrative case process.
- Committee and Board approve development of a pre-filing conference as part of the disciplinary process.
- Committee received a presentation by the Office of the Attorney General on its Annual Report to the Legislature including disciplinary case comparison data from FY 2018-19 and FY 2019/20.

2.6 Investigate options on the interoperability with a National Prescription Drug Monitoring Program.

Status May 2020: Assembly Bill 1751 (Low, Chapter 478, Statutes of 2018) established the authority for the Department of Justice to enter into an agreement with an entity operating an interstate data sharing hub for purposes of interstate sharing of controlled substances reporting information. The Department of Justice is in the process of implementing these provisions.

Status July 2021: The Department of Justice continues its efforts to implement information sharing across state lines.

2.7 Develop a process to submit complaints about inspectors anonymously and report back to the board.

Status May 2020: The board developed a brochure to be distributed to licensees at the time of inspection. Included in the brochure is information on filing a comment or complaint with the board's parent agency, the Department of Consumer Affairs. The brochure is also posted on the board's website. **Completed.**

2.8 Assess the collateral consequences of post discipline and research options.

Status May 2020: The Enforcement Committee initiated a review of the Board's Disciplinary

Guidelines during the March 2019 Board Meeting. Further work did not occur as the Committee focused on other competing priorities.
Status July 2021: Committee will resume its discussion and evaluation of the Board's Disciplinary Guidelines.

2.9 Evaluation of the Board's Citation and Fine program.
Status May 2020: The Committee has received several presentations on the citation and fine program and will continue to receive annual updates. The Committee completed its review of policy direction provided by the president and vice-president. Assessment and feedback by Board leadership continues including discussion on priorities and other factors that should be considered when issuing citations and fines. Annual review of the program will continue to assess trends and educational opportunities.
Status July 2021: Committee receives annual presentation on citation and fine program. Assessment and feedback by Board leadership continues, providing policy direction considerations when issuing citations and fines.

2.10 Review the role and responsibility of the PIC.
Status May 2020: Senate Bill 476 (Stone) would have created a task force to study and submit a report to the Legislature on the prevalence of management interference upon the ability of pharmacists-in-charge to do their jobs and any legislative recommendations for improvement. SB 476 was held in committee and under submission on May 16, 2019. No further action has been taken on this strategic goal. The committee agreed during through discussion that the role and responsibility of the PIC will be discussed with the review of the Disciplinary Guidelines.
Status July 2021: No subsequent action has been taken on this item.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review the current the goals and the status of each item and determine what if any changes should be recommended to the Board.

V. 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.

For Committee Consideration and Discussion
During the meeting a presentation will be provided 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.

Attachment 2 includes a copy of the presentation slides.

VI. 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

For Committee Consideration and Discussion

During the meeting members will receive a presentation providing updated information. Like last year's review, the most frequent violation for pharmacies and pharmacists is medication error. Also, like last year, the most frequent violation for interns is self-use. The most frequent violation for pharmacy technician during the current reporting period is conviction of a crime substantially related to the practice.

Attachment 3 includes a copy of the presentation slides.

VII. 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. The original proposal developed and considered by the Committee and Board was based on a model used by the Physical Therapy Board. The Committee and Board has dedicated as significant amount of time and considered various proposal 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.

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 test this process at the recommendation of the assigned Deputy Attorney General (DAGs). In the trial 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.

For Committee Discussion

During the meeting members will have the opportunity to consider the recommendations and provide guidance to staff of areas for further development and/or implementation.

Attachment 4 includes a flowchart that demonstrates conceptually how the process could work as well as the current process.

VIII. 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 Inspector 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.

For Committee Consideration and Discussion

To guide the Committee in its review, the following questions may be appropriate to consider in determining the next steps in its review:

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?

IX. 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.

For Committee Consideration and Discussion
During the meeting members will have an opportunity to review the governing statute and regulation to determine what, if any, changes are appropriate.

