Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Inventory Reconciliation

Section Affected: Amend Section 1715.65 of Article 2 of Division 17 of Title 16, California Code Regulations

Problems Addressed

The California State Board of Pharmacy (Board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies and pharmacists. The Board's mandate and its mission is to protect the public (Business and Professions Code [BPC] section 4001.1).

On April 1, 2018, the Board's regulation, Title 16, California Code of Regulations (CCR) section 1715.65, establishing the requirement for pharmacies and clinics to perform inventory reconciliation activities on all federal Schedule II controlled substances to detect and prevent the loss of controlled substances, became effective. In July 2019, the Board began a post-implementation review of the regulation to determine if any changes should be considered. During discussions with stakeholders at several Board meetings, the Board determined that the regulatory language should be amended to address frequent compliance questions the Board receives (See Inventory Reconciliation Frequently Asked Questions) and address the ongoing diversion of non-Schedule II controlled substances from pharmacies and clinics.

This proposed regulation will clarify what an inventory reconciliation is and define "inventory activities;" it will identity four non-Schedule II controlled substances (Alprazolam, 1 milligram/unit, Alprazolam, 2 milligrams/unit, Tramadol, 50 milligrams/unit, and Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product) that will require an inventory at least once every twelve months; and specify that all other controlled substances most have an inventory completed within 3 months of a discovered loss and at least once every two years, when no loss is found. Additionally, the proposal will require that all individuals involved in completing the inventory or preparing the report be identified, and that the individual who performs the inventory sign and date it. Furthermore, this proposal will allow for the use of a digital, electronic, or biometric identifier in lieu of a physical signature if a printed signed statement confirming the accuracy of the report is retained according to existing retention requirements. Finally, the proposal will clarify the inventory requirements for an inpatient hospital pharmacy where drugs are stored within a drug storage area under the pharmacy's control and for the inventory of an automated drug delivery system (ADDS) within the inpatient hospital.

Benefits

Protection of the public is the Board's highest priority in exercising its licensing, regulatory and disciplinary functions. This regulatory proposal will require pharmacies

and clinics to perform a physical count inventory at least once every twelve months for four non-Schedule II controlled substances, on top of the existing quarterly inventory of Schedule II controlled substances. The proposal will also require an inventory of all other non-Schedule II controlled substances biennially, which is an existing federal requirement (Title 21, Code of Federal Regulations (CFR) section 1304.11). According to the National Council on Alcoholism and Drug Dependence, Inc., the availability of opioids is partly the cause of the epidemic misuse of prescription medication. By requiring the inventory of the four non-Schedule II controlled substances yearly and of other non-Schedule II controlled substances biennially, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. This will reduce the supply of controlled substances available for misuse and abuse without denying pain relief for those that need it. Additionally, the proposal will improve clarity among the regulated public by addressing some of the frequently asked questions. Finally, the proposal will ensure that complete and accurate inventories are being completed, which will help prevent the ongoing diversion and excessive loss of controlled substances. Reducing the amount of controlled substances loss and diverted will reduce the supply available to the public for misuse.

Specific Purpose of Proposed Changes and Rationale

The section heading for 1715.65 is amended to read “Inventory Activities and Inventory Reconciliation Reports of Controlled Substances.” This amendment increases clarity that the regulation includes those “activities” that must be completed in addition to the inventory reconciliation report.

Subdivision (a) is amended to add “activities” following “periodic inventory” for consistency with the amended section heading. The term “activities” clarifies that there are specific actions that must be completed in addition to completing the reconciliation report. Additionally, the term “prepare” is being added before “inventory reconciliation” and “functions” is being deleted. This change is consistent with the addition to “activities” and is necessary to clarify that, in addition to performing the inventory activities, that licensee must also prepare the reconciliation report. The term “federal” is also added before “controlled substances” for clarity. The State of California and the Federal Government each have their own drug schedules. The Board determined the federal Schedule II is the most current and complete drug schedule, as the State schedule II has not been amended since 2010. Additionally, the federal Schedule is the standard for the purpose of reporting to the Controlled Substance Utilization Review and Evaluation System (CURES), as defined in Health and Safety Code section 11165(d). Finally, a clarifying sentence is added to specify that the inventory reconciliation report must be prepared on an ongoing basis for specific circumstances (identified in (a)(1) – (a)(3)(B)), except as specified within subdivisions (f) and (g). This ensures that Board licensees are aware that the inventory reconciliation report must be completed on an ongoing basis and it is not a onetime occurrence.

