Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Inventory Reconciliation Report of Controlled Substances

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

Specific Purpose of the Proposed Changes/Problems Addressed

The Board of Pharmacy (Board) proposes to adopt Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of adding to the Board's regulations specific requirements for inventory reconciliation reporting of controlled substances as part of the Board's efforts to combat drug loss and diversion from within pharmacies and prescription drug abuse within California, as specified below.

This proposal will require pharmacies and clinics to perform a physical count inventory at least every three months of all Schedule II controlled substances. By requiring at least a quarterly inventory of all 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.

The purpose of the Board's proposal makes the following additions:

Adopt 16 CCR Section 1715.65 Inventory Reconciliation Report of Controlled Substances.

Subdivision (a) adds "Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances." This is added to ensure all Board licensees that dispense controlled substances are required to perform the inventory defined under this proposal.

Subdivision (b) adds "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." This is added to ensure the licensee responsible for the pharmacy operations is reviewing the inventory and the reconciliation reports. Additionally, the facility needs to develop policies and procedures to ensure that each inventory reconciliation report is compiled utilizing the same methods to prevent inaccurate collection of data. Finally, the Board reviews policies and procedures while performing site inspections and will be able to confirm if the policies and procedures implemented by the pharmacy or clinic meet the regulatory requirements.

Subdivision (c) adds "A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:" This subdivision specifies the required time frame of at least every three months. While the Board is requiring the inventory to be completed quarterly, the term "at least" allows for the pharmacist-in-charge to use their professional judgment should they wish to perform the inventory more frequently. This also allows for a perpetual inventory system.

Subdivision (c)(1) adds “A physical count, not an estimate, of all quantities of 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;” This subdivsion specifies that a physical count must done. It is necessary to complete a physical count for accuracy as it is easy to miss count a medication when looking in a 1,000 tablet bottle. Additionally, this subdivision allows for the use of the federally required biennial inventory to be used as one of the proposals quarterly inventories. This specification will eliminate the need for repetitive inventories to meet state and federal requirements.

Subdivision (c)(2) adds “A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;” This subdivision adds the specification that purchases(acquisitions) and dispenses (dispositions) be reviewed. Part of any inventory is reviewing what entered and what left the pharmacy during the quarter.

Subdivision (c)(3) adds “A comparison of (1) and (2) to determine if there are any variances; and”. This subdivision specifies that physical count data be compared with what entered and left the pharmacy to determine if a discrepancy exists. This is the very essence of an inventory. The pharmacy will look at the starting inventory, what was added, what was removed, and what remains. If totals do not match, there is a variance. Any variance must be addressed as indicated in subdivision (d). Additionally, this reconciliation is necessary to ensure that controlled substances are not being ordered and diverted upon arrival without the knowledge of the pharmacist-in-charge.

Subdivision (c)(4) adds “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” This subdivision adds the requirement that the records used to compile the inventory reconciliation report will be readily available for review by Board inspectors as defined in B&P section 4081(a) and 4105(a). The three year time frame is defined in B&P section 4081(a) and 4105(c) and is maintained in this proposal.

Subdivision (d) adds “Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report” This subdivision specifies what the licensee is required to do if a loss of controlled substances is discovered. If a drug loss is discovered, it is necessary for the Board to be informed from a regulatory stance to determine if there is an issue with security at the pharmacy or clinic (as specified is 16 CCR section 1715.6). This subdivision specifies what the licensee is required to do if an overage of controlled substances is discovered. The Board does not need to be informed of the overage; however, it is necessary to educate and ensure that the pharmacy or clinic maintains better records of their controlled substances.

Subdivision (e) adds “The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years.” As the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that they countersign the inventory report to ensure they are aware and accountable for the inventory reconciliation. Additionally, this section requires that the inventory reconciliation report be readily available for review by Board inspectors as defined in B&P section 4081(a) and 4105(a). The three year time frame is defined in B&P section 4081(a) and 4105(c) and is maintained in this proposal.

Subdivision (f) adds “A new pharmacist-in-charge of a pharmacy shall complete an inventory within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).” This subdivision requires a new pharmacist-in-charge to complete an inventory. While this is currently recommended, it is not required. Requiring a new pharmacist-in-charge to complete an inventory within 30 days of becoming pharmacist-in-charge will familiarize the pharmacist with the pharmacies policies and procedures and will hold them accountable for the drug inventory and drug losses that may occur after they become pharmacist-in-charge. The Board selected the 30 day time frame to allow the new pharmacist-in-charge time to acclimate to their new position and to allow time to address day to day operations. While not being mandated, the Board is also recommending that the outgoing pharmacist-in-charge should complete an inventory upon their departure. Completing an inventory upon departing will reduce or eliminate suspicion and possible disciplinary action against the departing Pharmacist-in-Charge should a drug loss be discovered by the new Pharmacist-in-Charge. Additionally, the Board is keeping as a recommendation as there may be times with the outgoing pharmacist-in-charge is not available or cannot enter the pharmacy.

