California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

Enforcement and Compounding Committee Report
October 20, 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 July 15, 2021, Enforcement and Compounding Committee Meeting Minutes

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

IV. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

a. Assembly Bill 107 (Salas) Licensure: Veterans and Military Spouses.
Summary: Requires the Board to issue temporary licenses to practice. As provided, the Board would be required to issue the temporary license within 30 days of receiving fingerprint background checks. Further, pharmacist applicants would be required to take and pass the CPJE prior to issuance of the temporary license.
Implementation: Although the provisions become effective July 1, 2023, there are implementation activities that must begin in advance. Such activities include developing the appropriate attestations for each of the Board's license types, updating application and instruction forms, developing internal tracking systems, developing educational on the provisions and securing the necessary programming changes. It appears appropriate to develop regulations detailing the types of evidence needed to show compliance with the provisions (e.g., proof of marriage, domestic partnership, etc.) and well as under what circumstances the Board may request information. The Committee may wish to recommend referral of another committee to further development the scope and language for proposed regulations.

b. Assembly Bill 527 (Wood, Chapter 618, Statutes of 2021) Controlled Substances
Summary: Exempts specified non-narcotic combination product controlled substances from the California controlled substances schedule.
Implementation: Implementation efforts should be minimal and include education of the change.

c. Assembly Bill 1064 (Fong) Pharmacy Practice: Vaccines: Independent Initiation and Administration
Summary: Expands authority to allow a pharmacist to independently initiate and administer any vaccine that has been approved or authorized by the FDA and received an ACIP recommendation published by the CDC for persons 3 years of age and older.
Implementation: Implementation efforts will focus primarily on education of the change.

d. Assembly Bill 1533 (Assembly Committee on Business and Professions, Chapter 629, Statutes of 2021) Pharmacy
BPC 4001, 4003 Summary: This measure extends the operations of the Board until January 1, 2026. Further, modifies the allocation of pharmacist members to also include a pharmacy compounding specializing in human drug preparation.
Implementation: Staff recommends completion of an annual report to include the primary reporting elements of the Sunset report to be reviewed as part of the July meeting for each year. Staff notes that changes to the membership of the Board will be implemented by the administration.
BPC 4052(a)(13) Summary: Expands authority for pharmacists to initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with a healthcare provider with prescriptive authority.
Implementation: Implementation efforts will focus primarily on education about the provisions, which could be extensive.
BPC 4052(a)(14) Summary: Expands authority for pharmacists to provide medication-assist treatment pursuant to a state protocol.
Implementation: Will require the Board to develop a state protocol via regulation. It may be appropriate for the Committee to determine if a recommendation should be offered to the Board regarding which committee should spearhead this effort.
BPC 4052.6 Summary: Expands that authority for an advanced practice pharmacist to initiate, adjust, or discontinue drug therapy beyond health care facilities.
Implementation: Implementation efforts will focus primarily on education about the provisions and should reiterate the provisions for coordination of care and education with the patient's diagnosing prescriber.
BPC 4110, 4126.10 Summary: Establishes the requirement for a pharmacy to report, as part of the renewal application, notification to the Board regarding compounding practices and reporting requirements for pharmacies distributing compounded human drug preparations. Note: These provisions are necessary to allow the Board to enter into the FDA MOU. The Board will also need to secure the necessary resources to meet the obligations of the MOU.
Implementation: Implementation efforts will include updating renewal forms and data systems, instructions and other educational materials.

BPC 4129 Summary: Expands authority for outsourcing facilities licensed by the Board to dispense patient-specific compounded drug preparations under specified conditions, including that the outsourcing facility comply with the same requirements of a pharmacy.
Implementation: Implementation efforts will include the development of educational materials and extensive education on the relevant provisions that outsourcers must comply with when exercising this new authority. Such education is necessary to allow for harmony with federal provisions while ensuring patients have access to pharmacist care, including drug utilization review, patient-centered labeling, patient consultation, etc.
Section 4161 Summary: Creates alternative pathways to licensure as a nonresident third-party logistics provider to allow for a pre-licensure inspection by the Board or evidence of accreditation by the NABP Drug Distributor Accreditation program.
Implementation: Implementation efforts will include updating application instructions and forms and development of forms. Further, in response to the COVID-19 pandemic, under its waiver authority, the Board granted waivers to issue temporary licenses to entities to facilitate distribution of various items, including ventilators and vaccines. As these licenses are limited in duration, transition activities will need to be undertaken to ensure continuity of patient care effective January 1, 2022.
Section 4210 Summary: Alters the application requirements for an advanced practice pharmacy to allow for qualification under a single pathway, if the pathway requires completion of a second criterion.
Implementation: Implementation efforts will include updating application instructions and forms and the development of educational materials. Staff will also review pending applications to determine if the changes provided in the measure will impact applicant eligibility.
Section 4232.5 Summary: Requires a pharmacist with authority to prescribe a controlled substance to complete an education course on the risks of addiction to Schedule II drugs.
Implementation: Implementation efforts will include updating the Board's renewal application requirements via regulation to give notice of this requirement and how to demonstrate compliance. The Committee may wish to recommend referral of another committee to further development the scope and language for proposed regulations.
Section 4301.3 Summary: Requires the Board to convene a working group of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate. Also, requires the Board to make recommendations to the Legislature after these discussions.
Implementation: Education on standard of care, including how the Board currently uses such a model and assessment of further use will be required. Under the provisions of the Board's administrative procedure manual, the president has the authority to establish an ad hoc committee. Such an approach may be appropriate. Given the short duration of time to conduct this work and prepare a report, it is recommended that the efforts begin in the third quarter of the current fiscal year.
Section 4317.5 Summary: Provides the Board with authority to issue fines of up to $100,000 for repeated violations within five years by three or more community chain pharmacies operating under common ownership. Further provides the Board with authority to issue fines up to $150,000 for any violation of this chapter demonstrated to be the result of a written policy or which was expressly encouraged by the owner or manager. The measure provides an opportunity to cure a violation as long as the violation did not result in actual harm to any consumer or pose serious potential harm to the public.

