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

ENFORCEMENT COMMITTEE REPORT
July 10, 2019

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

1. **Call to Order and Establishment of Quorum**

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

3. **Approval of the March 14, 2019, Enforcement Committee Minutes**

   Attachment 1

   Attachment 1 includes a copy of the draft minutes from the March 14, 2019, Committee Meeting.

4. **Presentation and Discussion on the Board's Citation and Fine Program**

   Relevant Law

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

   Title 16, California Code of Regulations Sections 1775-1775.4, provide the board's regulations governing its citation and fine program. More specifically, Section 1775 includes the authority of the executive officer or designee to issue citations, which may contain either or both an administrative fine and an order of abatement and details the types of violation for which a citation may be issued.

   Section 1775.2 establishes the factors to be considered in assessing an administrative fine. Such factors include:
   1. The gravity of the violation.
   2. The good or bad faith of the cited person or entity.
   3. The history of previous violations.
   4. Evidence that the violation was or was not willful.
   5. The extent to which the cited person or entity has cooperated with the board's investigation.

6. The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violations.
7. Other matters as may be appropriate.
8. The number of violations found in the investigation.

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

Background
As part of the May 2018 Board Meeting, members suggested that staff consider using the abatement provisions, especially in cases where the violations involved a medication error. Since that time, board staff has been integrating abatements as demonstrated in the citation data below. Typically, the abatement provides that completion of additional training (typically ranging from 2-6 hours) will result in either the reduction or elimination of the fine. Such an approach creates an incentive for the respondent to seek the additional training being requested.

Since that time, the committee and board have been completing a comprehensive review of the program. In addition, the board's president and vice president have reviewed closed citations and provided feedback to staff. The results of this feedback were publicly reported during the March 2019 Enforcement Committee Meeting and the May 2019 Board Meeting.

For Committee Consideration and Discussion
During this meeting members will receive a presentation on citation and fine trends, including an update of the implementation of Order of Abatements. Following the presentation, the committee may wish to discuss the current statutes and regulations defining the citation and fine program to determine what, if any, changes should be recommended to the full board.

5. Post Implementation Review, Including Discussion and Consideration of Title 16, California Code of Regulations Section 1715.65, Related to Inventory Reconciliation Report of Controlled Substances

Attachment 2

Relevant Law
CCR Section 1715.65 establishes the board's requirements for pharmacies and clinics to perform inventory reconciliation activities to detect and prevent the loss of controlled substances.

Background
Following adoption of the regulation, in order to provide guidance to the regulated public, the board developed frequently asked questions that are published on the board's website.

Board staff continues to receive questions regarding the inventory reconciliation requirements. Further, given the recent enactment of legislation related to the use of automated drug delivery systems, it appears appropriate to complete a post implementation review of the regulation requirements to determine if any changes should be considered.

For Committee Consideration and Discussion
Should it be helpful for the committee's discussion, below is a sample of questions received about the reconciliation requirements:

- Could you please clarify whether the new quarterly inventory regulation for Schedule II drugs includes a quarterly inventory of inpatient hospital onsite automated drug delivery systems OR just inpatient hospital pharmacies and satellites?
- What is the expectation of the pharmacy responsibility for the controlled substances in the ADDS? At what point is it the nurse's responsibility? Is the pharmacy responsible for knowing what the nurse does with each dose?
- Controlled substance reconciliation reports - do the controlled substances in the Pyxis machines on the nursing stations have to be counted?
- Does a pharmacist need to count each dose dispensed through ADDS even though the count is done 3 times a day and verified by nursing staff in the perpetual log?
- How do I conduct a reconciliation of Schedule II drugs?
- Do we need to count all controlled drugs on premise? Do we go line by line to reconcile?
- Is the reconciliation report only for schedule III through V? What exactly needs to be on the report? Is it in a spreadsheet or word form?
- How often to do schedule II reconciliation? Does a controlled substance report from a wholesaler need to be in excel format?
- May a Director of Nursing countersign an inventory reconciliation report as described in 1715.65?
- As a compounding pharmacy we have some schedule II bulk powders. Do we need to reconcile those? I have been told in past that compounded schedule II's are not included on inventories.

Attachment 2 includes a copy of the current regulation requirements as well as the FAQs.

6. <u>Discussion and Consideration of Title 16, California Code of Regulations, Section 1715.6 Related to the Reporting of Drug Losses</u>

Attachment 3

<u>Relevant Law</u>
Title 16, CCR section 1715.6 currently states, "The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

Title 21 CFR 1301.76(b) states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft."

<u>Background</u>
As part of past board discussions related to the board's new inventory reconciliation regulation, the issue of drug loss reporting requirements was mentioned. It was brought to the board's attention the difference in the Federal Code of Regulations (FCR) requirements and California Code of Regulations (CCR). During the rulemaking process, it was suggested that the board amend its current drug loss requirement (CCR 1715.6) to mirror the DEA requirements. At that time members were advised that such a change could not be implemented as the language lacked the necessary clarity required to comply with the Administrative Procedures Act.

During its last meeting, the committee reviewed drug loss reporting information data.

Fiscal Year Reported	Dosage Units	# Drug Loss Reports
FY 12/13	1,151,704	754
FY 13/14[1]	1,524,833	1,367
FY 14/15	1,513,696	2,168
FY 15/16	1,646,380	3,481
FY 16/17	2,130,112	7,170
FY 17/18	3,230,016	8,435
July 2018 - Dec 2018	720,392	3,701
Total	**11,917,133**	**27,076**

1 One very large loss (1.6 million dosage units+) of benzodiazepines due to an out-of-state loss-in-transit drug loss was not included due to skewing of the data.

The table below reflects the number of reports received between 7/1/18 and mid-December 2018 categorized by the size of the losses.

Loss Size (in dosage units)	Number of Reports
Losses between 0 - 100	3,294
Losses between 100 - 500	204
Losses between 500 - 1000	21
Losses between 1000 - 5000	61
Losses over 5000 - 10000	15
Losses over 10,000	17
Total Losses	**3,701**

The committee requested that staff review the types of drug losses involved in loss range of 0-100 and report the data back to the committee.

For Committee Consideration and Discussion

As requested by the committee, **Attachment 3** provides the list of drugs reported for the range noted above. Should it be helpful to the committee for its discussion, the attachment also includes the dosage form and aggregate dosage units for each drug and dosage form included.

7. Discussion and Consideration of Proposal to Establish an Alternative Disciplinary Process

Attachment 4

Relevant Law

In general, the Administrative Procedures Act establishes the parameters for the disciplinary process. More specifically, Government Code section 11415.60 provides the authority for an agency to formulate and issue a decision by settlement pursuant to an agreement of the parties without conducting an adjudicative proceeding.

Background

Previously the committee received a presentation by the California Pharmacists Association, seeking to establish an alternative enforcement model. The committee expressed concerns with the proposal but directed staff to develop a possible alternative enforcement model that would meet

two primary goals - - reduce cost and reduce closure times. Consistent with the direction of the committee, staff worked with the committee chair on the basic framework for an alternative model.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to discuss the proposal. Should the committee and board agree with the basic framework and direction being offered, additional work will be necessary to refine and more fully develop the statutory framework.

Below is a brief description of the alternative model.

1. Investigation is completed and violations are substantiated that warrant referral to the Office of the Attorney General (AG's Office) for disciplinary charges.
2. Respondent is advised of the violations and the board's intentions to refer the matter to the AG's Office for disciplinary charges. As part of the advisement, respondent is provided the option to pursue the alternate model.
3. Matter is referred to the AG's Office.
4. Board receives respondent's notice electing to engage in the alternate model. Respondent may also provide any mitigation evidence.
5. Executive Officer and 2 board members (one public member and one licensee member) review investigation and mitigation, if any.
6. Settlement offer is developed and conveyed by AG's Office to respondent.
7. Upon agreement, the settlement along with the initial notice to respondent advising of the substantiated violations are considered by the board for action.

Provided in **Attachment 4** is a framework of a draft statutory proposal intended to detail the basic tenets of the proposal.

8. Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask An Inspector Program

Attachment 5

Background

At the January 2019 Board Meeting, the Communication and Public Education Committee provided an overview of the "Ask an Inspector" program". The "Ask an Inspector" program is staffed by one inspector each week. Inspectors responded to a total of 3,257 inquiries through the program between January 1, 2018 and December 20, 2018. The top ten inquiry types were reported and the highest percentage of questions involved controlled substances, which comprised 22% of the inquires last year.

Attachment 5 includes the draft FAQ's for the committee's review.

9. Discussion on the Posting of an Individual Licensee's Address of Record on the Board's Website

Attachment 6

Relevant Law

Government Code Section 6250, et seq, provides that the address of record of board licensees is public information.

CCR Section 1727.1 provides that the board shall not make an intern pharmacist's address publicly available on the internet.

Background

Beginning in December 2003, the board began posting the address of record for board licensees on its website. At that time, it was noted that similar information is provided online by other health profession regulatory boards (physicians, dentists, therapists.) The board noted that because the addresses of record are public record by law, those licensees who wish to withhold their residence address from the public may provide a post office box, a personal mailbox number, place of employment, etc. as the address of record as long as the resident address (which is not available to the public) is also provided.

Since that time the board has periodically reminded licensees in newsletters, application forms, etc. that the address of record information is posted online as well as the method by which to change the address of record.

For Committee Discussion and Consideration

During the meeting the committee may wish to discuss this policy and determine what if any changes should be made. **Attachment 6** includes a copy of the most recent article regarding the issue.

10. Presentation on Board's Jurisdiction in Enforcement Matters Regarding Pharmacies Operating Under Common Ownership or Management

During the meeting the committee will hear a presentation from Supervising Deputy Attorney General Joshua Room regarding the board's jurisdiction in enforcement matters regarding pharmacies operating under common ownership or management.