In preparation for the discussion, staff contacted an expert in the field, Dr. Gasper. Dr. Gasper noted that the protocol appears in general to still be appropriate and that some pharmacists may be "over operationalizing" the protocol. Further he noted that products have changed and use of the product is more familiar for both pharmacists and consumers.

To assist the Committee in its discussion the following questions may assist.

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. Given the comments from Dr. Gasper, 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?

X. 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.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to discuss the revised FAQs and provide feedback to staff.

Attachment 5 includes revised Automated Drug Delivery System FAQs.

XI. 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 6 includes the annual and three-year comparison enforcement statistics.

XII. Future Committee Meeting Dates

- October 20, 2021

Attachment 1

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ENFORCEMENT COMMITTEE
Draft MEETING MINUTES

DATE: April 22, 2021

LOCATION: Teleconference Public Committee Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-27-20, dated March 27, 2020, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member Chair
Jig Patel, Licensee Member Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Administration Manager
Christine Acosta, Supervising Inspector

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

Chairperson Maria Serpa called the meeting to order at 12:30 p.m. Dr. Serpa advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Newsom's executive order. Members of the public were provided with general instructions for the WebEx meeting and process to provide public comments.

A roll call was taken. Members present included Jignesh Patel, Greg Lippe, Ricardo Sanchez, Debbie Veale, Albert Wong and Maria Serpa. A quorum was established.

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

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, none were offered.

III. Approval of January 20, 2021, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes.

Motion: Approve the January 20, 2021 Committee Meeting minutes, including the correction identified.

M/S: Lippe/Patel

Members of the public were provided with an opportunity to provide public comment; however, no comments were provided.

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

IV. <u>Approval of February 18, 2021, Minutes, Informational Meeting on "White Bagging"</u>
Members were provided an opportunity to provide comments on the draft minutes.

Motion: Approve the January 20, 2021 Committee Meeting minutes, including the correction identified.

M/S: Veale/Lippe

Members of the public were provided with an opportunity to provide public comment. Members received a question from the public regarding the next scheduled discussion on the topic and was advised that the Committee will be providing an update to the Board during the Board Meeting.

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

V. <u>Presentation on the National Association of Boards of Pharmacy, Compounding Data Sharing Project</u>

Dr. Serpa advised members that the Chair Report detailed information on the conditions of the FDA MOU on Interstate Compounding and provided summary information including noting that the agreement establishes provisions for investigation of complaints relating to the compounded human drug products distributed outside of California, defines and establishes reporting requirements for the distribution of inordinate amounts of such products and mandates the submission and disclosure of information.

During our prior discussion, the Committee determined it would be beneficial to learn about the Information Sharing System developed by the National Association of Boards of Pharmacy (NABP) to facilitate some of the reporting and information sharing requirements established within the MOU.

Members received a presentation by Dr. Melissa Madigan, Associate Executive Director, Professional Affairs with the National Association of Boards of Pharmacy. Frances Gail Bormel, Acting Director, Office of Compounding Quality and Compliance with the Food and Drug Administration was also available to members for questions. (A copy of the presentation was included in the meeting materials.)

Dr. Madigan discussed the basic provisions of the MOU requirement and the state's obligations. Dr. Madigan discussed the provisions of inordinate amounts and provided background on the information sharing network developed by the NABP and its integration into the e-profile connect system.

Members were advised that the system will notify Boards about pharmacies whose data indicates they are distributing inordinate amounts and detailed the information that will be collected from the pharmacies. Members were advised how the system can facilitate the Board's obligation to notify the FDA the

requirements established in the MOU, including complaint information and that the system can also be used to fulfill reporting requirements for physician compounding to the FDA.

Ms. Bormel, FDA, stated that the system is a patient safety tool, and the importance of the MOU is the ability to share information centrally. Ms. Bormel noted the most pronounced patient safety tool is the adverse event report.

Members were provided with the opportunity to provide comments; however, none were provided.