Implementation: Implementation will include education about the provisions and evaluation of investigations to determine if the new authorities provided are applicable. Data on implementation will be maintained and reported back to the Committee and Board. Data collected will also be a required element of the Board's next Sunset Report.
Section 4427.65 Summary: Expands the locations where unit-dose automated drug delivery systems may be located.
Implementation: Implementation will include education on the provisions.

e. Senate Bill 306 (Pan, Chapter 486, Statutes of 2021) Sexually Transmitted Disease: Testing
Summary: This bill will allow a pharmacist to dispense a medication without an individual name if the prescriptions includes "expedited partner therapy" or EPT. Further, requires a pharmacist to provide a written notice that describes the right of an individual receiving EPT to consult with a pharmacist about the therapy and potential drug interactions.
Implementation: Implementation efforts will focus primarily on education of the change.

f. Senate Bill 310 (Rubio, Chapter 541, Statutes of 2021) Unused Medications: Cancer Medication Recycling
Summary: Creates a cancer medication collection and distribution program under the direction of a surplus medication collection and distribution intermediary licensed by the Board. Provides allowances for patients to donate previously dispensed medications back to a participating practitioner for redistribution to other patients of the same practitioner or medical practice. Provides authority for the Board to request records to evaluate for compliance with the provisions and to prohibit a practitioner from participating under specified conditions.
Implementation: Implementation efforts will focus primarily on education about the provisions of the measure to the public as well as extensive education of identified Board staff to ensure the appropriate development of policies and procedures, drug manufacturing requirements, etc. to ensure appropriate patient protections exist for the recycled medications. Data will be collected and reported to the Committee.

g. Senate Bill 311 (Hueso, Chapter 384, Statutes of 2021) Compassionate Access to Medical Cannabis or Ryan's Law
Summary: Requires health care facilities to allow a terminally ill patient to use medical cannabis under specified conditions. Specifies that health care facilities permitting patient use of medicinal cannabis must comply with drug and medication requirements applicable to Schedule II, III, and IV drugs and shall be subject to enforcement actions by the California Department of Public Health.
Implementation: Late amendments to the measure, notably HSC Section 1649.3, appear to create some conflicts within the measure itself including the requirements that medicinal cannabis comply with provisions related to Schedule II-IV medications. Such a requirement creates a number of questions about the applicability of provisions of the Board's regulations including storage, inventory control, acquisition, etc. It appears appropriate for the Committee to evaluate this issue and work to resolve the conflicts with other regulators and stakeholders. Similar issues have occurred in other states where additional concerns regarding federal laws and regulations that impact health facility licensure, accreditation and reimbursement have limited the access. In the interim, it may be appropriate for the Committee to consider if it is

appropriate to provide staff with direction on the approach to education and enforcement until clarification via statute can be achieved.

h. Senate Bill 362 (Newman, Chapter 334, Statutes of 2021) Chain Community Pharmacies: Quotas
Summary: Prohibits a community chain pharmacy from using a quota to evaluate the performance of a pharmacist or pharmacy technician.
Implementation: Implementation efforts will include education about the provisions as well as the process a pharmacist or pharmacy technician may use to file a complaint. Educational efforts should also include information about whistleblower protections. Data on implementation will be provided to the Committee.

i. Senate Bill 409 (Caballero, Chapter 604, Statutes of 2021) Pharmacy Practice: Testing
Summary: Expands authority for pharmacists to provide CLIA-waived tests under specified conditions.
Implementation: Implementation efforts will include education of the provisions and updates to the Board's Health Services Registry to capture these additional services for patients.

V. Discussion and Consideration of Released Revised Proposed Changes to USP Chapters 795 and 797 and the Board's Current Policy Statement

Relevant Law

Section 503A of the Food, Drug and Cosmetic Act establishes requirements for preparing human drug compounded preparations within a state-licensed pharmacy, federal facility, or by a licensed physician that is not registered with the FDA as an outsourcing facility.

BPC Section 4126.8 provides that compounding of drug preparations shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP-NF), including relevant testing and quality assurance. Further, the Board may adopt regulations to impose additional standards.

BPC Section 4127(c) requires the Board to review any formal revision to General Chapter 797 of the USP-NF relating to the compounding of sterile preparations, no later than 90 days after the revisions become official to determine whether amendments are necessary for the regulations adopted by the Board.

BPC Section 4342 provides authority for the Board to institute any action provided by law, that in its discretion, is necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength provided in the latest addition of USP or that violate any provisions of the Sherman Food, Drug, and Cosmetic Law.

California Code of Regulations Section 1708.3 – 1708.5 provides general requirements for radioactive drugs.

California Code of Regulations Section 1735 et seq. establish requirements for the compounding of preparations. Further, California Code of Regulations Section 1751 et. seq. establishes additional requirements for the compounding of sterile preparations.

Background

In response to significant proposed changes to USP compounding chapters, the Board established an ad hoc Compounding Committee to review the proposed changes and determine what, if any, changes to the Board's regulations were necessary to ensure appropriate, safe and efficacious compounded preparations are provided to California consumers. In 2019 the Committee convened several meetings to provide education on the new proposed chapters as well as consider current regulation requirements and offer recommendations to change the current requirements. The meetings were well attended and provided an opportunity for robust discussion and development of language in response to proposed 2019 changes. Appeals were received by USP in response to the proposed Chapters which resulted in a delay in implementation. Based on USP, the Board similarly postponed additional action.

On September 1, 2021, USP released proposed updates to USP General Chapters 795 and 797. As provided in these proposed revisions, the minimum standards described apply when preparing compounded nonsterile and sterile preparations for humans and animals.

For Committee Consideration and Discussion

Given the release of the proposed revisions it appears appropriate for the Committee to determine whether it should resume education efforts and begin evaluation of the Board's regulations. It may also be appropriate to release an updated policy statement providing guidance to licensees about the Board's understanding of the current status of the provisions governing the practice of compounding.

Provided in **Attachment 2** includes high level comparison charts detailing current USP standards, USP 2019 proposed version and newly released 2021 versions of USP Chapters 795 and 797. Also, provided is a draft policy statement that could be used to provide guidance to licensees.

VI. Updates on FDA Actions Related to Human Compounding

a. FDA's Final MOU on Interstate Distribution of Compounded Drug Products (For Information only)

On August 9, 2021, the FDA released a notice of extension of the period before it intends to begin enforcing the statutory five percent limit on out of state distribution of human drug products. Under the summary of the notice, the FDA is extending the period to October 27, 2022, providing states with an additional year to complete evaluation and make necessary changes to law to meet the obligations of the MOU.

b. Guidance for Industry Hospital and Health System Compounding (For Information Only)

On October 7, 2021 the FDA released a draft guidance document, Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. The draft guidance describes how the FDA intends to apply certain provisions of section 503A of the FD&C to human drug products that are compounded by state-licensed pharmacies for distribution within a hospital or health-system. Written comments must be submitted by December 6, 2021.

