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

ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT
September 14, 2018

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

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

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

3. Presentation on the Board's Enforcement Program

Attachment 1

During the meeting members will hear a presentation providing an overview of the board's enforcement program. The presentation will provide general workload and staffing information.

Attachment 1 includes a copy of the presentation.

4. Presentation on Enforcement Trends

Attachment 2

During the meeting members will hear two presentations on two areas of enforcement - - compounding and drug losses.

Compounding

Aggregate data on the outcomes of sterile and non-sterile pharmacy inspections conducted in 2017/18as well as the top violations found in each setting will be provided for the committee's review and discussion.

Drug Losses

Summary data from a review of drug loss reports submitted over the last three fiscal years will be provided for the committee's review and discussion. The statistics reveal that the number of loss reports submitted has 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.

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

One of the committee's strategic goals is to implement processes to shorten cycle time from initial investigation to case resolution. Below are the benchmarks currently measured by board staff:

1. Assignment – Measures the time frame from the date the complaint is received or initiated.
2. Investigation – Measures the duration from the date the matter is assigned to the date the investigation report is submitted.
3. Review Times – Measures the time from the date the investigation is submitted until review by the supervisor and second level review is completed.
4. Closure Times – Measures the duration from the time the investigation report is reviewed until the case is closed.

Committee Discussion and Consideration

Provided below is a snapshot of the board's current pending investigations, including the average days by the identified benchmarks as of August 1, 2018.

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

*Closure time are cases in the Enforcement Unit awaiting AG Referral, Cite and Fine, LOA, Office Conference, etc.

The department's target for intake is the number of days from complaint receipt to the date the complaint is closed or assigned to an investigator. The department's target average is 20 days. Average intake for FY 2017-18 for field investigations was 27 days, compared to 19 days for the month of July 2018.

Average Days for cases under investigation in the field during FY 2017-18 was 235 days versus 165 days for the month of July 2018.

The department's target for case investigations not transmitted to the Attorney General is 210 days, which includes both intake and investigation.

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

Attachment 4

Background Information

The board has asked staff to provide information regarding board-issued citations and fines. During this meeting, Board Chiefs of Enforcement Julia Ansel and Tom Lenox will provide 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.

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

Relevant Law

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

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.

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.

Background

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

For Committee Discussion and Consideration

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.

Some questions or 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?

Last fiscal year either the full board or a committee of the board convened meetings on 25 days.

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

Attachment 5

Summary of Regulation

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.

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.

The board has asked staff to provide information about the new reconciliation regulation. During this meeting, a board supervising inspector and chief of enforcement will provide general information on the board's inventory reconciliation process and frequently asked questions.

Recent Updates

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 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 is provided in **Attachment 5**.

Additionally, 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 is provided in **Attachment 5** and will be provided during the meeting.

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

Relevant Law

Business and Professions Code 4127.1 establishes the parameters of sterile compounding licensure requirements. Business and Professions Code section 4400(u) establishes the fees for issuance of sterile compounding licenses.

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 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.

Committee Discussion and Consideration

The issue before the committee is to consider whether the board deems it appropriate to charge a fee for conducting sterile compounding remodel inspections.

10. 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 regarding the study and time for the board to consider a regulation modification involving ADDS to provide medication to patients.

During its 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

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.

For Committee Discussion and Consideration

During the meeting, 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.

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

Attachment 6

Provided in **Attachment 6** is a statement by Supervising Deputy Attorney Joshua Room 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.

12. 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, Unlicensed Activity.

For Committee Discussion and Consideration

Attachment 7 contains the Enforcement Statistics for July 1 – August 31, 2018. The committee may wish to provide staff with feedback on the revised format and new data elements.

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

Background

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.

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. 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. Proposed meeting dates for both committees will be provided during the meeting.

14. Future Committee Meeting Dates

The Enforcement Committee will meet on December 13, 2018. A list of meeting dates for 2019 will be provided at the meeting.