Members were also provided with the opportunity to provide public comment. Public comment requested clarification on the frequency required to report data and was advised that the MOU requires one-year worth of data, by calendar year. The system will accept data in 2019 and 2020 and NABP is anticipating annual submissions.

Public comment sought clarification if the system can segregate out veterinary compounding and was advised that pharmacies should not be reporting veterinary compounding. Further, the commenter was advised that the FDA is interested in learning about challenges states have with implementation.

VI. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products

Following the presentation, Members proceeded with a discussion on the MOU. Members focused on larger policy questions including requesting confirmation from counsel if the Board had the authority to enter into the MOU. DCA Counsel Smiley confirmed that the Board does have the authority to enter into the MOU should it determine it can meet the obligations of the MOU. Ms. Smiley also noted that some confidentiality issues still require some additional evaluation.

The Committee discussed the potential benefits and negative impacts to California consumers if the Board enters into the agreement, noting that some pharmacies could choose to leave California if the Board does not enter the agreement, which could result in fewer options for California consumers, including those that require specialty items.

The Committee discussed the potential benefits and negative impacts to compounding pharmacies and residents outside of California if the Board does not enter into the MOU and noted the Board may lose its ability to regulate compounding as it currently does, and that specialty medication may not be available to patients in other states.

Members spoke in support of entering into the MOU.

Members of the public were provided with an opportunity to provide public comment. Public comment questioned if California should be reaching out the Medical Board. Ms. Smiley advised members that there is no requirement for the Board to request information from physician offices, rather just a reporting requirement if the Board becomes aware of the practice. A representative from McGuff referenced the petition submitted to the Board, encouraging the Board to sign the MOU and indicated that failure to sign could result in drug shortages.

Following the discussion on the larger policy issue, the Committee discussed policy questions related to implementation. Chair Serpa noted the meeting materials contained an example of a statutory frame work.

The Committee considered if the Board should require as a condition of renewal, that a pharmacy advise the Board that it distributes compounded preparations outside of California and determined such a requirement is appropriate.

After consideration, the Committee also determined that the Board should establish a requirement for such pharmacies to report sales to the Information Sharing Network as provided for in the MOU; noting such a requirement would make implementation feasible.

The Committee considered if the Board should establish a requirement for pharmacies to report adverse drug experiences and drug quality issues related to a drug compounded at the pharmacy; noting that as the Board is required to investigate such events, mandatory reporting is appropriate.

Members also considered if pharmacies that engage in interstate compounding should be required to affirm their understanding of the conditions of the MOU that must be fulfilled to engage in interstate compounding and concluded such a requirement is appropriate to ensure licensees have a full awareness of the requirements and obligations.

Members sought guidance from Ms. Smiley on the need to establish confidentiality provision to protect information sharing with the FDA. Ms. Smiley noted that agencies can share information through various methods.

Members also noted the importance of the Board developing educational materials for pharmacist that distribute products.

Motion: Recommend to the Board to move forward with draft statutory proposal including amending BPC 4110(a) and 4126.9 with change to 12 hours of notification and enter into the MOU provided sufficient resources and statutory changes are secured. Delegate to Executive Officer and Chair working with counsel to make nonsubstantive or clarifying changes.

M/S: Veale/Lippe

Members of the public were provided with an opportunity to provide public on the motion. Public comment suggested that the language be modified to clarify that the requirement only applies to human compounding.

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

The meeting was in recess from 2:02 p.m. to 2:22 p.m. Roll call was taken. Members present: Jignesh Patel, Greg Lippe, Ricardo Sanchez, Debbie Veale, Albert Wong, Maria Serpa.

VII. <u>Discussion and Consideration of Compounding with Components or other Materials that Could Result in Insanitary Conditions as Established in the FDA Insanitary Conditions at Compounding Facilities Guidance for Industry</u>

Dr. Serpa reminded members that the topic has been discussed several times over the course of the past few years and again more recently in detail at several meetings. Dr. Serpa noted the background information detailed in the meeting materials and noted the various resources and sources of information that surround this topic.

