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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ENFORCEMENT AND COMPOUNDING COMMITTEE
CHAIR REPORT

Allen Schaad, Licensee Member, Chair
Albert Wong, Licensee Member, Vice Chair
Victor Law, Licensee Member
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Ricardo Sanchez, Public Member

1. Presentation on the Board's Enforcement Program

Attachment 1

Background

Anne Sodergren provided an overview of the board's enforcement program. The presentation provided general workload and staffing information.

Attachment 1 includes a copy of the presentation.

Committee Discussion and Action

Ms. Sodergren informed the committee that board staff are collecting information specific to drug loss reports and whether law enforcement agencies are notified by the pharmacy. Once that data set is obtained the board would like the opportunity to review and determine whether it is normal practice to notify law enforcement at the time they determine employee pilferage. This data analysis would provide information on how integrated that practice is and whether a policy should be reconsidered. Additionally, Script articles could be published to recommend law enforcement notification.

As part of the public discussion, clarification was sought on what information is reported to the National Practitioner Data Bank (NPDB) and when is it reported. Board staff advised that disciplinary information is required to be reported to NPDB by Federal Law. Subsequently, once there is a change in the status of a license, for example once a licensee has completed probation, a follow up report is submitted to NPDB to inform them of the completed probation.

The committee did not take action on this item.

2. Presentation on Enforcement Trends

Attachment 2

Background

Virginia Herold presented information on compounding enforcement trends. Ms. Herold provided aggregate data on the outcomes of sterile and non-sterile pharmacy inspections conducted in 2017/18 as well as the top violations found in each setting.

Anne Sodergren presented information on drug loss enforcement trends. Ms. Sodergren provided a summary of data from a review of drug loss reports submitted over the last three fiscal years. The data revealed that the number of loss reports submitted had increased 153 percent. Further, the total dosage units reported as lost also increased, but at a much smaller rate, 16 percent.

Attachment 2 includes copies of the two presentations.

Committee Discussion and Action

As part of the committee's discussion on drug losses it was suggested that pharmacies may want to consider transitioning to a more real-time inventory for controlled drugs to reduce the stock on hand. Such a change could reduce the number of robberies and night break ins.

Further the committee noted that as the Inventory Reconciliation regulations take effect, it is expected that losses due to employee pilferage will also be reduced as identification of the losses should happen more quickly.

The committee did not take action on this item.

3. Presentation and Discussion on Efforts to Reduce Investigation Times and Case Resolutions

Attachment 3

Background

At the June 7, 2018 Enforcement Committee Meeting, the committee discussed average time frames for case investigations. Staff continues to work toward the goal of decreasing the number of aging case investigations outstanding.

One of the committee's strategic goals is to implement processes to shorten cycle time from initial investigation to case resolution.

Attachment 3 includes a flow chart of the board's enforcement process.

Committee Discussion and Action

Chiefs of Enforcement, Julia Ansel and Tom Lenox provided a presentation of the board's current pending investigations, including the average days by the identified benchmarks as of August 1, 2018.

The committee was informed that DCA's target for intake, which is defined as the number of days from receipt of the complaint to the date the complaint is either closed or assigned to an investigator, is 20 days. The Board of Pharmacy's average intake time, for FY 2017-18 was 27 days. For the month of July 2018, the intake time had improved to 19 days.

The committee was informed that DCA's target for case investigations, not transmitted to the Office of the Attorney General, is 210 days, which includes both intake and investigation. The Board of Pharmacy's average days for cases under investigation in the field during FY 2017-18 was 235 days. For the month of July 2018, investigation time had improved to 165 days.

Pending Field Investigations as of 8/1/2018			
Pending Case Status	**# of Cases**	**Avg. Days at this Status**	**Avg. Case Age**
Team Review for Assignment	76	19	27
Under Investigation	1070	165	209
Report Review	220	42	261
2nd Level Report Review	127	26	339
Closure Times	268	48	387

Public comment included a recommendation that the board establish a sub-committee whose responsibility would be to evaluate each case, before referral to the Office of the Attorney General. It was suggested that such a committee could include a peer review by an independent expert and provide board member input during the AG referral consideration process.

The committee did not take action on this item.

4. Discussion and Consideration of the Board's Citation and Fine Program

Attachment 4

Background

The committee asked staff to provide information regarding board-issued citations and fines. Board Chiefs of Enforcement Julia Ansel and Tom Lenox provided information on the board's citation and fine program.

Attachment 4 provides a snapshot of the board's citations issued for the month of July 2018.

Committee Discussion and Action

Ms. Ansel and Mr. Lenox provided a snap shot of data from board issued citations for the month of July 2018. The presentation revealed 279 violations, with an average fine amount of $608 per violation, for a total of $169,500 in fines assessed in the month of July. In addition, they reviewed the top citation violations issued for the month. Citations examples were provided to the committee which included various violations including medication errors, failure to provide documentation substantiating continuing education completion, unprofessional conduct, pharmacy security/ drug loss, duty to review drug therapy and compounding policy and procedures requirements. Ms. Ansel and Mr. Lenox commented that board staff has been reviewing citations for opportunities where abatements might be offered. Specifically, with some citations there may be instances where the licensee may have the option to take continuing education in a specific area of pharmacy law or education and upon proof of completion, the fine associated with the citation may be reduced or eliminated, depending on the circumstances of the case.

Public discussion included a request for clarification on what constitutes unlicensed practice and who determines the amount of citations and fines within the board. Ms. Herold provided examples of unlicensed practice and emphasized that in regard to unlicensed activity the primary goal is to obtain compliance; the board has the ability to issue cease and desist orders when unlicensed activities do not stop.

In addition, as part of the public discussion the board was asked who approved citations and fines. Mr. Lenox confirmed that the Chiefs of Enforcements review and approve citations and fines issued as a result of inspections and field investigations.

The committee did not take action on this item.

5. Discussion and Consideration of Convening Administrative Case Hearings Before Board Members

Background

During the June 2018 committee meeting, board members were informed that pharmacy boards in other states have opted for administrative case hearings to be heard with board members.

Chairperson Schaad explained that although the law allows for two different adjudication processes, the board's administrative case hearings are currently only heard before an Administrative Law Judge (ALJ). Alternatively, at the discretion of the agency, GC section 11517 also allows that an administrative case hearing may be heard by the agency itself with an ALJ presiding over the proceeding. This is similar to the method used by the board to consider petitions for modification to penalties.

Committee Discussion and Action

The committee took into consideration that in FY 17-18, 42 proposed decisions were received from ALJs. That equated to 62 days of hearings. Although the majority of cases heard before an ALJ are one day, as case complexity increases so do the number of hearing days, which are typically consecutive days.

The board members discussed areas of potential concern. No action was taken regarding disciplinary case adjudication.

6. Presentation on the Board's Inventory Reconciliation Process and Review of Frequently Asked Questions

Attachment 5

Background

On April 1, 2018, a new board regulation took effect – California Code of Regulations, Title 16, section 1715.65. The board believes this regulation will aid pharmacies and clinics in preventing losses of controlled drugs and identifying losses early.

Since the adoption of the regulation, the Executive Officer and board inspectors have received numerous questions from licensees regarding the new reconciliation regulation. In response, the board has focused on education to promote an understanding of the regulation. During this transition, inspectors will focus on the pharmacy's or clinic's good faith efforts to comply with the regulation.

Committee Discussion and Action

During the meeting, board supervising inspector Michael Ignacio and Chief of Enforcement, Tom Lenox provided general information on the board's inventory reconciliation process and frequently asked questions.

These FAQs were developed by board staff and DCA counsel. The first FAQs are available on the board's website and were published in the July 2018 edition of The Script. A second FAQs are being developed and include items identified during interactions between inspectors and licensees, typically as part of the inspection process.

The committee was advised that a presentation on the reconciliation regulation has also been incorporated into the board's quarterly Pharmacist Drug Abuse and Diversion Training Program. It was presented to over 200 pharmacists at the July 28, 2018 event. The next event was scheduled for September 22, 2018.

Ms. Herold informed the board that with the increased number of drug losses reported, it was expected that quantities reported would progressively decrease. Additionally, Ms. Herold encouraged the public to submit questions to the board for future FAQ sheet publications.

A copy of the first FAQ is provided in **Attachment 5**.

The committee did not take action on this item.

7. Discussion and Consideration of Remodel Inspections of Sterile Compounding Pharmacies and Possible Authority to Assess a Fee for Such Inspections

Background

A sterile compounding license shall not be issued or renewed until the location has been inspected by the board and found in compliance. A fee is assessed for the issuance or renewal of a sterile compounding license.

Under current law, the board does not charge a fee for an inspection resulting from the remodel of a sterile compounding pharmacy. Since the beginning of fiscal year 2015/16, the board has conducted approximately 60 sterile compounding remodel inspections. Inspections are conducted by the board after a facility has completed the remodel of their location. There is no requirement in the law for the board to conduct remodel inspections, but it is a safety issue that must nevertheless be done. Board staff believes that not conducting these remodel inspections could pose a patient safety risk. Remodel inspections are triggered by unforeseen damage, planned upgrades or expansion of a facility. The scope of a remodel ranges from simple projects to a full remodel or an expansion. All sterile compounding inspections have the same requirements, to ensure full compliance with regulations adopted by the board.

When notified of a pending remodel to a sterile compounding facility, the board attempts to conduct an inspection within six to eight weeks from the date of notification. Most remodel inspection requests are planned projects that the facility is aware of months in advance. Travel costs and inspector time for remodel inspections are currently being absorbed by the board.

Committee Discussion and Action

Stan Weisser requested clarification on what constitutes a remodel and whether the board needs to redefine a remodel.

Public discussion included whether sterile compounding facilities should be required to pay fees for inspecting the remodeled areas or if such a fee could be covered by other fees (e.g., renewal and application fees) necessary to maintain regulatory compliance. Further, it was questioned if inspection fees would discourage licensees from improving their facilities.

After further discussion, it was recommended that this issue should be discussed and considered by the Licensing Committee.

Committee Recommendation (Motion): Refer this issue to the Licensing Committee for further consideration.

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8. Update on the University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

Background

At the July 2017 Board Meeting, the board heard and discussed the results of the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. This study involves a waiver of California Code of Regulations Title 16, section 1713, in that it allows first-time fills to be dispensed via an ADDS machine, and the ADDS is not adjacent to a pharmacy counter but is installed in a hospital location.

During the July Board Meeting, the board heard the final report of this study and supported a request from UCSD to extend the study for one year to provide additional data.

Ultimately, the board voted to both expand and extend the study. During that meeting the board also directed UCSD to provide study updates to the Enforcement Committee every six months. The report to the committee was to fulfil this requirement.

Committee Discussion and Action

Ms. Herold informed the committee that the next UCSD presentation is scheduled for March 2019.

Ms. Herold reminded the committee that the board had requested a data comparison of people who received truly new prescriptions versus those who were getting refills. Due to the reported difficulty in collecting this data, Ms. Herold asked the committee if they still wanted UCSD researchers to continue this collection of data. The committee opted to discontinue collection of this data category.

Committee Recommendation (Motion): Direct UCSD to discontinue the collection of truly new prescription data.

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9. Discussion and Consideration of Federal and State Law Regarding Cannabidiol

Attachment 6

Background

Supervising Deputy Attorney General (SDAG) Joshua Room authored an opinion on the legal status of products containing cannabidiol (CBD), in light of the FDA approval of Epidiolex and AB 710 (Wood), which was enacted in mid-2018.

Provided in **Attachment 6** is the opinion by Supervising Deputy Attorney Joshua Room.

Committee Discussion and Action

SDAG Room clarified that the opinion regards only the prescribing of products containing CBD, not the selling of products. He informed the committee that current Federal and State law has not changed in status, for the purpose of prescribing or dispensing. In addition, the Federal Drug Enforcement Agency (DEA) has taken no action to reschedule CBD and there is no indication on their agency website they will.

SDAG Room was asked what a pharmacist should do if he/she has knowledge that a patient is currently taking a product containing CBD, which may have negative interactions with medication being dispensed. SDAG Room responded that a pharmacist is still responsible for consulting with the patient and informing the patient of the possible impact of the CBD product on their dispensed medication.

Public discussion, in part, included whether the board should partner with other agencies to discourage the sale of CBD products in non-pharmacy settings and advocate to reschedule CBD.

The committee did not take action on this item.

10. Discussion and Consideration of Board's Enforcement Statistics

Attachment 7

Background

During the June 2018 committee meeting, members directed board staff to include the following data elements into the Enforcement Statistics: Proof of Abatements Requested, Average Investigation Times, Cease & Desist Orders, and Unlicensed Activity.

Attachment 7 contains statistics describing the enforcement activities of the board. During the first quarter of the fiscal year, the board has initiated 773 investigations, closed 772 and had 1,889 pending.

The board denied 9 applications, issued 79 letters of admonishment, issued 425 citations/citations and fines, and referred 67 investigations to the Office of the Attorney General.

The board was also granted restrictions on two licenses pursuant to Penal Code section 23.

The committee did not take action on item.

11. Discussion and Consideration of Bifurcation of the Enforcement and Compounding Committees

Background

During the May 2018 Board Meeting, members voted to pursue a statutory proposal to incorporate USP compounding chapters into the board's requirements for compounding drug preparations. As part of its discussion, the board noted that two of the compounding chapters, <795> and <797>, are in the revision process by USP and USP <800> has been finalized, but is not yet in effect.

Subsequent to that meeting, in recognition of the large impending policy work that will be required, President Law bifurcated that Enforcement and Compounding Committee into two committees. Provided below is the membership for the respective committees.

Enforcement Committee
Allen Schaad, Chair
Albert Wong, Vice-Chair
Victor Law
Greg Lippe
Ricardo Sanchez
Stan Weisser

Compounding Committee
Stan Weisser, Chair
Allen Schaad, Vice-Chair
Shirley Kim
Victor Law
Maria Serpa

It is anticipated that the Compounding Committee will begin its work in early 2019.

12. Future Committee Meeting Dates

Enforcement Committee:
December 13, 2018
March 14, 2019
July 2, 2019
September 25, 2019

Compounding Committee:
To Be Determined

The draft meeting minutes from the June 7, 2018 and September 14, 2018 meetings have been provided in **Attachment 8**.

Attachment 1

www.pharmacy.ca.gov

Enforcement Program Overview

CALIFORNIA STATE BOARD OF PHARMACY

SEPTEMBER 14, 2018

Be Aware and Take Care: Talk to your Pharmacist!