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

- Inspection
- Interviews
- Records Assessment
- Report Writing

- 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

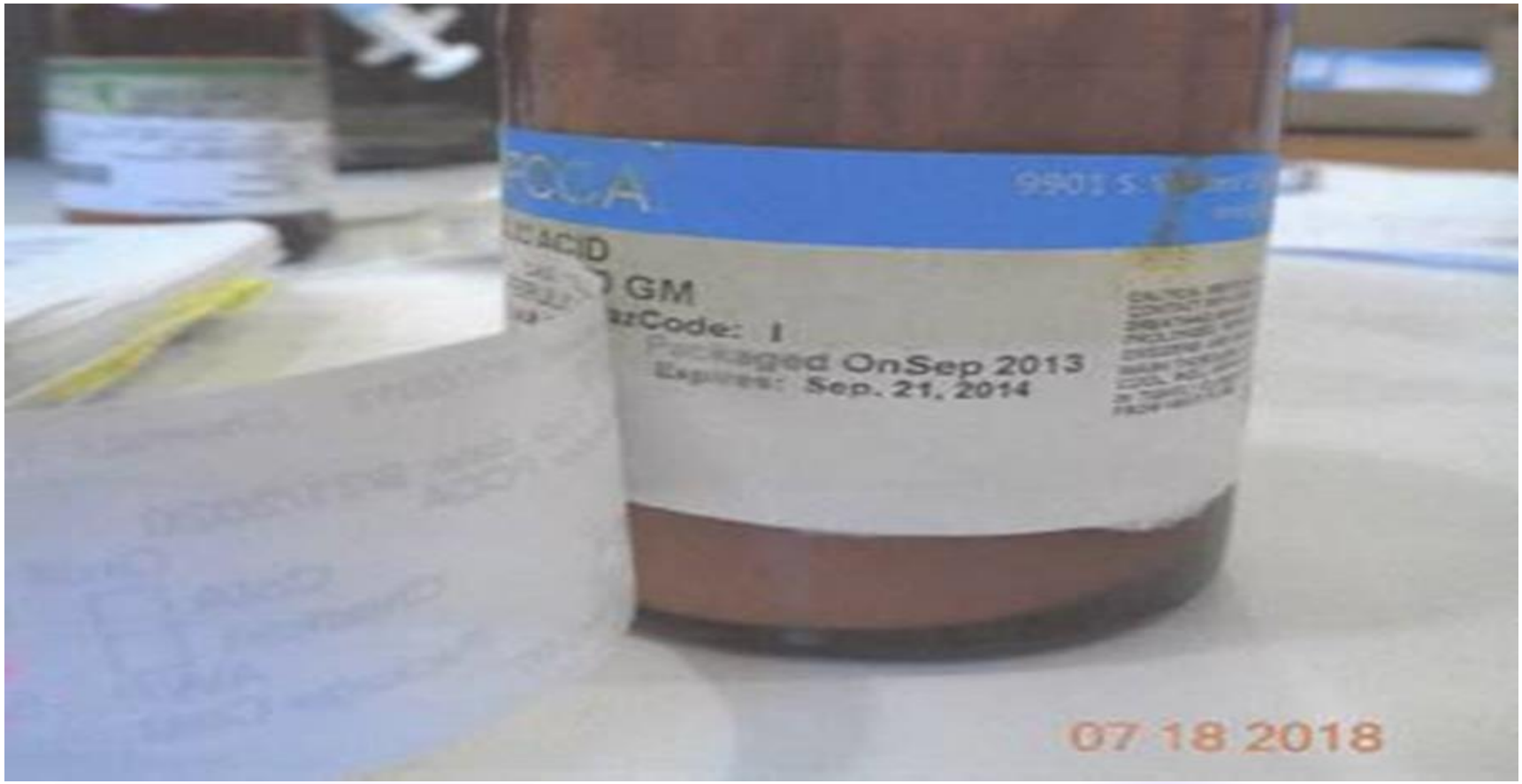
- **Enforcement Unit**
  - Letters of Admonishment
  - Citations
  - Administrative Cases
  - Reporting to National Databank
- **Overview**
  - 1 Manager, 6 Analysts (1 vacancy), and 3 Clerical
  - 350 Cases Referred to AG
  - 300 Mail Votes
  - 2168 Citations Issued
  - 442 Letters of Admonishment Issued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

