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

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

ENFORCEMENT COMMITTEE
CHAIR REPORT

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

The Enforcement Committee met on July 10, 2019.

a. Discussion and Consideration of Citation and Fine Program Including Summary of Presentation

Attachment 1

Background

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.

For several meetings we discussed aspects of the board's citation and fine program. Several provisions of pharmacy law that govern the board's citation and fine program including the board's authority to issue citations as well as the factors to be considered in assessing an administrative fine were provided to the committee.

During the May 2018 Board meeting, members suggested that staff consider using the abatement provisions, especially in cases where the violations involved medication errors. The committee continues our review of the citation and fine program; we received a presentation on the program and some common violations provided by Interim Executive Officer Anne Sodergren.

Committee Discussion and Action

As part of the committee discussion, the members were provided data on citations issued and the number of citations appealed as of June 25, 2019. Members were also informed of the significant increase in the Orders of Abatement, which is consistent with the board's mandates. Additionally, the top citation violation were provided along with examples of most commonly made errors and their outcomes. The committee was advised that moving forward a summary of the top violations resulting in the issuance of a citation will be included in the board's newsletter.

As part of the public discussion, inquiries arose regarding under what circumstances and conditions an Order of Abatement is issued. CPhA requested clarification on the criteria used to determine the issuance of an Order of Abatement.

No action was taken on this item. **Attachment 1** includes a copy of the presentation provided during the meeting.

b. Discussion and Consideration of Post Implementation Review of Inventory Reconciliation Requirements for Controlled Substances, Including Discussion and Consideration of Title 16, California Code of Regulations Section 1715.65

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

The board's inventory reconciliation requirements took effect in April 2018. Since that time the board has provided guidance documents including FAQs that are published on the board's website.

Board staff continue to receive questions regarding the regulation requirements. **Attachment 2** provides an example of the types of questions received.

Committee Discussion and Action

As part of the committee discussion, it was noted that in light of the recent enactment of the Automated Drug Delivery Systems (ADDS) provisions, it was appropriate to

complete a post implementation review of the regulation to determine if additional guidance or changes may be necessary to meet the board's policy goal of the regulation.

The committee was asked by board staff to consider what kind of policy direction the members want in respect to drugs in the ADDS devices in the hospital setting and the satellite locations.

As part of the public discussion, members of the public addressed hospitals procedures and existing internal control systems in relation to ADDS as well as roles and responsibilities of pharmacy staff in relation to the inventory of ADDS. In addition, clarification was requested on the Inventory Reconciliation Regulation - Summary and FAQ.

No action was taken on this item however the committee requested that comments on the current FAQs should be submitted to the board staff for consideration. **Attachment 2** includes a copy of the regulation language and the previously released related FAQs

c. Discussion and Consideration of Reporting of Drug Losses to the Board Pursuant to Title 16, California Code of Regulations, Section 1715.6

Attachment 3

Relevant Law

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."

Background

The board requires any drug loss to be reported, however under federal law, the DEA only requires the reporting of a significant drug loss.

The board has previously discussed this issue in the past and detailed the challenges with taking a similar approach to that of the DEA regarding reporting losses. Most notably previous advice that such a change could not be implemented because of the requirements of the Administrative Procedures Act.

Committee Discussion and Action

As part of the committee discussion, the committee directed board staff to work with the committee chair offline to review the current regulations and discuss the possible development a new reporting requirement.

As part of the public discussion, the committee was encouraged to evaluate the requirement to report "any loss" and to take into consideration the DEA sanction consequences, once a report is submitted. Additionally, the public recommended that the committee adopt regulations that mirror the DEA reporting requirements.

No action was taken on this item. Provided in **Attachment 3** is a summary of data regarding drug losses. Attachment 3 also provides additional information regarding the types of losses that fall within the 1-100 dosage unit range.

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

Attachment 4

Background

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.

During the last committee meeting, the committee received a presentation from CPhA regarding an alternative enforcement model. The committee did not agree with the presentation but requested that staff work on a possible alternative method.

Committee Discussion and Action

During the committee meeting, Ms. Sodergren provided a brief summary of a possible alternative method. Provided 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.

As part of the committee discussion, the committee agreed to the general direction of the proposal. Ms. Sodergren was given the authority to work with the committee chair on areas of concern and bring the matter back to committee.

As part of the public discussion, the committee heard opinion regarding the number of licensed board members participating on the panel tasked with reviewing the investigation and any mitigation. It was suggested that the committee may also wish to review the enforcement processes in the states of Arizona and Texas.