11. Discussion and Consideration of Citations as Non-Disciplinary Actions and Proposal to Amend Business and Professions Code, Section 4314 to include Provisions to that Effect

Attachment 7

Relevant Law

BPC 4314 establishes the general statutory authority for the board to issue citations containing fines and orders of abatement for specified violations of law.

Background

The board routinely advises requesting parties that citations issued by the board do not constitute discipline. Rather a citation is an administrative action taken by the board. Regrettably, there are times when regulators from other jurisdictions may apply a different meaning to the citation.

Staff notes that under the letter of admonishment provisions in BPC 4315, a provision is included in the statute that explicitly states that a letter of admonishment shall not be construed as a

disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure. No similar provision exists in the board's citation statute.

For Committee Discussion and Consideration
It may be appropriate for the committee to consider if an amendment to BPC 4314 is appropriate to establish similar clarification on application of a citation issued by the board.

Should the committee agree with the policy proposal, the following language could be amended into BPC 4314 as follows:

Amend BPC 4314 as follows:
…
(e) The issuance of a citation pursuant to subdivision (a) shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

Attachment 7 includes a copy of BPC 4314 in its entirety with the recommended language.

13. Discussion and Consideration of Committee's Strategic Goals

Background
In 2016 the board finalized its current strategic plan.

For Committee Discussion and Consideration
It is recommended that the committee discuss the status of its strategic goals for the coming fiscal year as well as the remainder of the plan.

Provided below are the goals currently included in the board's strategic plan along with a brief status.

2.1 Implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.
Status: During the March 2019 committee meeting a review of FY 18/19 data reported a significant decrease in the number of pending investigations over 1 year and an improvement in overall investigation times for cases that are closed.

2.2 Strengthen patient consultation outcomes for Californians and increase medication safety.
Status: Inspectors continue include in their routine inspections pharmacy staff's compliance with consultation laws.

2.3 Collect data and report to board members about enforcement trends that are presented at case closures, so the board can better educate licensees about board priorities.
Status: Multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action. Presentations are provided regarding the citation and fine program and the

common violations resulting in the issuance of citations.

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

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

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

Status: In coordination with the Office of the Attorney General, the board has initiated process to improve the efficiency of the disciplinary process. The overall goal with the cooperation of the Attorney General's Office is to process all cases through the office of the Attorney General within one year.

July 2019: Committee considers an alternative enforcement model.

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

Status: No work has been done on this strategic goal.

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

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

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

Status: The board has developed a brochure to be distributed to licensees at the time of inspection. Included in the brochure is information on filing a comment or complaint with the board's parent agency, the Department of Consumer Affairs. The brochure is currently under review with the DCA's Legal Department.

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

Status: The enforcement committee has initiated a review of the board's Disciplinary Guidelines.

2.10 Evaluation of the board's Citation and Fine program.

Status: The committee has received several presentations on the citation and fine program and will continue to receive annual updates. At the policy direction of the board, staff is availing itself of the Order of Abatement authorities at a much higher rate. Further, under the direction of the president and vice president, policy direction on other factors that should be considered has been integrated in

at the staff level. Annual review of the program will continue to assess trends and educational opportunities.

2.11 Review the role and responsibility of the PIC.

Status: Senate Bill 476 (Stone) would have created a task force to study and submit a report to the Legislature on the prevalence of management interference upon the ability of pharmacists-in-charge to do their jobs and any legislative recommendations for improvement. SB 476 was held in committee and under submission on May 16, 2019. No further action has been taken on this strategic goal.

14. Discussion and Consideration of Board's Enforcement Statistics

Annual enforcement statistics will be provided during the meeting. A review of case closure times for the past fiscal year indicate that 64 percent of the board's field investigations were closed within one year, 31 percent were closed within 1-2 years and the remaining 5 percent were closed in over two years. It is important to note that this does not include cases that were referred to the Office of the Attorney General.

The board currently has 1,698 field investigations pending, as of June 24, 2019, 76 percent of which are less than a year old and 22 percent are between 1-2 years old. Below is a breakdown providing more detail in the various investigation process:

- 92 cases under review for assignment, averaging 12 days
- 1006 cases under investigation, averaging 101 days
- 309 investigations under supervisor review, averaging 92 days
- 79 investigations under second level review, averaging 48 days
- 212 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 48 days

15. Future Committee Meeting Dates

Consistent with the action from the board's May meeting, the next several committee meetings will be convened on the first day of the scheduled board meeting. The next committee meeting date will be November 5, 2019. As the board meeting dates for next year are finalized, additional dates will be posted on the board's website.

16. Adjournment **Upon Conclusion of Business**

ATTACHMENT 1

Enforcement Committee Minutes

March 14, 2019

California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
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ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE:	March 14, 2019
LOCATION:	Department of Consumer Affairs 1625 N. Market Blvd First Floor Hearing Room Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Dr. Albert Wong, Licensee Member, Vice Chair Victor Law, Licensee Member Greg Lippe, Public Member Stan Weisser, Licensee Member Ricardo Sanchez, Public Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Laura Freedman, DCA Staff Counsel Joshua Room, Supervising Deputy Attorney General MaryJo Tobola, Senior Enforcement Manager Rob Buckner, Criminal Conviction Unit Manager

1. <u>Call to Order and Establishment of Quorum</u>
Chairperson Allen Schaad called the meeting to order at 9:05AM. A quorum was established.

2. <u>Public Comment on Items Not on the Agenda, Matters for Future Meetings</u>
Chairperson Schaad invited public comment.

Dr. Steven Gray suggested the following items to be considered:

- The enforcement of the statute that requires pharmacies to provide prescription retail prices upon request by the public, however communicated.
- Requiring pharmacies to provide phone numbers that will directly connect the caller to a pharmacy rather than just a call center.
- Discussion about hospitals outsourcing (out of state or out of the country) the required review of hospital orders, in their effort to comply with the Joint Commission's requirement that a pharmacist review the hospital order before the drug is administered to the patient.
- Discussion and clarification of enforcement implementation of the two bills which require pharmacists to tell the patient if the retail price of the medication is less than their copayment.

Kim Allen with Sharp Healthcare requested clarification of SB 1447, which addresses the stocking and restocking of automated drug delivery systems (ADDS). Ms. Allen expressed concern that two Business and Professions Code (BPC) sections conflict with each other. Specifically, BPC Code section 4186 states that an ADDS must be stocked by a pharmacist, but BPC Code section 4427.4 allows ADDS to be stocked by a pharmacist, pharmacy technician or intern pharmacist. Ms. Allen opined that in order to maximize the role of a pharmacist in the pharmacy, the restocking of ADDS should be the responsibility of a pharmacy technician.

Chairman Schaad recommended that the board consider, as a future agenda item, a discussion for clarification of the posting of a pharmacist's address of record on the board website.

Board President and Committee Member Victor Law suggested that the board consider, as a future agenda item, the promulgation of statutory change to discipline the common owner of multiple pharmacies in violation of laws or regulations, rather than disciplining each pharmacy.

3. **Approval of the December 20, 2018 Enforcement Committee Minutes**

Chairperson Schaad requested the review and approval of the minutes from the December 20, 2018 Enforcement Committee meeting.

As part of the public comment, Dr. Gray requested that on the bottom of Page 3 of 15, last paragraph, "Health and Safety Code section 4052" be amended to "Business and Professions Code section 4052".

Motion: Approve the minutes with the corrections identified.

M/S: Weisser / Law

Support: 5 Oppose: 0 Abstain: 1

4. **Presentation, Discussion and Consideration of Ethics Course Provisions in California Code of Regulations (CCR), Title 16, Section 1773.5 CCR**

Chairperson Schaad provided background and relevant law. In 2009, CCR section 1773.5 established that when directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course as a condition of probation, license reinstatement or as abatement for citation and fine. Board approval must first be obtained prior to the commencement of ethics courses.

Chairperson Schaad stated that various healing arts boards were asked by board staff to provide a sample of an approved ethics course, the provider, and the cost.

The Committee heard a presentation from Ms. Leslie Anne Iacopi from the Institute of Medical Quality (IMQ) regarding the content and objectives of IMQ's ethics courses, the cost of each course as well as their measurements for success.

Committee Member Stan Weisser asked what the participant cost is for the IMQ ethics program. Ms. Iacopi stated the cost is $1,995, which includes a full two-day program as well as the follow-up

program consisting of a 6-month progress report and a 12-month final report and includes all post and pre-tests.

Chairperson Schaad asked if students are failed from the ethics program. Ms. Iacopi stated that the course design is not intended to fail students, but rather works with their individual issues and focuses on how each participant can move forward and be a better pharmacist.

Chairperson Schaad asked what type of feedback the students provide to IMQ. Ms. Iacopi stated that upon completion of the 12-month report, the board receives a letter from IMQ which verifies the participants completed the 2-day course and the contents reported in the 6-month progress report and 12-month final report.

Chairperson Schaad asked board staff how course providers are recommended to participants. Interim Executive Officer Anne Sodergren informed the committee that staff suggests programs to licensees that have been used successfully in the past, but licensees are free to locate providers on their own. Providers are then approved by the board if they can demonstrate their program satisfies the requirements of the law.

As part of public comment, Holly Strom shared her support of the IMQ ethics program. Ms. Strom asked the committee what a participant would need to do to get a course provider approved. DCA Counsel Laura Freedman stated that as a condition of probation, staff would approve the course and provider based on the requirement identified in the terms of their probation.

President Law asked Ms. Iacopi if IMQ's student satisfaction evaluations were provided to the board. Ms. Iacopi stated that those surveys were internal, but they could be provided to the board upon request. The committee requested a report of the evaluations be provided to the board annually. Board staff was directed to work with IMQ to obtain annual feedback on student satisfaction.