Dr. Serpa advised members that, as requested, staff discussed the issue with the FDA, who has confirmed that compounding from inappropriately graded products could result in violations of the guidance document regarding insanitary conditions. This would be consistent not only with the FDA alerts highlighting concerns with using dietary grade ingredients but also with the FDA 483 that was included in our prior meeting materials. Dr. Serpa continued advising members that NABP also recently confirmed that they share issues regarding inappropriately graded products with the state boards when identified.

Dr. Serpa provided information on the Board's ongoing education noting that educational efforts typically focus on provisions of the law, the importance of understanding the quality of ingredients prior to use, the importance of working with a supplier to improve the quality of bulk ingredients, to name a few.

Members of the public were provided with the opportunity to provide public comments. A representative from the California Pharmacist Association requested the Committee consider if additional testing would assist a pharmacist in determining and requested that the Board define a pharmaceutical grade ingredient.

Dr. Serpa noted that the Board needs to follow the information provided by the FDA. The educational materials provided during inspections were detailed in the meeting materials.

Additional public comment from Dr. Smith, stated that the FDA knows how needed methylcobalamin is and that the Board needs to protect access.

Dr. Serpa reiterated that the Board is focusing on providing education and in step with the FDA.

The Committee also received public comment from a compounding compliance officer speaking in support of the need for quality to be built into the entire compounding process.

Members concluded that no additional action is required, noting that staff will continue to educate and use enforcement discretion.

VIII <u>Discussion and Consideration of Opportunities to Improve Naloxone Accessibility through Auxiliary Labels for Opioid Prescriptions</u>

Dr. Serpa provided summary information on the agenda topic, noting that the meeting materials detail out the relevant laws and included a link to the Drug Safety Communication issued by the FDA. This communication recommends that health professions discuss the availability of naloxone. Members were reminded that this issue was added to the agenda following public comment at the October 27, 2020 meeting.

Members were provided with the opportunity to provide comments. Members noted that current labeling requirements are appropriate and that pharmacists providing appropriate consultation on a prescription for an opioid should include information on the use of naloxone. Members comments also noted that if the Board is interested in changes, it may be appropriate to consider establishing a requirement to dispense naloxone under specified conditions.

Members of the public were provided the opportunity to provide public comment. Comments provided suggested that the impediment to naloxone may be the requirements of the current protocol in place and indicated the Board could make such a change through Assembly Bill 1533. Other comments expressed concern if the Board were to establish a requirement for an additional auxiliary label.

Dr. Serpa advised members that a future agenda will include the opportunity for members to discuss the current naloxone protocol to determine if changes are appropriate.

IX. Discussion and Consideration of Assembly Bill 2789 (Wood, Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission

Dr. Serpa advised members that in 2018 legislation was passed to facilitate e-prescribing, noting that the legislation included a delayed effective date to allow for a period of implementation and transition. As the provisions take effect January 1, 2022, the matter was agendized to allow the Committee the opportunity to consider if development of FAQs would be appropriate.

Dr. Serpa references the provisions of the legislation detailed in the meeting materials, noting there are a number of exceptions to the requirement and highlighting that a pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription falls within one of the exceptions.

Chair Serpa noted that it appears appropriate to consider if prescribing and dispensing medications within a single e-HR platform can be defined as "electronic transmission", versus sending prescriptions electronically to outside pharmacies.

After discussion, members determined development of FAQs and other educational materials should be referred to the Communication and Public Education Committee.

Members received public comment in support of the FAQs and noted that information on the provisions for transferring a prescription would be appropriate. Public comment also suggested that there may need to be an extension of the timeline for compliance with the provisions.

X. Discussion and Consideration of Federal Food and Drug Administration Final Rule Related to Importation of Certain Canadian Prescription Drugs

Dr. Serpa advised members last year the FDA finalized its rule to implement provisions of federal law that allow for the importation of certain prescriptions from Canada.