Committee Recommendation (Motion): *Allow board staff the authority to work with the committee chair on items discussed during the meeting and bring a revised proposal back to the committee.*

Provided in **Attachment 4** is a framework of a draft statutory proposal intended to detail the basic tenets of the proposal and a high-level flowchart of the suggested alternative resolution model.

e. 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 have 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.

Committee Discussion and Action

The committee agreed to invite the public to submit comments regarding the draft FAQ's to the board. Upon receipt of comments board staff will work with the committee chair to make any necessary changes in preparation for committee discussion and action at the next Enforcement Committee meeting.

No action was taken on this item. **Attachment 5** includes the draft FAQ's for the committee's review.

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

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

Committee Discussion and Action

Under California law, the address of record of board licensees is public information. With the exception for interns, this information is currently posted on the board's website. Such information has been posted since December 2003.

As part of the committee discussion, DCA Legal counsel informed the committee that even if an address is removed from the website the address or record would still be provided upon request.

As part of the public discussion, the committee was asked to consider the practicality of publishing licensee addresses of record, in light of the increase of crimes in connection with the opioid crisis; specifically, in making public personal addresses of those staff tasked with securing keys to pharmacies. In relation to this comment DCA legal counsel provided a reminder that the Address of Record does not have to be a licensee's personal address, the address provided could be the address of an employer. Further, it was noted that licensees of the Bureau of Cannabis Control similarly post the address of record for its licensees as do several other programs within the DCA.

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

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

The committee was provided 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.

SDAG Room discussed some of the current limitations the board has in such actions and identified some possible policy remedies. Ms. Sodergren suggested that as the board goes through Sunset Review this could be one of the challenges identified and an area where the board asks legislature to look at the issue and provide their input or recommendation.

Committee Recommendation (Motion): *Recommend to forward this issue to the Organizational Development Committee for development of an issue statement for inclusion into the Sunset Review.*

h. 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 has routinely advised requesting parties that citations do not constitute discipline, however it appears that other regulators may apply a different meaning to the board's action.

While the board's letter of admonishment provisions explicitly state that a letter of admonishment shall not be construed as a disciplinary action, there is not similar provision within the board's existing citation statutes.

For Committee Discussion and Consideration

As part of the public discussion, the public inquired on the board's National Practitioners Data Bank reporting practice as it relates to citations and fines. Board staff confirmed that since citations and fines are not considered disciplinary they are not reported to the NPDB.

Committee Recommendation (Motion): *Recommend to the board to sponsor statutory change to amend BPC section 4314, as included in the meeting materials.*

Provided in **Attachment 7** is section BPC section 4314, in its entirety along with the recommended language that could be used to establish such a similar provision.

i. Discussion and Consideration of Committee's Strategic Goals

Background

In 2016 the board finalized its current strategic plan.

For Committee Discussion and Consideration

The committee reviewed each of the goals as well as the status of action taken, if any.

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 to include in their routine inspections, pharmacy staff's compliance with consultation laws.

As part of the committee discussion, board staff was directed to research the number of routine inspections where consultation violations were identified. Staff will report back with that data at a future meeting.

As part of the public discussion, the public was informed that data regarding patient consultation violations has been provided in the past, but not part of the quarterly statistics.

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.

During the July 2019 meeting the committee considered 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.

As part of the committee discussion, it was agreed that the committee would agree to remove 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.

As part of the committee discussion, board staff was directed to start the collection of data in relation to the number of complaints submitted. The report will be made available to the committee in six months.

As part of the public discussion, it was confirmed that the brochure would be discussed at the next Public Education Committee meeting.

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.

As part of the committee discussion, it was agreed upon that the role and responsibility of the PIC will be discussed with the review of the Disciplinary Guidelines.

As part of the public discussion, the committee was informed that SB 476 is a two-year bill and will be discussed again in January 2020.

Committee Recommendation (Motion): *Remove Strategic Goal 2.6 "Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery," from the Enforcement Committee Strategic Goals.*

j. <u>Discussion and Consideration of Board's Enforcement Statistics</u>

Annual enforcement statistics were 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

No Action was taken on this item.

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

The committee discussed the need to establish a committee date in advance of the November 5, 2019 meeting. Upon identification of a date, the board's website will be update.

Additional meetings will be convened on the first day of the scheduled board meeting, consistent with the action from the board's May meeting.