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

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

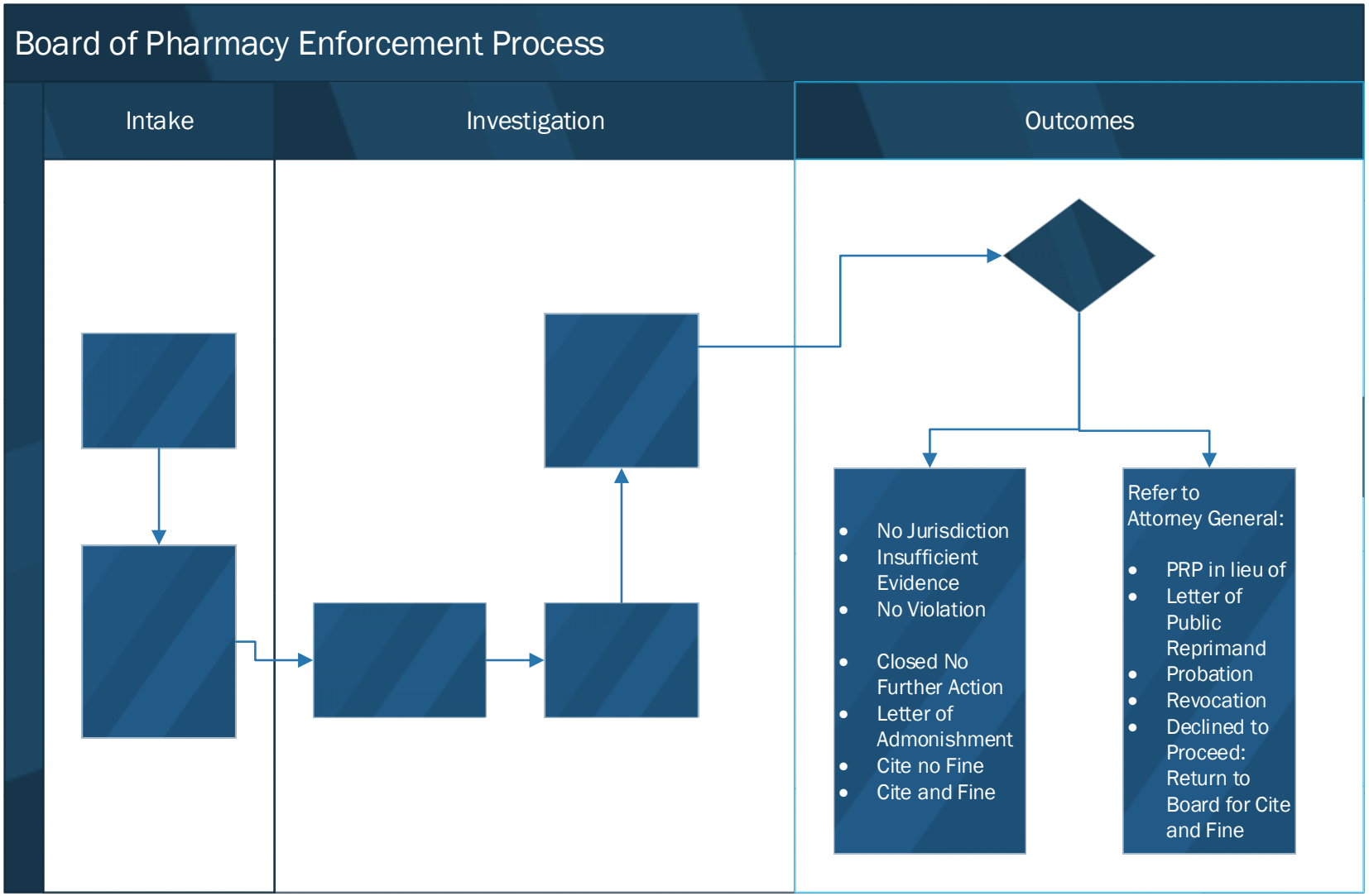
Robbery

- 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

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
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

Workload Statistics			July - August	Oct - Dec	Jan - March	Apr - Jun
Complaint Investigations						
	Received		514			
	Closed		466			
	Pending		1,988			
	Average Days for Investigation		268			
Cases Under Investigation (By Team)						
	Compliance/Routine		798			
	Drug Diversion/Fraud		344			
	Rx Abuse		78			
	Compounding		136			
	Outsourcing		6			
	Probation/PRP		64			
	Mediation/Enforcement		267			
	Criminal Conviction		295			
Application Investigations						
	Received		98			
	Closed					
		Approved	40			
		Denied	8			
		Total	***59***			
	Pending		131			
Letter of Admonishment/Citations						
	LOA Issued		55			
	Citations Issued		302			
		Proof Of Abatement Requested	56			
		Appeals Received	46			
		Dismissed	1			
	Total Fines Collected		***291,042***			
Administrative Cases						
	Referred to the AG's Office		32			
	Pleadings Filed		49			
	Pending					
		Pre Accusation	187			
		Post Accusation	243			
		Total	***474***			
	Closed		56			
	Revocation					
		Pharmacist	6			
		Intern Pharmacist	1			
		Pharmacy Technician	16			
		Designated Representative	0			
		Wholesaler	0			
		Sterile Compounding	0			
		Pharmacy	4			
		Total	***27***			
	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	6			
	Intern Pharmacist	0			
	Pharmacy Technician	2			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	0			
	Pharmacy	3			
	Total	***11***			
Surrender/Voluntary Surrender					
	Pharmacist	5			
	Intern Pharmacist	0			
	Pharmacy Technician	4			
	Designated Representative	1			
	Wholesaler	1			
	Sterile Compounding	0			
	Pharmacy	6			
	Total	***17***			
Public Reproval/Reprimand					
	Pharmacist	7			
	Intern Pharmacist	0			
	Pharmacy Technician	0			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	0			
	Pharmacy	0			
	Total	***7***			
Licenses Granted					
	Pharmacist	2			
	Intern Pharmacist	0			
	Pharmacy Technician	2			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	0			
	Pharmacy	1			
	Total	***5***			
Licensed Denied					
	Pharmacist	0			
	Intern Pharmacist	0			
	Pharmacy Technician	1			
	Designated Representative	0			
	Wholesaler	0			
	Sterile Compounding	0			
	Pharmacy	0			
	Total	***1***			
Cost Recovery Requested		264,394			
Cost Recovery Collected		131,405			
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	218	0	0	0
	Intern Pharmacist	8	0	0	0
	Pharmacy Technician	27	0	0	0
	Designated Representative	1	0	0	0
	Wholesaler	5	0	0	0
	Sterile Compounding	15	0	0	0
	Pharmacy	79	0	0	0
	Total	***353***	***0***	***0***	0
Probation Office Conferences		27	0	0	0
Probation Site Inspections **		80	0	0	0
Successful Completion		12	0	0	0
Referred to AG for non-compliance		0	0	0	0