California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item VI. Discussion and Consideration of Adoption of Board Approved Regulation, 16 California Code of Regulations Section 1715.65 Related to Inventory Reconciliation and Discussion and Consideration of Public Comments received during the 45-day comment period.

Background:

At the May 11, 2020 Board meeting, the Board approved proposed regulation text to amend Section 1715.65 related to inventory reconciliation. This proposal amends and clarifies the requirements for the completion of the inventory reconciliation report.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on September 17, 2021, which ended on November 1, 2021. Several comments were received during the comment period. Attached following this memo are the following:

1. The proposed text released for 45-day public comment.
2. Board staff prepared summarized comments with recommendations
3. Board staff recommended modified text
4. Comments received during the 45-day comment period

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed on September 17, 2021 for 45-day comment.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses, approve the staff recommended modified regulation language, and initiate a 15-day public comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1715.65 as noticed. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Inventory Reconciliation 16 CCR § 1715.65 Proposed Text Released for 45-Day Comment

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend Section 1715.65 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports 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 activities and prepare inventory reconciliation functions reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:
(1) For federal Schedule II controlled substances, at least once every three months.
(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
(A) Alprazolam, 1 milligram/unit.
(B) Alprazolam, 2 milligrams/unit.
(C) Tramadol, 50 milligrams/unit.
(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery.
(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance.

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

(c) A pharmacy or clinic shall compile an An inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation prepared pursuant to this section shall require include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). 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. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

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

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) 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 federal controlled substances.

(e)(1) ~~The~~ An 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~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall 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)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) 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)~~ for those controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory

reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for,~~ within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

(h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~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.~~

Note: 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 Section 1261.6, Health and Safety Code.

Inventory Reconciliation 16 CCR § 1715.65 Board Staff Comment Recommendations

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Proposed Regulation to Amend Title 16 CCR Section 1715.65, Inventory Reconciliation

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Summarized 45-day Comments Regarding Inventory Reconciliation with Board Staff Recommendations:

Written Comments from Valley Children's Hospital

Comment 1: The commenter requests clarification on the meaning of "inventory activities" in subsection (a)(3)(B) as it related to schedule III-V controlled substances reconciliation. Commenter recommends adding "perform 1 month of reconciliation activities" based on periodic definition in (a).

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the language specifically states that controlled substances not identified must be performed at least once every two years. Additionally, the subsection defines what "inventory activities" means as it relates to the requirements to identify a drug loss, specifically, "For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance." Board staff notes that the pharmacy can perform more frequent inventories based on the needs of the pharmacy to prevent losses. Limiting the requirement to only one month of reconciliation activities would not accurately capture the inventory of the pharmacy for the controlled substances identified in subsection (a)(3)(B). However, board staff are recommending changes to the regulatory text to further define "inventory activities."

Comment 2: The commenter indicates that they believe the review of all acquisitions and disposition of controlled substances as required in subsection (c)(2) is contradictory to the "periodic inventory activities" required in subsection (a). Commenter recommends that the language be amended to add "periodic review" of all the records.

Response to Comment 2: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that periodic inventory activities and the inventory reconciliation report are two separate tasks. The periodic inventory activities, as defined in subsection (a)(3)(B), do not require the full inventory reconciliation report activities. The inventory reconciliation report in (c)(2) requires a review of all acquisitions and dispositions of controlled substances during the process of completing the report. Reviewing

what was acquired and dispensed is a necessary aspect of the inventory reconciliation report to identify what entered, what left, and what should be remaining in the pharmacy during the quarter.

Comment 3: The commenter request clarification on the meaning of "in writing" and if electronic communication (email) is acceptable.

Response to Comment 3: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the language does not prohibit email notification. Additionally, Board staff note that the Board has a specific email designated for licensees to report drug theft, drug losses and impaired licensees (DEA106@dca.ca.gov).

Comment 4: The commenter requests clarification on whether the reconciliation report completed by the new PIC within 30 days be part of the quarterly reconciliation process.

Response to Comment 4: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that the inventory reconciliation report must be completed by the new PIC within 30 days of the individual becoming PIC. That inventory reconciliation report can be used as the quarterly inventory report for the quarter it is completed in, so long as all inventory activities for the quarter, as required by the regulation, are completed.

Written Comments from John Gray, PharmD., Kaiser Permanente

Comment 5: The commenter recommends that the Board define acquisitions and dispositions with respect to dispensing from an ADDS. The commenter recommends that subsection (c)(2) be amended to add: "(A) For the purposes of this subdivision, "acquisitions" means transactions, including but not limited to purchases, that result in obtaining a federal controlled substance into the pharmacy's inventory. (B) For the purposes of this subdivision, "dispositions" means transactions, including but not limited to dispensing a prescription or an order from the pharmacy or from an ADDS, that result in the removal of a federal controlled substance out of the pharmacy's inventory."