In a nutshell

- **Office Staff**
  - Complaint Unit
  - Criminal Conviction Unit
  - Enforcement Unit
- **Field Staff**
  - Compliance Team
  - Compounding Team
  - Drug Diversion/Fraud
  - Drug Diversion Self-Use and Probation Monitoring
  - Outsourcing Team
  - Prescription Drug Abuse

Investigative Process

Triggering Event

- Consumer Complaint
- Subsequent Arrest Notification
- Referral from Other Agency
- Inspection

Investigation

- Inspection
- Interviews
- Records Assessment
- Report Writing

Outcome

- No Violation/Insufficient Evidence
- Findings Determine Outcome

Office Staff

Complaint Unit

- Complaint Unit
  - Opens and routes cases for field investigations
  - Point of contact for consumers
  - Evaluates Drug Loss Reports
  - Provides support to Prescription Drug Abuse Team
- Overview
  - 1 Supervisor, 7 Analysts, and 1 Clerical
  - 6,400 Cases Routed
  - 7,754 Calls/Emails Received
  - 9,249 DEA 106/4104 Reports Received
  - 2,004 CURES Reports Run

Criminal Conviction Unit

- **CCU – Desk Investigations**
  - Application Investigations
  - Subsequent Arrest Investigations
  - Failure to Report – e.g., Change of PIC, Ownership, Location
  - CE Audits
  - Out of State Discipline
- **Overview**
  - 1 Manager, 6 Analysts, 1 Clerical
  - 1182 Investigations Completed (130 referred to the AG's Office)
  - 3,459 Applications Review

Enforcement Unit

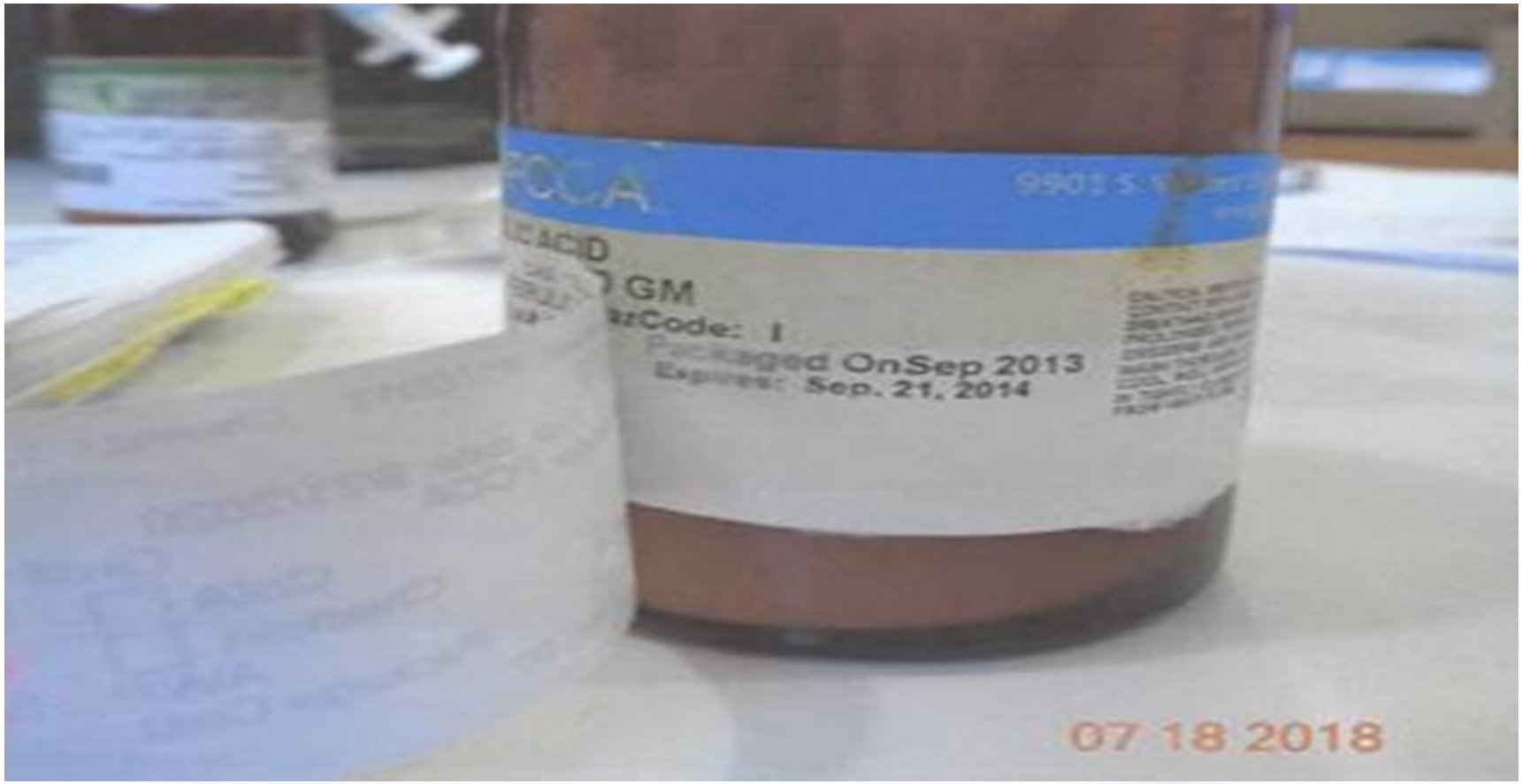
- **Enforcement Unit**
  - Letters of Admonishment
  - Citations
  - Administrative Cases
  - Reporting to National Databank
- **Overview**
  - 1 Manager, 6 Analysts (1 vacancy), and 3 Clerical
  - 350 Cases Referred to AG
  - 300 Mail Votes
  - 2168 Citations Issued
  - 442 Letters of Admonishment Issued
  - 670 Reports to NBDB

Field Staff

Compliance Team

- Field Investigations (typically consumer complaints, medication errors, failure to provide patient consultation)
- Routine Inspections
- Administrative Case Hearings
- Overview
  - 3 Supervising Inspectors and 13 Inspectors (2 vacancies)
  - 777 Inspections (Routines, Investigation & Sterile Compounding)
  - 831 Investigations Completed (28 cases referred for discipline)
  - 17 Administrative Hearings (29 days)

Routine Inspection



Routine Inspection

Compounding Team

- **Licensing and Enforcement Functions**
  - Annual Inspections of Sterile Compounding Facilities
  - Routine Inspections
  - Investigations
  - Administrative Cases
- **Overview**
  - 2 Supervising Inspectors and 9 Inspectors (3 vacancies)
  - 611 Inspections
  - 165 Investigations Completed (13 cases referred for formal discipline)
  - 1 Administrative Hearing

Nonsterile Compounding

Sterile Compounding

Drug Diversion/Fraud Team

- Investigations including assisting other Agencies (DEA, Health Care Services, FDA)
- Routine Inspections
- Administrative Cases
- Overview
  - 2 Supervising Inspectors (1 vacancy) and 9 Inspectors (1 vacancy)
  - 353 Inspections
  - 357 Investigations Completed (69 cases referred for formal discipline)
  - 10 Administrative Hearings (13 days)

Drug Diversion/Fraud Team

Drug Diversion Self-Use & Probation Monitoring Team

- **Investigations (typically licensee impairment notification)**
- **Administrative Hearings**
  - Worksite Assessments
  - Interviews
- **Overview**
  - 1 Supervising Inspector and 5 Inspectors
  - 441 Inspections
  - 97 Investigations Completed - 51 cases referred for formal discipline
  - 5 Administrative Hearings - 6 days

Outsourcing Team

- **Licensing and Enforcement Functions**
  - Inspections of Outsourcing Facilities
  - Investigations
  - Administrative Cases
- **Overview**
  - 1 Supervising Inspector and 2 Inspectors
  - 100 Inspections
  - 101 Investigations Completed (2 cases referred for formal discipline)

Prescription Drug Abuse Team

- **Proactive Team**
  - Sales Data
  - CURES Data
  - Routine Inspections
- **Administrative Cases**
- **Reactive Team**
  - Corresponding Responsibility
- **Overview**
  - 1 Supervising Inspector and 5 Inspectors
  - 215 Inspections
  - 225 Investigations Completed - 23 cases referred for formal discipline
  - 9 Administrative Hearings -15 days

Attachment 2

Compounding Inspections FY 2017-2018

CALIFORNIA STATE BOARD OF PHARMACY
SEPTEMBER 14, 2018

Nonsterile Compounding Done By Pharmacies Without A Sterile Compounding License

Number of Inspections Conducted Where Violations Of Law Where Identified	66
Number of Violations Identified	153

Top Corrections Ordered For Non-Sterile Compounding Pharmacies

Type of Correction	Number of Corrections
Compounding Log Inadequate or Nonexistent - 1735.3(a)(2)	13
Beyond Use Date Inappropriate - 1735.2(i)(1)	9
Policies and Procedures Not Updated & Reviewed Annually – 1735.5(b)	8
Ingredients Without Expiration Dates (Max 3 Years) – 1735.2 (l)(1)	8
No Self Assessment for Compounding – 1735.2(k)	7

Top Notice of Violations Issued to Non-Sterile Compounders

Type of Violation	Number of Violations
No Self Assessment for Compounding Pharmacy - 1735.2(k)	3
No Documentation of Personnel Training - 1735.7(a)	2
Inappropriate Beyond Use Date – 1735.2(i)(1)	2
Furnishing An Inappropriate Amount For Prescriber Office Use – 1735.2(c)	2

Sterile Compounding and Outsourcing Inspections

Type of Inspection	Number of Inspections
Sterile In-State	910
Sterile Non-Resident	90
Outsourcing In-State	1
Outsourcing Non-Resident	28
Total Inspections	**1,029**

- Total Violations Identified – 3,067
- Corrections Orders – 2,401
- Violation Notice Issued - 162

Top 10 Corrections Issued To Sterile Or Outsourcing Facilities

Correction	Number of Corrections
Compounding Log - CCR 1735.3(a)(2)	110
Germicidal Detergent Cleaning of Sterile Compounding Area/Equipment CCR 1751.4(d)	95
Sterile Compounding Equipment/Area made of Materials Easily Cleaned and Disinfected CCR 1751.4(c)	64
Sterile Compounding Gloves and Handwashing Requirements CCR 1751.5(a)(5)	63
Pharmacy Fixtures and Equipment Clean and Orderly; Hot and Cold Running Water CCR 1714(c)	46
Compliance with Sterile Compounding Training Requirements CCR 1751.6(e)(1)	43
Properly Maintained Pharmacy for Safe, Properly Prepared, Maintained, Secured and Distributed Drugs CCR 1714(b)	40
Demonstrate competency on aseptic technique and aseptic area practices CCR 1751.7(b)(1)	39
Video of Smoke Studies in all ISO Certified Spaces CCR 1751.1(a)(5)	39
Requirements to Extend Beyond Use Date CCR 1735.2(i)(3)	33

Top 10 Violations Issued To Sterile Or Outsourcing Facilities

Type of Violation	Number of Violations
Compounding Log - CCR 1735.3(a)(2)	5
Maintain Sterile Compounding Written Policies and Procedures - CCR 1751.3(a)	5
Viable Surface and Viable Air Sampling Shall Be Performed - CCR 1751.4(j)	4
Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality - CCR 1751.4(f)	4
All Cleaning Materials must be Non-Shedding, Segregated and Dedicated to the Use in the Clean Room - CCR 1751.4(d)(4)	4
Negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces - CCR 1735.6(e)(2)	4
Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly. - CCR 1751.4(d)(2)	3
No Sterile Compounding if Environment Fails to Meet Criteria in Written Policies and Procedures - CCR 1751.4(a)	3
Sterile Compounding Gloves and Handwashing Requirements - CCR 1751.5(a)(5)	3
No Sterile Compounding Without Written Master Formula Documentation; Requirements - CCR 1735.2(e)	3

Reported Drug Losses

CALIFORNIA STATE BOARD OF PHARMACY
SEPTEMBER 14, 2018

Legal Requirements

- BPC 4081Records requirements including requirement to maintain a current inventory
- CCR 1715.6 Reporting any C/S loss within 30 days of discovery
- BPC 4105.5(c)(3) Reporting of any drug loss from an ADDS
- BPC 4119.01 (a)(6)Reporting of inventory losses from an EMSADDS within 7 days
- CCR 1715.65 (d) Required reporting of identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion or self-use, which requires reporting within 14 days

Loss Resulting in Discipline

- **Case One**
  - Pharmacy license surrendered and PIC placed on probation for 5 years
  - Total of 99,608 dosage units lost over a 26 month period.
    - 42,760 norco 10/325 & 49,019 alprazolam 2mg
- **Case Two**
  - Pharmacy issued public reproval and $60,00 administrative fine (license was already cancelled) and PIC placed on 4 years probation with a 14-day suspension
  - Total of 111,100 dosage units lost
    - May 2010 - May 2013 over 86,000 hydrocodone 10/325 &
    - May 2013 – May 2014 over 19,000 hydrocodone 10/325

Drug Losses FY 2015-2016

FY 2015-2016 Count of Loss Reports by Loss Type		
Row Labels	Count of Record	Total Dosage Units
Armed Robbery	112	197,100
Customer Theft	53	16,706
Employee Pilferage	169	817,157
Lost in Transit	218	92,074
Night Break In	186	578,428
Other	2,766	235,901
Robbery	2	5,558
Unknown	24	131,035
Total Losses Reported	3,530	2,073,960

Drug Losses FY 2016-2017

FY 2016-2017 Count of Loss Reports by Loss Type		
Row Labels	Count of Record	Total Dosage Count
Armed Robbery	14	49,031
Customer Theft	51	15,978
Employee Pilferage	179	283,654
Lost in Transit	301	89,443
Night Break In	260	1,108,525
Other	1,242	83,728
Robbery	178	259,428
Unknown	4,945	239,975
Total Losses Reported	7,170	2,129,761

Drug Losses FY 2017-2018

FY 2017-2018 Count of Loss Reports by Loss Type		
Row Labels	Count of Record	Total Dosage Count
Customer Theft	38	8769
Employee Pilferage	194	252,273
Lost in Transit	273	40,568
Night Break In	277	1,203,493
Other	1,128	39,875
Robbery	265	616,419
Unknown	6,762	250,863
Total Losses Reported	8,937	2,412,260