Subdivision (g) adds “For inpatient hospital pharmacies, a separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.” This subdivision specifies that separate quarterly inventories are required for the each satellite location. This allows for an inpatient hospital pharmacy better control and inventory management. If losses are occurring, separate inventory reconciliation reports will allow the hospital to identify which location is experiencing the loss and may make identifying the cause easier.

Subdivision (h) adds “The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that.” This subdivision is being added to specify the requirements for automated drug delivery systems. Automated drug delivery systems have restricted access and increased security as only specific employees have access. Additionally, the employees generally have to sign into the machine to access the controlled substances within the machine and they log what they are removing and what count remains in the machine. For these reasons, the Board established different inventory reconciliation requirements.

Subdivision (h)(1) adds “All controlled substances added to an automated drug delivery system are accounted for;” This is added to ensure that the quantity of controlled substances added to the system is actually the amount added. By doing an initial count, if there is a variance later when a controlled substance was removed from the system, they have a confirmed accurate starting balance.

Subdivision (h)(2) adds “Access to automated drug delivery systems is limited to authorized facility personnel;” This is added to ensure that only authorized facility personnel can access the automated drug delivery system. This will prevent unauthorized access to the controlled substances and reduce diversion.

Subdivision (h)(3) adds “An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;” This is subdivision specifies that facilities to continue to evaluate automated drug delivery systems when discrepancies or unusual access is identified. This ongoing evaluation will help identify the cause of the discrepancies and prevent additional discrepancies in the future. Additionally, if unusual access is identified, it is important

to going to evaluate what occurred and how it occurred to prevent the issue from happening again.

Subdivision (h)(4) adds "Confirmed losses of controlled substances are reported to the board; and." This subdivision requires that losses from automated drug delivery systems be reported to the Board, as required is 16 CCR section 1715.6.

Subdivision (h)(5) adds "A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses." This subdivision is added to require that a pharmacy or clinic take action to prevent further drug loss if they are unable to identify the reason for the initial loss. The Board determined 30 days to be sufficient time to allow the pharmacy or clinic to work to identify the cause of the drug loss. Allowing additional time may result in continued drug losses. This is necessary to reduce the amount of controlled substances being loss or diverted. The Board is not specifying what additional steps are needed. The additional step would be determined by the pharmacist-in-charge or consultant pharmacist using their professional judgment based on the facility and what they determine would be effective in preventing additional losses.

"Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, and 4332, Business and Professions Code" was added to ensure compliance with the Administrative Procedures Act.

Factual Basis/Rationale

B&P section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy (Board) in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

B&P section 4081 generally specifies the record requirements for the manufacture, sale, acquisition, receipt, shipment, and disposition of dangerous drugs or dangerous devices. Additionally, this section generally specifies that a current inventory to be kept by all licensees who maintain a stock of dangerous drugs or dangerous devices.

B&P section 4104 generally specifies the requirements for reporting theft or division of a licensed employee.

B&P section 4105 generally specifies the record requirements for the acquisition and disposition of dangerous drugs or dangerous devices in a readily retrievable form.

B&P section 4332 specifies that any person who fails to maintain or produce a drug or device record is guilty of a misdemeanor.

16 CCR Section 1714 specifies that the pharmacy and pharmacist are responsible for the security of the prescription department while on duty, including effective control against theft and diversion of drugs, devices, and records.

16 CCR Section 1715.6 specifies that the pharmacy shall report the loss of any controlled substance within 30 days of discovery. The loss shall include the amount of the loss and the strengths.

16 CCR Section 1718 defines "current inventory" as used in B&P sections 4081 and 4332 to be complete accountability for all dangerous drugs handled by every licensee enumerated in B&P sections 4081 and 4332.

According to the Centers for Disease Control and Prevention (CDC) forty-four (44) people die in the United States each day from a prescription drug overdose. The most commonly abused medications are opioids (Hydrocodone, Oxycodone, Oxymorphone, and Methadone). As published in the Los Angeles Times, in 2014, four CVS locations within Northern California could not account for over 37,000 hydrocodone tablets. Additionally, an employee of a fifth CVS location was arrested and admitted to stealing in excess of 20,000 hydrocodone tablets from the pharmacy. The drugs diverted from a pharmacy are diverted for self-use or sold on the black market due to the high street value of each tablet. According to drug loss reports submitted to the Board, in 2013, 3.06 million dosage units of controlled substances were reported as lost.

According to the National Institute on Drug Abuse in a research report on prescription drug abuse, an estimated 52 million people have misused a prescription drug at least one. In 2010, 1 in 12 high school seniors reported misuse of Vicodin (a Hydrocodone product) and 1 in 20 reported misuse of OxyContin (Oxycodone). Since 1999, the number of unintentional overdose deaths involving opioids has quadrupled. Finally, in 2010, approximately 6.6 percent of high school seniors reported consuming cough syrup "to get high."