Response to Comment 5: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff believe that the terms "acquisition" and "disposition" are well known and understood and adding the definitions to the regulation is not necessary. Board staff note that varying levels of technology exist within ADDS systems utilized andsuch variances further emphasize the importance of maintaining the Board's requirements.

Comment 6: The commenter requests that subsection (d) be modified to change "the cause" to "likely vulnerabilities that contributed to the loss" as the commenter does not believe that the cause will be identified if it was not identified during the inventory reconciliation process.

Response to Comment 6: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff disagrees with the recommended language change. Additionally, the regulation requires further investigation if the cause is not identified with 30 days. This further investigation would continue after the 30-day requirement to notify the Board to allow the pharmacy more time to investigate. Determining the cause of the loss is necessary in order to prevent future losses.

Comment 7: The commenter requests that subsection (g) be modified to read "The inventory counts described under subdivision (c)(1) that are used to prepare the inventory reconciliation report or reports shall include the aggregate amounts of all federal controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control." (The language in red is added language by the commenter). The commenter does not believe that "the movement of medications within a pharmacy's inventory, for example from a controlled substance storage vault to an ADDS under the pharmacy's control constitutes neither an acquisition nor a disposition."

Response to Comment 7: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff believe, for example, an aggregate total may mask losses in one area should there be an overage in another area under the pharmacy's control.

Written Comments from Mark Johnston, R.Ph, CVS Health

Comment 8: The commenter recommends that subsection (a)(3)(A) be amended to add the term "reportable" to clarify that an inventory is not required for the loss of a single tablet and to mirror the language changes in the Reporting Drug Loss rulemaking (16 CCR § 1715.6).

Response to Comment 8: Board staff have reviewed this comment and recommend that the language be amended to establish a minimum criteria to initiate an inventory reconciliation report stemming from a loss. Board staff have provided recommended modified language within the meeting materials.

Comment 9: The commenter requests that subsection (d) be modified to add "in accordance with regulation 1715.6."

Response to Comment 9: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that subsection (d) is existing regulation language and do not believe the additional language is necessary.

Comment 10: The commenter believes that it is not possible for a pharmacy to complete "all other functions necessary" without the Board detailing the functions and recommends that the language be amended to read "other functions sufficient to identify diversion."

Response to Comment 10: Board staff have reviewed this comment and do not recommend any changes to the text based thereon; however, board staff are recommending changes to the regulatory text to further define "inventory activities." Board staff believe a pharmacy can identify within their policies and procedures what functions are sufficient to identify loss outside the inventory reconciliation process that meet the operational practice of the pharmacy.

Comment 11: The commenter requests that Corporate entities be allowed to perform the inventory reconciliation on behalf of the PIC and be able to communicate the results of the inventory to the PIC. The commenter states that if the PIC is diverting, the PIC should not be aware that the audit is occurring.

Response to Comment 11: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Under provisions of pharmacy law, the PIC is responsible for the operation and security of the pharmacy, as such, the PIC is responsible for the inventory activities. Further, the law provides that the pharmacy owner shall vest the PIC with adequate authority to ensure compliance with the laws governing the operation of the pharmacy. Additionally, Board staff note that the regulation does not prohibit a corporate entity from conducting separate inventory activities and/or reconciliation reports.

Comment 12: The commenter requests that the requirement to physically sign a printed statement confirming the accuracy of the inventory report in (e)(1) be removed as electronic signatures are widely accepted within California.

Response to Comment 12: Board staff have reviewed this comment and do not recommend any changes thereon. Board staff note that computer technology varies based on pharmacy and some systems only record the first user to sign in for the day. As such, it would not be possible to identify the person who completed the inventory reconciliation report. Further, in July and November 2019 and January 2020, the Board previously determined that "wet signatures" on a single statement would ensure that the person signing the written statement is the same person signing it electronically and stressed the importance of the accuracy of the information.

Comment 13: The commenter requests that 1715.65(h) be amended to remove the inpatient hospital specification within the regulation as the ability to use ADDS within different settings has expanded since the regulation was approved by the Board.

Response to Comment 13: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that technology varies based on the ADDS machine and the Board is not requiring the use of a specific device. Additionally, a pharmacy may not always be the one loading the ADDS. Therefore, without a physical count, the pharmacy would be unable to identify a loss.

Comment 14: The commenter requests a one-year implementation delay for IT Changes.