Type of Losses

Type of Loss	2015/16	2016/17	2017/18	Percentage Change
Armed Robbery/ Robbery*	114	192	265	132
Customer Theft	53	51	38	-28%
Employee Pilferage	169	179	194	15%
Lost in Transit	218	301	273	25%
Night Break In	186	260	277	49%
Other	2,766	1,242	1,128	-59%
Unknown	24	4,945	6,762	281%
Total Losses Reported	3,530	7,170	8,937	153%

*There were no armed robbery reports for 2017/18

Types of Losses

Type Loss Type	2015/16	2016/17	2017/18
	Total Dosage Units	Total Dosage Units	Total Dosage Units
Armed Robbery/Robbery	197,100	308,459	616,419
Customer Theft	16,706	15,978	8769
Employee Pilferage	817,157	283,654	252,273
Lost in Transit	92,074	89,443	40,568
Night Break In	578,428	1,108,525	1,203,493
Other	235,901	83,728	39,875
Unknown	131,035	239,975	250,863
Total Losses Reported	2,073,960	2,129,761	2,412,260

Employee Pilferage Losses

- Losses reported has increased from 169 in FY 2015/16 to 194 in FY 2017/18.
- However, significant decrease in the overall dosage units loss.
  - 817,157 dosage units FY 2015/16
  - 283,654 dosage units FY 2016/17
  - 252,273 dosage units FY 2017/18

Employee Pilferage Losses

- **Top 5 Drugs or Combos**

2015/16		2016/17		2017/18	
Codeine & Combos	297,292	Alprazolam	147,772	Alprazolam	93,320
Alprazolam	197,045	Codeine and Combos	57,184	Codeine and Combos	60,019
Hydrocodone & Combos	195,901	Oxycodone and Combos	18,633	Hydrocodone and Combos	55,523
Acetaminophen/Codeine	33,054	Hydrocodone and Combos	15,673	Tramadol and Combos	13,451
Tramadol	19,596	Carisoprodol	15,561	Fentanyl	13,278
Employee Pilferage Total	817,157	Employee Pilferage Total	283,654	Employee Pilferage Total	252,273

Night Break In

- Losses reported has increased from 186 in FY 2015/16 to 277 in FY 2017/18
- Significant increase in the overall dosage units loss.
  - 578,428 dosage units FY 2015/16
  - 1,108,525 dosage units FY 2016/17
  - 1,203,493 dosage units FY 2017/18

Night Break In

- **Top 5 Drugs or Combos**

2015/16		2016/17		2017/18	
Hydrocodone & Combos	148,802	Hydrocodone and Combos	320,548	Hydrocodone and Combos	323,660
Codeine & Combos	71,633	Oxycodone and Combos	210,816	Oxycodone and Combos	255,897
Alprazolam	61,676	Amphetamine and Salts	97,900	Amphetamine and Salts	131,561
Oxycodone	40,947	Codeine and Combos	85,509	Codeine and Combos	102,980
Oxycodone/Acetaminophen	26,172	Alprazolam	59,544	Dex/Methylphenidate	73,523
Night Break In Total	578,428	Night Break In Total	1,108,525	Night Break In Total	1,203,493

Robbery

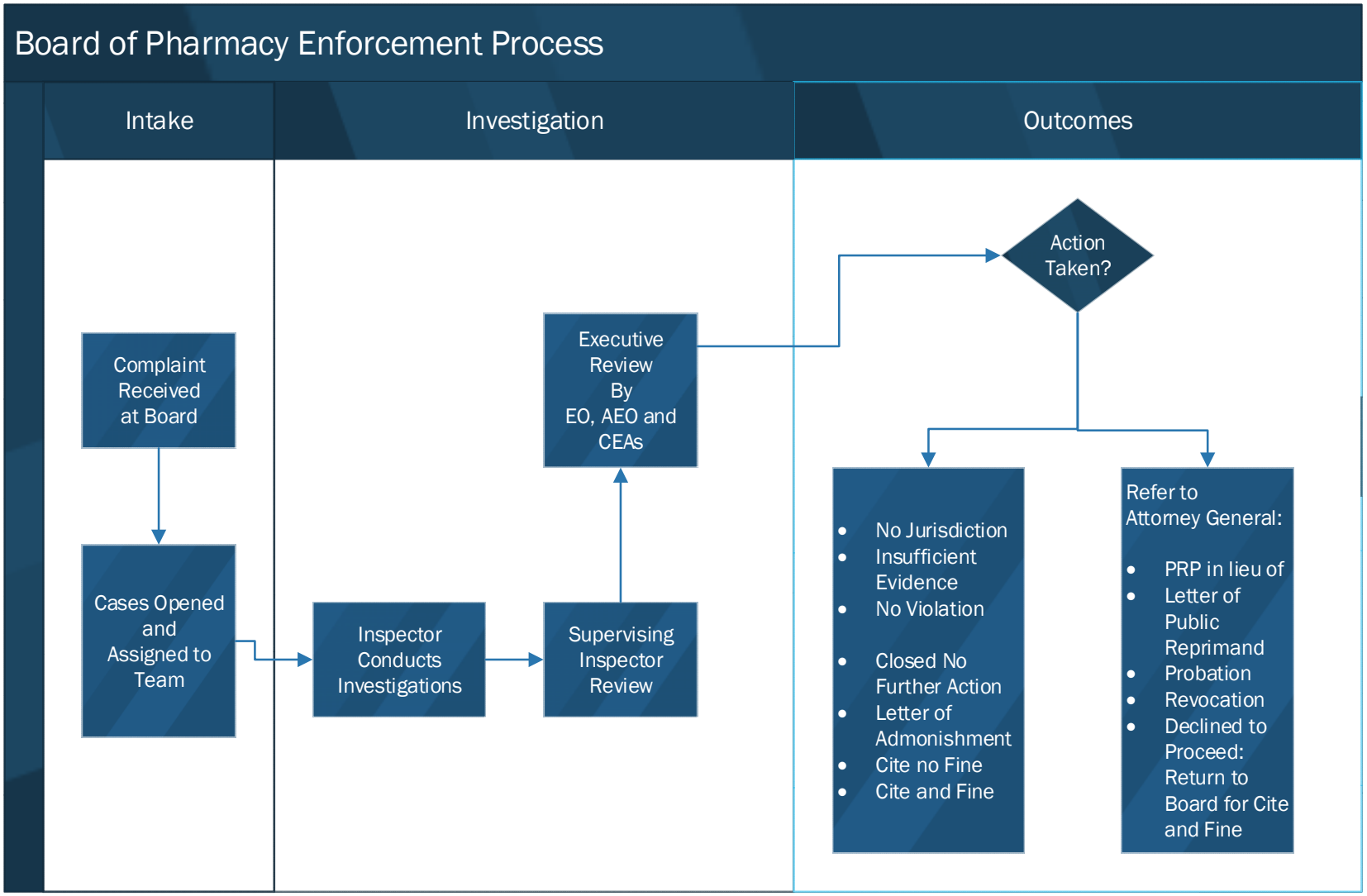
- Losses reported has increased from 114 in FY 2015/16 to 265 in FY 2017/18
- Significant increase in the overall dosage units loss.
  - 202,658 dosage units FY 2015/16
  - 308,459 dosage units FY 2016/17
  - 616,419 dosage units FY 2017/18

Robbery

- **Top 5 Drugs or Combos**

2015/16		2016/17		2017/18	
Hydrocodone & Combos	93,206	Hydrocodone and Combos	121,465	Hydrocodone and Combos	202,283
Codeine & Combos	31,922	Oxycodone and Combos	61,529	Oxycodone and Combos	191,788
Alprazolam	27,373	Codeine and Combos	56,851	Codeine and Combos	72,599
Oxycodone	13,278	Alprazolam	11,123	Amphetamine and Salts	35,697
Morphine	5,859	Morphine	9,291	Alprazolam	25,372
Robbery Total	202,658	Robbery Total	308,459	Robbery Total	616,419

Attachment 3


Board of Pharmacy Enforcement Process
Intake
Investigation
Outcomes
Complaint Received at Board
Cases Opened and Assigned to Team
Inspector Conducts Investigations
Supervising Inspector Review
Executive Review By EO, AEO and CEAs
Action Taken?
No Jurisdiction
Insufficient Evidence
No Violation
Closed No Further Action
Letter of Admonishment
Cite no Fine
Cite and Fine
Refer to Attorney General:
PRP in lieu of
Letter of Public Reprimand
Probation
Revocation
Declined to Proceed: Return to Board for Cite and Fine

Attachment 4

Citations Issued: July 2018

CALIFORNIA STATE BOARD OF PHARMACY
SEPTEMBER 14, 2018

Citations Issued: July 2018

License Type	# of Violations	Total Fines	Average Fine
Pharmacy	84	$51,000	$607
Pharmacist (36 working in capacity of PIC but fined as RPH)	70	$42,200	$603
Pharmacist-in-Charge	39	$25,550	$655
Technician	15	$5,600	$373
Hospital	25	$8,250	$330
Sterile In-State	27	$15,000	$556
Sterile Out-of-State	11	$4900	$445
Unlicensed	4	$17,000	$4,250
Wholesaler	3	$0	$0
Designated Representative	1	$0	$0
TOTAL	**279**	**$169,500**	**$608**

Top Citation Violations: July 2018

Description	Total # by License Type	Average Fine	Fine Amounts
Medication Error CCR 1716	11 PHY 1 NRP 5 PIC 5 RPH	$155	16 No Fine 6 Fines from $250 to $1000
Pharmacy Security/ Drug Loss CCR 1714 (b)	10 PHY 2 PIC	$167	9 No Fine 3 Fines from $500 to $1,000
Unprofessional Conduct: Providing False Statement/ Signature 4301(g)	2 PHY 1 LSC 1 PIC 7 RPH 1 TCH	$488	8 No Fine 4 Fines from $600 to $2000
Unprofessional Conduct: Self Administration BPC 4301(h)	2 RPH 5 TCH	$107	6 No Fine 1 Fine $750

Top Citation Violations Continued…

Description	Total # by License Type	Average Fine	Fine Amounts
Unprofessional Conduct: Conviction of a Crime BPC 4301(l)	2 RPH 5 TCH	$471	3 No Fine 4 Fines from $250 to $1,250
Failure to provide Documentation Substantiating CE Completion BPC 4231(d)/CCR 1732.5	6 RPH	$700	6 Fines from $150 to $900
Maintain and Follow Written Policies and Procedures related to Compounding CCR 1735.5(a)	1 HPE 1 HSP 1 LSE 1 LSC 1 PIC 1 RPH	$750	2 No Fine 4 Fines from $500 to $2,000
Duty to Review Drug Therapy/ Erroneous or Uncertain Rx CCR 1707.3/1761	2 PHY 1 PIC 1 RPH	$250	2 No Fine 2 Fines $500

Citation Examples: Medication Errors

CCR 1716 Medication Error	Fine
Pharmacy dispensed trazodone 200mg with directions to take 2 tablets by mouth every 8 hours versus RX of trazodone 200mg with directions to take 2 tablets by mouth every 8pm as prescribed.	• $750 Cite and Fine to the Pharmacist • Abate $750 Complete Med Dispensing Error CE – 4 hours (one prior $1,750 fine 2017 no consultation and dispensed promethazine/codeine written on Rx document containing significant errors and omissions)
Prescription written correctly and labeled as clindamycin-benzoyl peroxide 1.5% cream and required reconstitution with purified water prior to dispensing. Rx sold to patient without being reconstituted.	• Cite no Fine to the Pharmacist in Charge • $750 Cite and Fine to the Pharmacist in Charge No Quality Assurance Report Completed CCR1711(d)(e)
Prescription was written for hydrocodone/acetaminophen 10-325mg tablets but incorrectly filled comingled with lamotrigine 25mg tablets to the patient.	• Cite no Fine to the Pharmacist
Patient A's escitalopram 10mg Rx was furnished in a bag along with patient B's prescriptions. Patient B ingested patient A's Rx and suffered adverse effects due to the error. Patient A's personal information was revealed to Patient B without authorization.	• $1,000 Cite and Fine to the Pharmacist • $1,000 Cite and Fine to the Pharmacist Unauthorized Disclosure CCR 1764/ CCC 56.10 • Abate $1,000 Complete Med Dispensing Error CE – 6 hours
Prescription was written for Cipro 500mg tablets, correctly labeled but filled with cephalexin 500 mg capsules. Patient did not ingest medication.	• $500 Cite and Fine to the Pharmacist • Abate $500 Complete Med Dispensing Error CE – 4 hours

Citation Examples: Continuing Education Documentation

BPC 4231(d)/ CCR 1732.5 Failure to provide documentation substantiating completion of continuing education/Renewal Requirements for pharmacists	Fine
The Board's audit revealed RPH was deficient 28 hours of CE's during the specified renewal period	• $900 Cite and Fine to the Pharmacist • Cite with No Fine to the Pharmacist BPC 4301(g) (One prior $750 Fine – 2014 No QA: Wrong med instructions)
The Board's audit revealed RPH was deficient 27 hours of CE's during the specified renewal period	• $900 Cite and Fine to the Pharmacist • Cite with No Fine to the Pharmacist BPC 4301(g)
The Board's audit revealed RPH was deficient 24 hours of CE's during the specified renewal period	• $900 Cite and Fine to the Pharmacist • Cite with no Fine to Pharmacist under BPC 4301(g)
The Board's audit revealed RPH was deficient 19.5 hours of CE's during the specified renewal period	• $700 Cite and Fine to the Pharmacist • Cite with no Fine to Pharmacist under BPC 4301(g) (One prior $700 Fine – 2014 Med Error)
The Board's audit revealed RPH was deficient 18 hours of CE's during the specified renewal period	• $650 Cite and Fine to the Pharmacist • Cite with no Fine to Pharmacist under BPC 4301(g) (2 prior Fines both related to role of PIC; Compounding strength inaccurate, $2000/2014;$700/2016)
The Board's audit revealed RPH was deficient 8 hours of CE's during the specified renewal period	• $150 Cite and Fine to Pharmacist • Cite with no Fine to Pharmacist under BPC 4301(g)

Citation Examples: Knowingly Making or Signing False Documents

BPC 4301(g) Unprofessional Conduct Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	Fine
PHY was recording a different temperature on their process validation records than what was found on their incubator temperature logs	• $600 Cite and Fine to the Pharmacist-in Charge
PHY processed 5 prescriptions through patient's insurance plans. These 5 prescriptions were returned to stock without being reversed	• $2000 Cite and Fine to the Pharmacist-in Charge