VII. Review and Discussion of Enforcement Statistics

Since July 1, 2021, the board received 715 complaints and has closed 813 investigations. The board has issued 92 Letters of Admonishment, 359 Citations and referred 49 cases to the Office of the Attorney General. The board has secured 0 interim suspension orders and granted 0 Penal Code 23 suspensions. Further, the board has revoked 19 licenses, accepted the disciplinary surrender of 18 licenses, denied 1 application, and imposed other levels of discipline against 31 licensees and/or applicants.

As of October 1, 2021, the board had 974 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

	July 3, 2021		October 1, 2021	
	Volume	Average Days	Volume	Average Days
Cases Under Review for Assignment	41	18	71	14
Cases Under Investigation	631	150	560	146
Investigation Pending Supervisor Review	141	40	134	40
Investigations Pending Second Level Review	30	16	42	47
Investigations Awaiting Final Closure	410	70	167	75

Attachment 3 includes the current fiscal year enforcement statistics.

VIII. Future Committee Meeting Dates

- January 18, 2022
- April 20, 2022
- July 19, 2022
- October 19, 2022

Attachment 1

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Business, Consumer Services and Housing Agency
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ENFORCEMENT COMMITTEE
Draft MEETING MINUTES

DATE: July 15, 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
Seung Oh, Licensee Member Vice-Chair
Debbie Veale, Licensee Member

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

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

Chairperson Maria Serpa called the meeting to order at 9:03 a.m.

DCA meeting moderator provided updated WebEx instructions.

Chairperson Serpa took Roll Call; a quorum was established.

II. Public Comments 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.

A member of the public asked for the status of the appointment of board member with compounding background to the Committee. In response, DCA Staff Counsel Eileen Smiley informed the Committee recruitment efforts are generally handled outside of the executive officer.

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

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

Motion: Approve the April 22, 2021 Committee Meeting minutes as presented.

M/S: Veale/Oh

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

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Serpa	Yes
Oh	Yes
Veale	Yes

IV. Discussion and Consideration of Committee's Strategic Goals

Dr. Serpa referenced the Committee's Strategic Goals included in the meeting materials. Members were invited to provide comments or ask questions on any of the goals. In addition, Dr. Serpa invited motions to provide recommendations to the board in order to update or change the Strategic Goals.

Member Veale requested clarification of goal 2.10. She asked for background information regarding the discussion of the role of the Pharmacist-in-charge (PIC) together with the Disciplinary Guidelines. EO Sodergren provided context that the PIC and Disciplinary Guidelines are being discussed together to explore whether the PIC is empowered with the appropriate authority to actually effectuate the changes necessary, within some environments, to comply with the law. In response, Dr. Serpa suggested a rewording of goal 2.10 to provide clarification. The committee discussed the overall intent of goal 2.10 in order to determine a clearer title for the goal.

Members of the committee were provided the opportunity discuss any other strategic goals; however, there were no additional comments by members.

Motion: Make a recommendation to the Board to change Strategic Goal 2.10 title to "Review the current status to ensure the PIC has the authority to meet the legal needs to be the PIC."

M/S: Veale/Oh

Members of the public were provided with an opportunity to provide public comment.

A member of the public suggested making the pharmacy owner or licensee responsible rather than the PIC.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Serpa	Yes
Oh	Yes
Veale	Yes

V. Presentation and Discussion on Board's Inspection Program

Dr. Serpa advised members that the Committee receives an annual presentation on the Board's Inspection Program.

Members received a presentation from Executive Officer (EO) Anne Sodergren. She stated inspections provide significant opportunity for education as part of the inspection process. The board established a policy goal to inspect all pharmacies every four years. While the inspection provides field inspectors the opportunity to observe and evaluate for compliance, it also provides an opportunity to educate and communicate with the licensee.

EO Sodergren reviewed the inspection process with the Committee, which include in large part, the observation and the practice and activity in that location. EO Sodergren continued by sharing a list of items reviewed. In addition, the inspector will also ask to see the information and confirm compliance with various aspects of Pharmacy Law. As the inspection progresses the inspector will inspect the condition of the physical plant, review security measures and overall cleanliness, and conduct an audit of expiration dates.

EO Sodergren explained that during the inspection there are opportunities for the licensee to ask questions. Board inspectors use this opportunity to educate

licensees on current laws. Current topics inspectors are covering with licensees are: COVID; Waivers that are in place; Current regulations in place; Warning Labels; Inventory Reconciliation and Self-Assessments. The Board strives to standardize the inspection procedure to ensure, at a minimum, all licensees have had the same basic items covered during the inspection process.

EO Sodergren stated Board staff performed over 2,800 inspections in FY 20/21. The Committee was informed that in-person inspections were suspended for parts of the year during various periods of COVID-19, as the conditions warranted. Board staff conducted desk audits to assess primarily sterile compounding and outsourcing facilities when the Board was unable to conduct physical inspections.

A breakdown of the different types of inspections was provided. The routine number represented those inspections that were not triggered by some other factor. EO Sodergren emphasized that it was important to note that in most cases, an inspection, irrespective of the triggering event, will encompass a routine assessment. She explained desk audit inspections were used to ensure that there was some level of assurance of compliance when the Board was unable to conduct onsite physical observation. Determining appropriateness of desk audits in lieu of onsite inspections were about what the conditions were at the time and balancing that information with the interest of patient care.

A breakdown of different routine inspection outcomes was provided. She noted no issues were found in 58% of inspected pharmacies; corrections orders were issued in 41% of inspected pharmacies; less than 2% were issued a Notice of Violation.

The following lists were provided to the Committee: A list of Top Ten Corrections on a Routine Pharmacy Inspections FY20/21, Top Ten Violations Notices on Routine Pharmacy Inspections FY 20/21 and Current Pharmacy Licensees Year of Last Routine Inspection.

EO Sodergren reviewed data relevant to findings during routine visits regarding violations of Duty to Consult. Data from the data set indicates consultation was not provided to a patient in 7 of 44 inspections. Further, in 37 of 44 inspections, the site was not providing written notice of consultation on delivered or mail order prescriptions.

A summary of current pharmacy licensees' year of last routine inspection was

presented. EO Sodergren explained that the Board has a policy goal to inspect all pharmacies at least once every four years; the summary provided data to show the Board's progress in meeting the goal. EO Sodergren highlighted that the Board has visited about 80% of all licensees that have been licensed since January 2013.

Members of the committee were provided the opportunity discuss the presentation or ask questions; however, there were no additional comments by members.