This proposal will require pharmacies and clinics to perform a physical count inventory at least every three months of all Schedule II controlled substances. 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 at least a quarterly inventory of all 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. This will reduce the supply of controlled substances available for misuse and abuse without denying pain relief to those that need it.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held March 27, 2014 (Meeting Materials Pages 1, 6 and Attachment 5, Minutes Pages 1, 8-9).
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 23-24, 2014 (Meeting Materials Pages 1, 7-8 and Attachment 5, Minutes Pages 1, 27-28).
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held September 16, 2014 (Meeting Materials Pages 1, 4-7 and Attachment 3, Minutes Pages 1, 8-13).
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 28-29, 2014 (Meeting Materials Pages 1, 4-8 and Attachment 3, Minutes Pages 1, 29-34).
5. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held December 17, 2014 (Meeting Materials Pages 1, 5-8 and Attachment 5, Minutes Pages 1, 8-13).

6. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2015 (Meeting Materials Pages 1, 5-9 and Attachment 5, Minutes Pages 1, 42-43).
7. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held March 26, 2015 (Meeting Materials Pages 1, 6-8 and Attachment 6, Minutes Pages 1, 11-15).
8. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 21-22, 2015 (Meeting Materials Pages 1, 8-10 and Attachment 6, Minutes Pages 1, 14-16).
9. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held June 24, 2015 (Meeting Materials Pages 1, 3-6 and Attachment 4, Minutes Pages 1, 13-17).
10. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 27-29, 2015 (Meeting Materials Pages 1, 4-9 and Attachment 4, Minutes Pages 1, 10-15).
11. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held February 24-25, 2016 (Meeting Materials Agenda Item XXI, Minutes Pages 1 and 60).
12. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 27-28, 2016 (Meeting Materials Agenda Item XX, Minutes Pages 1 and 35).
13. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held June 1, 2016 (Meeting Materials Pages 1, 3 and Attachment 2, Minutes Pages 1, 5-6).
14. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 27-28, 2016 (Meeting Materials Pages 1-3 and Attachment 2, Excerpt from Minutes).
15. Centers for Disease Control and Prevention, *Understanding the Epidemic* Last Updated 8/17/2015 (http://cdc.gov/drugoverdose/epidemic/index.html)
16. Los Angeles Times, *CVS Probed in alleged loss of painkillers*, March 10, 2014 (http://articles.latimes.com/print/2014/mar/10/business/la-fi-lazarus-20140311)
17. National Council on Alcoholism and Drug Dependence, Inc., *Reduce the Supply.* March 13, 2012 (https://ncadd.org/get-help/addiction-medicine/298-reduce-the-supply)
18. National Institute on Drug Abuse, *Prescription Drug Abuse*. Revised November 2014. (https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/prescriptiondrugrrs_11_14.pdf)
19. National Institute on Drug Abuse, Drug Facts: Prescription and Over-the-Counter Medications. December 2014 (http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications)
20. American Journal Health-System Pharmacy, *The opioid abuse and misuse epidemic: Implications for pharmacists in hospitals and health systems*. Vol. 71, September 15, 2014 (http://www.ashp.org/DocLibrary/AJHP/Opioid-abuse-and-misuse.pdf)
21. Pharmacy Purchasing and Products, *Four Case Studies on Diversion Prevention*. Vol. 11, No. 3 (http://www.pppmag.com/article/1469/March_2014/Four_Case_Studies_on_Diversion_Prevention/)

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, 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.

Economic Impact Assessment

This regulatory proposal will have the following effects:

It will not create or eliminate jobs within the State of California because the proposed regulation will require better inventory and control of controlled substances. Under 16 CCR section 1714, each pharmacist is currently responsible for the security of the pharmacy or clinic, including the effective control against theft and diversion of controlled substances. This regulation establishes a needed method of control against theft and diversion.

It will not create new business or eliminate businesses within the State of California because the proposed regulation will require better inventory and control of controlled substances. Under 16 CCR section 1714, each pharmacist is currently responsible for the security of the pharmacy or clinic, including the effective control against theft and diversion of controlled substances. This regulation establishes a needed method of control against theft and diversion.

It will not affect the expansion of businesses currently doing business within the State of California because the proposed regulation will require better inventory and control of controlled substances. Under 16 CCR section 1714, each pharmacist is currently responsible for the security of the pharmacy or clinic, including the effective control against theft and diversion of controlled substances. This regulation establishes a needed method of control against theft and diversion.

This regulatory proposal benefits the health and welfare of California residents 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 amount of drugs being misused and abused. This will result in improved health for Californians. Additionally, if fewer people are misusing and abusing controlled substances, there may be a corresponding reduction in petty crimes seeking prescription medication.

This regulatory proposal benefits worker safety because the proposed regulation will require better inventory and control of controlled substances. Reducing the amount of controlled substances diverted will reduce the amount of drugs being misused and abused. On the job accidents will decrease if fewer employees and/or co-workers are working under the influence of a controlled substance.

The regulatory proposal benefits the state's environment 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 amount of drugs flushed down the toilet or thrown out in the trash, contaminating lakes, rivers, streams, and soil.

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 begin implemented or made specific. The only alternative would be to not implement an inventory and reconciliation requirement. This is not reasonable as it would not mitigate the ongoing diversion of controlled substances from pharmacies within California.