As part of public comment, Dr. Gray stated his support of the IMQ ethics program. Additionally, Dr. Gray suggested that it would be beneficial for pharmacy students to know what type of disciplinary scenarios result in an ethics course being included as a term of probation. Dr. Gray stated it is the common opinion among pharmacy law educators there is not enough time to teach law and ethics in one course. Dr. Gray expressed concern that at some schools of pharmacy law an ethics course is only a one or two-unit class.

5. <u>Presentation on the Board's Routine Pharmacy Inspections</u>

Chairperson Schaad introduced Board Inspector Steven Kyle. Inspector Kyle presented "How to Prepare for a CA Board of Pharmacy Inspection".

As part of his presentation, Inspector Kyle discussed the following areas: when an inspection or investigation is conducted, designating a pharmacist-in-charge (PIC), responsibilities of a PIC, items

reviewed during a routine pharmacy inspection, and a review of sterile compounding inspections and pharmacy law resources.

Chairperson Schaad requested that questions and comments pertaining to Inspector Kyle's presentation be held until after the next speaker.

6. Discussion and Consideration of Senate Bill 1442 (Wiener, Chapter 569, Statutes of 2018) Relating to Community Pharmacies Staffing

Chairperson Schaad welcomed and introduced State Senator Jeff Stone who would be commenting on the implementation of SB 1442.

Senator Stone stated that SB 1442 was introduced by Senator Scott Weiner and himself. He shared his own experiences as a pharmacy intern working with a pharmacist who was shot during a robbery and he shared his experience as a pharmacist, working for Thrifty's in Southern California, tasked with additional retail responsibilities.

Senator Stone stated that SB 1442 was written with the belief that pharmacists should not be working alone, especially at night. He explained that although during the night there are smaller volumes of prescriptions being filled, there are many patients picking up prescriptions and requiring consultations. Senator Stone informed the committee that we now see pharmacists who administer immunizations, dispense naloxone, take blood pressures, take blood sugar levels, while also tending to their own personal issues like using the restroom and taking a break. The Senator shared with the committee that a pharmacist communicated with him that he will not go to work while he is taking his diuretic medication because he cannot safely leave the pharmacy to use the restroom. Senator Stone shared that pharmacists have shared their concern over their increased responsibilities in the middle of the night in these types of retail environments. He expressed his concern that pharmacists are working alone at night, answering telephones, ringing up sales, doing immunizations and dealing with patient demands; he warned it is these types of interruptions of routine which could cause errors.

Senator Stone urged the committee to strongly consider creating a statewide enforcement task force that would conduct after-hour visits and observe activities that happen in pharmacies, especially in the more rural and urban areas, where we see this abuse taking place. Additionally, Senator Stone said some employers are not placing adequately trained personnel in the pharmacy who understand how to work the pharmacy computer system, understand how to answer the patient calls or how to track a prescription. He questioned whether a lay person, without pharmacy training or knowledge, should be left alone in a pharmacy while a pharmacist relieves themselves. Senator Stone stated that there may be unintended consequences of this bill. Further, the Senator continued he and Senator Weiner are willing to address these unintended consequences through future legislation.

Senator Stone concluded with his request that inspection staff review and understand SB 1442 requirements and ensure that it is appropriately implemented throughout the state in the best interest of patient safety and in the best interest of pharmacists who are being pulled in many different directions.

Chairperson Schaad thanked Senator Stone for following up on SB 1442. President Law shared with the Senator that there have been many discussions regarding the implementation of SB 1442; he asked if the Senator would consider amending the law to clarify that pharmacy technicians are required to provide assistance to the pharmacist. Senator Stone agreed that the most logical person who should be with a pharmacist is a pharmacy technician. Additionally, President Law suggested a second amendment that would allow pharmacies to consolidate their late-night hours to specific stores and staff those designated stores with a pharmacists and pharmacy technicians. Mr. Weisser also thanked Senator Stone for his advocacy for the consumers of California.

7. <u>Presentation on the Board's Routine Pharmacy Inspections</u>

Chairperson Schaad invited committee and public comments regarding the presentation of routine pharmacy inspections presented earlier by Inspector Kyle.

Mr. Weisser asked Inspector Kyle if he was satisfied with the amount of consultation being provided to patients. Inspector Kyle answered, in his observation, consultation is not enough of a standard practice.

Committee Member Albert Wong suggested that Inspector Kyle's presentation be provided on the Board's website for viewing. Ms. Sodergren confirmed that a video of this module would be provided on the board website.

President Law encouraged pharmacy students to view this module in order to learn inspection expectations.

As part of the public discussion, Joe Grasela asked if out of state pharmacies are inspected. Ms. Sodergren clarified that some out-of-state pharmacies are inspected; outsourcers and sterile compounding are inspected but authority out-of-state is limited. Mr. Grasela stated that he believes that there are many compounding pharmacies that are sending prescriptions into California that are non-sterile and not compliant with California laws. He suggested that the National Association of Boards of Pharmacy conduct out-of-state California inspections. Counsel Laura Freedman suggested that this could be considered as a future agenda item. Mr. Gray asked if inspections are conducted during nights, weekends and/or holidays. Inspector Kyle confirmed that visits are conducted during nights, weekends and/or holidays, as they relate to the investigation. Additionally, Mr. Gray stated that in the area of cite and fines many pharmacy owners are paying the fines for their PICs who are found in violation, which defeats the purpose of sanctioning that specific employee for their mistake. President Law re-stated that his earlier suggestion to cite the owner of the pharmacy.

The committee paused for break at 11:05 a.m. and returned at 11:21 a.m.

8. <u>Discussion and Consideration of Senate Bill 1442 (Wiener, Chapter 569, Statutes of 2018) Relating to Community Pharmacies Staffing</u>

Chairperson Schaad provided information regarding SB 1442 which prohibits pharmacists from working alone. At the last committee meeting, the committee directed staff to work with counsel to research DEA requirements and to determine whether a background check for non-licensed personnel would be required under the Code of Federal Regulations (CFR) or whether the board should develop such a requirement. Ms. Sodergren informed the board that Title 21 CFR section

1301.90, which discusses the non-practitioner screening procedures for employees, had been provided for their review.

As part of public comment, Title 21 CFR section 1301.76 which is the basis for section 1301.90, was provided to the committee by Dr. Gray. Dr. Gray clarified that section 1301.76 applies to institutional practitioners, meaning hospitals, pharmacies and wholesalers. As part of public comment, a pharmacist working in a retail store stated that, in his experience, the staff sent to assist in retail pharmacies currently lack the training, knowledge and pharmacy skills necessary to assist the pharmacist or customers. Additionally, it was suggested that when inspectors conduct inspections, a copy is made of the employee schedules to verify who is assigned to the pharmacy to verify compliance with SB 1442.

Dr. Wong voiced his concern that pharmacies are unwilling or unable to staff appropriately. Dr. Wong stated he believed that Primary Benefit Manager (PBM) reimbursements are the root of this inability to staff appropriately.

Ms. Sodergren informed the committee that she is aware of at least one complaint alleging non-compliance with SB 1442.

Dr. Gray stated that with the approval of remote dispensing pharmacies, pharmacists will be required to supervise the pharmacy technicians at the remote dispensing pharmacy, in addition to their responsibilities at their actual pharmacy location. With the increased pharmacist responsibility there could be security issues in addition to concerns regarding consultation and service.

9. <u>Update on and Discussion of Board's Citation and Fine Program</u>

Chairperson Schaad stated that Goal 2.1, of the board's Strategic Plan calls for evaluation of the board's citation and fine program.

Chairperson Schaad explained that the chair report details several provisions of pharmacy law that govern the board's citation and fine program. During the discussion, Chairperson Schaad hoped to focus on two areas: post evaluation of order of abatement provisions since the board's May 2018 meeting and review of the policy considerations and guidance staff have been provided, by both the president and vice president, as it relates to completed citations issued with a fine of $2,000 or greater.

Chairperson Schaad directed the committee to the citation and fine data in the chair report. The data provided in the report demonstrated that orders of abatement are used with a far greater frequency than in previous years. This is consistent with the board's direction. Whereas, in 2016/17 about 1% of citations were issued with an abatement order, this year about 20% contain such an order. It appears abatements acceptance is relatively low.

Ms. Sodergren explained that typically when issuing an order of abatement, the board is giving the respondent a period of time in which to complete the abatement before the citation is completed, therefore, it would be helpful if staff could provide another follow up report to see if the actual abatement rate is higher because of the compliance period.

President Law informed the committee that since he and Vice President Greg Lippe have been reviewing citations, the number of citations has decreased.

As part of public comment, members of the public expressed concern regarding the expenditure of Cite and Fine monies. In relation, a member of the public asked why the board was not just part of the State General Fund. Supervising Deputy Attorney General (SDAG) Joshua Room provided the following clarification: the board is a Special Fund Agency and does not receive General Funds. Fines collected by the board are not the board's to spend, as special authorization is required to spend those funds, therefore, there is no financial incentive to collect additional fines because the board has no idea whether it will be allowed to spend those funds.

Ms. Sodergren recommended that further discussion regarding these budgetary issues could be discussed as an agenda item at the Organizational Committee. Vice President Lippe agreed to the recommendation.

10. Discussion and Consideration on Efforts to Reduce Investigation Times and Case Resolutions

Chairperson Schaad informed the committee that Goal 2.1, of the board's Strategic Plan seeks to 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.

Chairperson Schaad stated that for several meetings the committee has been discussing investigation closure times and receiving updates on current data. Included in the chair report for review are pending investigation case historical and current data as well as case closure data.