Subdivision (a)(1) adds the language for all federal Schedule II controlled substances to be inventoried at least once every three months. This is existing law and is not a new

requirement. It is simply being relocated from subdivision (c) for clarity within the restructured regulation text.

Subdivision (a)(2) adds the requirement for products containing specific substances in specific strengths per tablet, capsule, other unit, or volume to have an inventory reconciliation report prepared at least once every twelve months. The products are as follows:

- Subdivision (a)(2)(A) adds Alprazolam, 1 milligram/unit
- Subdivision (a)(2)(B) adds Alprazolam, 2 milligrams/unit
- Subdivision (a)(2)(C) adds Tramadol, 50 milligrams/unit
- Subdivision (a)(2)(D) adds Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product

The Board selected these products as they are the four non-Schedule II products with the highest reported drug losses to the Board (See January 2020 Board Meeting Materials. Additionally, these products are also subject to abuse and misuse, which makes them a target for diversion within the pharmacy. Existing Federal law (21 CFR section 1304.11), requires that a biennial inventory be complete of all federal controlled substances. The Board determined that by requiring at least a yearly inventory of these four non-schedule II-controlled substances, pharmacists, pharmacies, and clinics will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring.

Subdivision (a)(3)(A) adds the requirement for an inventory reconciliation report to be prepared within three months of the discovery of a drug loss of any controlled substance not covered in subdivision (a)(1) and (a)(2) – (a)(2)(D). The report shall cover the time period between the last physical count through the date of discovery of the loss. The Board determined that an inventory reconciliation report should be completed when a loss is identified as it requires a physical hand count. Additionally, it provides for a detailed review of the inventory stock, including acquisitions and dispositions in an effort to identify the cause of the loss and if any additional losses of that controlled substance are uncovered. Understanding the cause of a drug loss will help ensure that pharmacists, pharmacies, and clinics are better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring in the future. The Board determined that three months was the appropriate timeframe as it would allow for the inventory to be completed as part of the quarterly inventory.

Subdivision (a)(3)(B) adds the requirement for inventory activities and all other functions necessary to identify drug losses be completed at least once every two years for each controlled substance not covered in (a)(1) and (a)(2). Existing Federal law (21 CFR section 1304.11), requires that a biennial inventory be complete of all federal controlled substances. The Board determined that it was necessary to include the requirement here for enforcement purposes so that inspectors can ensure that the inventory is being

completed. If Board inspectors determine that the inventory is not being completed, action can be taken to ensure that pharmacists, pharmacies, and clinics comply.

Subdivision (b) is amended to change “consultant” to “consulting” for consistency with BPC section 4182, which defines the duties of a consulting pharmacist. Additionally, the terms “activities performed” and “prepared pursuant to this section” and “federal” have been added for clarity and consistency with the text amendments made in subdivision (a). Furthermore, “drugs” has been changed to “substances” to accurately reflect the industry standard terminology used within the practice of pharmacy when referring to controlled substances. Finally, the requirements for the policies and procedures (P&P) have been updated to clearly identify that the P&P must contain the requirements for performing the inventory activities and preparing the inventory reconciliation report. This change is consistent with the changes made in subdivision (a), which clarify the difference between the inventory activities and the preparation of the inventory reconciliation report.

Subdivision (c) is amended to remove the relocated requirement for the federal Schedule II inventory to be done quarterly. This requirement was relocated to subdivision (a)(1) and as such, it is no longer needed in this subdivision. For grammatical clarity this subdivision was re-written to read: “An inventory reconciliation report prepared pursuant to this section shall include all of the following” which will require any inventory reconciliation report prepared, as identified in subdivision (a), to all contain the same information, regardless if it is for federal Schedule II or non-Schedule II controlled substances. The term “require” was changed to “all of the following” for clarity to ensure that licensees understand that all of the requirements specified in the regulation text must be included as part of the report.