Dr. Serpa provided a reminder that the Board has available an education pamphlet on preparing for an inspection posted on the Board's website.

Members of the public were provided with an opportunity to provide public comment.

The Board inspectors were commended for conducting inspections during this pandemic year. Public comment recommended that a similar report be provided to members which includes clinics, wholesalers, outsourcing facilities, and other licenses not included in this current report. In response, EO Sodergren stated some of that information is included in the presentation, but staff can augment the report in the future at request of the Committee. Dr. Serpa added similar data is provided in Licensing Committee and Enforcement Committee statistics.

Public comment asked whether a sample inspection checklist will be available specifically for clinics that hold a clinic permit. In response, Dr. Serpa stated that more information for all license categories will be provided soon.

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

Dr. Serpa advised members the Committee receives an annual presentation on the Board's Citation and Fine Program.

Members received a presentation from EO Anne Sodergren. She informed the Committee that depending on the nature and severity of the violation, the outcomes can range from educating the licensee, issuance of a Letter of Admonishment, or the issuance of a citation. She stated when the Board takes a disciplinary action it is done under the provisions of the Administrative Procedures Act. EO Sodergren provided the reminder that a citation is not considered discipline.

EO Sodergren provided that most of the citations issued by the board are issued pursuant to Business and Professions Code section 4314. She explained that the

board uses its authority to issue citations to address important violations that are serious in nature but do not rise to the level of removal or restriction of a license through the administrative case process. She explained that staff use policy direction provided by the Board when making decisions on outcomes, including the levels of fines, noting that the board has indicated that the highest fines are really reserved for the most serious violations. In most cases the board is limited to a maximum of $5000 per investigation although there are some exceptions.

EO Sodergren explained to the Committee the factors considered in assessing administrative fines pursuant to CCR section 1775.2; these factors serve as guiding principles.

The citation process was reviewed. Once an investigation is completed and violation(s) had been substantiated the inspector submits the investigation report to a supervising inspector (SI)for review. Upon review by the SI, a recommended outcome is determined. The recommendation is forwarded for second level review where the chief of enforcement and executive officer meet to review the investigation and recommendation to ensure consistency. Cases with recommendations for the issuance of a citation are reviewed using this process. Citations can be issued with or without a fine or with or without an abatement. Once the citation is issued, the licensee has the opportunity to pay the fine, comply with an abatement order, or appeal the matter. If they opt to appeal, they can choose to have an informal office conference with Board representatives or go to a formal hearing with an Administrative Law Judge.

EO Sodergren provided historical data. She noted the number of fines issued, the amount of fines assessed, and the fines collected have all been trending down.

EO Sodergren shared the Boards processing times which indicated a significant increase over the past five fiscal years. She expects this number will decrease as staff vacancies are filled.

She reviewed orders of abatement and explained to the committee that compliance with an order of abatement typically results in either a reduction or forgiveness of a fine. EO Sodergren explained the different abatement types and how each type might be recommended. Data was provided detailing the total abatements issues and total abatements satisfied during FY20/21. Member Veale asked what percent of abatements, after removing licensees who opted to pay in lieu of abatement, are actually satisfied. EO Sodergren stated that specific data point would be collected and provide later. A list of violations that lend themselves to abatements was presented.

EO Sodergren stated licensees are always provided the opportunity to appeal. The informal office conference allows the opportunity to present additional or

mitigating information to the Board's Executive Officer or designee and an SI. In addition, a licensee may submit a formal appeal to the board within 30 days of issuance of a citation for referral to the Office of the Attorney General.

EO Sodergren provided data on citation appeal outcomes for FY 20/21, noting that data suggests participation in the office conference appeal can lead to modifications of the citation, reduction to a letter of admonishment or even dismissal.

EO Sodergren provided data on the top ten violations resulting in the issuance of a citation for pharmacies, pharmacists, interns and technicians for FY 20/21. Data was provided on citations issued specific to violations of Duty to Consult CCR section 1707.2.

Members of the committee were provided the opportunity discuss the presentation or ask questions; however, there were no additional comments by members.

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

The meeting was in recess from 10:16 a.m. to 10:25 a.m. Roll call was taken. Members Maria Serpa, Debbie Veale, Seung Oh.

VII. Discussion and Consideration of Pre-filing Settlement Conference

Dr. Serpa reminded members during the last Committee meeting, the members considered an alternative case resolution proposal that could be implemented to reduce the time and cost associated with resolving a disciplinary matter. At that time, the committee expressed support for establishing a pre-accusation and settlement conference.

Dr. Serpa noted, since the last meeting, staff and representatives of the Office of the Attorney General have worked to further develop a general implementation plan as well as a flowchart that demonstrates what the process could look like. The flowcharts were included in the meeting materials.

Dr. Serpa presented, as proposed, the conference model will be used initially through cases assigned to the Board's two assigned Deputy Attorney Generals (DAG). The DAGs will work with Board staff to identify cases appropriate for this model.

Members of the committee were provided the opportunity discuss, ask questions or propose a motion to recommend this model to the Board.

Vice-Chair Oh requested clarity on whether the pre-filing case flow could serve as a settlement as well. In response, Ms. Smiley advised the pre-filing could be the opportunity to evaluate whether evidence is inappropriate and serve as a starting point for some type of settlement. However, Ms. Smiley stated a settlement cannot be approved until an accusation is filed. EO Sodergren clarified, in the pre-accusation conference model the investigation is completed, it has been determined that the violation(s) are egregious enough and warrants formal discipline, the matter is then referred to the Office of the Attorney General (OAG). At the OAG, the violations are assessed and confirmed. The DAGs then draft the pleading; before the pleading is filed the respondent is provided the opportunity to discuss and provide additional information to the DAG.

Member Veale stated that she envisioned the pre-filing settlement conference taking place before the matter is referred to the OAG.

EO Sodergren clarified that all disciplinary matters are referred to the OAG. Under this model the respondent is provided one additional opportunity, before the pleading is served to provide additional information or explanation.

Dr. Serpa clarified that once it has been determined by the Board that an investigation has resulted in a disciplinary action the matter must be forwarded to the OAG. In this model the pre-filing conference occurs after the matter has been forwarded to the OAG, but offers the respondent an opportunity to have further discussion outside of the interim process of the investigation to discuss the allegations to perhaps mitigate, remove or change the pleading. Additionally, Dr. Serpa informed the members that this model does not require statutory change, as directed by the Board.