Chairperson Schaad informed the committee that in the review of the Age of Field Pending Investigations, he noted a significant decrease in the number of pending investigations over 1 year, which shows progress. Additionally, a review of the Age of Field Cases Closed also reflects improvement in overall investigation time for cases that are closed. He recommended that the committee continue to monitor this progress.

President Law thanked staff for reducing investigation time. He noted that cases sent to board members by mail vote are also more current.

Chairperson Schaad thanked the staff for responding to direction by the committee. He stated that the board has heard the professions concern with efficiency and increased transparency in the discipline program.

11. Discussion on Attorney General Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies

Chairperson Schaad stated that Goal 2.5 of the board's Strategic Plan is to evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.

As required by law, the Office of the Attorney General (AG) is required to publish data annually on certain disciplinary matters. Chairperson Schaad invited SDAG Joshua Room to provide a brief presentation on the AG's Report.

SDAG Room informed the committee that this is the second reporting year for the Annual Report. This is an effort by the legislature to collect data on how quickly cases are moving. SDAG Room reported that numbers are improving overall. He explained that Board of Pharmacy cases do not move as quickly due to complexity, number of respondents in each case and number of opposing counsels, which slows down the progress. SDAG Room stated right now it is taking about six months for a case to go from receipt of the case at the AG's office to the filing of the Accusation with the goal being to get that time down to three months. The overall goal is to get Board of Pharmacy in and out of the AG's office within one year.

President Law inquired about the suspension of a license when a licensee is subject to a criminal case. SDAG Room confirmed that the process to suspend in such a case would be initiated pursuant to Penal Code (PC) section 23. SDAG Room confirmed that the board has pursued PC 23 suspensions, whenever possible

Ms. Sodergren stated the board attempts to obtain an Interim Suspension Order (ISO) when the PC 23 is not an option.

No public comment.

12. <u>Discussion and Consideration of AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction</u>

Chairperson Schaad informed the committee that AB 2138 places restrictions on the acts and convictions the board can consider when reviewing an applicant's criminal history and had been previously discussed.

DCA Counsel Laura Freedman provided a brief overview of the bill. She stated that AB 2138 primarily changes the board's ability to deny an application. The bill contains two different provisions related to substantial relationships and rehabilitation.

Ms. Sodergren stated that AB 2138 reduces the opportunity for the board to consider some of the criminal activities that people engage in as a cause for discipline or denial of a license. The trigger in the statute is no longer necessarily substantial relationship, there is a hard deadline on when we can no longer consider the criminal activity. Ms. Sodergren informed the committee that the discussion today is whether AB 2138 is consistent with the board's mandate. Although the policy was decided, and the bill was enacted, this committee previously discussed this legislation and directed staff to see if there are opportunities to request changes to the statute. Also, Ms. Sodergren added, as part of the statute, the board is required to make changes to the board's substantial relationship regulations and make updates to the pharmacy technician application form to conform with the law.

Chairperson Schaad stated that based on the draft language recommendations, statutory changes would allow the following:

1. Consideration of convictions of felony financial crimes;
2. Consideration of acts that would be grounds for denial of a federal registration to distribute controlled substances;

3. Consideration of acts that involve fraud in violation of state or federal law related to healthcare.
4. Consideration of convictions related to identify theft;
5. Consideration of convictions related to the sale of counterfeit products.

SDAG Room clarified that as of July 1, 2020, the conviction or the end of incarceration would have to have occurred within seven years of the application date, in order for the conviction to be considered for denial or discipline. There are certain exceptions which are not subject to the seven-year period such as serious felonies and sex crimes. Additionally, there are various other types of crimes, for specific agencies, that are not subject to the seven-year limitation, for example, financial crimes for the Fiduciaries Board. SDAG Room explained that a proposed amendment would put the Board of Pharmacy among the boards with the financial crime exception. Additionally, this proposed amendment would carve out a special set of crimes just for the pharmacy board, which would allow the board to continue to use in the consideration of denials and discipline.

Ms. Sodergren suggested drafting language to also allow the board to consider an applicant's criminal history, if they have something within the allowable seven years and history previous to that.

SDAG Room clarified, if someone has a lengthy criminal history, for example, 12 convictions leading up to eight years ago, then they have a period of legality, then they have one more conviction from three years ago; for purposes of their application, under the current law we would only be allowed to consider three years ago.

SDAG Room recommended the committee consider all amendments presented and after deciding which amendment to pursue, staff should seek an author for the amendments agreed upon by the board.

Motion: Committee recommended the board seek an author to make the statutory amendments that are proposed in Attachment 7 and include language specific to criminal history.

M/S: Lippe/Weisser

Support: 6 Oppose: 0 Abstain: 0

As part of the committee discussion, DCA Counsel Laura Freedman reviewed proposed draft language and options for regulatory amendments that would conform to AB 2138.

Motion: Approve draft regulations to include Section 1 with optional language, subdivision (c) and for Section 2, include Option A, without the variation. Make any non-substantive changes consistent with policy.

M/S: Lippe/Weisser

Support: 6 Oppose: 0 Abstain: 0

As part of public comment, concerns were raised regarding the consideration of crimes committed in other states, and whether the National Practitioner Data Bank (NPDB) could still be reviewed in the consideration of applications SDAG Room clarified that this regulation will have no effect on the process, just the criteria used consider an applicant for disciplinary action or denial.

Holly Strom of Strom & Assoc. asked if the applicant would need to disclose a conviction on the application. SDAG Room clarified the applicant would no longer be required to disclose, although the applicant could voluntary disclose and show rehabilitation.

13. <u>Presentation and Discussion on Disciplinary Guidelines</u>

Chairperson Schaad, informed the committee that as required by CCR section 1760, the board uses its Disciplinary Guidelines when considering disciplinary action. He stated that it is his intent to dedicate time at the next several meetings to discuss the current guidelines and determine what, if any, changes should be recommended to the full board for consideration.

Chairperson Schaad invited SDAG Room to provide a summary on the Disciplinary Guidelines.

The Disciplinary Guidelines are adopted and are therefore mandatory. They must provide guidance to the board in the decision of disciplinary actions. SDAG Room reviewed the various sections and categories in the Disciplinary Guidelines and informed the committee of the Uniform Standards.

Ms. Freedman clarified that the Uniform Standards speak only to substance-using licensees and the specific criteria were created by a specific organization of executive officers for healthcare.

Ms. Sodergren stated that when the board was considering the Disciplinary Guidelines at the policy level, the committee identified which of those standards should be included in the Disciplinary Guidelines. There were different types of directions within the Standards: directions to the board itself, directions to board staff on testing frequency recommendations, directions to respondents on what their requirements would be and directions for those boards who have a recovery program. As policy makers, the committee included in the guidelines those that were incumbent upon the respondent to satisfy.

Ms. Freedman informed the committee that DCA was the head of the organization that created the Uniform Standards.

President Law stated that the current process consists of an inspector completing a report and forwarding the file to a supervising inspector with a recommendation for cite and fine or referral to the AG's Office. President Law stated that previous discussions have recommended that the board should have a process to screen cases before they are issued a cite and fine or referral to the Attorney General's Office. President Law stated that only cases of the most serious nature should be referred to the AG's office.

Ms. Strom and Jenny Partridge expressed support of a more thorough review process.

The committee paused for lunch break at 1:05p.m. The committee returned and called the meeting back to order at 1:38p.m.

14. Presentation by the California Pharmacists Association on a Proposal to Modify the Board's Current Enforcement Process

Chairperson Schaad introduced Danny Martinez, Government Relations and External Affairs for the California Pharmacists Association (CPhA). Mr. Martinez introduced Veronica Bandy, CPhA President.

Mr. Martinez presented "Proposal for a Pharmacy Advisory Committee". Mr. Martinez's presentation included a review of the Board of Pharmacy's Enforcement Process, CPhA's proposed changes to the Enforcement Process, and the proposal of a Pharmacy Advisory Committee.

As part of the presentation, Mr. Martinez's proposed that prior to initiation of the formal disciplinary process (referral to the AG's office), the board should permit licensees to go before a consortium of their practicing peers in order to help the board prioritize serious issues from less significant issues. Mr. Greg Lippe informed the presenter that the charge of the board is the protection of consumers and to recommend a consortium of only pharmacists is in opposition to the whole idea behind the board.

Mr. Martinez shared a proposed flowchart of the intake, investigation and outcomes process. Ms. Sodergren and SDAG Room expressed concern that the flowchart provided did not match the process suggested in the proposal. Mr. Martinez stated that the flowchart would need to be corrected in order to match his proposal and he informed the committee that his proposal is open to changes and suggestions.

Mr. Martinez stated that the Medical Board of California (Medical Board) has a process similar to the CPhA proposal, where a practicing licensee conducts a review of the investigation and provides a recommendation on whether they should proceed. If the evidence is not clear, it is sent to a second expert reviewer. SDAG Room provided clarification to the presenter that the Medical Board uses internal staff experts, as well as external experts; internal experts are employees of the Medical Board. Additionally, SDAG Room stated some agencies like the Dental Board, Medical Board and Veterinary Board employ in-house consultants to determine standards of care issues because they do not have subject matter experts on staff like the Board of Pharmacy. SDAG Room further stated that in-house consultants' sole mission is to determine whether there is enough of a possibility of a deviation from the standard of care that it should be sent out for an expert review; they are not making recommendations on whether a board or staff should pursue a case. Mr. Martinez stated that the information he was providing today was confirmed on the Medical Board website.

Mr. Martinez stated that the proposal is a hybrid of the Medical Board process as well as the process used by the Maryland Pharmacy Board.

Mr. Martinez stated to the committee that CPhA would like to recommend that board staff work with CPhA to modify this process to something to which the committee is comfortable.