Subdivision (c)(1) is amended to change “federal Schedule II controlled substances” to “each federal controlled substance covered by the report that the pharmacy or clinic had in inventory, except as provided in subdivision (h). This change ensures that each controlled substance identified in subdivision (a) within the pharmacy or clinics inventory has an inventory reconciliation report prepared and inventory activities completed and not just the federal Schedule II controlled substances. Finally, the Board determined that the individual that performs the inventory should sign and date the inventory or the report, as specified in subdivision (e)(1), to ensure accountability. This is an existing requirement that was relocated from subdivision (e) and allows for the pharmacist-in-charge or professional director to delegate the performance of the physical count inventory activity to another pharmacy staff person and ensures that the Board will be able to identify who completed the physical count should questions arise. The Board further determined that having an individual sign and date the physical count inventory may increase accountability as the individual has to sign their name to the document.

Subdivision (c)(2) is amended to remove “Schedule II” and change “substances” to “substance.” This change ensures that the acquisition and disposition of each controlled substance is reviewed while preparing the inventory reconciliation report. This change is necessary to ensure consistency within the regulation text. Additionally, “covered by the report” and “covering that controlled substance” have been added to clarify that the

acquisition and disposition records need to be reviewed for the controlled substance that the report is being prepared for. For example, if the inventory reconciliation report is being prepared for Alprazolam, 1 milligram/unit [subdivision(a)(2)(A)], only the acquisition and disposition records for that controlled substance need to be reviewed. The individual completing the review would not have to review the records for other controlled substances. This requirement is added for clarity on which records to be reviewed. The Board determined that reviewing the records for other controlled substances, when the report was focused on a specific controlled substance was not necessary, as it would not provide meaningful information, and could create a workload burden to the pharmacy and/or clinic.

Subdivision (c)(4) is amended to require the identification of all records used to compile the inventory reconciliation report. Previously, the records were required to be incorporated into the report. The Board determined that it was appropriate for the records to be maintained with the report, but not be incorporated into the report. It was determined that it may be difficult for some pharmacies or clinics to incorporate the documents into the report due to different software programs or if some documents are maintained as a hard copy or an electronic copy. Allowing the documents to be maintained separately, but still readily available, as required in subdivision (e)(2), will help ensure compliance.

Subdivision (c)(5) is added to require the identification of each individual involved in preparing the inventory reconciliation report. This allows for the pharmacist-in-charge to delegate the performance of the preparation of the report and review of the records to other pharmacy staff and ensures that the Board will be able to identify who completed the inventory activities and complied the report should questions arise in the future.

Subdivision (c)(6) is amended to remove the statement that causes of overages shall be identified in writing and incorporated into the report. While the causes must still be incorporated, the statement of incorporating the information into the report is being removed as it is duplicative. Subdivision (c) states that the inventory reconciliation report needs to include all the items identified in (c)(1) through (c)(6) so including the statement again in this section is not necessary.

Subdivision (d) is amended to add the term “federal” before “controlled substances” in the last sentence. This change is for clarity and consistency within the regulation text to ensure all subdivisions appropriately refer to federal controlled substances.

Subdivision (e)(1) is amended to remove the requirement for the individual(s) performing the inventory to sign and date as this requirement was relocated to subdivision (c)(1). Additionally, the regulation no longer requires a countersignature, asthe pharmacist-in-charge or professional director must sign the inventory reconciliation report. A countersignature is not needed because the person who completed the inventory must sign and date, as required by (c)(1). This signature is an existing requirement and is not being added. Further, added is the ability to use a digital or electronic signature or biometric identifier in lieu of a physical signature provided that the individual also signs and dates a written statement confirming the accuracy of the

inventory or report, which shall be retain on file pursuant to subdivision (e)(2). This addition was included at the request of Board licensees to accommodate current security practices. The Board acknowledged the electronic signatures can be altered via the electronic system. A biometric identifier is new technology used by some licensees to access computer systems. It is used as an electronic signature by some licensees. The Board determined that electronic signatures should be permitted to allow for electronic record storage purposes so that licensees do not have to print the report and documents; however, wet signatures should also be retained. This allows for an electronic signature on the inventory reconciliation report; while also ensuring that the person signing the written statement is the same person signing it electronically and it stresses the importance of the accuracy of the information. Previous subdivision (e) has been split into two subdivisions to separate the signature requirement from the record storage requirement as they are two separate things.