Ms. Smiley informed the Committee that what the pre-filing conference is going to give the respondent is an opportunity to have a conference with the DAG before an accusation or statement of issues is made public and served on them. It gives the respondent the opportunity to potentially influence the DAG or convince the DAG assigned to the case that the allegation shouldn't be made before possible publicity.

EO Sodergren stated disciplinary matters which will be allowed use the pre-filing conference will be evaluated on a case-by-case basis. She cautioned that some cases will not lend themselves to this process, such as cases with eminent public harm or Category 4 which are of the most serious nature. This will be a learning process.

Motion: Recommend the Pre-Filing Settlement Conference model be forwarded to the Board for discussion and consideration.

M/S: Veale/Oh

Members of the public were provided with an opportunity to provide public comment.

Public comment suggested making the pharmacy owner or licensee responsible rather than the PIC.

A representative from California Pharmacists Association (CPhA) sought clarification on why a case is forwarded to the OAG and whether there are any instances, when discipline is being discussed, that does not involve a license being revoked, suspended, limited or conditioned? Ms. Smiley stated, with respect to how the Board generally operates, a pleading is required before any type of disciplinary proceeding can be instituted. On behalf of CPhA, he stated this process does not appropriately safeguard the rights that licensees have under the APA. He added, if statute forbids this conference before referral to the OAG, the CPhA recommends that the Committee table this discussion and this model not move forward to the Board.

Additional public comment requested supplemental information on steps that can be taken after the negotiation of the settlement. Options after a settlement is negotiated are to send it back to the Board for more investigation or the Board could withdraw the case. He believed showing these steps would show due process. He opined that this model is good but needs more work.

Public comment also stated that problems arise when DAGs are involved in the conversation. He requested that the conference include pharmacists, board members and/or board staff. He argued DAGs are not trained in the area of pharmacy.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Serpa	Yes
Oh	Yes
Veale	Yes

Discussion and Consideration of Board's Disciplinary Guidelines

Dr. Serpa informed members, the Board's Disciplinary Guidelines are incorporated by reference into Board regulation. As included in the Guidelines, the Board

provides the Guidelines for those involved in and/or affected by the disciplinary process including the general public, attorneys of the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, the courts, board staff and board members.

The Board provides that the Guidelines are to be followed in disciplinary actions noting that individual cases may necessitate a departure of the Guidelines, in such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision transmittal memo accompanying a proposed stipulation.

Dr. Serpa reminded the members during the April 2021 Board Meeting, it was recommended that the Board consider the current provisions as it relates to underlying actions involving Driving Under the Influence convictions. However, given the current Guidelines were previously adopted in February 2017, it may be appropriate to determine if a broader review would be appropriate.

Dr. Serpa advised members any changes that are recommended to the Disciplinary Guidelines must ultimately be made through the regulation process. She asked the Committee to also consider scheduling a dedicated meeting to complete their review.

Dr Serpa asked if it was the Committee's preference to limit the review of the Guidelines to specific areas. She provided examples of specific areas including penalty ranges for various categories of violations, types of violations and current category classifications, and nature and type of mitigation or rehabilitation.

Vice-Chair Oh expressed support of a broader review of the Disciplinary Guidelines since much has changed in pharmacy law since 2017.

Dr. Veale expressed support for limiting the review to specific areas. She stated that the Guidelines are flexible. She stated the current guidelines are well written and work very well.

Dr. Serpa stated she saw benefits of both reviewing in detail and leaving the guidelines as they are. She stated she would support a separate meeting to review the Disciplinary Guidelines.

Dr. Serpa asked as changes in the law have occurred since the Guidelines were most recently adopted, would it be helpful to the Committee if staff recommend changes to incorporate new licensing programs as well as recommend solutions to resolve conflicts between the Guidelines and other areas of Pharmacy law.

Dr. Veale suggested that Board staff should identify laws which are not addressed in the Guidelines.

Vice Chair Oh expressed his agreement at evaluating the Guidelines to incorporate new licensing programs. He agreed Board staff should identify laws which are not addressed in the Guidelines.

Dr. Serpa asked whether the Guidelines should be updated to incorporate a Letter of Public Reproval as a disciplinary outcome.

Vice-Chair Oh stated he did support the inclusion of a Letter of Public Reproval.

Dr. Veale suggested the Committee start with its review of incorporating new licensing programs and solutions; through that review process a Letter of Public Reproval might be considered.

Members of the public were provided with an opportunity to provide public comment.

Public comment was received to review Guidelines from the perspective of pharmacists. Secondly, he encouraged the consideration of a Letter of Public Reproval.

Another public comment stated that to add a Letter of Public Reproval to formal discipline would be a mistake. He stated a Letter of Public Reproval could cause negative implications on anyone with a license in another jurisdiction. This public comment supported a review of Guidelines at a special in-person meeting.

The committee concluded that a separate meeting to discuss and review Disciplinary Guidelines within Enforcement and Compounding Committee would be scheduled at a future date. Board staff will bring forward recommendations which would add value to the Guidelines for consideration. The committee stated an in-person meeting could be beneficial but was not required.

VIII. Discussion and Consideration of Authority for Pharmacists to Furnish Naloxone Hydrochloride, including the Protocol in Title 16, California Code of Regulations Section 1746.3

Dr. Serpa provided background information and reminded members, public comment was provided at the previous Committee meeting that suggested the current regulatory requirements could impede access. At this meeting, the Committee had the opportunity to review the legal requirements to determine whether changes should be recommended.

Dr. Serpa asked members if it was appropriate to request the Communication and Public Education Committee consider the development of educational materials.

Dr. Serpa informed the Committee the Board will convene a workgroup, pursuant to AB 1533, to consider if a transition to a standard of care enforcement would be feasible and appropriate. The Committee agreed the evaluation of this issue would be incorporated into the work of the workgroup.

Members of the public were provided with an opportunity to provide public comment.

Public comment was received which urged the Committee to consider the current opioid crisis, take a more immediate action and not wait for the standard of care process. He stated AB 1533 has not passed yet; after passage the workgroup would not be required to convene until July 2022.

Members of the committee were provided the opportunity discuss or ask questions.

Vice-Chair Oh requested, from the public, substantial information showing reasons or causes for the pharmacist to not be able to perform these duties. He asked for information to be sent to the Executive Officer.

EO Sodergren clarified that some may be overcomplicating the protocol. She shared board staff have indicated the protocol is appropriate.

Members of the public were provided with an opportunity to provide public comment.