President Law inquired, regarding the Maryland Pharmacy Board, where their review committee sits in the CPhA proposed model. Mr. Martinez stated that the committee, mandated by statute, sits at the beginning when the accusation is filed.

As part of the committee discussion, members expressed various areas of concern. Firstly, the charge of the board is the protection of consumers; to recommend a consortium of only pharmacists is in opposition to that concept. In addition, the membership criteria for CPhA's proposed advisory committee would exclude retired licensees who are still active members in the pharmacy profession. Mr. Weisser expressed his disappointment in the model proposed by CPhA.

SDAG Room presented a few possible legal objections to the CPhA proposal:

1) Committee members would have access to confidential information generally only shared with board staff who are subject to criminal and civil penalties for the potential release or abuse of private information.
2) The proposal could be considered a violation of statute or an unconstitutional delegation of this body's authority to another body. Creating the committee would require a statutory amendment.
3) By what process is a board of thirteen members going to appoint a subcommittee of five members?
4) The board has been previously briefed on anti-trust possibilities of treading to close to the line of having licensees exclusively policing other licensees under the North Carolina Dental Board case. If the board, which has been consciously constituted of professional and public members, were to delegate some portion of its authority to a subcommittee made up exclusively of members of the profession, who might have competitive interests involved in any case, the risks of liability, under the North Carolina case, would increase significantly. Other possible requirements like insisting on the president or executive officers be pharmacists, would put the members of the board in greater jeopardy for a trust violation.

SDAG Room stated he disagreed with Mr. Martinez's implication that the investigations performed by inspectors were somehow inferior due to an assumption incompetence, bias or inability to act as a jury of peers for their peers. SDAG Room stated most inspectors are dragged reluctantly to the conclusion that a member of their profession has failed the standards. Mr. Martinez stated that the proposal was not indicative of any feeling of biased or lack of confidence in the inspectors. He stated the intent of the proposal was to allow for discussion.

President Law stated that the proposal presented by CPhA was a concept that could be further developed. President Law explained that as the pharmacy profession progresses, there are different areas of specialization such as long-term care and Advanced Practice Pharmacists (APH). Many cases come to an inspector's attention, he stated that the board

cannot possibly have inspectors who are experts in all fields. President Law provided an example of an inspector who may have expert-level experience at a hospital pharmacy but may not have experience in a retail pharmacy. President Law stated there might be a place for the use of peer expertise in these particular areas to advise the board in decision making. President Law stated that he hopes to see in the future that as more difficult case come before the board, a way that the board can use different areas of expertise for Long-Term Care or APH. For example, if there is something wrong with an APH he hoped that there would be an APH expert to determine exactly if a practice is safe or just a simple mistake that may have just due to a lack of education. He stated looking forward it may not be a bad idea to explore this concept and expedite the process. President Law clarified that the proposal is a screening process and the final vote would still come to this board for consideration.

Ms. Freedman informed the committee that as an option the board has the authority pursuant to the BPC to hire subject-matter experts to assist and when they encounter a situation where the staff does not have the necessary expertise.

Mr. Weisser voiced his confidence in the level of diversity among the and backgrounds of inspectors as well as with the diversity of their training received at the board.

Dr. Wong stated that based on the possible breach of confidentiality, he proposed a committee of inspectors to review and approve recommendations, as opposed to a committee of persons outside of the board.

A member of the public stated that the proposed process would allow a licensee an opportunity to explain their side of the story to committee members before being sanctioned. Additionally, he informed the committee that the states of Iowa, Texas and Florida all allow licensees the opportunity to be heard. Another member of the public emphasized the specific need to seek pharmacists who are experts in the area of collaborative drug therapy pharmacy, to consult and guide the process; he suggested there are more areas in which investigators and board members need guidance, due to lack of in-house experience.

Ms. Sodergren stated that this year, the board has referred about 150 cases to the AG's office.

DCA Counsel Kelsey Pruden, provided the committee members with an overview of the review process for the State of Texas. SDAG Room stated that other than the inclusion of a board member, the Texas process is the same as California. SDAG Room explained that every administrative case offers the licensee the opportunity to seek settlement by communication with the AG's office to arrange a settlement conference with Office of Administrative Hearings.

President Law asked if the board could pay for per diem experts. SDAG Room confirmed that the board could hire experts and has already done so in the past

The committee heard comment from Lauren Walmsey of Walgreens who serves on the Arizona Pharmacy Board. She informed the board that in Arizona all disciplinary matters start

at a sub-committee level discussion, made up of a public member, a pharmacy technician and two practicing pharmacists who are all board members appointed by the Governor. The committee makes a recommendation on the discipline and the full board decides how to move forward. An investigator conducts an investigation, an investigation summary is written, the summary is reviewed by the committee, and then a recommendation is made by the committee. The committee may recommend dismissing the case, formal discipline, or suggest continuing education. SDAG Room clarified that in AZ there is no requirement for a pleading to be filed prior to discipline. Ms. Walmsey responded that each state has a variety of ways to handle disciplinary cases, pursuant to each state's statutes.

As part of the public discussion, a community pharmacist, stated that if a licensee was afforded the right to present testimony prior to disciplinary action, it would allow for a learning opportunity to identify barriers and discuss what tools or assistance are available to correct the violation as well as open lines of communication between the board and licensees. Another member of the public called attention to the inconsistency of disciplinary actions for similar violations; she supported the idea of using expert consultants before determining formal disciplinary action.

President Law acknowledged that board members are not always provided the opportunity to hear the licensees side of the case. He stated the committee is trying to determine a process which helps the profession and protects the consumer.

Mr. Weisser stated that when presented with the opportunity to vote on a case he reviews all materials provided and he is given the option to agree, disagree and/or comment. Mr. Lippe stated that the board policy is that if two members object then the case is brought back to the board.

Ms. Freedman confirmed with committee members that the committee requests a future discussion on how the enforcement program is structured.

The committee directed board staff to explore additional avenues and granted permission for staff to work with the chair of the committee.

DCA Counsel suggested that the committee request a future discussion on how the enforcement program is structured. President Law agreed and directed board staff to research other state enforcement models and continue the discussion on disciplinary matters

15. **Review of Final Report Submitted by 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)**
Ms. Sodergren informed the committee that the study will end in June 2019 and the board should expect to receive a final report in Fall 2019.

16. **Discussion and Consideration of Proposed Changes to Self-Assessment Forms Incorporated by Reference in Title 16, California Code of Regulations, Section 1715 and 1784**
Chairperson Schaad informed the committee that CCR section 1715 establishes the requirements for completion of the pharmacy and hospital pharmacist self-assessment forms. CCR section 1784

establishes a similar requirement for completion of a wholesaler self-assessment. In all cases, the self-assessment is a compilation of relevant laws that are intended to allow for the entity to self-evaluate compliance with various provisions of law. Because the various forms are incorporated by reference in the respective regulation sections, a regulation change is necessary whenever the forms require update. The proposed revisions incorporate recent changes to pharmacy law. Copies of these forms are available near the sign in sheet for the meeting. A copy of the proposed revised forms was included in the meeting materials.

Motion: Recommend to the board approval of the draft self -assessment forms.

M/S: Weisser/Sanchez

Support: 6 Oppose: 0 Abstain: 0

17. **Discussion and Consideration of Title 16, California Code of Regulations, Section 1715.6 Related to the Reporting of Drug Losses**

Chairperson Schaad stated that as part of the committee's discussion on the development of its inventory reconciliation requirements, the requirement to report drug losses was discussed. He explained an owner is required to report any loss of a controlled substance, including the amount and strength. This report must be made to the board within 30 days.

Previous discussions noted the difference between California Law and DEA reporting requirements. Included in the chair report was data for both types of loss reports for several fiscal years and the first six months of FY 2018/19. Also included was a breakdown of the number of reports received based upon the loss in dosage units. Ninety-one percent of loss reports indicated a loss of less than 100 dosage units.

President Law acknowledged that the number of drug losses has reduced significantly but noted concern over the 17 cases identified with over losses over 10,000.

As part of public comment, Dr. Gray stated he has been asked about the new regulation regarding inventory and reconciliation every quarter and for every controlled substance. He stated the implication is that on all the other controlled substances, Schedules 3, 4 and 5, there also must be a reconciliation. If they have to report every missing tablet, it means each time they do a reconciliation on that many products, they would have something missing. If there is no ability to say if a loss is significant then pharmacies would rather wait once every two years to inventory Schedules 3, 4 and 5. He requested that the committee revisit the process of reporting drug losses to do what DEA does and establish criteria for reporting a loss, which varies depending on the schedule of the controlled substance. Paige Talley of CCAP, encouraged the committee to determine a definition of "significant loss" in numbers.

Ms. Freedman advised the committee that the board would have to describe what significant means to the board and create standards.

Ms. Sodergren suggested, and the board agreed, that staff would survey a couple other states for their drug loss reporting requirements and research the types of drugs that are in that 0 to 100 threshold.

Dr. Wong asked if a drug loss could be submitted electronically. Ms. Sodergren stated that the board is working on an interface to submit losses electronically.

Mr. Weisser left the meeting at 3:24 p.m.

18. **Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask An Inspector Program**

This item was moved to the next committee meeting.

19. **Discussion and Consideration of Board's Enforcement Statistics**

Chairperson Schaad informed the committee that they have been provided a copy of the enforcement statistics reflecting data from July 1, 2018, through February 28, 2019.

The committee agreed to review the data, and if they have any questions, they would be addressed at the next committee meeting.

20. **Future Meeting Dates**

Chairperson Schaad stated that the next meetings are scheduled for July 2, 2019 and September 25, 2019.

The meeting adjourned at 3:31 p.m.

ATTACHMENT 2

CCR 1715.65

Reconciliation FAQ

1715.65. Inventory Reconciliation Report of Controlled Substances

(a) 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.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

(c) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:

(1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

(2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) 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; and

(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(d) A pharmacy or clinic shall report in writing 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 in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances.