Members were provided a brief presentation on the federal requirements, including the requirements of an Importation Program Proposal, definitions of "eligible drugs",

"foreign seller" and "importer." Members were advised about provisions for FDA authorization as well as testing and recall requirements.

Members indicated it is appropriate to monitor this issue but that no action is required at this time.

Public comment was received suggesting that the State confer with Canadian colleagues before working to implement the provisions of the federal rule.

XI. <u>Office of the Attorney General, Presentation on the Annual report to the Legislature Pursuant to Business and Professions code Section 312.2</u>

Dr. Serpa introduced Carl Sonne, Senior Assistant Attorney General, with the Licensing Section of the California Department of Justice for his presentation.

Mr. Sonne provided background on the policy that resulted in the reporting requirements, including the Consumer Protection Enforcement Initiative, with the goal of reducing investigation and disciplinary timelines.

Mr. Sonne provided members with information on the data collection method used to develop the report. Mr. Sonne provided statistics from referrals for accusations, include the number of referrals, number of cases rejected by the Attorney General's Office, the cases returned for further investigation, and number of cases adjudicated.

Mr. Sonne summarized Board specific information and concluded noting that with data you can measure outcomes.

Members were provided with the opportunity to provide questions but did not have any.

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

Meeting was in recess from 3:48 p.m. to 3:58 p.m. Roll call was taken. Members present: Jignesh Patel, Greg Lippe, Ricardo Sanchez, Debbie Veale and Maria Serpa. Member Wong returned at 4:20 p.m.

XII. <u>Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model</u>

Dr. Serpa referenced the relevant provisions in the law included in the meeting materials and reminded members that as part of the July 2020 meeting, a presentation was provided on the administrative case process. As was shared during that presentation, the administrative case process has two fundamental guiding principles: due process of the respondent and public protection. As part of

the presentation, members were reminded that the state has the duty and responsibility to ensure a licensee is competent and trustworthy.

Chair Serpa advised members that during the prior discussion, members directed staff to develop recommendations to achieve the policy goal to reduce case resolution times and reduce associated costs, that would not require statutory changes. Dr. Serpa referred members to the meeting materials including information on a pre-accusation conference that is used by the Board of Accountancy and a model used by the Department of Managed Health Care (DMHC). Dr. Serpa noted that a transition to the full model used by DMHC would require statutory changes.

Members considered the pre-pleading conference and several policy questions related to the proposed solution. As part of its discussion members noted that the pre-pleading conference appeared to be a good solution and noted support of the concept.

Members also noted that such a conference may not be appropriate for all cases and that the model did provide an appropriate balance of consumer protection and due process. Members also determined that use of such a process could reduce case resolution times and that the process could result in cost savings for the Board and for licensees.

Mr. Sonne advised members that the AG's office considers the pre-pleading conference of great value because it provides an opportunity for the licensee to provide additional information. Mr. Sonne noted, that if agreement is reached with the parties, it can front end the settlement after the accusation is filed. Mr. Sonne noted that not all cases may be appropriate for this process.

In response to member questions, Mr. Sonne advised the Committee the licensee and their representative, if applicable, participate in the pre-pleading conference.

XIII. Review and Discussion of Enforcement Statistics

Dr. Serpa referenced the enforcement statistics provided in the meeting materials.

Members were provided with the opportunity to provide comments; however, none were provided.

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

XIV. Future Committee Meeting Dates

The Committee was reminded that the next Committee meeting is scheduled for July 15, 2021.

XV Adjournment

Chairperson Serpa adjourned the meeting at 4:19 p.m.

Attachment 2

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?