Subdivision (e)(2) is amended to add that "the report and all records used to compile the report shall" to the beginning of the sentence. This was an existing requirement that has been relocated from previous subdivision (c)(4). The phrase "the report" is being added for clarity that in addition to the records used to compile the report, the report itself must also be maintained. While this is current practice for licensees, the regulation language did not specifically identify the report. Additionally, the requirement not to require a countersignature by the pharmacist-in-charge or professional director if they are personally completing the inventory reconciliation report has been removed. The regulation no longer requires a countersignature; however, the pharmacist-in-charge or professional director must still sign the inventory reconciliation report as required by subdivision (e)(1). A countersignature is not needed because the person who completed the inventory, if not the pharmacist-in-charge or professional director must sign and date, as required by (c)(1).

Subdivision (f) is amended to remove reference to subdivision (c) from the first and second sentence as subdivision (c) no longer identifies when the inventory reconciliation report shall be completed. This information has been relocated to subdivision (a). The phrases "for all federal controlled substances described in paragraphs (1) and (2) for subdivision (a)" has been added to the first sentence and "for those controlled substances" has been added to the second sentence. These changes provide clarity to which controlled substances an incoming new pharmacist-in-charge shall complete the inventory reconciliation report for, and which controlled substances an outgoing pharmacist-in-charge should, when possible, complete the inventory reconciliation report for.

Subdivision (g) is amended to clarify the inventory requirements for an inpatient hospital pharmacy. Subdivision (g) requires that an inpatient hospital pharmacy prepare an inventory reconciliation report on the federal controlled substances identified in subdivision (a)(1) and (a)(2) on a quarterly basis. The requirement to perform a quarterly inventory reconciliation report on the controlled substances identified in (a)(1) is an existing requirement. The amended language adds the requirement for the inventory reconciliation report to include those controlled substances identified in (a)(2). Furthermore, the report or reports shall include the controlled substances "within" each

pharmacy satellite location and within each drug storage area in the hospital under the pharmacy's control. The requirement to include pharmacy satellite locations is existing language; however, we changed the term "for" to "within" for clarity. Finally, the requirement to include each drug storage area within the pharmacy's control in the report or reports is new. As a pharmacy is responsible for the security of the drugs within its control (CCR 1714), and because inpatient hospitals maintain multiple drug storage areas, it is appropriate to include all drug storage areas within the hospital under the pharmacy's control in the regulation. Because outpatient facilities do not typically maintain separate storage areas, it is not necessary to extent the same requirement to them.

Subdivision (h) is amended to provide clarity with respect to the use of automated drug delivery systems (ADDS) within an inpatient hospital pharmacy. BPC section 4427.4(d) specifies that drugs and devices stored in an ADDS are deemed to be part of the inventory of the pharmacy holding the ADDS license and that the drugs and devices dispensed from the ADDS are considered to have been dispensed by the pharmacy. The regulation is being amended to allow for an inventory count of drugs and devices stored within the ADDS to be accounted for using a means other than a physical count, for example, a perpetual inventory.

Subdivision (h)(1) – (h)(4) is being stricken from the regulation. The Board determined that the requirements within (h)(1) – (h)(4) were duplicative within other areas of statute, specifically BPC section 4427.4, which specify the requirements to ensure an accurate record of all drugs being added to or removed from the ADDS and requires access to the ADDS be controlled and tracked. Additionally, the inpatient hospital pharmacy will still need to complete an inventory reconciliation report of the ADDS device [subdivision (g)], which includes an evaluation of the controlled substances within the device and will require reporting of confirmed losses.