(e) The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory and countersigned by the pharmacist-in-charge or professional director (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever

possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).

(g) For inpatient hospital pharmacies, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

(h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

(1) All controlled substances added to an automated drug delivery system are accounted for;

(2) Access to automated drug delivery systems is limited to authorized facility personnel;

(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and

(4) Confirmed losses of controlled substances are reported to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

Inventory Reconciliation Regulation – Summary and FAQs

California Code of Regulations, title 16, section 1715.65, Inventory Reconciliation Report of Controlled Substances took effect April 1, 2018.

Section 1715.65. Inventory Reconciliation Report of Controlled Substances

(a) 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.

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) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

Subsection (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) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:

(1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

(2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) 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; and

(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

Subsection (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).

Collection and retention of records to compile each inventory report.

The report must identify the possible causes of overages.

(d) **A pharmacy or clinic shall report in writing 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 in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances**.

Subsection (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) **The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report**.

Subsection (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) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).

Subsection (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, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

Subsection (g) requires INPATIENT HOSPITAL PHARMACIES to complete 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) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

1) **All controlled substances added to an automated drug delivery system are accounted for;**
2) **Access to automated drug delivery systems is limited to authorized facility personnel;**
3) **An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and**
4) **Confirmed losses of controlled substances are reported to the board.**

Subsection (h) requires the PIC of any pharmacy servicing an AUTOMATED DRUG DELIVERY SYSTEM (regardless of location) 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.**

FAQs about CCR section 1716.65

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.

19. How does a reconciliation report help detect drug diversion?

A reconciliation report aids in the identification of controlled substance inventory discrepancies. Pharmacies can respond to inventory shortages or overages by initiating a close review, which may aid in detection of drug diversion. Recording of an inventory alone lacks review and analysis of acquisition and disposition information.

20. Wouldn't a perpetual inventory identify diversion?

A perpetual inventory is a beneficial tool and may aid in identification of drug diversion. However, a perpetual inventory with no discrepancies is not evidence of a lack of diversion. A perpetual inventory may only account for known drug acquisitions and dispositions. If acquisition invoices are destroyed or fraudulent prescriptions are processed and later deleted, a perpetual inventory may show no discrepancies. Further, all categories of drug acquisition and disposition may not be entered into a perpetual inventory.

21. The computer already counts acquisitions and dispositions of Schedule II controlled substances for the perpetual inventory. Is the count in the computer sufficient for the reconciliation report?

No. Electronic records can be used to aid in calculation of total acquisition and disposition information for the reconciliation report, but this information must be used in conjunction with an initial physical count and a final physical count to complete the requirement of CCR 1715.65. Any electronic records used should be reviewed for unauthorized manipulation and evaluated against other available records for consistency. Other records may include hard copy drug acquisition invoices, purchase orders, signatures for dangerous drug deliveries, drug acquisition summaries from wholesalers, reverse distribution documents, return to wholesaler for credit documents, drug destruction documents and/or hard copy prescription documents.

22. In an inpatient pharmacy, would "disposition" of Schedule II drugs refer to drugs that are 1) supplied into an ADDS (Pyxis, Omnicell, etc.) or as floor stock; or 2) dispensed to the patient?

In an inpatient pharmacy, disposition would refer to medications dispensed directly to the patient. Please see additional requirements for inpatient hospital pharmacies found in 1715.65(g)-(h).

23. Does the regulation require a reconciliation of all controlled substances or only Schedule II controlled substances?

As referenced in 1715.65(c), the compilation of a quarterly inventory reconciliation report is required only for all federal Schedule II controlled substances. However, as referenced in 1715.65(a), every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, still must perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. Additionally, other sections of pharmacy law (BPC 4081 and CCR 1718) require a pharmacy to have complete accountability of all dangerous drugs handled by every licensee.

24. Could you provide more guidance on periodic reconciliations of Schedule III – V drugs? For example, can Schedule III-V counts be estimates – as allowed for biennial inventories – or

must they also be exact counts? Should Schedule III-V reconciliations be done more frequently?

CCR 1715.65(c)(1) requires a physical count, not an estimate of, of all quantities of federal Schedule II controlled substances. The regulation is silent regarding estimation of Schedule III – V counts; however, because BPC 4081 and CCR 1718 require licensees, including a pharmacy, to have complete accountability of all dangerous drugs, it is recommended Schedule III – V drugs be exact counts.

25. **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. But the regulation only specifies the 90-day 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 and under the circumstances of the pharmacy.

26. **I am the PIC of a pharmacy that is so small there are no other staff. Do I still have to complete a reconciliation report, or is the perpetual inventory sufficient?**

    Yes. All pharmacies, regardless of size or staff, that stock federal Schedule II controlled substances must comply with CCR 1715.65.

27. **I work in a chain pharmacy, where we store the data used to perform the reconciliation at the corporate level and keep a signed face sheet in the pharmacy. Are the acquisition and disposition records used to complete the reconciliation report required to be attached to the reconciliation/signature page?**

    Attachment is not mentioned in the regulation, but as referenced in 1715.65(c)(4), 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. The board recommends all documents related to compilation of an inventory reconciliation report be stored together.

ATTACHMENT 3

Drug Loss Report

Drug Name	Sum of Dosage Units
Alfentanil Total	**1**
Alfentanil syringe	1
Alprazolam Total	**1,907**
Alprazolam tablet	1,572
Alprazolam unknown form	335
Amphetamine Total	**109**
Amphetamine capsule	1
Amphetamine ml	45
Amphetaminetablet	19
Amphetamine unknown form	44
Amphetamine Salts Total	**2,443**
Amphetamine Salts capsule	859
Amphetamine Salts tablet	1,553
Amphetamine Salts unknown form	31
Armodafinil Total	**61**
Armodafinil tablet	31
Armodafinil unknown form	30
Buprenorphine Total	**105**
Buprenorphine Film	3
Buprenorphine patch	1
Buprenorphine tablet	76
Buprenorphine unknown form	25
Buprenorphine/Naloxone Total	**229**
Buprenorphine/Naloxone Film	115
Buprenorphine/Naloxone tablet	107
Buprenorphine/Naloxone unknown form	7
Butalbital/APAP/Caffeine Total	**19**
Butalbital/APAP/Caffeine capsule	12
Butalbital/APAP/Caffeine tablet	7
Butalbital/Aspirin/Caffeine Total	**34**
Butalbital/Aspirin/Caffeine capsule	32
Butalbital/Aspirin/Caffeine tablet	1
Butalbital/Aspirin/Caffeine unknown form	1
Butalbital/Codeine/APAP/Caffeine Total	**25**
Butalbital/Codeine/APAP/Caffeine capsule	22
Butalbital/Codeine/APAP/Caffeine tablet	3
Butalbital/Codeine/Aspirin/Caffeine Total	**33**
Butalbital/Codeine/Aspirin/Caffeine tablet	33
Butorphanol Total	**2**
Butorphanol ml	1
Butorphanol vial	1
Butorphanol Tartrate Total	**1**
Butorphanol Tartrate ml	1
Carisoprodol Total	**421**
Carisoprodol tablet	368
Carisoprodol unknown form	53

Drug Name	Sum of Dosage Units
Chlordiazepoxide Total	**74**
Chlordiazepoxide capsule	62
Chlordiazepoxide tablet	11
Chlordiazepoxide unknown form	1
Chlordiazepoxide/Clidinium Total	**19**
Chlordiazepoxide/Clidinium capsule	15
Chlordiazepoxide/Clidinium tablet	4
Clobazam Total	**14**
Clobazam tablet	13
Clobazam unknown form	1
Clonazepam Total	**1,425**
Clonazepam ml	21
Clonazepam tablet	1,158
Clonazepam unknown form	246
Clorazepate (Clorazepic acid) Total	**3**
Clorazepate (Clorazepic acid) tablet	2
Clorazepate (Clorazepic acid) unknown form	1
Cocaine Total	**20**
Cocaine GM	20
Codeine Total	**39**
Codeine tablet	38
Codeine unknown form	1
Codeine/APAP Total	**645**
Codeine/APAP ml	168
Codeine/APAP tablet	449
Codeine/APAP unknown form	28
Codeine/Aspirin Total	**3**
Codeine/Aspirin unknown form	3
Codeine/Guaifenesin Total	**94**
Codeine/Guaifenesin ml	94
Dexmethylphenidate Total	**90**
Dexmethylphenidate capsule	43
Dexmethylphenidate tablet	43
Dexmethylphenidate unknown form	4
Dextroamphetamine Total	**121**
Dextroamphetamine capsule	75
Dextroamphetamine tablet	44
Dextroamphetamine unknown form	2
Diazepam Total	**712**
Diazepam ml	7
Diazepam syringe	1
Diazepam tablet	640
Diazepam unknown form	64
Diphenoxylate/Atropine Total	**68**
Diphenoxylate/Atropine ml	12