Citation Examples: Pharmacy Security/Drug Loss

CCR 1714(b) Pharmacy Security/ Drug Loss Operational Standards and Security	Fine
Pharmacy had drug losses of Hydrocodone: 64 qty - 10/325 27 qty – 5/325 101 qty - 7.5/325 Employee terminated for taking 60 qty 7.5/325 & 120 qty 10/325	• Cite No Fine to the Pharmacist-in Charge
Pharmacy had drug losses of 74.5 pints of Promethazine w/Codeine	• $500 Cite and Fine for CCR 1714(b) to the Pharmacist-in Charge • $500 Cite and Fine for BPC 4081/4105 to Pharmacist-in Charge (Records of Acquisition and Disposition & Current inventory relative to loss of Promethazine w/Codeine) (Prior C/F fin 2016 483or compounded related Violations)

Citation Examples: Unprofessional Conduct

BPC 4301(l) Unprofessional Conduct Conviction of a crime substantially related to the practice of pharmacy BPC 4301(h) Unprofessional Conduct Administering to oneself of any controlled substance or the use of any dangerous drug or alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself.	Fine
Pharmacist was arrested for driving under the influence, test revealed a BAC at .143 Resulted in a misdemeanor conviction	• $1250 Cite and Fine to the Pharmacist {BPC 4301(l)} • Cite No Fine to the Pharmacist {BPC 4301(h)}
Pharmacist was arrested for driving under the influence, test revealed a BAC at .08 Resulted in a misdemeanor conviction	• $1000 Cite and Fine to the Pharmacist {BPC 4301(l)} • Cite No Fine to the Pharmacist {BPC 4301(h)}

Citation Examples: Duty To Review Drug Therapy/Erroneous Prescription

CCR 1707.3/1761 Duty to review drug therapy/Erroneous uncertain prescription	Fine
RPH overrode Drug Utilization review for a Rx with a dose that was outside the of acceptable safety range – did not verify/clarify with prescriber. Pt ingested high dose for 3 ½ days	• $500 Cite and Fine to the Pharmacist
RPH(PIC) did not review Pt's medication record-a DUR alert occurred and RPH(PIC) overrode it thus filling a duplicate Rx over the course of three months. There was duplicate therapy: citalopram 20mg & escitalopram 20mg RPH failed to contact the prescriber regarding therapeutic duplication	• $500 Cite and Fine to the Pharmacist

Citation Examples: Compounding Policies & Procedures

CCR 1735.5(a) Compounding Polices & Procedures Any pharmacy engaged in compounding shall maintain a written Policy and Procedures Manual for compounding	Fine
Pharmacy failed to follow their Policies and Procedures for glove fingertip testing in that the policy said contact plates were used but testing records substantiated touch paddles	• $500 Cite and Fine to the Pharmacist-in-Charge (1 of 9 compounding related violations identified)
Pharmacy's Sterile Compounding policies and procedures were documented as last reviewed by PIC in May 2014 (Board's inspection was in 02/2017)	• $500 Cite and Fine to the Pharmacist-in-Charge (1 of 7 compounding related violations identified)

Closed Case Outcomes: July 2018

Outcomes	# of Cases
Referred to AG	21
Citation Issued	132
Letter of Admonishment Issued	40
Closed No Further Action	33
Subject Educated	1
Insufficient Evidence	39
No Jurisdiction	20
No Violation	10
Consolidated	6
Application Approved	6
Application Denied	**4**
Application Withdrawn	6
Total	**318**

Attachment 5

Inventory Reconciliation Regulation – FAQs

On April 1, 2018, a new board regulation took effect – California Code of Regulations, title 16, section 1715.65, Inventory Reconciliation Report of Controlled Substances.

The board believes this regulation will aid pharmacies and clinics in preventing losses of controlled drugs and identifying losses early.

As with any regulation, the board seeks compliance as early as possible. For the first few months, the board will focus on education to promote understanding of the regulation. During the transition, any inspection will focus on the pharmacy's or clinic's good faith efforts to comply with the regulation.

Here is a summary of CCR section 1715.65 by subsection:

(a) Requires all pharmacies, and all clinics licensed under Business and Professions Code section 4180 or 4190 ("clinics"), to perform periodic inventory and reconciliation functions for all controlled drugs. (Note: No frequency of these duties is specified in the regulation except for Schedule II drugs, which are discussed below.)

(b) Requires the pharmacist-in-charge (PIC) or the clinic's consultant pharmacist to:

(1) Establish and maintain secure methods to prevent losses of controlled drugs.
(2) Establish written policies and procedures for performing reconciliation reports.
(3) Review all inventory and reconciliation reports.

(c) Requires each pharmacy or clinic to prepare at least a **quarterly** inventory reconciliation report of all federal Schedule II medications, which is based on:

(1) A physical count of all federal Schedule II medications at the time of each inventory.
(2) A review of all acquisition and disposition records since the last inventory.
(3) A comparison of 1 and 2 to identify any differences (losses or overages).
(4) Collection and retention of records to compile each inventory report.
(5) The report must identify the possible causes of overages.

(d) Requires a pharmacy or clinic to file a report of losses and known causes to the board within 30 days of discovery or within 14 days if theft, self-use or diversion by a board licensee is the cause. If the cause is unknown, this section requires the pharmacy or clinic to further investigate to identify the causes and to take corrective action to prevent additional losses.

(e) Requires the inventory reconciliation report to be signed and dated by the individual(s) performing the inventory and countersigned by the PIC or professional director (for a clinic).

(f) Requires a new PIC to complete an inventory reconciliation report within 30 days of becoming PIC. Encourages the outgoing PIC to do a reconciliation report before leaving.

(g) For INPATIENT HOSPITAL PHARMACIES: Requires a separate quarterly inventory reconciliation report for federal Schedule II drugs stored within the pharmacy and for each of the pharmacy's satellite locations.

(h) For any pharmacy servicing an AUTOMATED DRUG DELIVERY SYSTEM (regardless of location): Requires the PIC to:

(1) Ensure that all controlled substances added to any automated drug delivery system are accounted for.
(2) Ensure that access to any automated drug delivery system is limited to authorized facility personnel only.
(3) Ensure that any discrepancy or unusual access to the controlled substances in the automated drug delivery system is evaluated.
(4) Ensure that confirmed losses are reported to the board timely.

1. The regulation took effect April 1, 2018. Should I have performed my initial inventory beginning April 1, 2018?

No. The board expects pharmacies and clinics to transition to satisfy the inventory reconciliation requirements over a short period of time, but not necessarily by April 1. An initial physical count of the Schedule II medications is the first step.

2. Are there any drugs in addition to federal Schedule II controlled substances affected by the requirement to do a physical count and reconciliation each quarter?

No. The regulation requires a quarterly count and reconciliation of only federal Schedule II drugs. California and the federal government have separate controlled substances schedules, although there is much similarity between the two. Nevertheless, the board determined that the federal Schedule II drug list is more current and complete, and the federal list is the reference for reporting dispensing into the Controlled Substances Utilization Review and Evaluation System (CURES) in California. A pharmacy may on its own add additional drugs to its reconciliation program.

3. Can a pharmacy or clinic estimate (instead of physically counting) federal Schedule II medications for the quarterly inventory?

No. A physical count of every Schedule II medication is required for the quarterly inventory reconciliation report.

4. Subsection (a) of the regulation requires a pharmacy or clinic to "periodically" perform inventory and reconciliation functions for controlled substances. Does this mean every quarter I must count and reconcile all controlled substances?

No. However, periodically (and under federal law at least every two years) all controlled substances must be inventoried. The board encourages more frequent counting of controlled

medications to identify and prevent losses of Schedule III, IV and V drugs. The regulation only specifies the frequency of reconciliation duties for federal Schedule II drugs; the appropriate frequency for all other controlled drugs should be determined by the standard of practice in the community under the circumstances of the pharmacy.

5. Does a perpetual inventory system satisfy the requirements of this regulation?

No. The use of a perpetual inventory system does not satisfy the regulation. The regulation requires both a physical count and reconciliation with all acquisitions and dispositions be performed every 90 days.

6. If I use a perpetual inventory, can I use the physical counts made for the perpetual inventory instead of physically counting the drugs specifically for the inventory reconciliation report?

It depends. The regulation requires a physical count of each Schedule II medication every quarter, which is then used as part of the inventory reconciliation analysis and report. If, for example, the pharmacy or clinic physically counts the specific drug stock each time a Schedule II drug is dispensed or acquired, that count might be used to fulfill the physical count required by the inventory reconciliation regulation, but the PIC or consultant will need additional data. For any drug where there were no dispositions or acquisitions during the quarterly reconciliation period (and therefore no physical count through the perpetual inventory system), a physical count of the Schedule II drug must be made because each drug must be physically counted at least quarterly.

7. I have a recent physical count for each Schedule II drug. What do I compare that to? What do I do with that information?

For each medication, the PIC or consultant would start with the physical count of the medication from the last inventory reconciliation report and:

1. Add all acquisitions and subtract all dispositions that occurred during the reconciliation period (no greater than 90 days) to identify the amount of drug stock that should be on hand (expected drug stock).
2. Compare the expected drug stock to the actual physical inventory count.
3. If there is a difference, attempt to identify the source of overage or shortage. **NOTE:** If there is a discrepancy and the recent physical count is from a perpetual inventory system, the board urges the facility to initiate a supplementary physical count of the medication. Determine if the facility needs to take corrective action, including modify its policies and procedures, conduct an investigation, institute additional security or modify its practices.
4. Whether or not there is a discrepancy, the results must be recorded in your inventory reconciliation report.

8. Does an inpatient hospital pharmacy or a pharmacy servicing onsite or offsite emergency kits (e-kits) have to complete an inventory reconciliation report for the Schedule II controlled substances contained within the e-kits?

There is no specific reconciliation report for the kits themselves, although a pharmacy's replenishment of Schedule II drugs removed from the emergency kits would be part of a pharmacy's disposition of medication.

9. An inventory reconciliation report of all Schedule II drugs shall be compiled at least every three months and, in order to complete the report, the inventory must be compared with a review of drugs that entered and left the pharmacy since the previous inventory reconciliation. Since no reconciliation report exists before April 1, 2018, does that mean that the first inventory reconciliation report will not be due before July 1, 2018?

To initiate the reconciliation process and establish a baseline for future inventory reconciliation reports, a physical count of all Schedule II medications must be undertaken. The board would generally expect a pharmacy to perform this count on or after April 1, 2018. To allow time to develop meaningful written policies and procedures for the inventory reconciliation process, the board recommends a pharmacy or clinic perform the inventory counts within the first 90 days after April 1 (i.e., July 1, 2018).

Additionally, any new PIC on or after April 1, 2018, is required to prepare a report upon assuming the PIC position. Within the first three months after April 1, 2018, the board would expect the new PIC, within 30 days, to have performed an inventory count of all Schedule II medications consistent with the requirements to prepare an inventory reconciliation report.

10. An initial inventory does not appear to be required as part of this rule change. Since a reconciliation report cannot be compiled without an initial reference count, would it be appropriate for pharmacies or clinics to perform a physical count of all Schedule II drugs during the initial three-month period (after April 1), and then begin reconciliation processes after July 1st?

Yes. See the response to question 9.

11. A PIC must complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge. If there is a PIC change on April 1, 2018, how can the PIC create a reconciliation report, given there may not be a recent inventory or reconciliation report to refer to?

In this specific case, if prior data were unavailable because of the implementation date of the regulation, the board would expect the PIC to at least perform an inventory of all Schedule II medications consistent with the requirements to prepare the reconciliation report within 30 days (May 1, 2018).

12. Should the inventory reconciliation report encompass only significant losses, as defined by the DEA, or should the report encompass any discrepancy? If the former, doesn't a pharmacy's or clinic's filing of DEA Form 106 with the DEA already provide the requested information to the board if the board receives a copy of that report?

California law requires that any loss of controlled substances be reported to the board within 30 days – and reported within 14 days where drug theft, self-use or diversion have been committed by a board licensee. These are existing requirements, predating the inventory reconciliation requirements. The reconciliation regulation restates the reporting of drug loss requirements for clarity. A DEA Form 106 may be used to make this report to the board. Also, a separate report is required to the DEA (on a Form 106) of any significant loss of a controlled substance.

13. Will the board create a new process for reporting Schedule II controlled substances drug losses? Is there a standard form or email address to submit this information?

The board will not create a new or additional process for reporting the loss of controlled substances. A DEA Form 106 or a written statement containing specified details of the loss is sufficient. Check the board's website on how to report a drug theft or loss.

14. If my pharmacy or clinic is unable to identify the cause of the loss, should we wait to report the loss to the board until the cause is determined?

No. Reporting is required for any loss of controlled substances within, at most, 30 days regardless if a cause of the loss was identified. Should a cause be identified later, an additional report can be made to the board. If the cause is theft, diversion or self-use by a board licensee, the report must be made within 14 days.

However, the regulation also directs that "further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substance" where the source of a loss cannot be readily identified.

15. Does a pharmacy have to maintain actual paper documents of the records used to compile each inventory reconciliation report? Are electronic records acceptable?

All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form. Provided the records are readily retrievable, electronic records are acceptable.

16. Can the inventory reconciliation report be completed by multiple persons?

Yes. All persons involved in performing the inventory must sign and date the report, which also must be countersigned by the PIC or professional director (if a clinic).

17. How do I physically count liquid Schedule II medications for the reconciliation report?

The board does not expect a count or measurement of every liquid you have as part of the quarterly reconciliation. Instead, the board recommends:

- **Where there is a unit of use container,** a pharmacist should accept the measurement printed on the container and include it in the physical count. However, if the unit of use container looks damaged or altered in some manner, treat the item as quarantined.
- **Where multidose containers are used,** a pharmacist should subtract the amount dispensed from the measurement printed on the container. Subsequently, the pharmacist should document the remaining amount on the container itself. Example: A pharmacist dispensed 240ml from a 473ml stock bottle. The pharmacist would subtract 240ml from 473ml and document the difference of 233ml on the stock bottle. The remaining amount of 233ml would be used as the physical count for the reconciliation report.

18. Can unlicensed personnel (e.g., clerks) perform the inventory necessary to complete the inventory reconciliation report?

As identified in CCR section 1793.2, the counting of pharmaceuticals is considered a "nondiscretionary task" – a duty a pharmacy technician may perform. Accordingly, unlicensed personnel cannot complete the inventory function.

###

Medication Reconciliation

Effective April 1, 2018

Section 1715.65

- Purpose: to require more frequent, periodic counts of controlled substances, principally C-II medications by physically counting and reconciling records to identify losses sooner.