Dr. James Gaspar was invited by the Committee to speak as a guest. He recognized the concern that some of the guidelines may be perceived as a barrier. Requirements including the training could be perceived as a barrier. He stated, in general, the process that is outlined in the guidelines is very consistent with what the standard practice would be. He opined the anecdotal reports may be overstating the complexity and the larger issue may be the stigma in the profession which may be keeping more pharmacists from participating. Dr. Veale asked if Dr. Gaspar thought a change in protocol was necessary to improve access. In response, Dr Gaspar informed the Committee that barriers could be decreased to improve access, but in his opinion the larger issue is pharmacist participation.

Public comment responded that training is not the problem; the issue is employers are not providing pharmacists the time to furnish Naloxone, pursuant to the current

protocol.

Dr. Veale stated that the problem may be getting pharmacists to offer Naloxone.

Public comment shared providers are providing Naloxone inhalers to the homeless population through Naloxone distribution programs set up by Department of Health Care Services (DHCS). Due to their limitation of not having pharmacist guidance, there may be issues with ensuring integrity of the Naloxone inhalers.

Dr. Gaspar stated there are no barriers in place that override the pharmacist's willingness to participate. The protocol requires patient engagement and pharmacists do not want to or are not comfortable with engaging with patients. He stated there could be improvements made to the protocol's efficiency, but it is not the real barrier.

Dr. Veale suggested that education to pharmacists would be beneficial.

The Committee recommended this information be forwarded to the Communication and Public Education Committee for the development of educational materials to assist pharmacists with understanding the value of Naloxone and how to make it part of their operation.

IX. Discussion and Consideration of Draft FAQs related to Regulations Governing Automated Drug Delivery Systems

Dr. Serpa reviewed the draft automated drug delivery systems (ADDS) FAQs with members.

Members of the committee were provided the opportunity discuss the FAQs or ask questions.

Both Dr. Veale and Vice-Chair Oh expressed satisfaction with the FAQs.

Dr. Serpa informed the Committee that Question 21 was updated and information was added. Dr. Serpa requested language clarification be added for hospitals that are using the service after hours, since it is not appropriate to use ADDS when the hospital pharmacy is open.

The Committee suggested the following language, "*Should your hospital provide*

discharge medications from the drug stock contained within an ADDS when the pharmacy is not open the board respectively requires your facility to secure licensure for each ADDS in that environment to be compliant with these requirements."

Motion: Recommend approval of FAQ consistent with the Committee's discussion and include the discussion into the FAQs in advance of the Board meeting later this month.

M/S: Serpa/Veale

Members of the public were provided with an opportunity to provide public comment.

Public comment was received requesting consideration to reevaluate Question 18 and Questions 21. He asked the Committee to take into consideration ADDS in smaller communities where there are limited resources. Additionally, he asked consideration be given to reevaluate the guidance given and reconsider the licensing requirement for ADDS.

Additional public comment stated the FAQ did not address whether an ADDS machine placed in a Board licensed clinic needs an ADDS license; the machine is for inventory tracking and nurses remove medication and not for directly dispensing medications to patients. She asked, will these types of machines require inspector visits and licensing prior to medication being stocked in the machine.

In response to the first public comment EO Sodergren stated the FAQs are a correct interpretation of the law. The development of the FAQs included input from supervising inspectors, counsel, and senior staff. The Board is strongly encouraging the goal to secure licensure compliance rather than strong enforcement.

In response to the second public comment, EO Sodergren suggested that questions be sent directly to the Ask Inspector line and board staff can provide guidance.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Serpa	Yes

Oh	Yes
Veale	Yes

X. Review and Discussion of Enforcement Statistics

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

Members were provided 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.

XI. Future Committee Meeting Dates

The Committee was reminded that the next Committee meeting is scheduled for October 20, 2021.

XII. Adjournment

Chairperson Serpa adjourned the meeting at 12:17 p.m.

Attachment 2

Item	Current 2008	USP 2019	USP 2021
Personal Hygiene and Garbing	No specific requirements	Gloves are required for all compounding activities Other garb must be used as appropriate for the type of compounding	If gown is to be reused it must remain in the compounding area
Garb and Glove requirements	No specific requirements	A gown may be reused if not soiled and stored in the compounding area. Gloves, shoe covers, face and head covers and masks may not be reused. Non-disposal garb must be appropriately sanitized with 70% IPA.	No additional requirements
Building and facilities	Adequate space specifically designated for compounding and well organized. components, equipment and containers stored off the floor.	Compounding non-hazardous CNSPs shall not be in the same area as hazardous CNSP. Surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets must be cleanable and kept clean. Carpet is not allowed	Designated space for nonsterile compounding Space is controlled Space is cleanable and clean Must monitor temperatures in the storage area
Cleaning and Sanitizing	No specific requirements	CVE and work surfaces outside CVE: each shift, after spills , contamination, between CNSPs Clean and sanitize the horizontal work surface of the CVE between compounding of different drugs. Equipment: Before first use and per manufacture	Work surfaces: each shift, after spills , contamination, between CNSPs Floors: daily Walls: 3 months Ceilings/storage shelving: when soiled or contamination Cleaning must always be performed prior to sanitizing. Must be documented
Equipment	Store and cleaned appropriately. Special equipment to avoid cross contamination.	Must be non-reactive. Stored to prevent contamination. Manipulation of any component must take place in the CVE CVE must be cleaned CVE must be certified annually	No additional requirements
Components	Allows the use of non-FDA components or analytical grade components. Purified water shall be used	APIs must be manufactured by an FDA-registered facility Each API must be accompanied by a valid COA	Purified water USP or better must be used in compounding.
Component Storage and evaluation	Store per manuf. Guidelines and off the floor. If no expiration date, three years from purchase.	Packages of ingredients that lack vendor expiration must not be used after 1 year from the date of receipt. Verify component prior to use.	Packages of ingredients that lack vendor expiration must not be used after 3 year from the date of receipt.
Master Formulation and Compounding records	Master Formulation and Compounding record must be reviewed by the compounder. Comply with local state BOP for records requirements	Master formulation record (MFR) for each unique formulation of a CNSP. 8 required elements for MFR Compounding record created for all CNSPs. 13 required elements for compounding record	13 required elements for MFR
BUD 795	Water containing oral formulations = 14 days Water-containing topical/dermal and mucosal liquids and semisolid = 30 days Nonaqueous formulations = 180 days	Non-preserved aqueous (Aw > 0.6) = 14 days Preserved aqueous (Aw > 0.6) = 35 days Nonaqueous dosage forms (Aw ≤ 0.6) = 90 days Solid dosage forms = 180 days	Without stability information: Aqueous (Aw > 0.6) Non-preserved = 14 days frig Aqueous (Aw > 0.6) preserved = 35 days CRT or frig Nonaqueous (Aw ≤ 0.6) oral liquid = 90 days CRT or frig Nonaqueous (Aw ≤ 0.6) other dosage forms = 180 days CRT or frig With stability information: Aqueous must have USP antimicrobial effectiveness test Must assign per USP-NF monograph Max 180 days