ATTACHMENT 1

Citation Presentation

CALIFORNIA STATE BOARD OF PHARMACY ENFORCEMENT COMMITTEE MEETING

CITATIONS

Citations Issued

(*as of 6/25/2019)

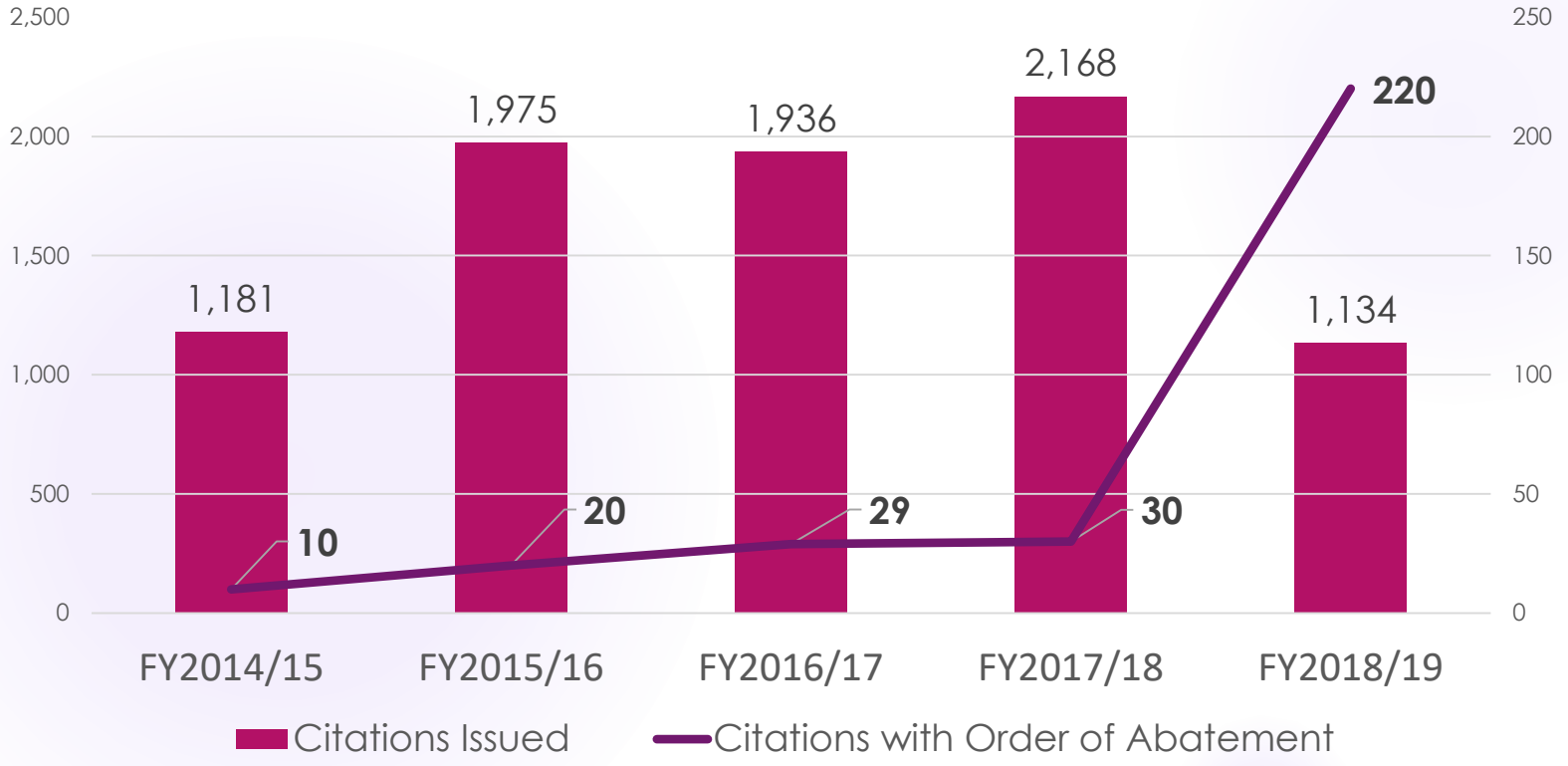
	FY2014/15	FY2015/16	FY2016/17	FY2017/18	FY2018/19
Citations Issued	1,181	1,975	1,936	2,168	1,134
Citations Issued Without Fine	208	376	439	504	339
Citations Issued With Fine	973	1,599	1,497	1,664	795
Fines Assessed	$1,699,080	$2,264650	$2,354,525	$2,268,625	$1,166,700
Fines Collected	$1,641,615	$2,145,398	$2,071,478	$2,079,806	$1,212,077

Citations Data Continued

(*as of 6/25/2019)

	FY2014/15	FY2015/16	FY2016/17	FY2017/18	FY2018/19
Citations Completed	1,245	1,753	1,855	2,112	1,116
Citations Appealed at Office Conference	110	201	191	140	148
Citations Appealed at the Attorney General's Office	54	54	61	50	29