- The provisions apply to all pharmacies and clinics.

Medication Reconciliation

Overview:

- The regulation (in subsection (a))

  Requires all pharmacies, and all clinics licensed under Business and Professions Code section 4180 or 4190, to perform periodic inventory and reconciliation functions for all controlled drugs.

  Note: No frequency of these duties is specified in the regulation except for Schedule II drugs.

Medication Reconciliation

PIC and consultant pharmacist for a clinic shall:

- Review all inventory and reconciliation reports taken
- Establish and maintain secure methods to prevent losses of controlled drugs
- Develop written policies and procedures for performing reconciliation reports
- Report identified losses timely

Medication Reconciliation

Pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II drugs every 3 months:

1. A physical count --not an estimate -- of every C-II
   - Note: Can use biennial inventory for one of these counts
2. A Review of all acquisitions and dispositions since last report
3. A comparison of item 1 and 2 to identify variances

Medication Reconciliation

- For INPATIENT HOSPITAL PHARMACIES:

  Requires a separate quarterly inventory reconciliation report for federal Schedule II drugs stored within the pharmacy and for each of the pharmacy's satellite locations

Medication Reconciliation

- All records used to compile the reconciliation must be kept in pharmacy or clinic for 3 years in a readily retrievable form

- Possible causes of overages and shortages shall be identified in writing and incorporated as part of the inventory reconciliation report

Medication Reconciliation

- Losses must be reported to the board within 30 days
- Or within 14 days **if** theft, diversion or self use is identified
- If loss cannot be identified, further investigation must be undertaken to identify the cause, and actions necessary to prevent additional losses

Medication Reconciliation

- The inventory must be signed and dated by the individual(s) performing the inventory
- The inventory must be countersigned by the PIC or professional director (for a clinic)
- The signed inventory and associated documents must be readily retrievable for 3 years

Medication Reconciliation

- New PIC shall do inventory report within 30 days of becoming PIC
- The outgoing PIC encouraged do inventory reconciliation as well

Medication Reconciliation

- The PIC of an inpatient hospital or a pharmacy servicing onsite or offsite automated drug delivery systems must ensure that:
  - All controlled substances added to an ADDS are accounted for
  - Access to an ADDS is limited to authorized facility personnel
  - An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed
- Confirmed losses of controlled substances are reported to the board

Medication Reconciliation

- Getting started:

  Start with a count

Prescribers Checking CURES

- Effective October 2, 2018, prescribers must check CURES before writing a C-II, III or IV prescription the first time and every four months. Includes order, prescribe, administer or furnish
- Provisions exist in Health and Safety Code section 11165.4

Email Addresses Must Be Reported to Board

- Each pharmacist, intern pharmacist, pharmacy technician, designated representative-3PL shall join the board's email list within 60 days of licensure or at the time of license renewal – beginning July 2017
- Email addresses shall updated by licensee within 30 days of a change in the email address.
- The email address shall not be posted on the board's online license verification system.
- Reminders placed on each renewal to report and keep current the email address with the board.

B&P Code 4013

Newer Requirements

- Effective with the July 2019 pharmacist renewals

  Pharmacists must complete two hours of board-prepared coursework in law in ethics as part of the 30 hour CE requirement.

  This program fulfills this requirement for the renewal period.

Attachment 6

XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

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August 29, 2018

Virginia K. Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Re: Legal Status of Products Containing Cannabidiol (CBD), In Light of Approval of Epidiolex and AB 710 (Wood)

Dear Ms. Herold:

As you requested, the following is my opinion regarding the status, under federal and California law, of products containing cannabidiol (CBD), a cannabinoid that may be derived from and/or is a component part of the cannabis sativa/marijuana plant.[1] As you may be aware, another component part of the plant, tetrahydrocannabinol (THC), is the primary psychoactive component of marijuana. CBD does not cause intoxication or euphoria.

The Board has received inquiries regarding the legal status of CBD and CBD-containing products following (1) the June 25, 2018 FDA approval of Epidiolex, a CBD oral solution, for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome, and Dravet syndrome, in patients two years of age and older, and (2) the passage of AB 710 (Wood), an urgency statute which added, effective July 9, 2018, section 11150.2 to the California Health and Safety Code. That statute now reads in pertinent part:

> 11150.2. (a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

[1] I remind you that what follows is solely my own opinion, my best effort to provide legal assistance to you and/or to the Board. This is not an official "opinion" of the Attorney General.

In response to the inquiries received, the short answer is that neither Epidiolex, nor any other CBD or CBD-containing product, may yet be legally prescribed or dispensed, under either federal or California law.[2] Cannabis/marijuana, and all of its component parts and derivatives, remain Schedule I under both federal and California law. (21 C.F.R. § 1308.11(d), (d)(23), (d)(38), (d)(58); Health & Saf. Code, §§ 11018, 11018.1, 11054, subds. (d), (d)(13), (d)(20).) Drugs containing cannabis/marijuana or any of its component parts or derivatives, including CBD, may therefore not currently be lawfully prescribed or dispensed. (21 U.S.C. §§ 841, 842, 843; Health & Saf. Code, §§ 11054, 11210; 62 Ops.Atty.Gen. 65 (1979).)

While it is true that the FDA approved Epidiolex for limited purposes on June 25, 2018, it did so subject to a separate requirement that the DEA take action to re-schedule either Epidiolex or its CBD component. The DEA was supposed to do so within 90 days, by September 23, 2018. But the DEA has not yet done so, and there is no publicly-available information indicating that the DEA has even begun the process to do so. Nor is there any publicly-available information on the nature or scope of any re-scheduling the DEA might undertake, e.g., whether only Epidiolex would be exempted from Schedule I, whether CBD would be exempted, or some other outcome.

The lack of action by the DEA also precludes any change in California law effected by AB 710 (Wood). New Health and Safety Code section 11150.2 predicates legal prescribing, furnishing, or dispensing of a CBD product on either (1) CBD being excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or (2) a product composed of cannabidiol being approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act. Neither of these predicates has taken place. Thus, there has been no change in California law effected by operation of AB 710 (Wood).

Accordingly, neither the approval of Epidiolex nor the enactment of AB 710 has made any change in the legal status of CBD or any products containing this cannabinoid.

I hope this clarification of the law is helpful to you and the Board.

Sincerely,

JOSHUA A. ROOM
Supervising Deputy Attorney General

For XAVIER BECERRA
Attorney General

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[2] This opinion does not address the possession or use of cannabis or cannabis products made lawful by Proposition 64 (2016) and ensuing statutes (the Medicinal and Adult-Use Cannabis Regulation and Safety Act [MAUCRSA]) and regulations, including Health & Safety Code § 11362.1 et seq., Business & Professions Code § 26001 et seq., and 16 CCR § 5700 et seq.

Attachment 7

California State Board of Pharmacy
Citation and Fine Statistics
July 1, 2018 - September 30, 2018

426 Citations were Issued this Fiscal Year

Citation Breakdown by license type

Total Issued	RPH with Fine	RPH no Fine	PHY with Fine	PHY no Fine	PIC with Fine**	PIC no Fine**	TCH with Fine	TCH no Fine
426	155	33	66	102	67	49	26	1

Citation Breakdown by Miscellaneous license type

Wholesalers	Designated Reps	Clinics	Drug Room	Exempt Hosp.	Hosp. Pharmacy	Misc.*	Unlicensed Premises	Unlicensed Person
3	2	0	0	1	6	1	12	1

*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

**These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	52%	1716 - Variation from prescription	52%	1716 - Variation from prescription	29%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	8%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	14%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	18%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	7%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	8%	4113(c)/1714(b) - Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy/Operational Standards and Security; pharmacy responsib	11%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	6%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	6%	1714(c) - Operational Standards and Security; Pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	10%
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 pat	5%	1714(c) - Operational Standards and Security; Pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	9%
11164(a)/1761(a) - Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription	4%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	4%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	7%
4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	4%	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 pat	4%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%
1714(c) - Operational Standards and Security; Pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	4%	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%	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 pat	4%
1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	4%	1726(a) - The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision	2%	1726(a) - The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision	4%
4231(d)/1732.5 - Failure to provide documentation substantiating completion of continuing education/Renewal Requirements for Pharmacist	4%	1761(a)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Schedule II,	2%	1735.5(a) - Compounding Policies and Procedures- Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding…	4%

Board of Pharmacy Enforcement Statistics

Workload Statistics			July - Sept	Oct - Dec	Jan - March	Apr - Jun
Complaint Investigations						
	Received		773			
	Closed		772			
	Pending		1,889			
	Average Days for Investigation		375			
Cases Under Investigation (By Team)						
	Compliance/Routine		803			
	Drug Diversion/Fraud		329			
	Rx Abuse		97			
	Compounding		94			
	Outsourcing		29			
	Probation/PRP		63			
	Mediation/Enforcement		193			
	Criminal Conviction		281			
Application Investigations						
	Received		133			
	Closed					
		Approved	85			
		Denied	9			
		Total	***94***			
	Pending		110			
Letter of Admonishment/Citations						
	LOA Issued		79			
	Citations Issued		425			
		Proof Of Abatement Requested	56			
		Appeals Received	46			
		Dismissed	1			
	Total Fines Collected		***413,450***			
Administrative Cases						
	Referred to the AG's Office		67			
	Pleadings Filed		87			
	Pending					
		Pre Accusation	175			
		Post Accusation	256			
		Total	***474***			
	Closed		56			
	Revocation					
		Pharmacist	9			
		Intern Pharmacist	1			
		Pharmacy Technician	21			
		Designated Representative	0			
		Wholesaler	0			
		Sterile Compounding	0			
		Pharmacy	6			
		Total	***37***			
	Revocation; stayed suspension/probation					
		Pharmacist	0			
		Intern Pharmacist	0			
		Pharmacy Technician	0			
		Designated Representative	0			
		Wholesaler	0			
		Sterile Compounding	0			
		Pharmacy	1			
		Total	***1***			

Workload Statistics		July - August	Oct - Dec	Jan - March	Apr - Jun
Revocation; stayed; probation					
	Pharmacist	13			
	Intern Pharmacist	0			
	Pharmacy Technician	4			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	1			
	Pharmacy	7			
	Total	***25***			
Surrender/Voluntary Surrender					
	Pharmacist	7			
	Intern Pharmacist	0			
	Pharmacy Technician	4			
	Designated Representative	1			
	Wholesaler	1			
	Sterile Compounding	0			
	Pharmacy	10			
	Total	***23***			
Public Reproval/Reprimand					
	Pharmacist	8			
	Intern Pharmacist	0			
	Pharmacy Technician	0			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	0			
	Pharmacy	0			
	Total	***8***			
Licenses Granted					
	Pharmacist	2			
	Intern Pharmacist	0			
	Pharmacy Technician	3			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	0			
	Pharmacy	1			
	Total	***6***			
Licensed Denied					
	Pharmacist	0			
	Intern Pharmacist	0			
	Pharmacy Technician	3			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	0			
	Pharmacy	0			
	Total	***3***			
Cost Recovery Requested		382,706			
Cost Recovery Collected		210,763			
Immediate Public Protection Sanctions					
Interim Suspension Order		0	0	0	0
Automatic Suspensions		0	0	0	0
Penal Code 23 Restrictions		2	0	0	0
Cease and Desist - Unlicensed		0	0	0	0
Cease and Desist - Sterile Compounding		0	0	0	0

Workload Statistics			**July - August**	**Oct - Dec**	**Jan - March**	**Apr - Jun**
Probation Statistics						
	Licenses on Probation					
		Pharmacist	214	0	0	0
		Intern Pharmacist	8	0	0	0
		Pharmacy Technician	25	0	0	0
		Designated Representative	1	0	0	0
		Wholesaler	4	0	0	0
		Sterile Compounding	14	0	0	0
		Pharmacy	78	0	0	0
		Total	***344***	***0***	***0***	0
	Probation Office Conferences		40	0	0	0
	Probation Site Inspections **		176	0	0	0
	Successful Completion		19	0	0	0
	Referred to AG for non-compliance		2	0	0	0

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 abuse disorders.

*The data reported for the first quartely includes only July and August. The full quarter will be reported at the next board meeting.

Board of Pharmacy	*July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 18/19
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	3				3
PRP Under Investigation					
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	3				3
New Probationers					
Pharmacists	1				1
Intern Pharmacists					
Pharmacy Technicians	4				4
Total New Probationers	5				5
PRP Participants and Recovery Agreements					
Total PRP Participants	53				N/A
Recovery Agreements Reviewed	32				32
Probationers and Inspections					
Total Probationers	331				N/A
Inspections Completed	115				115
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1				1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	592				592
Drug Tests Conducted (PRP and Probationers)	581				581
Relapses					
Relapsed (PRP and Probationers)					
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	5				5
Termination from PRP	1				1
Probationers Referred for Discipline	1				1
Closure					
Successful Completion (PRP and Probationers)	4				4
Termination (Probation)					
Voluntary Surrender (Probation)					
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)	1				1
Non-compliance (PRP and Probationers)					
Other (PRP)					
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)	None	None	None	None	None