Adapted from: USP Open Forum on 9/8/21, https://www.usp.org/events-training/virtual-open-forum-series-proposed-revisions-to-compounding-general-chapters

Item	Current 2008	USP 2019	USP 2021
Visual observation of hand hygiene and garbing	Annually	Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs	Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs
Gloved fingertip and thumb sampling	Initially 3 separate times Low/Medium-Risk CSPs: Annually High-Risk CSPs: Semi-annually	Initially 3 separate times then every 6 months	Initially 3 separate times Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency
Media-fill testing	Low/Medium-Risk CSPs: Annually High-Risk CSPs: Semi-annually	Every 6 months	Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs
Garbing Requirements	Gown Dedicated shoes or shoe covers Head and facial hair covers Face masks Sterile gloves	Gown Disposable covers for shoes Disposable covers for head and facial hair Face mask Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	Gown Disposable covers for shoes Disposable covers for head and facial hair Face mask Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves Category 3: 1.Not allow any exposed skin in the buffer room. (i.e., face and neck must be covered) 2. All low-lint garb must be sterile 3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle
Viable air sampling	Every 6 months	Initially then every 6 months	Category 1 & 2: Initially then every 6 months Category 3: Monthly
Surface sampling	Periodically	Initially then monthly	Category 1 & 2: Initially then monthly Category 3: Initially then weekly
Master Formulation Record	No specific requirements	CSPs are prepared in a batch for multiple patients or when CSPs are prepared from nonsterile ingredients	Required for: Category 1, Category 2, Category 3, and immediate-use CSPs prepared for more than one patient or CSPs prepared from nonsterile ingredient(s)
Compounding Record	No specific requirements	Every CSP prepared	Required for: Category 1, Category 2, Category 3, and immediate-use CSPs prepared for more than one patient or CSPs prepared from nonsterile ingredient(s)
Release Inspections and Testing	1) Visual Inspection: solutions 2) Sterility Testing: High-risk: ≥ 25, MDV, extended pre-sterilization time 3) Bacterial Endotoxins Testing: High-risk: ≥ 25, MDV, extended pre-sterilization time	1) Visual Inspection 2) Sterility Testing: Required for - Category 2 CSPs assigned a BUD that requires sterility 3) Bacterial Endotoxins Testing: Required for - Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing	1) Visual Inspection: 2) Sterility Testing: Required for - Category 2 CSPs assigned a BUD that requires sterility testing, and for all Category 3 CSPs 3) Bacterial Endotoxins Testing: Required for - Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing Category 3 injectable CSPs compounded from one or more nonsterile component(s)
BUD	Immediate use CSPS: 1 hr Low risk in SCA: 12 hrs Low risk: 48 hrs CRT, 14 days frig, 45 days frozen Medium Risk: 30 hrs CRT, 9 days frig, 45 days frozen High risk: 24 hrs CRT, 3 days frig, 45 days frozen	Immediate use CSPS: 4hrs Category 1: ≤ 12hr CRT, ≤ 24 hrs frig Category 2: Nonsterile – sterility test: 1 day CRT, 4 days frig, 45 days frozen Sterile – no sterility test: 4 days CRT, 10 days frig, 45 days frozen Nonsterile or sterile + sterility test: 30 days CRT, 45 days frig, 60 days frozen Terminally sterilized – sterility test: 14 days CRT, 28 days frig, 45 days frozen Terminally sterilized + sterility test: 45 days CRT, 60 days frig, 90 days frozen	Immediate use CSPS: 4 hrs Category 1: same Category 2: same Category 3: Aseptically processed: 60 days CRT, 90 days Frig, 120 days frozen Terminally sterilized: 90 days, CRT, 120 days Frig, 180 days frozen Max: 180 days is additional requirements are met

Adapted from: USP Open forum Event 9/15/21, https://www.usp.org/events-training/virtual-open-forum-series-proposed-revisions-to-compounding-general-chapters

Draft Policy Statement

In light of the September 1, 2021 release by USP of proposed updates to USP General Chapters <795> and <797>, the California State Board of Pharmacy (Board) wishes to update its stakeholders on the anticipated next steps the Board will be taking and also remind stakeholders about the current status of legal requirements for pharmacies compounding drug preparations. It is the Board's understanding that USP published proposed revisions to USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and General Chapter <797> Pharmaceutical Compounding – Sterile Preparations for public comment. It is the Board's understanding that comments may be submitted on or before January 31, 2022. Further, USP will host virtual Compounding Open Forum Series in January 2022.

The Board understands that based on the appeals to the 2019 proposed revisions to Chapters <795> and <797>, further changes were made to these proposed chapters. Accordingly, the current Chapters <795> (last revised in 2014) and <797> (last revised in 2008) remain the official versions of USP standards. In addition, all licensees must adhere to all relevant sections of Pharmacy Law and regulations, including but not limited to the Board's current regulations – title 16, California Code of Regulations, section 1735 et. Seq (Article 4.5, Compounding); section 1751 et. Seq. (Article 7, Sterile Compounding); and section 1708.3 to section 1708.5 (related to radioactive drugs) – and Business and Professions Code section 4126.8 and other relevant state and federal provisions.

It is the Board's understanding that USP is not offering any additional changes to Chapter <800> or Chapter <825>. Because Chapter <800> and Chapter <825> are not referenced in the current versions of Chapters <795> and <797>, Chapters <800> and <825> appear informational and not compendially applicable (or a required standard under USP) until the amendments in Chapters <795> and <797> are finalized. Like USP, the Board encourages utilization of amended Chapter <800> in the interest of advancing public health before it becomes a required USP standard by USP adoption of revised Chapters <795> and <797>. States and other regulators with jurisdiction, also may incorporate USP chapters that are not compendially applicable (required USP standards) into their own statutes or regulations, or "through other steps in accordance with their own policy making processes" to apply or enforce chapters that are not yet required USP standards.