Citations Issued/Orders of Abatement



www.pharmacy.ca.gov

Top Citation Violations April 1, 2019 through June 25, 2019

Violation Code	Description	Number of Violations by License Type	Total	Average Fine	Fine Amounts
CCR 1716	Medication Error	PHY - 33 RPH - 30	63	$ 1,089	32 Without a Fine 31 With Fines From $250 to $5,000
CCR 1714(b)	Pharmacy Security / Drug Loss	PHY - 28 RPH - 11	39	$ 1,200	18 Without a Fine 21 With Fines From $200 to $5,000
BPC 4081(a)	Records Kept Open for Inspection 3 Years	PHY - 13 RPH - 12 WLS - 1 EXC - 1	27	$ 1,650	17 Without a Fine 10 With Fines From $250 to $5,000
BPC 4301(l)	Unprofessional Conduct - Conviction of a Crime	RPH - 2 TCH - 20 INT - 5	27	$ 668	4 Without a Fine 23 With Fines From $75 to $1,200
BPC 4301(h)	Unprofessional Conduct - Self Administration	RPH - 2 TCH - 20 INT - 5	27	$ 717	24 Without a Fine 3 With Fines From $500 to $900

Top Citation Violations April 1, 2019 through June 25, 2019 (Continued)

Violation Code	Description	Number of Violations by License Type	Total	Average Fine	Fine Amounts
CCR 1764	Unauthorized Disclosure of Prescriptions	PHY - 11 RPH - 3 NRP - 2	16	$ 2,250	10 Without a Fine 6 With Fines From $500 to $5000
CIV 56.10	Disclosure of Protected Health Information	PHY - 10 RPH - 3 NRP - 1	14	$ 2,000	11 Without a Fine 3 With Fines From $500 to $5000
CCR 1718	Current Inventory Defined	PHY - 4 RPH - 6	10	$ 1,950	5 Without a Fine 5 With Fines From $250 to $5000
CCR1711(d)	Quality Assurance Program - develop pharmacy systems and workflow processes	PHY - 5 RPH - 3	8	$ 1,250	3 Without a Fine 5 With Fines From $500 to $2000
H&SC 11165(d)	Failure to Report to CURES	PHY - 4 RPH - 2	6	$ 3,417	3 Without a Fine 3 With Fines From $250 to $5000

Citations Examples: Medication Errors/ Prescription Disclosure Errors

	Fine
CCR 1716 Variation from a Prescription (Medication Error) Pharmacist filled a prescription on two different dates to a patient with the wrong prescriber information.	• Cite no fine to pharmacy • Cite no fine to pharmacist
Prescription was written for glyburide 10mg and pharmacist filled it with glipizide 5mg.	• Cite no fine to pharmacy • $500 to pharmacist (with abatement)
Pharmacist dispensed ear drops (Debrox) instead of artificial tears eye drops as prescribed.	• $500 to the Pharmacy (past history included med error and drug loss of promethazine) • $500 to the Pharmacist in Charge
Prescription label read to take prescription four times daily instead of three times daily as prescribed.	• Cite no fine to pharmacy • $500 to pharmacist (with abatement)
Pharmacy mistakenly dispensed Naproxen to a patient who was not prescribed this drug.	• $750 to the Pharmacy
Pharmacist dispensed guanfacine instead of prescribed amoxicillin-claculanate	• $5,000 to the pharmacist

Citations Examples: Medication Errors/ Prescription Disclosure Errors

CCR 1764/ CIV 56.10 (a) Unauthorized Disclosure of Prescriptions	**Fine**
Pharmacy shipped patient A's prescription to patient B, disclosing patient A's prescription information to patient B.	• Cite no Fine to the Pharmacy
Nonresident pharmacy incorrectly dispensed prescription for Prolensa for patient G to patient K, disclosing patient G's protected health information.	• $500 to the Nonresident Pharmacy
During an inspection patient drug names were visible on finished prescriptions from the pickup counter. Exposing patient names and drug information without authorization is a violation.	• $1,000 to the Pharmacy

Questions?

Thank You

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**
Morphine ampule	1
Morphine capsule	34

Drug Name	Sum of Dosage Units
Morphine carpuject/tubex	18
Morphine MG	21
Morphine ml	111
Morphine syringe	20
Morphine tablet	686
Morphine unknown form	65
Morphine 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

Suggested Alternative Resolution Model

A copy of this documents will be made available for public inspection at the meeting and are available upon request. Requests may be emailed to debbie.damoth@dca.ca.gov

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

Continued from page 17

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>