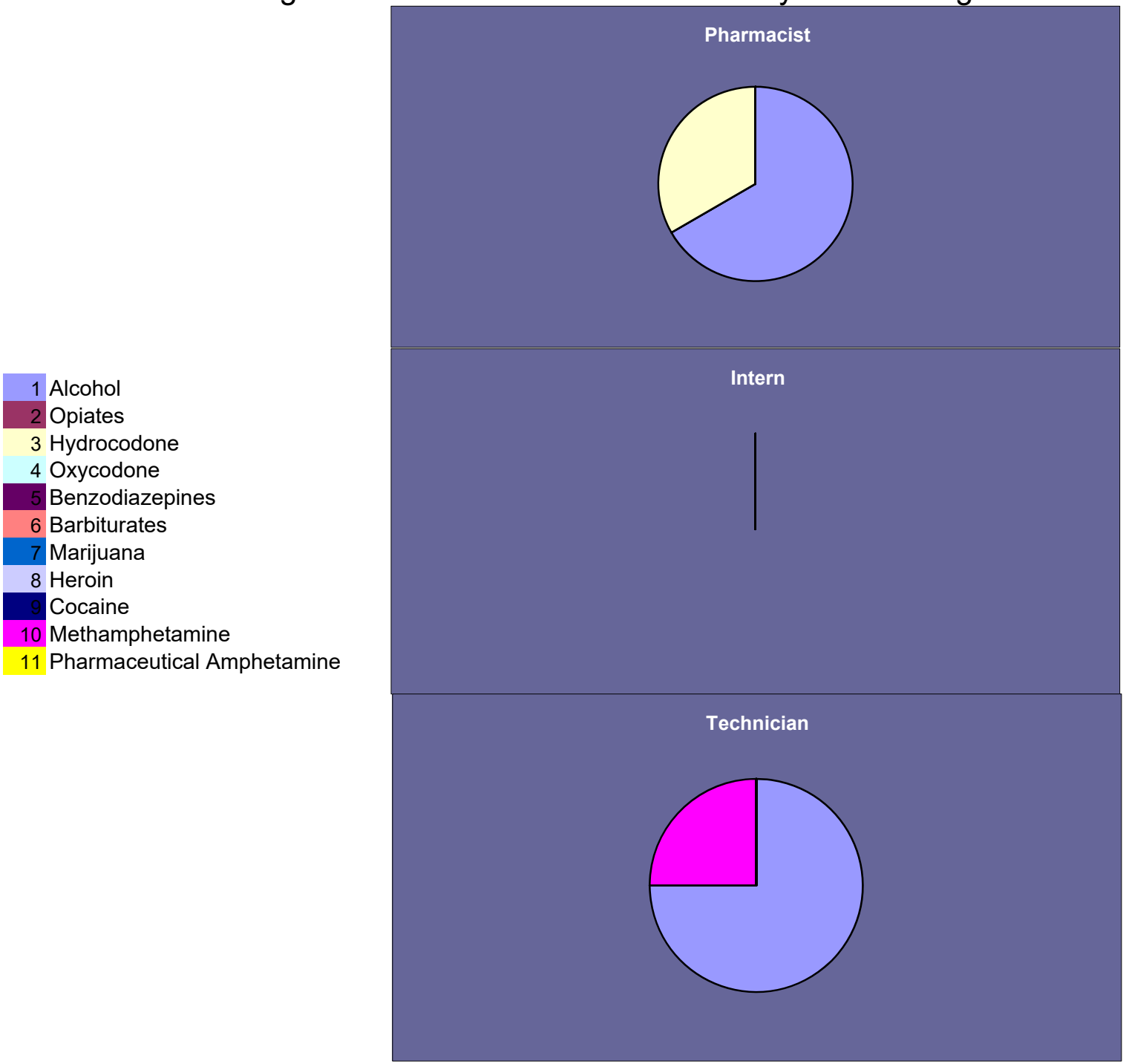
SB 1441 Uniform Standards

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

*The data reported for the first quartely includes only July and August. The full quarter will be reported at the next board meeting.

Board of Pharmacy	*July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 18/19
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 18/19**
Alcohol	2				2
Ambien					
Opiates	1				1
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 18/19**
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 18/19**
Alcohol	3				3
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine	1				1
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2018 to August 2018



Printed on 10/10/2018

Attachment 8

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINUTES

DATE:	June 7, 2018
LOCATION:	Department of Consumer Affairs First Floor Hearing Room 1625 North Market Blvd Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Amy Gutierrez, PharmD, Licensee Member, Vice Chair Gregory Lippe, Public Member Stan Weisser, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Valerie Munoz, Public Member
STAFF MEMBERS PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel Joshua Room, Supervising Deputy Attorney General Laura Hendricks, Staff Analyst MaryJo Tobola, Senior Enforcement Manager

1. Call to Order and Establishment of Quorum and General Announcements

Chairperson Allen Schaad called the meeting to order at 10:01 a.m.

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Dr. Steven Gray requested that the committee consider the issue of when a pharmacist prescriber must consult the CURES database. Dr. Gray noted that recently released information from DOJ did not include prescriber pharmacists, as may be required by the law. Dr. Gray estimated that over 3,000 pharmacists may have DEA permits.

Paige Talley, California Council for the Advancement of Pharmacy requested that the committee consider the issue of developing a definition of a "significant loss" as referenced in regulation.

Danny Martinez, CPhA, requested the committee consider the issue of contracting with non-resident inspection agencies to aid Board of Pharmacy inspectors.

Robert Stein, KGI School of Pharmacy, requested that the committee consider discussing the circumstances under which a pharmacist has the authority to prescribe controlled substances pursuant to travel medication protocols. Board staff suggested that this could be addressed through an article in the newsletter.

Jenny Partridge independent pharmacist, also requested the committee consider outside accrediting agencies to help the board conduct inspections of nonresident pharmacies.

3. Discussion and Consideration of Enforcement Committee Strategic Goals for Fiscal Year 2018/19 and Thereafter

Chairperson Schaad stated that in 2016 the board finalized its current Strategic Plan. He recommended that the committee discuss its strategic goals for the coming fiscal year as well as the remainder of the plan.

Chairperson Schaad identified the goals currently include in the board's strategic plan, along with their status. He requested the committee consider modifying and updating the current 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.

The committee discussed investigation timelines and investigative criteria. The committee expressed concern with how to ensure consumer protection between the time a violation is identified and the time the license is disciplined.

Board staff clarified that through the Consumer Protection Enforcement Initiative (CPEI), DCA has determined that the current goal to complete a case, resulting in formal discipline, is 540 days from the date the case is received to discipline. As a result, the board staff developed cycle times based on benchmarks determined by DCA.

Deputy Attorney General Joshua Room, informed the committee that a completion time from the receipt of the case investigation to prosecution of 540 days was always meant to be aspirational and not based on existing timelines.

Board staff informed the committee the board may issue Interim Suspension Orders, Cease and Desist Orders, and utilize PC 23 to ensure consumer safety while pursuing disciplinary action.

Ms. Sodergren stated board staff would prepare case prioritization for committee review to offer the committee the opportunity to adjust prioritization and establish benchmarks for data gathering purpose.

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

Chairperson Schaad stated that the board is seeking to strengthen patient consultation requirements for mail order pharmacies. In addition, the board has received general information about board investigations involving patient consultation violations and efforts taken by district attorneys reaching settlements, as a way to gain better compliance.

Chairperson Schaad suggested that the committee could identify specific goals or actions by which improvement can be measured.

Board staff suggested a partnership with the Attorney General's office to identify better ways to investigate and substantiate patient consultation violations. Ms. Sodergren informed the committee that there have been challenges with proving these violations, from an evidentiary standpoint. She requested that the committee allow staff to work in coordination with the AG's office, in order to create investigative benchmarks, collect data based on the new benchmarks, and present that data to the committee during a future meeting.

Ms. Sodergren stated board staff would work with the Office of the Attorney General's to improve the board's investigations into patient consultation compliance and segment out cases involving patient consultation.

Public comment was heard. Dr. Gray pharmacist, encouraged the collection of data for all strategic goals. He encouraged the review of "integrity agreements" reached as part of the settlements with the District Attorneys.

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.

Chairperson Schaad and board staff informed the committee that multi-year enforcement statistics are currently provided on an annual basis during the July board meeting.

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

Chairperson Schaad stated that the board convened a technology summit on the use of automated drug delivery systems (ADDS) and evaluated the findings of a pilot project expanding the use of ADDS. The board is currently sponsoring legislation to establish a regulatory framework for ADDS and expand the conditions when an ADDS can be used.

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

Chairperson Schaad stated that during this meeting the committee will hear a presentation on the disciplinary process and performance statistics provided by the Office of the Attorney General.

2.6 Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery.

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

Chairperson Schaad confirmed that there is pending legislation regarding the National Prescription Drug Monitoring Program.

In addition to these existing strategic goals, Chairperson Schaad recommended that the committee consider feedback received from pharmacists in practice, in particular Pharmacists in Charge (PICs), regarding complaints about inconsistent enforcement of compounding regulations, fear of retaliation, and expense and time in the development of a licensee's defense. Chairperson Schaad suggested creating a process where pharmacists could anonymously complain about inspectors and the inspections. He expressed his desire for the committee and the board to be informed of these complaints in a timely manner.

Ms. Herold informed the board that complaints about board employees, such as inspectors, is a personnel matter and have been handled internally. She stated that in order to keep the members informed a new feedback system to the members must be developed. Ms. Herold informed the committee that there may be union bargaining issues if personnel actions are made public.

Dr. Gutierrez stated that she and other members have received complaints by email regarding inspectors and inspections. She encouraged a system to be developed where complaints could be directed to the board for investigation by the Executive Officer or the Assistant Executive Officer. Dr. Gutierrez also inquired how other boards are handling complaints about their own investigative staff.

Chairperson Schaad said he would like some way for pharmacy professionals, who find themselves victims, to bring up these complaints outside of the board of pharmacy.

Ms. Sodergren stated that staff could research systems developed by other boards. She also informed the board that encouraging anonymous complaints could prove to be problematic, in that it is often difficult to obtain evidence or provide follow-up, during the course of the investigation.

The committee heard public comment. CPhA expressed support of the motion and suggested establishing an ombudsman position.

Motion: Amend the strategic plan to include the recommendation to add a policy goal to

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

M/S: Gutierrez/Lippe

Support: 4 Oppose: 0 Abstain: 0

In addition, Chairperson Schaad expressed his interest in assessing unintended consequences of discipline. He asked the committee to discuss consequences, such as the time and expense of defending a disciplinary action, the expense of Maximus for probationers and the adverse effect that a disciplinary action could have on an out of state license.

Motion: Amend the strategic plan to include the assessing of collateral consequences post discipline and research options.

M/S: Weisser/Lippe

Support: 4 Oppose: 0 Abstain: 0

Mr. Weisser recommended that more frequent meetings would help address these additional strategic goals during this current fiscal year.

In response to Mr. Weisser's suggestion, Ms. Sodergren informed the committee that the frequency of meetings is scheduled to increase after June 2019, to allow the committee the opportunity to work on the implementation of the revised compounding chapters and implementation of USP 800.

Ms. Sodergren informed the committee that for board members who are interested, they can attend office cite and fine office conference appeals. This would allow the member to sit through the process and have an opportunity to discuss and observe.

Public comment was heard. Dr. Steve Gray, pharmacist, stated that he is in favor of a complete review, but cautioned about having board members express their opinions during office conferences because of varying interest and opinions of individual members.

Motion: Amend the strategic plan to include the recommendation to complete an evaluation of the board's Citation and Fine process.

M/S: Gutierrez/Lippe

Support: 4 Oppose: 0 Abstain: 0

Ms. Sodergren stated that board staff has recently experienced an influx of issues and concerns regarding partial fills and the insurance problems that resulting from the partial fills. Ms. Sodergren asked the board if they would like to direct staff to collect data

regarding insurance problems with providing partial fills. She stated that the data collected could be forwarded to another regulating agency to assist them in determining if an amendment to their regulations are necessary to resolve the issues.

Public comment was heard. Dr. Gray pharmacist, anticipates that there will be an increase in complaints due to changes in law effective July 1, 2018. Additionally, Dr. Gray indicated that the problem is increasing because Medi-Care and Medi-Cal are enforcing against medication amounts dispensed versus what was prescribed. CPhA expressed support, as they are also aware of these partial fill issues in regard to Medi-Cal.

Chairperson Schaad advised that insurance adjudication on partial fill prescriptions should be a future agenda item.

The committee discussed whether a Pharmacist in Charge (PIC) should be solely responsible. Chairperson Schaad stated that discussion should include that PICs have overwhelming responsibility without the power to make changes.

Dr. Gutierrez informed the committee that Idaho and Maryland are no longer holding PICs responsible, but now the store or pharmacy owners. She suggested researching their current policies.

Motion: Amend the strategic plan to include the recommendation to review the role and responsibility of the PIC.

M/S: Weisser/Gutierrez

Support: 4 Oppose: 0 Abstain: 0

Member Stan Weisser exited the meeting at 12:14.

4. Discussion and Presentation of the Administrative Case Process and Case Resolution Times for Matters Referred to the Office of the Attorney General

Supervising Deputy Attorney General (SDAG) Joshua Room provided a presentation on the disciplinary process. SDAG Room provided insight into some of the challenges that may impede more swift resolution of disciplinary matters.

Listed below are questions presented by the committee members and answers provided by SDAG Room.

Q: Are assessments of each case's ability to meet the burden of proof conducted at your office or at the county?
A: The office of the AG is divided into the various cities: Oakland, San Francisco, Sacramento, Los Angeles, San Diego and Fresno. Cases are assigned by geographic proximity. Ultimately, the assigned DAG, in consultation with their supervisor, decides if a case can be filed.

Q: Do DAGs maintain specialty areas of law?
A: There is some specialization, but all DAGs should be capable of handling pharmacy cases.

Q: Does Board of Pharmacy have a statute of limitations?
A: The Board of Pharmacy does not.

Q: How does a criminal conviction impact the AG's case?
A: It depends on how much evidence already exists. If it is in relation to the boards case then the AG's case is much stronger. If we have enough evidence, I will often advise that we plead the case and file it now. Each case has to be handled on a case by case basis. Criminal cases could lead to a significant delay.

Q: If there is a criminal case pending, do you wait for its outcome before pursuing?
A: Sometimes we do, because if we go through with our case and we lose, it could prevent the criminal case from going forward. It would depend on the seriousness and proximity. Individual determinations need to be made. Typically, we place the case on hold.

Q: Where does the pleading originate?
A: The pleading comes directly from the AG's Office.

Q: If the composition of the board changes and has a different operating philosophy, how do you reconsider that offer, keeping in mind the new philosophy, when the offer is returned?
A: A returned settlement offer is returned to the same assigned DAG for the prosecution and the DAG is aware of the background that was used in determining the offer. Usually, decisions are made based on disciplinary guidelines. Individual board members' perspectives cannot be used to determine how to respond, rather board staff must rely on common actions of the board. The board staff that the DAG consults with have to use their historical knowledge of "common actions" when making amendments to settlement offers.

Q: How many cases are settled?
A: We have to settle at least 80% of our cases. 15-20% of our cases go to hearing, across all matter types.

Q: When is the standard of proof "clear and convincing" and when is it "preponderance of evidence"?
A: For any professional license, such as a pharmacist, the standard of proof is "clear and convincing". For vocational licenses, such as a pharmacy technician, the standard of proof is "preponderance of evidence".

Q: What is burden of proof for sites?
A: The board has determined that sites are non-professional licenses and therefore the

standard of proof is “preponderance of evidence”. The only licenses deemed “professional” are those commensurate with a professional degree.

Q: When there is a case where a pharmacy and a pharmacist are both involved, is the pharmacist license held to a higher standard or burden of proof?
A: There should be a different burden of proof for each respondent in that case.