As required in Business in Professions Code section 4127(c), the Board's Enforcement and Compounding Committee intends to resume it discussion of the new proposed revised chapters. Although it is the Board's goal to seek conformity with USP where possible, consistent with the Board's consumer protection mandate and the authority granted to the Board by the Legislature in Business and Professions Code section 4126.8, it is anticipated that the Board's efforts may result in updates to its current regulations, including higher standards if deemed necessary for public protection. Information on meetings will be posted on the website and meeting materials made available in advance.

October 2021

Attachment 3

Enforcement Workload Statistics FY 2021/22

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	661	0	0	0	661
Closed	755	0	0	0	755
Pending	1,308	0	0	0	1,308
Average Days for Investigation	246	0	0	0	246

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	484	0	0	0	484
Drug Diversion / Fraud	144	0	0	0	144
Prescription Drug Abuse	107	0	0	0	107
Compounding	38	0	0	0	38
Outsourcing	15	0	0	0	15
Probation / PRP	19	0	0	0	19
Enforcement	235	0	0	0	235
Criminal Conviction	266	0	0	0	266

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	54	0	0	0	54
Closed					
Approved	36	0	0	0	36
Denied	16	0	0	0	16
Total Closed (includes withdrawn)	***54***	***0***	***0***	***0***	***54***
Pending	74	0	0	0	74

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	189	0	0	0	189
Non-Jurisdictional	119	0	0	0	119
No Violation	92	0	0	0	92
No Further Action	59	0	0	0	59
Other - Non-Substantiated	7	0	0	0	7
Subject Educated	20	0	0	0	20

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	92	0	0	0	92
Citations Issued	359	0	0	0	359
Proof of Abatement Requested	89	0	0	0	89
Appeals Received	27	0	0	0	27
Dismissed	5	0	0	0	5
Total Fines Collected	***$205,461***	***$0***	***$0***	***$0***	***$205,461***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	44	0	0	0	44
Pleadings Filed	51	0	0	0	51
Pending					Quarter Ending
Pre-Accusation	85	0	0	0	85
Post-Accusation	153	0	0	0	153
Total Pending	**242**	**0**	**0**	**0**	**242**
Total Closed	50	0	0	0	50

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	0	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	5	0	0	0	5
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Pharmacy	10	0	0	0	10
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***19***	***0***	***0***	***0***	***19***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***0***	***0***	***0***	***0***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	10	0	0	0	10
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	6	0	0	0	6
Sterile Compounding	2	0	0	0	2
Outsourcing	0	0	0	0	0
Total	***19***	***0***	***0***	***0***	***19***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	4	0	0	0	4
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	0	0	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	11	0	0	0	11
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***18***	***0***	***0***	***0***	***18***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	3	0	0	0	3
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	5	0	0	0	5
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***10***	***0***	***0***	***0***	***10***

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

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	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	***1***	***0***	***0***	***0***	***1***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$348,542***	***$0***	***$0***	***$0***	***$348,542***
Cost Recovery Collected	***$262,261***	***$0***	***$0***	***$0***	***$262,261***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	0	0	0	0	0
Automatic Suspension Orders	1	0	0	0	1
Penal Code 23 Restrictions	0	0	0	0	0
Cease and Desist - Outsourcing	1	0	0	0	1
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	223	0	0	0	223
Intern Pharmacist	3	0	0	0	3
Pharmacy Technician	29	0	0	0	29
Designated Representative	2	0	0	0	2
Wholesaler	3	0	0	0	3
Pharmacy	68	0	0	0	68
Sterile Compounding	10	0	0	0	10
Total	***338***	***0***	***0***	***0***	***338***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	18	0	0	0	18
Probation Site Inspections	127	0	0	0	127
Probation Terminated / Completed	30	0	0	0	30
Referred to AG for Non-Compliance	6	0	0	0	6

As of 9/30/2021

Board of Pharmacy

Citation and Fine Statistics FY 2021/22

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	88	0	0	0	88
Pharmacist no Fine	61	0	0	0	61
Pharmacy with Fine	74	0	0	0	74
Pharmacy no Fine	66	0	0	0	66
Pharmacist-in-Charge with Fine*	44	0	0	0	44
Pharmacist-in-Charge no Fine	70	0	0	0	70
Pharmacy Technician with Fine	20	0	0	0	20
Pharmacy Technician no Fine	0	0	0	0	0
Wholesalers	2	0	0	0	2
Designated Representative	4	0	0	0	4
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	2	0	0	0	2
Hospital Pharmacy	4	0	0	0	4
Miscellaneous**	36	0	0	0	36
Unlicensed Premises	2	0	0	0	2
Unlicensed Person	1	0	0	0	1

*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	52%	1716 - Variation from prescription	50%	1716 - Variation from prescription	38%
1764/56.10 - Unauthorized disclosure of prescription and medical information	9%	1764/56.10 - Unauthorized disclosure of prescription and medical information	15%	1764/56.10 - Unauthorized disclosure of prescription and medical information	10%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	7%	1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	8%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%	1707.3 - Duty to review drug therapy	6%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	8%
1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	6%	1714(C) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	4%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	7%
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	5%	1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	4%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	7%
1735.3(a)(2)(F) - Records of Compounded Drug Products- For each compounded drug preparation, the pharmacy record shall include a compounding log consisting of a single document containing the manufac	5%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	3%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5%
4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	5%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	3%	1735.3(a)(2)(F) - Records of Compounded Drug Products- For each compounded drug preparation, the pharmacy record shall include a compounding log consisting of a single document containing the manufac	5%
1707.3 - Duty to review drug therapy	5%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	3%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	5%
4301(l) - Unprofessional Conduct - Conviction of a crime substantially related to the practice of pharmacy	4%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	3%	1707.3 - Duty to review drug therapy	5%

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 21/22
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals					
PRP Under Investigation	1				1
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	1				1
New Probationers					
Pharmacists	1				1
Intern Pharmacists					
Pharmacy Technicians	1				1
Total New Probationers	2				2
PRP Participants and Recovery Agreements					
Total PRP Participants	52				N/A
Recovery Agreements Reviewed	40				40
Probationers and Inspections					
Total Probationers	70				N/A
Inspections Completed	44				44
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1				1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	694				694
Drug Tests Conducted (PRP and Probationers)	661				661
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)					
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	1				1
Termination from PRP					
Probationers Referred for Discipline	3				3
Closure					
Successful Completion (PRP and Probationers)	3				3
Termination (Probation)					
Voluntary Surrender (Probation)	2				2
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance (PRP and Probationers)	51				51
Other (PRP)					
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 21/22
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1				
Ambien					
Opiates					
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1				1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					