Note: Sections 4105.5 and 4119.1 have been removed from the reference section. Both sections were repealed effective January 1, 2020 and are no longer valid.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board Meeting held January 29-30, 2020
2. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held January 9, 2020
3. Relevant Meeting Materials and Minutes from Board Meeting held November 5-6, 2019
4. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held November 5, 2019
5. Relevant Meeting Materials and Minutes from Board Meeting held July 24-25, 2019
6. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held July 10, 2019

7. Inventory Reconciliation Frequently Asked Questions (https://www.pharmacy.ca.gov/laws_regs/1715_65_inv_rec_rpt_faq.pdf)

Business Impact

The Board has made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, pharmacies and clinics are currently required to perform an inventory reconciliation on all Schedule II controlled substances. While this proposal does add an additional four non-Schedule II controlled substances that must be inventoried, the Board does not anticipate an impact on businesses from this additional requirement. The Board notes that the proposed regulation does not require the use of specific computer software. The inventory counts are to be completed by hand and can be recorded using pen and paper or basic computer spreadsheet software that the pharmacy currently utilizes. Although the proposed regulation will directly affect businesses statewide, the Board concludes that the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant.

Economic Impact Assessment:

The Board has determined that:

(1) this proposal will not create jobs within California;
(2) this proposal will not eliminate jobs within California;
(3) this proposal will not create new businesses within California;
(4) this proposal will not eliminate existing businesses within California;
(5) this proposal will not expand businesses currently doing business in the State of California.

Existing pharmacy law at CCR section 1714 establishes that each pharmacist is responsible for the security of the pharmacy or clinic, including the effective control against theft and diversion of controlled substances. Additionally, the existing regulation at section 1715.65 requires that inventory reconciliation be completed quarterly for all federal schedule II-controlled substances. Furthermore, Title 21, Code of Federal Regulations (CFR) section 1304 requires that a controlled substance inventory be taken every two years. This proposal amends existing regulation to allow for technology updates (electronic records and signatures) and establishes that inventory reconciliation must completed on 4 additional non-schedule II-controlled substances. While the proposal does impact businesses, it will not create or eliminate jobs or businesses or expand businesses doing business in California.

The Board determined that the additional inventory required can be completed using pen and paper or computer software currently available to the pharmacy or clinic. New computer software is not required.

Additionally, some pharmacies utilize a perpetual inventory system, which is a system of inventory control in which the number of units of any inventory item on any day can be obtained from the stock records. Any pharmacy that utilizes a perpetual inventory system (PIS) will meet the quarterly physical count requirement so an additional physical count of the non-Schedule II controlled substances would not be required. As of January 1, 2020, the Board currently has 8,800 licensees that may be impacted by this regulation. Of that figure, approximately 3,800 are Chain Stores and 475 are hospitals. It is the Board's belief that all Chain stores and Hospitals currently have a PIS for accountability and stock management. That leaves approximately 4,525 licensees impacted.

The Board estimates that approximately 10% of the remaining licensees (453 licensees) do not currently utilize a PIS and will need to hand count their non-Schedule IIs annually or they will institute a hand count PIS within their location.

The ongoing economic impact is estimated to be $81,450 per year as follows:

Ongoing Economic Impact to Pharmacies, Clinics, and Inpatient Hospitals

Workload Activity	Time (hours)	Cost per hour	Total Costs
Pharmacist Staff	2	$61	$122
Pharmacy Technician	2	$16	$32
Clerk	2	$13	$26
		Subtotal:	$180
Number of Impacted Licensees:		453	$81,450

The total economic impact over the next ten years is estimated to be $814,500.

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents and worker safety because the proposed regulation will require better inventory and control of controlled substances. By reducing the amount of controlled substances diverted, it will reduce the number of drugs being misused and abused. This will result in improved health for Californians. Additionally, on the job accidents may decrease if fewer employees and/or co-workers are working under the influence of a misused or abused controlled substance. The proposed regulation will not impact the state's environment.

Fiscal Impact Assessment:

The regulations do not result in a fiscal impact to the state. The Board will be required to ensure pharmacies and clinics comply with the inventory requirement as proposed in the regulations through routine inspections and no additional workload or costs are anticipated.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The Board considered the following alternative:

The Board considered requiring an annual inventory of all controlled substances within Schedules III-V; however, the Board determined that a more targeted approach was appropriate. The Board determined that focusing on the non-Scheduled II controlled substances with the largest drug losses would have the greatest impact on the health and safety of California residents while also accounting for the pharmacy staff time necessary to complete the inventories.