Q: How do you reconcile taking action against a licensee when four or five years has passed since the violations occurred, as people change.
A: Typically, a delay in resolution of a matter is a benefit to the respondent in the matter because the delay has afforded the respondent time to show themselves as rehabilitated. The passage of time itself should not deter the board from giving a person the disciplinary penalty that is appropriate for their conduct under the board’s disciplinary guidelines.

Q: How long do ISO’s take to issue?
A: Ideally, the goal is to issue an ISO within 30 days.

Q: Are rehabilitation efforts considered when determining a settlement agreement?
A: Yes.

Q: How are Cite and Fines considered in an accusation.
A: Cite and Fines are not disciplinary, but they are administrative sanctions so they are included for disciplinary consideration. They have a small marginal effect.

5. Discussion and Consideration of Implementation Strategy for Anticipated Statutory Changes to Incorporate USP Compounding Chapters

Chairperson Schaad stated that this topic will be an ongoing discussion at future Enforcement Committee meetings, in order to consistently address problems and questions, and provide clarification on implementation.

Dr. Gutierrez asked the audience if they were aware of pharmacies that would be challenged in meeting the December 1, 2019 implementation date. Ms. Herold confirmed that the board has granted about 400 waivers.

Public comments were heard. CPhA requested a basic checklist about what will require compliance by December 1, 2019. Jenny Partridge, Pharmacist, indicated that it has been her observation that independent retail compounding pharmacies are generally compliant with USP 800. Dr. Gray, Pharmacist, suggested that the committee may need to be split back into a compounding committee and an enforcement committee, and suggested the language be changed in the proposed statute to allow more flexibility. Kristopher Le of Dynalabs expressed concern regarding current revised Chapter 797 maximum BUD 45-day max. The committee requested additional data on potency testing results room Dynalabs.

Ms. Herold stated that there are three provisions in our current regulations that have USP 800 provisions in them. Those provisions require specific types of exhaust venting. The waivers granted provide time for pharmacies to complete the required construction of an exhaust vent outside of a room.

Dr. Gutierrez stated that until the board changes statute, pharmacies will be expected to comply with current statutes and regulations.

SDAG Room stated that in his experience USP is typically not drafted in language which allows for easy compliance. He anticipates that regulations will be required in order to interpret USP language for compliance and regulatory enforcement.

Ms. Sodergren stated that the committee has not yet been informed of the progress of hospitals or chains that perform hazardous compounding. She stated that it would be helpful for the committee to be informed about progress in those specific communities. Chairperson Schaad encouraged public representatives from these communities to attend future meetings to update the committee on progress.

6. Discussion and Consideration of Possible Board Policy Relating to Transparency Involving the Issuance of Citations and Fines

Chairperson Schaad stated that during the April 2018 Enforcement Committee meeting, the committee requested that board staff survey all DCA healing arts boards to determine how each board handles general transparency related to the issuance of citations and fines.

Chairperson Schaad informed the committee that all DCA healing arts boards were surveyed to determine whether each board posted citations and fines issued to licensees on their websites.

Chairperson Schaad stated the survey showed fifteen of the eighteen DCA healing arts boards post citations and fines on their website; however, the duration of the postings vary. Chairperson Schaad noted that most boards surveyed are actively using the BreEZe System, which may be programmed to upload citations and fines to their respective sites. The chart detailed the boards surveyed, whether the board posts citations and fines, the length of time citations and fines are posted, and whether or not the board participates in the BreEZe System.

SDAG Room cautioned that posting citations and fines could make settlement cases more difficult; a consequence of making a more public display gives people a reason to appeal and go to hearing.

Public comment was heard. Dr. Gray, Pharmacist, commented that he believed that the posting of citations would result in more appeals received. Further, the adverse

consequences of the posting of such documents, must be fully discussed and considered. CPhA, stated concern that posting could cause the public to lose faith in the profession. Robert Stein of KGI School of Pharmacy, showed support of posting citations and fines and indicated that consumers have the right to be aware of the citations in order to make an informed decision. Additionally, Mr. Stein suggested statutory changes. Paige Talley of CCIP, cautioned that public postings of citations and letters of correction could result in pharmacy benefit managers (PBM) rejecting claims, which would result in a loss of patients and/or revenue.

SDAG Room informed the committee that parameters vary between the DCA boards and there is a lack of uniformity.

Motion: Recommend that the committee move forward to direct staff to identify possible parameters on posting mechanisms and conditions under which citations and fines would be posted for 3 years.

M/S Gutierrez/Lippe

Support: 3 Oppose: 0 Abstain: 0

7. Discussion and Consideration of Laws and Regulations Related to Petitions for Reduction of Penalty (Reinstatement, etc.) of Disciplined Licenses

Chairperson Schaad provided background information. Business and Professions Code section 4309 establishes the conditions under which an individual may petition the board for reinstatement of license that has been revoked or suspended. It also establishes the conditions under which a licensee may petition the board for a modification to a penalty, including modifications to probationary terms or early termination of probation. This section further specifies the time frames that must be satisfied before a petition can be considered including:

(1) At least three years for reinstatement of a revoked license.
(2) At least two years for early termination of probation of three years or more.
(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

Further Chairperson Schaad stated that this section provides that a petition cannot be considered while the individual is under sentence for a criminal offense, including any period in which the individual is on court-imposed probation or parole. In addition, a petition cannot be considered if there are additional accusations or a petition to revoke probation pending with the board.

Chairperson Schaad stated that in recent years the board has considered such petitions at specially convened board meetings where the primary focus of the agenda is consideration of such petitions. Although the law allows for different adjudication processes, the board's

policy in this area is to convene these petition matters as part of a board meeting whenever possible and to have the hearing presided over by an administrative law judge (ALJ). Following the hearings, board members meet in closed session with the ALJ to deliberate on the matters presented during open session hearing. Once the board makes its determination, the ALJ drafts the decision on behalf of the board.

In the event a quorum of the board cannot be achieved, the board's policy allows for petitions to be heard by a committee of the board. In such cases, the ALJ will draft a proposed decision for each petition and the decision will then be considered by all members as part of the mail vote process.

Under the law, a third option also exists where petitions are considered by an ALJ independent of the board. In such cases, the ALJ renders a proposed decision, which is then considered by all members as part of the mail vote process.

In all three scenarios the respondent provides a packet of information and supporting materials intended to provide the board with information in advance of the hearing. Such information includes:

- Personal Information and license history information.
- Letters of recommendation from board licensees.
- Letters of recommendation from citizens.
- Continuing education.

Chairperson Schaad informed the committee that the respondent is also afforded the opportunity to provide oral testimony under oath. In addition to the respondent's testimony, a representative of the Attorney General's Office is present and represents the people of California. The AG's Office is allowed to question the respondent as well as any witnesses. Although not done in all cases, the AG's Office may offer a recommendation to board on the outcome of the petition. Technically, the board does not have representation in these petitions, and typically board staff does not offer testimony.

Since July 1, 2015, the board has considered 41 petitions including 26 petitions for early termination, two petitions for modification of penalty and 13 license reinstatements. Decisions are not final for all of the petitions heard, but of those where decisions have been rendered, 13 petitions have been approved and 17 petitions have been denied.

For committee discussion, Chairperson Schaad stated that as provided in law, the board may consider factors including, but not limited to, the following:

1. All the activities of the petitioner since the disciplinary action was taken.
2. The offense for which the petitioner was disciplined.
3. The petitioner's activities during the time the license was in good standing.
4. The petitioner's documented rehabilitative efforts.
5. The petitioner's general reputation for truth and professional ability.

To assist in the collection of the relevant information and to provide guidance to potential petitioners, the board has developed petition packets that detail both required and supplemental materials sought from the petitioners and some FAQs about the process.

Chairperson Schaad stated that the criteria established in the law is very general. Staff is hopeful that the committee will provide policy guidance recommendations that ultimately can be considered by the full board when considering petitions. Such policy discussion will assist staff in ensuring the petition information collected is meaningful.

Chairperson Schaad identified some questions the committee may wish to consider:

1. Is the current process for hearing petitions sufficient, or should the board consider reevaluating its policy?
2. Would it be helpful to have board staff testify regarding compliance with terms and conditions of probation, rehabilitative efforts demonstrated by the respondent, public protection concerns, etc?
3. Would it be helpful to request additional information in advance of the hearing from the petitioner to aid the board in making its decision?
4. Does the board wish to establish additional parameters a petitioner must satisfy prior to being eligible to petition the board?
5. Should a time frame be established that provides clarity on how long a petitioner has to satisfy the requirements set by the board for reinstatement? For example, pass the NAPLEX, pass the CPJE, pay fines, etc.

As part of the discussion, board staff was directed to send petition materials to coincide with the release of the agenda, ten days before the hearing.

Dr. Gutierrez recommended to clarify petition question #15 to include “except for this action.”

Ms. Sodergren requested the committee to provide policy direction on allowing board staff the discretion to postpone a non-compliant petitioner’s hearing in order to address their compliance issues. She informed them that this would allow compliant petitioners to be scheduled for hearings sooner.

Additionally, Ms. Sodergren asked the committee if they were interested in amending statute to state that if a reinstatement is granted the person has a specified amount of time to satisfy the conditions for licensure. With the committee’s approval of the concept, board staff could draft an implementation plan that could be brought to the full board to demonstrate the committee’s policy recommendation and suggestions for facilitation.

Legal staff identified that Business & Professions Code section 4309 would require such an amendment.

Public comment was heard. Dr.Gray, Pharmacist, recommended that the committee limit the numbers of petitioners heard.

Motion: Direct board staff to develop statutory language to establish a requirement for 1 year to complete the requirements for reinstatement.

M/S: Gutierrez/Lippe

Support: 3 Oppose: 0 Abstain: 0

Motion: Authorize board staff to identify ways to prioritize those probationers that are compliant.

M/S Gutierrez/Lippe

Support: 3 Oppose: 0 Abstain: 0

8. Discussion and Consideration of Current Board Investigation Time Frames and Performance Measures

Chairperson Schaad presented the pending field investigations as of June 1, 2018.

Ms. Sodergren asked if it would be helpful to have new or additional information about investigative time frames at future meetings.

Dr. Gutierrez suggested converting the data into percentages.

Public comment was heard. A member of the public suggested that confusion may be due to lack of information shared by the inspector at the visit. In response, board staff stated that in most cases, the inspector is unaware of what administrative actions result from their investigation or inspection.

Mr. Lippe suggested that correspondence be sent to the licensee which informs them their case has been forwarded to the AG's office, which would prepare them for future communication from the AG's office.

9. Discussion and Consideration of the Board's Enforcement Statistics

Chairperson Schaad introduced the enforcement statistics for the first 10 months of the fiscal year.

Ms. Sodergren suggested that in addition to reviewing the statistics, the committee may wish to provide staff with feedback on the current format and data elements provided as well as suggested changes.

The committee recommended that board staff include Proof of Abatements issued, average investigation times, strategic goal(s) measures, and cease and desist orders for

unlicensed activity.

10. Discussion and Consideration of Potential Statutory or Regulatory Amendments to Allow a Reverse Distributor to Accept Medications for Destruction in Limited Circumstances from a Previously Licensed Source

Chairperson Schaad informed the committee that under current law, a reverse distributor is prohibited from acquiring dangerous drugs and devices from an entity unless the entity is licensed. This occasionally creates a barrier to the removal and destruction of such products when a pharmacy, wholesaler or other license is cancelled, surrendered or revoked.

Chairperson Schaad stated that the board staff is requesting that the committee consider pursuing a change in the law that would create a limited exception to allow for a reverse distributor to remove and arrange for the destruction of the drug products for a limited period after a license is cancelled, surrendered or terminated. Should the committee and board agree, staff will work with counsel to develop language.

MOTION: Direct board staff to develop a proposal to allow for a reverse distributor to take back some medications.

M/S: Lippe/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

11. Future Committee Meeting Dates

An error was identified on the agenda. The correct meeting dates are September 5, 2018 and December 13, 2018. Additional date(s) may be considered, to be announced at a later date.

Meeting adjourned at 3:49 p.m.

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ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: September 14, 2018

LOCATION: California Board of Accountancy
4th Floor Conference Room
2450 Venture Oaks Way
Sacramento, CA 95833

COMMITTEE MEMBERS PRESENT: Allen Schaad, Licensee Member, Chair
Albert Wong, Licensee Member, Vice Chair
Victor Law, Licensee Member
Gregory Lippe, Public Member
Ricardo Sanchez, Public Member
Stan Weisser, Licensee Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel
Joshua Room, Supervising Deputy Attorney General
Laura Hendricks, Staff Analyst
MaryJo Tobola, Senior Enforcement Manager

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

Chairperson Allen Schaad called the meeting to order at 9:31 a.m. A quorum was established.

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

Member of the Public, Dr. Gray, asked the committee to consider a discussion on the new laws going into effect and how they will be enforced. Dr. Gray noted that some legislation creates new requirements and it would be helpful to have policy discussions on how the board intends to enforce these new requirements. Dr. Gray also noted that there is also a need to discuss the standard of care for pharmacists that are providing pain management.

Chairperson Schaad noted that it would fall under the strategic goal 2.3 relating to improved education.

Member of the Public, Ms. Talley, requested that the committee discuss the term "significant loss." She requested that the committee discuss a statutory change.

3. Update on the University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

Chairperson Schaad stated that at the July 2017 Board Meeting, the board heard and discussed the results of the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. Chairperson Schaad explained that this study involves a waiver of California Code of Regulations Title 16, section 1713, in that it allows first-time fills to be dispensed via an ADDS machine, and the ADDS is not adjacent to a pharmacy counter but is installed in a hospital location.

Chairperson Schaad informed the committee that during the July Board Meeting, the board heard the final report of this study and supported a request from UCSD to extend the study for one year to provide additional data regarding the study and time for the board to consider a regulation modification involving ADDS to provide medication to patients.

Additionally, during the November 2017 Board Meeting, the board considered further updates to the study as well as a recommendation to modify the parameters of the study as detailed below:

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

Chairperson Schaad stated that ultimately the board voted to both expand the study as well as extend it. During that meeting the board also directed UCSD to provide study updates to the Enforcement Committee every six months. This report to the committee is to fulfil this requirement.

Chairperson Schaad informed the committee that for today's discussion the committee will have the opportunity to review a written update provided by UCSD on the progress and findings of the study. No formal presentation will be provided, but representatives of the study will be available to respond to committee member questions.

Ms. Herold informed the committee that the next UCSD presentation is scheduled for March 2019.