Response to Comment 14: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff determined that this is a policy decision for the Board.

Written Comments from Steven Anderson, FASAE, CAE, IOM, National Association of Chain Drug Stores

Comment 15: The commenter requests that the Board not expand the regulation to include the controlled substances beyond schedule II as it is overly burdensome and not required the Drug Enforcement Agency (DEA). The commenter provided recommended regulatory text (included with comments) in which it removed all references to non-schedule-II controlled substances.

Response to Comment 15: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff does not agree that adding a requirement to inventory four non-schedule-II controlled substances once every 12 months or the inventory of other controlled substances within three months of an identified loss is overly burdensome. Board staff note that if losses are not identified, the pharmacy would only be required to inventory the non-schedule-II controlled substances once every two years, which is consistent with the DEA requirements.

Comment 16: The commenter requests that the requirement to physically sign a printed statement confirming the accuracy of the inventory report in (e)(1) be removed as electronic signatures are widely accepted within California.

Response to Comment 16: Board staff have reviewed this comment and do not recommend any changes thereon. Board staff note that computer technology

varies based on pharmacy and some systems only record the first user to sign in for the day, as such, it would not be possible to identify the person who completed the inventory reconciliation report. Further, in July and November 2019 and January 2020, the Board previously determined that "wet signatures" on a single statement would ensure that the person signing the written statement is the same person signing it electronically and stressed the importance of the accuracy of the information..

Comment 17: The commenter requests a one-year implementation delay for IT Changes.

Response to Comment 17: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff determined that this is a policy decision for the Board.

Written Comments from Rachel Michelin, California Retailers Association

Comment 18: The commenter requests that the Board not expand the regulation to include the controlled substances beyond schedule II as it is an administrative burden and recommended the inventory requirement should be restricted to schedule-II controlled substances.

Response to Comment 18: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff do not agree that adding a requirement to inventory four non-schedule-II controlled substances once every 12 months or the inventory of other controlled substances within three months of an identified loss is overly burdensome. Board staff note that if losses are not identified, the pharmacy would only be required to inventory the non-schedule-II controlled substances once every two years, which is consistent with the DEA requirements.

Comment 19: The commenter requests that the requirement to physically sign a printed statement confirming the accuracy of the inventory report in (e)(1) be removed as electronic signatures are widely accepted within California.

Response to Comment 19: Board staff have reviewed this comment and do not recommend any changes thereon. Board staff note that computer technology varies based on pharmacy and some systems only record the first user to sign in for the day, as such, it would not be possible to identify the person who completed the inventory reconciliation report. Further, in July and November 2019 and January 2020, the Board previously determined that "wet signatures" on a single statement would ensure that the person signing the written statement is the same person signing it electronically and stressed the importance of the accuracy of the information.

Written Comments from John Grubbs, MS, MBA, RPh, University of California

Comment 20: The commenter requests clarification in subsection (a)(3)(A) on whether "all" controlled substances need to be inventoried upon discovery or only the controlled substance with the loss.

Response to Comment 20: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that the language identifies that the inventory is specific to "that controlled substance." Board staff recommend that the language of the section be amended to establish a minimum criteria to initiate an inventory reconciliation report stemming from a loss. Board staff have provided recommended modified language within the meeting materials.

Comment 21: The commenter requests clarification on whether a blind count and maintaining regularly scheduled discrepancy reports for controlled substances stored in ADDS meets the requirement for subsection (h) under "using means other than a physical count.

Response to Comment 21: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff do not believe enough information regarding the blind count and review of discrepancy reports has been provided to provide a specific answer to the commenter's questions as the answer could vary based on the specific situation and the specific type of ADDS utilized by the inpatient hospital.

Written Comments from Vipul Patel, Cedars Sinai

Comment 22: The commenter recommends that subsection (a)(3)(A) be amended to add the phrase "any significant loss reported to the Drug Enforcement Administration" to clarify that an inventory is not required for the loss of a single tablet and to mirror the language changes in the Reporting Drug Loss rulemaking (16 CCR § 1715.6).

Response to Comment 22: Board staff have reviewed this comment and do not recommend that the language be amended based on the comment; however, board staff due recommend that the language be amended to establish a minimum criteria to initiate an inventory reconciliation report stemming from a loss. Board staff have provided recommended modified language within the meeting materials.

Comment 23: The commenter recommends that subsection (g) be amended to add the phrase "outside of an automated drug delivery system (ADDS)." Commenter states the addition of a quarterly report specific to each ADDS

location could have significant operational impact for inpatient pharmacies.