Drug Name	Sum of Dosage Units
Diphenoxylate/Atropine tablet	51
Diphenoxylate/Atropine unknown form	5
Dronabinol Total	**61**
Dronabinol capsule	61
Estrogen Total	**19**
Estrogen unknown form	19
Estrogen/Methyltestosterone Total	**26**
Estrogen/Methyltestosterone unknown form	1
Estrogen/Methyltestosterone tablet	25
Eszopiclone Total	**246**
Eszopiclone tablet	221
Eszopiclone unknown form	25
Fentanyl (Dermal, Transmucosal, or Injection) Total	**201**
Fentanyl (Dermal, Transmucosal, or Injection) MCG	50
Fentanyl (Dermal, Transmucosal, or Injection) ml	113
Fentanyl (Dermal, Transmucosal, or Injection) patch	11
Fentanyl (Dermal, Transmucosal, or Injection) syringe	6
Fentanyl (Dermal, Transmucosal, or Injection) unknown form	10
Fentanyl (Dermal, Transmucosal, or Injection) vial	11
Hydrocodone Total	**44**
Hydrocodone ml	10
Hydrocodone tablet	18
Hydrocodone unknown form	16
Hydrocodone/APAP Total	**6,888**
Hydrocodone/APAP ml	142
Hydrocodone/APAP tablet	6,447
Hydrocodone/APAP unknown form	300
Hydrocodone/Chlorpheniramine Total	**195**
Hydrocodone/Chlorpheniramine ml	195
Hydrocodone/Homatropine Total	**217**
Hydrocodone/Homatropine ml	166
Hydrocodone/Homatropine tablet	51
Hydrocodone/Ibuprofen Total	**64**
Hydrocodone/Ibuprofen tablet	64
Hydromorphone Total	**455**
Hydromorphone ampule	5
Hydromorphone carpuject/tubex	20
Hydromorphone MG	5
Hydromorphone ml	22
Hydromorphone syringe	15
Hydromorphone tablet	306
Hydromorphone unknown form	68
Hydromorphone vial	15
Hydromorphone/APAP Total	**1**
Hydromorphone/APAP tablet	1

Drug Name	Sum of Dosage Units
Ketamine Total	**75**
Ketamine MG	60
Ketamine ml	7
Ketamine syringe	7
Ketamine vial	1
Lacosamide Total	**211**
Lacosamide tablet	211
Lisdexamfetamine Total	**320**
Lisdexamfetamine capsule	255
Lisdexamfetamine unknown form	166
Lisdexamfetamine tablet	34
Lorazepam Total	**1,738**
Lorazepam MG	2
Lorazepam ml	26
Lorazepam syringe	1
Lorazepam tablet	1,516
Lorazepam unknown form	31
Lorazepam vial	28
Meperidine Total	**4**
Meperidine ampule	1
Meperidine ml	0
Meperidine syringe	1
Meperidine tablet	2
Methadone Total	**258**
Methadone ml	6
Methadone syringe	3
Methadone tablet	231
Methadone unknown form	18
Methylphenidate Total	**1,194**
Methylphenidate capsule	129
Methylphenidate ml	2
Methylphenidate tablet	1,050
Methylphenidate unknown form	13
Midazolam Total	**25**
Midazolam MG	8
Midazolam ml	5
Midazolam syringe	2
Midazolam tablet	2
Midazolam vial	8
Modafinil Total	**123**
Modafinil tablet	122
unknown form form	1
Morphine Total	**998**
Modafinil ampule	1
Modafinil capsule	34

Drug Name	Sum of Dosage Units
Modafinil carpuject/tubex	18
Modafinil MG	21
Modafinil ml	111
Modafinil syringe	20
Modafinil tablet	686
Modafinil unknown form	65
Modafinil vial	42
Opium (incl. tinctures) Total	**3**
Opium (incl. tinctures) ml	3
Opium/Belladonna Total	**2**
Opium/Belladonna supp	2
Oxazepam Total	**2**
Oxazepam capsule	1
Oxazepam tablet	1
Oxycodone Total	**2,036**
Oxycodone capsule	25
Oxycodone MG	10
Oxycodone ml	13
Oxycodone tablet	1,787
Oxycodone unknown form	201
Oxycodone/APAP Total	**1,718**
Oxycodone/APAP tablet	1,669
Oxycodone/APAP unknown form	49
Oxycodone/Aspirin (ASA) Total	**4**
Oxycodone/Aspirin (ASA) tablet	4
Oxymorphone Total	**2**
Oxymorphone tablet	2
Perampanel Total	**30**
Perampanel tablet	30
Phendimetrazine Total	**5**
Phendimetrazine unknown form	5
Phenobarbital Total	**234**
Phenobarbital ml	24
Phenobarbital tablet	209
Phenobarbital unknown form	1
Phentermine Total	**258**
Phentermine capsule	148
Phentermine tablet	107
Phentermine unknown form	3
Pregabalin Total	**718**
Pregabalin capsule	534
Pregabalin tablet	148
Pregabalin unknown	36
Promethazine/Codeine Total	**496**
Promethazine/Codeine ml	493

Drug Name	Sum of Dosage Units
Promethazine/Codeine unknown form	3
Promethazine/Codeine/Phenylephrine Total	**59**
Promethazine/Codeine/Phenylephrine ml	59
Remifentanil Total	**1**
Remifentanil ml	0
Remifentanil syringe	1
Suvorexant Total	**66**
Suvorexant tablet	66
Tapentadol Total	**87**
Tapentadol tablet	86
Tapentadol unknown form	1
Temazepam Total	**246**
Temazepam capsule	111
Temazepam tablet	82
Temazepam unknown form	53
Testosterone Total	**164**
Testosterone grams (g)	75
Testosterone ml	4
Testosterone pump	83
Testosterone unknown form	2
Tramadol Total	**1,264**
Tramadol tablet	1,163
Tramadol unknown	101
Tramadol/APAP Total	**3**
Tramadol/APAP tablet	1
Tramadol/APAP unknown form	2
Triazolam Total	**44**
Triazolam tablet	43
Triazolam unknown form	1
Zaleplon Total	**166**
Zaleplon capsule	86
Zaleplon tablet	80
Zolpidem Total	**1,521**
Zolpidem tablet	1,190
Zolpidem unknown form	331
Grand Total	**31,211**

ATTACHMENT 4

Draft Statutory Proposal

Proposal to Add Section 4300.2

Notwithstanding the provisions of Government Code section 11415.60, the Executive Officer may offer, and a licensee may accept, a stipulated agreement to license discipline without and in advance of the filing of an accusation or other agency pleading, under the following conditions:

1. The board conducted an inspection or investigation as provided for in this chapter and substantiated violations of law.
2. The board advised the licensee of the substantiated violations in writing.
3. The licensee, within 15 days of being advised of the violations, notified the board in writing of his or her willingness to waive the administrative adjudication provisions of the Administrative Procedure Act, including notice and hearing requirements, and to consider a pre-filing settlement as an alternative to action taken on the basis of a pleading. The Executive Officer retains discretionary authority to extend the deadline to respond in writing beyond 15 days.
4. The agreed settlement is based on the violations alleged or found, and any discipline proposed is consistent with the board's Disciplinary Guidelines.

If no pre-filing settlement between the Executive Officer and the licensee is agreed to in writing within 60 days of the licensee's notification of waiver, the Executive Officer may proceed to direct the Attorney General's Office to prepare the appropriate pleading.

Any pre-filing settlement agreement reached between the Executive Officer and a licensee is contingent on approval by the board itself. The board itself retains full authority and discretion to adopt or reject any such agreement. If the agreement is rejected by the board itself, the Executive Officer may offer a revised pre-filing settlement agreement consistent with any guidance from the board itself or may proceed to direct the Attorney General's Office to prepare the appropriate pleading.

ATTACHMENT 5

Draft FAQ

Ask An Inspector Program

FREQUENTLY ASKED CONTROLLED SUBSTANCE QUESTIONS FOR SCRIPT NEWSLETTER

Question #1: How long is a controlled substance prescription valid from the date written?

Answer: No person shall dispense or refill a controlled substance prescription more than six months after the date the prescription was written.

References: Health and Safety Code (HSC) 11200, 11166

Question #2: Can a pharmacy in California fill an e-Script for a Schedule II controlled substance received from a physician in another state?

Answer: Sometimes. A California pharmacy may fill a Schedule II prescription from an out of state physician for delivery to a patient in another state if the prescription complies with all prescription requirements from the physician's state. (The pharmacy must still report the prescription to CURES.)

If the prescriber is out of state and is licensed to practice in California, pursuant to California's telehealth law, a pharmacy may fill the Schedule II prescription, if the patient is in CA.

However, if the prescriber is out of state and is not licensed in California, and the patient is in CA, the CA pharmacy cannot fill the Schedule II prescription.

References: HSC 11164.1, HSC 11164.5; Business and Professions Code (BPC) 4005(b); Title 16, California Code of Regulations (CCR) 1717(d), BPC 4059.5(e), BPC 2290.5; Title 21 Code of Federal Regulations (CFR) 1306.08.

Question #3: Am I required to transmit to CURES when I dispensed zero controlled substance prescriptions?

Answer: Yes. The Department of Justice sent out a notification on December 9, 2010 of the significant changes including reporting zero controlled substance dispensed (zero fills). Instruction on how to submit zero fill refer to the Prescription Drug Monitoring Program Instruction Manual prepared by Atlantic Associates at https://www.aaicures.com/Atlantic_Associates_CACures_Instructions.pdf
References: July 2011 Script Newsletter, HSC 11165

Question #4: What needs to be in the prescriber's handwriting for a controlled substance prescription to be valid?

Answer: The prescriber must sign and date a controlled substance prescription form in ink. However, prescription forms ordered pursuant to HSC 11162.1(c) that are printed by a computerized prescription generation system by a licensed health care facility, a clinic specified in HSC 1200, or a clinic specified in HSC 1206(a) that has 25 or more physicians or surgeons, the date may be printed.

References: HSC 11162.1, 11164(a)(1), March 2013 Script Newsletter

Question #5: If there is an error on a controlled substance prescription, such as the wrong directions, what information can be corrected by the pharmacist?

Answer: Upon receiving a controlled substance prescription containing an error, such as wrong directions, the pharmacist must contact the prescriber to obtain information to validate the prescription. Other than the prescriber's signature and date of the prescription which are required to be written in ink by the prescriber, the pharmacist can document the information obtained from the prescriber, such as the correct directions, on the prescription. Standard of practice includes documenting the date, the name of person authorizing the correction, and the pharmacist's initials.