CALIFORNIA STATE BOARD OF PHARMACY
Be aware and take care. Talk to your Pharmacist!

www.pharmacy.ca.gov

Attachment 3

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

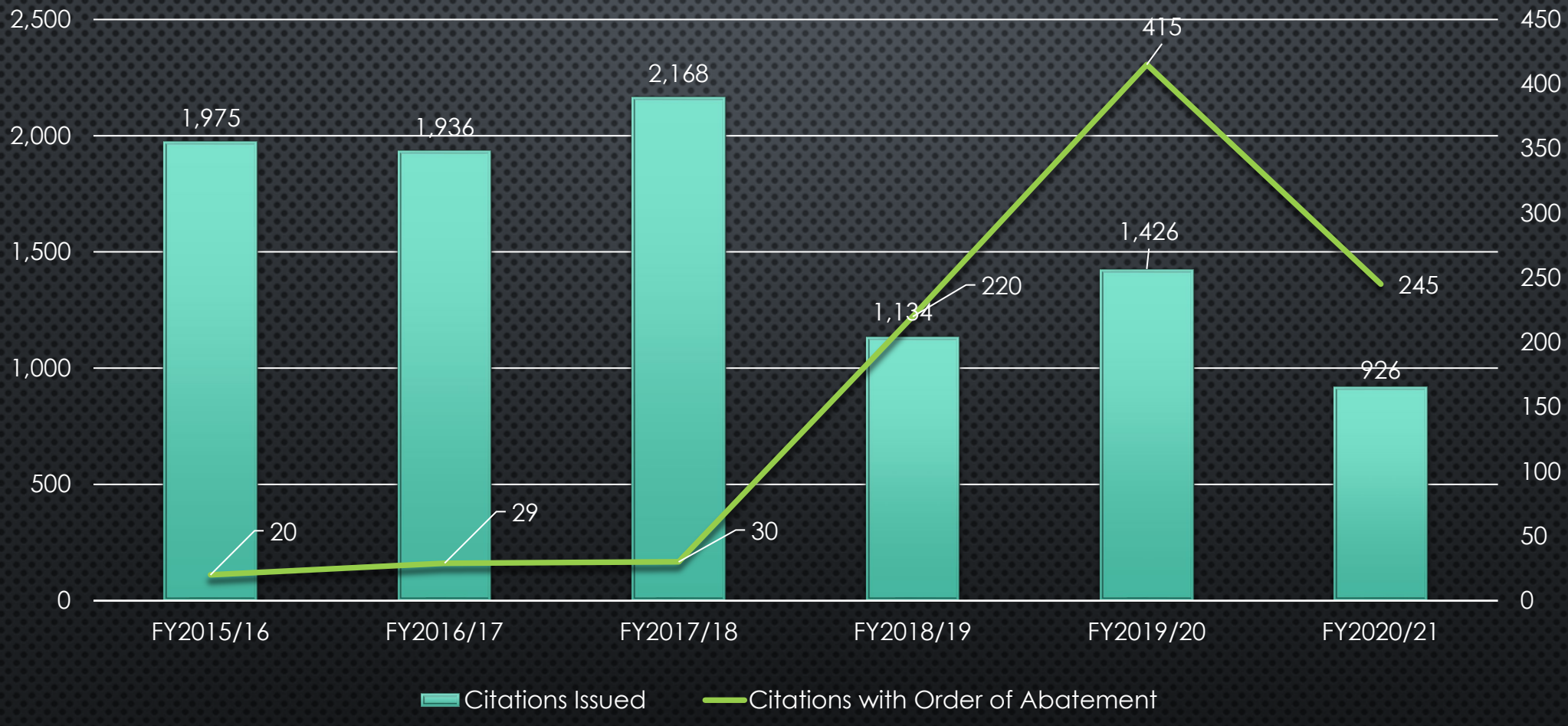
Abatement Types

- 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

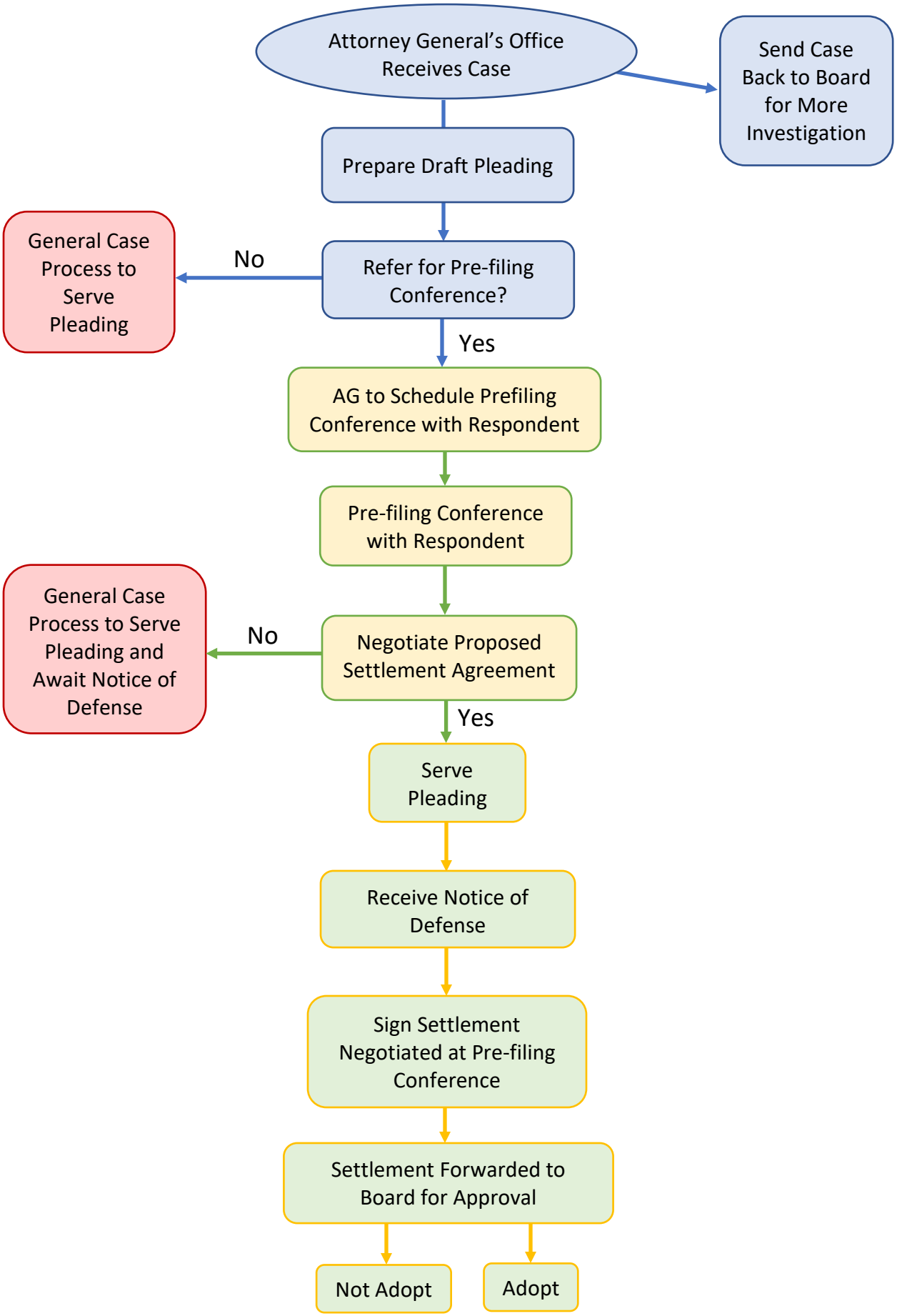
	FY 19/20	FY 20/21
Total Duty to Consult Citations (Includes Pharmacists and Pharmacies)	64	60
Pharmacy Citations	30 (23 with fine, 7 without)	28 (21 with fine, 7 without)
Average Citation Amount for Pharmacies	$3,117	$3,798
Pharmacist Citations	34 (12 with fine, 22 without)	32 (19 with fine, 13 without)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