Ms. Herold reminded the committee that the board had requested a data comparison of people who received truly new prescriptions versus those who were getting refills. Due to the reported difficulty in collecting this data, Ms. Herold asked the committee if they still wanted UCSD

researchers to continue this collection of data. The committee opted to discontinue collection of this data category.

Motion: Direct UCSD to discontinue the collection of Truly New Prescription data.

M/S: Lippe/Sanchez

Support 6 Oppose: 0 Abstain:0

4. Presentation on the Board's Enforcement Program

Anne Sodergren provided an overview of the board's enforcement program. The presentation provided general workload and staffing information.

Committee discussion included the possible referral of employee pilferage cases for criminal prosecution. Ms. Sodergren reminded the committee that both the Enforcement Committee and the board has previously considered whether to adopt a policy to require pharmacies to always report to law enforcement agencies, the policy decision at that time was to not require such reporting.

Ms. Sodergren informed the committee that the board staff are collecting information specific to drug loss reports and whether law enforcement agencies are notified by the pharmacy. Once that data set is obtained the board would like the opportunity to review and determine whether it is practice to notify law enforcement at that time that they determine employee pilferage. This data analysis would provide information on how integrated that practice is and whether a policy should be reconsidered. Additionally, Script articles could be published to recommend law enforcement notification.

As part of the public discussion, clarification was sought on what information is reported to the National Practitioner Data Bank (NPDB) and when is it reported. Board staff advised that disciplinary information is required to be reported to NPDB by Federal Law. Subsequently, once there is a change in the status of a license, for example once a licensee has completed probation, a follow up report is submitted to NPDB to inform them of the completed probation.

5. Presentation on Enforcement Trends

Ms. Herold provided the committee with a presentation on compounding enforcement trends. Aggregate data on the outcomes of sterile and non-sterile pharmacy inspections conducted in 2017/18 as well as the top violations found in each setting were provided for the committee's review and discussion.

Ms. Sodergren provided the committee with a presentation on drug loss enforcement trends. The committee was provided with summary data from a review of drug loss reports submitted over the last three fiscal years for the committee's review and discussion. The statistics reveal that the number of drug loss reports submitted has increased 153 percent. Furthermore, the total dosage units reported as lost also increased, but at a much smaller rate of 16 percent.

Ms. Sodergren suggested that a follow-up presentation, to drug loss enforcement trends, could be provided to the committee yearly.

As part of the committee's discussion on drug losses it was suggested that pharmacies may want to consider transitioning to a more real-time inventory for controlled drugs to reduce the stock on hand. Such a change could reduce the number of robberies and night break ins.

Further the committee noted that as the Inventory Reconciliation regulations take effect, it is expected that losses due to employee pilferage will also be reduced as identification of the losses should have more quickly.

6. Presentation and Discussion on Efforts to Reduce Investigation Times and Case Resolutions

Chiefs of Enforcement, Julia Ansel and Tom Lenox provided a presentation of the board's current pending investigations, including the average days by the identified benchmarks as of August 1, 2018.

The committee was informed that DCA's target for Intake, which is defined as the number of days from receipt of the complaint receipt to the date the complaint is either closed or assigned to an investigator; DCA's target average is 20 days. The Board of Pharmacy's average Intake for FY 2017-18 for field investigations was 27 days, compared to the improved 19 days for the month of July 2018.

In addition, the committee was informed that the average days for cases under investigation in the field during FY 2017-18 was 235 days compared to the improved 165 days for the month of July 2018.

The committee was informed that DCA's target for case investigations, not transmitted to the Office of the Attorney General, is 210 days, which includes both intake and investigation.

Public comment included a recommendation that the board establish a sub-committee that would evaluate each case before being referred to the Office of the Attorney General. It was suggested that such a committee could include a peer review by an independent expert and provide active board member input during the AG referral consideration process.

Chairperson Schaad agreed to discuss this referral issue during a future committee meeting.

The committee was released for lunch at 12:35 p.m. and reconvened at 1:19 p.m.

7. Discussion and Consideration of the Board's Citation and Fine Program

Chairperson Schaad stated that the board has asked staff to provide information regarding board-issued citations and fines.

Ms. Ansel and Mr. Lenox provided a snap shot of data from board issued citations for the month of

July 2018. The presentation revealed 279 violations, with an average fine amount of $608 per violation, for a total of $169,500 in fines assessed in the month of July. In addition, they reviewed the top citation violations issued for the month. Citations examples were provided to the committee which included various violations including medication errors, failure to provide documentation substantiating continuing education completion, unprofessional conduct, pharmacy security/ drug loss, duty to review drug therapy and compounding policy and procedures requirements. Ms. Ansel and Mr. Lenox commented that board staff has been reviewing citations for opportunities where abatements might be offered. Specifically, with some citations there may be instances where the licensee may have the option to take continuing education in a specific area of pharmacy law or education and upon proof of completion, the fine associated with the citation may be reduced or eliminated, depending on the circumstances of the case

Public discussion included a request for clarification on what constitutes unlicensed practice and who determines the amount of citations and fines within the board. Ms. Herold provided examples of unlicensed practice. Mr. Lenox confirmed that the Chiefs of Enforcement review and approve citations and fines issued as a result of inspections and investigations.

8. <u>Discussion and Consideration of Convening Administrative Case Hearings Before Board Members</u>

Chairperson Schaad informed the committee that Government Code (GC) section 11517 establishes the requirements for adjudication of contested cases before an Administrative Law Judge (ALJ) or before an agency itself.

Chairperson Schaad explained that although the law allows for two different adjudication processes, the board's administrative case hearings are currently only heard before an ALJ. Alternatively, at the discretion of the agency, GC section 11517 also allows that an administrative case hearing may be heard by the agency itself with an administrative law judge presiding over the proceeding. This is similar to the method used by the board to consider petitions for modification to penalties.

Chairperson Schaad highlighted that under this second construct all of the following conditions must be in place if a contested case is heard before an agency itself, all of the following provisions must apply:

(1) An ALJ shall be present during the consideration of the case and, if requested, shall assist and advise the agency in the conduct of the hearing.
(2) No member of the agency who did not hear the evidence shall vote on the decision.
(3) The agency shall issue its decision within 100 days of the submission of the case.

Chairperson Schaad stated that during the June 2018 committee meeting, board members were informed that pharmacy boards in other states have opted for administrative case hearings to be heard with board members.

Chairperson Schaad suggested that while discussing this issue the committee may wish to take into consideration that in FY 17-18, 42 proposed decisions were received from ALJs. That equated to 62 days of hearings. Although the majority of cases heard before an ALJ are one day, as case

complexity increases so do the number of hearing days, which are typically consecutive days.

Chairperson Schaad presented questions and areas of concerns the committee may wish to consider include:

- What is the purpose of eliminating the ALJ hearing?
- Determine what, if any, challenges exist with the current process of adjudication of contested cases.
- Would eliminating the ALJ hearing the case remove significant delays in the administrative case process?
- Discuss the consequences and/or challenges of a contested case being heard by the agency itself.
- What parameters would the board use to determine if a case is to be heard before the board or before an ALJ alone?
- Would it be possible for board members to absorb this additional time and resource commitment?

Additionally, Chairperson Schaad stated that last fiscal year either the full board or a committee of the board convened meetings on 25 days.

The board members discussed areas of potential concern. No action was taken regarding disciplinary case adjudication.

9. <u>Presentation on the Board's Inventory Reconciliation Process and Review of Frequently Asked Questions</u>

Chairperson Schaad provided background information which clarified that Title 16, California Code of Regulations (CCR) section 1715.65 requires that every pharmacy and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

Chairperson Schaad informed the committee that on April 1, 2018, a new board regulation took effect – California Code of Regulations, Title 16, section 1715.65. The board believes this regulation will aid pharmacies and clinics in preventing losses of controlled drugs and identifying losses early.

In order to clarify, Chairperson Schaad stated that the board asked staff to provide information about the new reconciliation regulation. Board supervising inspector Michael Ignacio and Chief of Enforcement, Tom Lenox provided general information on the board's inventory reconciliation process and frequently asked questions.

Chairperson Schaad informed the committee that since the adoption of the regulation, the executive officer and board inspectors have received numerous questions from licensees regarding the new reconciliation regulation. The board has focused on education to promote an understanding of the regulation. During this transition, inspectors will focus on the pharmacy's or clinic's good faith efforts to comply with the regulation.

In order to provide additional guidance to the regulated public, board staff worked with the DCA

counsel to draft FAQs. The first FAQ was made available on the board's website and was published in the July 2018 edition of The Script. A second FAQ is being developed based on interaction during inspections between inspectors and licensees. A copy of the first FAQ was provided.

Chairperson Schaad informed the committee that in addition, a presentation on the reconciliation regulation has been incorporated into the board's quarterly Pharmacist Drug Abuse and Diversion Training Program. It was presented to over 200 pharmacists at the July 28, 2018 event. The next event is scheduled for September 22, 2018. A copy of the presentation was also provided.

Ms. Herold informed the board that with the increased number of drug losses reported, it is expected that quantities reported will progressively decrease. Additionally, Ms. Herold encouraged that questions from the public should be forwarded to the board for future publications of FAQ sheets.

10. <u>Discussion and Consideration of Remodel Inspections of Sterile Compounding Pharmacies and Possible Authority to Assess a Fee for Such Inspections</u>

Chairperson Schaad provided relevant law and background information. Specifically, Business and Professions Code 4127.1 established the parameters of sterile compounding licensure requirements. Business and Professions Code section 4400(u) established the fees for issuance of sterile compounding licenses.

A Sterile compounding license shall not be issued or renewed until the location has been inspected by the board and found in compliance. A fee is assessed for the issuance or renewal of a sterile compounding license.

Chairperson Schaad stated that under current law, the board does not charge a fee for the remodel of sterile compounding pharmacy inspections. Since the beginning of fiscal year 2015/16, the board has conducted approximately 60 sterile compounding remodel inspections. Inspections are conducted by the board after a facility has remodeled their location. There is no requirement in the law for the board to conduct remodel inspections. Board staff believes that not conducting these remodel inspections could pose a patient safety risk. Remodel inspections are triggered by unforeseen damage, planned upgrades or expansion of a facility. The scope of a remodel includes simple projects to a full remodel or expansion. All sterile compounding inspections have the same requirements, to ensure full compliance with regulations adopted by the board.

When notified of a pending remodel to a sterile compounding facility, the board attempts to conduct an inspection within six to eight weeks from the date of notification. Most remodel inspection requests are planned projects that the facility is aware of months in advance. Travel costs and inspector time for remodel inspections are currently being absorbed by the board.

Chairperson Schaad informed the committee that for discussion and consideration the issue to consider is whether the board deems it appropriate to charge a fee for conducting sterile compounding remodel inspections.

Stan Weisser requested clarification on what constitutes a remodel and whether the board needs to redefine a remodel.

Public discussion included whether sterile compounding facilities should be required to pay fees for the inspecting remodeling that is necessary to maintain regulatory compliance and whether inspection fees would discourage licensees from improving their facilities.

Mr. Weisser motioned to have board staff establish an appropriate fee and conditions for remodel inspection for a sterile compounding licensing facility and delegate the committee chair to work with staff to refine the proposal. This motion was seconded by President Law.

After further discussion, it was recommended that this issue should be discussed and considered by the Licensing Committee. As a result, the motion introduced by Mr. Weisser was tabled.

MOTION: Move to table the motion to have board staff establish an appropriate fee and conditions for remodel inspection for a sterile compounding licensing facility and delegate committee chair to work with staff to refine the proposal.

M/S: Weisser/Lippe

Support: 6 Oppose: 0 Abstain: 0

MOTION: Move to refer this issue to the Licensing Committee.

M/S: Weisser/Lippe:

Support: 6 Oppose: 0 Abstain :0

11. Discussion and Consideration of Federal and State Law Regarding Cannabidiol

Chairperson Schaad stated that Supervising Deputy Attorney Joshua Room has written his opinion on the legal status of products containing cannabidiol (CBD), in light of the FDA approval of Epidiolex and AB 710 (Wood), which was enacted in mid-2018.

SDAG Room clarified that the opinion regards only the prescribing of products containing CBD not the selling of products. He informed the committee that currently Federal and State law has not changed in status for the purpose of prescribing or dispensing. In addition, the Federal Drug Enforcement Agency (DEA) has taken no action to reschedule CBD and there is no indication on their agency website that they will.

SDAG Room was asked what a pharmacist should do if he/she has knowledge that a patient is currently taking a product containing CBD, which may have negative interactions with medication being dispensed. SDAG room responded that a pharmacist is still responsible for consulting with the patient and informing the patient of the possible impact of the CBD product on their dispensed medication.

Public discussion, in part, included whether the board should partner with other agencies to discourage the sale of CBD products in non-pharmacy settings and advocate to reschedule CBD.

12. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad informed the committee that during the June 2018 committee meeting, members directed board staff to include the following data elements into the Enforcement Statistics: Proof of Abatements Requested, Average Investigation Times, Cease & Desist Orders, Unlicensed Activity.

Chairperson Schaad introduced for committee discussion and consideration the revised Enforcement Statistics for July 1 – August 31, 2018. Chairperson Schaad invited committee feedback on the revised format and new data elements.

No questions or comments were presented by the board.

13. Discussion and Consideration of Bifurcation of the Enforcement and Compounding Committees

Chairperson Schaad informed the committee that during its May 2018 board meeting, members voted to pursue a statutory proposal to incorporate USP compounding chapters into the board's requirements for compounding drug preparations. As part of its discussion, the board noted that two of the compounding chapters, <795> and <797>, are in the revision process by USP and USP <800> has been finalized but is not yet in effect.

Chairperson Schaad stated that subsequent to that meeting, in recognition of the large impending policy work that will be required, President Law has bifurcated that Enforcement and Compounding Committee into two committees. Chairperson Schaad provided the membership for the respective committees.

Enforcement Committee
Allen Schaad, Chair
Albert Wong, Vice-Chair
Victor Law
Greg Lippe
Ricardo Sanchez
Stan Weisser

Compounding Committee
Stan Weisser, Chair
Allen Schaad, Vice-Chair
Shirley Kim
Victor Law
Maria Serpa

Chairperson Schaad anticipates that the compounding committee will begin its work in early 2019. Proposed meeting dates for both committees will be provided during the meeting.

14. <u>Future Committee Meeting Dates</u>

Chairperson Schaad informed the committee that the Enforcement Committee will meet on December 13, 2018. A list of future meeting dates for 2019 was provided at the meeting.

Chairperson Schaad adjourned this meeting at 3:46 p.m.