References: CCR 1761, HSC 11162.1, 11164(a)(1)(2), July 2011 and March 2012 Script Newsletter

Question #6: When can a pharmacy partially fill a Schedule II controlled substance?

Answer: There are four scenarios where a pharmacist may dispense a partial quantity for a Schedule II controlled substance prescription.

Scenario 1: If a pharmacist is unable to supply a full quantity of the prescription, the remaining portion may be filled within 72 hours.

Scenario 2: A prescription for a terminally ill patient may be partially filled any number of times, provided the total quantity dispensed in all fills does not exceed the written quantity. The prescription must be tendered and at least partially filled within 60 days of the date issued. No portion may be dispensed more than 60 days from the date issued.

Scenario 3: A prescription for a patient in a long-term care facility may be partially filled any number of times, provided the total quantity dispensed does not exceed the written quantity. The prescription must be tendered and at least partially filled within 60 days of the date issued. No portion may be dispensed more than 60 days from the date issued.

Scenario 4: A prescription may be partially filled if requested by the patient or the prescriber. the total quantity dispensed in all partials fills cannot exceed the total prescribed. Any remaining portion must not be filled more than 30 days after the date the prescription was written.

References: 21 CFR 1306.13, 21 USC 829(f), CCR 1745, BPC 4052.10, HSC 11159.3, March 2018 Script Newsletter.

Question #7: Does the supervising prescriber's name required to be on the controlled substance prescription form, if a physician assistant, nurse practitioner, or pharmacist is writing the prescription?

Answer:

Physician Assistant prescription: Controlled substance prescriptions written by a physician assistant for controlled substances is required to have preprinted the supervising physician's name, category of licensure, license number, federal controlled substance registration number, address, and telephone number on the prescription form meeting the requirements of HSC 11162.1. In addition, the physician assistant's name, license number, and federal controlled substance registration number must be printed or stamped on the controlled substance prescription with the signature of the physician assistant. The same information is also required for electronic prescriptions for controlled substances (EPCS).

Nurse Practitioner: Controlled substance prescriptions written by a nurse practitioner for controlled substances is required to have preprinted the nurse practitioner's name, category of licensure, license number, federal controlled substance registration number, telephone number and address. The signature of the nurse practitioner is deemed to be the signature of the prescriber.

Pharmacist: Controlled substance prescriptions authorized by a pharmacist are required to have preprinted the pharmacist's name, category of licensure, license number, federal controlled substance registration number, telephone number and address. The signature of the pharmacist is deemed to be the signature of the prescriber.

Reference: HSC 11162.1(a)(9), BPC 4040(a)(1)(D), BPC 3502.1(d), BPC 2836.1, BPC 4052(b)

Question #8: A doctor in my building wants to purchase a #100 count bottle of Norco and two #100 count bottles of alprazolam 1mg for office use. Is it okay to process the purchase as a prescription?

Answer: No. A prescription may not be issued as a means for a doctor to obtain controlled substances for supplying the individual doctor for the purpose of general dispensing to his/her patients. The purchase of the controlled substance must be under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the controlled substance, and the quantity. If the controlled substance is a Schedule II, the doctor must also provide the pharmacy a DEA Form 222 for the Schedule II controlled substance(s).

References: 21 CFR 1306.04(b), BPC 4059(b)

Question #9: Can a California pharmacist fill a controlled substance prescription written by a military-based physician, even though the prescribing physician is not licensed in California, but licensed in another state?

Answer: Yes. Military dependents often obtain prescriptions from their military base facilities but take the prescriptions to California retail pharmacies for filling. In many cases the physicians are not licensed in California. Section 1301.23 of Title 21, Code of Federal Regulations (21 CFR) waive the requirement of registration of any official (physician) of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not procure or purchase, controlled substances in the course of his/her official duties.

The physicians listed in the above military base facilities, Public Health Services, or Bureau of Prisons, must follow the procedures set forth in 21 CFR 1306 regarding prescriptions and must state the branch of service or agency and the service identification number of the issuing official in lieu of the registration number required on prescription forms.

Each paper prescription must have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

References: 21 CFR 1301.23, 1306.05(h)

Question #10: I noticed the manufacturer bottles for Donnatol and Fioricet do not have any federal controlled substance schedule marking on the bottles. Are Donnatol and Fioricet classified as a controlled substance in California?

Answer: Federal law exempts Donnatol and Fioricet as controlled substances. However, California law does not have the same exemption. Therefore, Donnatol is classified as a Schedule IV controlled substance due to the phenobarbital component and Fioricet a Schedule III controlled substance due to the barbituric component.

Answer: HSC 11057(d)(26), 11056(c)(3), 21 CFR 1308.32

Question #11: Can I transfer a Schedule II Controlled Substance prescription to another pharmacy that was entered into the computer, placed on hold and never dispensed?

Answer: The answer depends on how the Schedule II prescription was received.

Paper prescription: If the Schedule II controlled substance prescription was received in paper form, then the answer is no. No Schedule II controlled substance prescription can be dispensed without a prescription meeting the requirements of HSC 11164, and the receiving pharmacy must have a compliant paper prescription from which to fill.

However, a patient may pick up the unfilled prescription from the first pharmacy and take the paper prescription form to another pharmacy.

Electronic prescription: Although DEA regulations does not allow for the transfer of an unfilled Schedule II controlled substance prescription in any form, in 2017, DEA issued written policy statements that an unfilled electronic prescription for controlled substance (EPCS), including Schedule II, may be transferred from one DEA registered pharmacy to another DEA registered pharmacy, provided the EPCS is transmitted electronically. The Board follows DEA's policy guidance in applying DEA regulations.

Schedule II controlled substance prescriptions may be transmitted electronically from a retail pharmacy to a central fill pharmacy. Refer to 21 CFR 1306.15 for the required documentation for the retail pharmacy transmitting the prescription information and the central fill pharmacy receiving the electronic transmitted prescription. Although permitted under federal law, California law prohibits transmitting (including transferring) a Schedule II controlled substance prescription by facsimile.

Federal law requires certain documentation for pharmacies transmitting prescriptions. See 21 CFR 1306.15 and 1306.25 for guidance.

References: HSC 11158(a); HSC 11164(b), 21 CFR 1306.15; See also July 2011, March 2013 and October 2017 issues of the Script Newsletter, https://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm

ATTACHMENT 6

Script Article

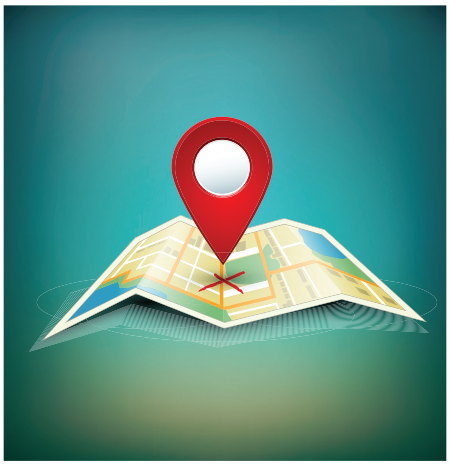
Your Address of Record is Available to Public

Your address of record is available to public

Licensees should be aware that once you are licensed by the Board of Pharmacy, the address of record you provided on your license application form becomes public information, pursuant to the California Public Records Act (Government Code section 6250 *et seq.*).

Your address of record is visible in a public search of license records on the board's website. It is also the location where the board sends all official correspondence – including licenses, permits and renewal notices.

If you do not want your home address to be available to the



public, you may provide an alternate address – a post office box, personal mailbox or other location – as your address of record. Be sure to check this location regularly for official mail from the board.

If your address of record is not your home, you must also provide the board with your residence address, which will be kept confidential. Licensees must notify the board of a change in home address or address of record within 30 days.

To notify the board of a change in your address of record or your home address, you may go the Change of Address and/or Name page at the board's website. You may change your address online or download and fill out a change-of-address form for mailing to the board.

PRP - a personal experience

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Although there were no criminal charges filed, I did make a statement to the Board of Pharmacy describing specifically any controlled substances I had taken from the store. For my actions, the Board of Pharmacy placed my license on five years' probation. After four and one-half years I appealed, and my license was released from probation.

Now, 23 uninterrupted years later, I am still alcohol- and substance-free. My family life is lovely, I am spiritually connected, and I have been practicing in the same outpatient pharmacy for 21 years.

Current studies show that up to 15 percent of nurses, doctors and pharmacists will misuse or abuse controlled substances without a prescription during their career. Another study shows up to 46 percent of all pharmacists have used a controlled substance at some point without a prescription.

We think we can control it ... until we can't. "Institutional, local, and statewide impaired-physician programs are now available for the active treatment and rehabilitation of impaired healthcare professionals. Many of these programs are also designed to assist the clinician with re-entry into clinical practice. Rarely is punitive action taken when the health care provider undergoes successful treatment and ongoing follow-up management. Overall recovery rates for impaired health care professionals seem to be higher compared with other groups, particularly with intensive inpatient management and subsequent follow-up care." ("Impaired healthcare professional," Dr. Marie R. Baldisseri, Critical Care Medicine, 35(2):S106-S116, February 2007.)

The California Pharmacist Recovery Program is an excellent resource. As stated on the program's webpage, "Through this program, the chemically dependent or mentally troubled pharmacist is provided with the hope and assistance required for a successful recovery."

Dr. Leuck is a California pharmacist and publisher of VIEWPOINTRX, an opinion blog.

ATTACHMENT 7

Proposal to Amend BPC 4314

Proposal to Amend BPC 4314 as follows:

(a)The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b)Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c)Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d)Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

<u>(e) The issuances of a citation pursuant to subdivision (a) shall not be construed as disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.</u>