THANK YOU

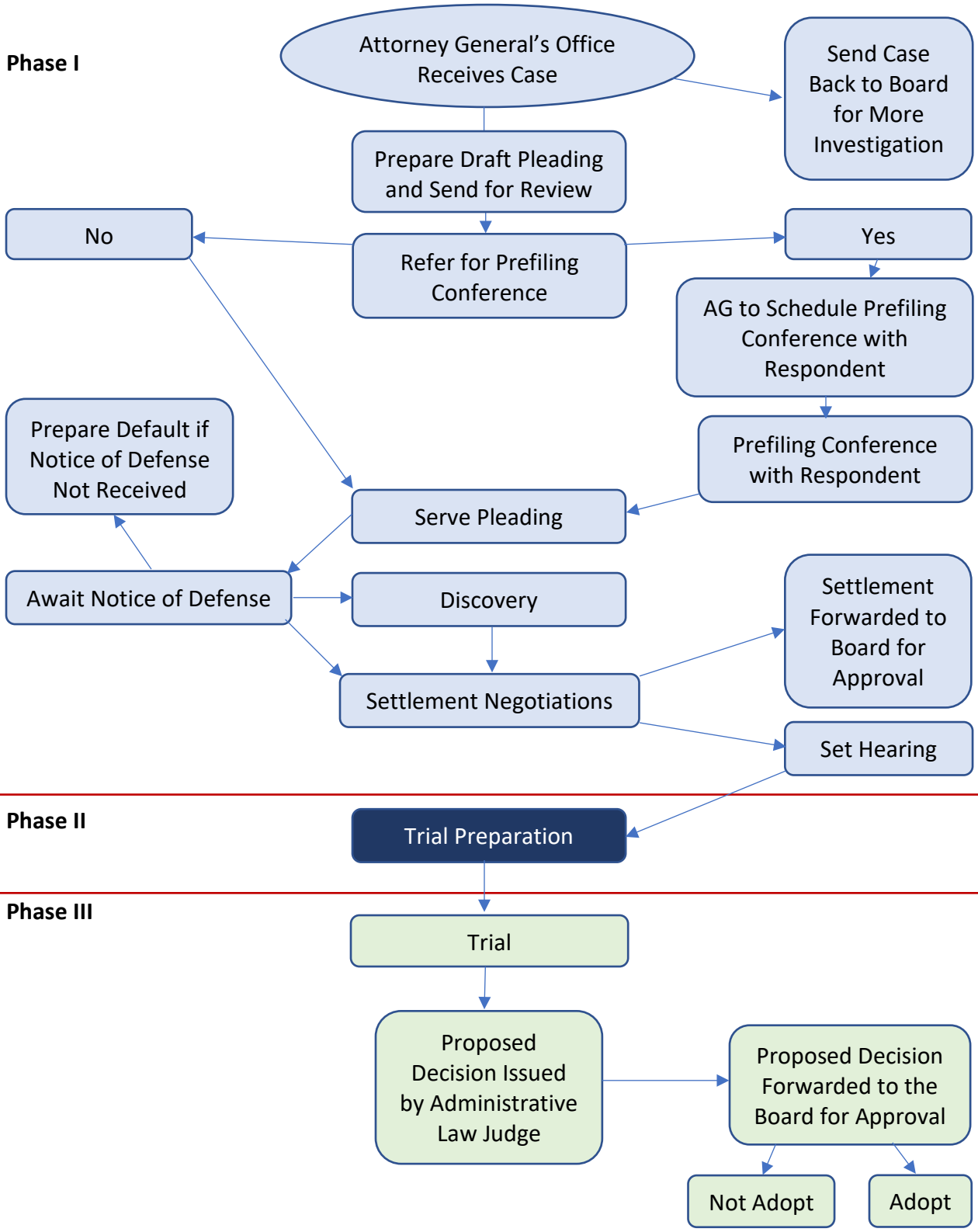
QUESTIONS?

Attachment 4

Pre-Filing Case Flow



GENERAL CASE PROCESS



Attachment 5

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, the board respectfully requests that your facility secure licensure to be compliant with these requirements.

Attachment 6

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			