Response to Comment 23: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that inpatient hospitals would comply with subsection (h) as it is specific to inpatient hospitals utilizing ADDS. A non-inpatient pharmacy must comply with subsection (g) and is responsible for drugs and devices stored in an ADDS as the drugs and devices 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 per Business and Professions Code section 4427.4(d).

Inventory Reconciliation 16 CCR § 1715.65 Recommended Modified Text

Title 16. Board of Pharmacy
Staff Recommended Modified Text

Proposed changes to the current regulation language are shown ~~by strikethrough~~ for deleted language and underline for added language.

Modified changes to the current proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Amend Section 1715.65 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports 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 activities and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:
(1) For federal Schedule II controlled substances, at least once every three months.
(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
(A) Alprazolam, 1 milligram/unit.
(B) Alprazolam, 2 milligrams/unit.
(C) Tramadol, 50 milligrams/unit.
(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
(3)(A) For any controlled substance not covered by paragraph (1) or (2), an inventory reconciliation report shall be prepared for identified controlled substances lost no later than three months after discovery of the ~~any~~ loss of that controlled substance. This report shall be completed if the loss is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of ~~the~~ that controlled substance before the loss was discovered through the date of discovery. At a minimum, any pattern(s) of loss(es) identified by the pharmacist in charge shall require an inventory reconciliation report for each pattern of loss identified, as defined by the pharmacy's policies and procedures. Any reportable loss, as specified in section 1715.6, shall also require an inventory reconciliation report.
(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions ~~necessary~~ sufficient to identify loss~~es~~ of ~~the~~ controlled substances. The functions

sufficient to identify loss outside of the inventory reconciliation process shall be identified within the pharmacy's policies and procedures.

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

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). 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. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

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

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) 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 federal controlled substances.

(e)(1) ~~The~~ An 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~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall 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)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) 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)~~ for those controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for,~~ within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

(h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~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.~~

Note: 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 Section 1261.6, Health and Safety Code.

Inventory Reconciliation 16 CCR § 1715.65 45-Day Public Comment

Title 16. Board of Pharmacy Proposed Text section 16 CCR ***1715.65*** *Inventory Activities and Inventory Reconciliation Reports of Controlled Substances*

Institution:	Valley Children's Hospital 9300 Valley Children's Place Madera, CA 93636	
State Board Section	**Proposed Language**	**Comments/Recommendations**
16 CCR 1715.65	B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance. (2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance; (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	Comments: Request for clarification of the "inventory activities" for C III-V reconciliation. Consider adding "Perform 1 month of reconciliation activities" based on periodic definition in (a) A review of all acquisitions and dispositions seems contradictory to the terminology in (a) which requires periodic inventory activities. Consider adding additional language "A periodic review of all acquisitions and dispositions…" Request for clarification that "in writing" includes electronic communication such as an email.

	prevent additional losses of federal controlled substances. (f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~as identified in subdivision (c)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) 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)~~ for those controlled substances.	Request clarification on whether the reconciliation report must be completed with review of acquisitions and dispositions by the new PIC, or could this task be performed as a part of the usual process for quarterly reconciliation as long as the PIC fulfills the federal requirement of a physical inventory within 30 days?

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November 1, 2021

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Proposal to Amend Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed amendments to the Board's regulations pertaining to inventory activities and inventory reconciliation reports of controlled substances.

Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

Kaiser Permanente commends the Board's ongoing efforts to promulgate regulations that enhance controlled substance accountability in order to prevent misappropriation and misuse of these dangerous drugs. We are also supportive of the Board's efforts to amend this regulation to specifically address many of the questions about the regulation that are frequently asked of Board staff by the regulated public. Our comments on the proposed amendments to the regulation seek to further clarify a handful of critically important questions about the application of the regulation, particularly in the inpatient hospital setting. We believe that the Board can clarify these remaining ambiguities in the proposed regulation by (1) defining the terms acquisition and disposition within the regulation and (2) indicating that the inventory counts used to prepare an inpatient hospital pharmacy's inventory reconciliation report shall include the aggregate inventory of the controlled substances in all medication storage areas under the pharmacy's control.

Definition of the terms acquisition and disposition

We believe that it would be of benefit to clarify within the regulation that the act of dispensing a medication from an ADDS constitutes a disposition of the medication. This clarification is particularly important for the reconciliation reports that must be prepared by inpatient hospital pharmacies as described in 16 CCR 1715.65(g). Specifically, the regulation should clearly indicate that, upon dispensing a unit-of-use medication such as a unit-dose tablet or a single dose vial from an ADDS for administration to a patient, the entire dosage unit has been removed from the pharmacy's inventory and is tallied as a disposition. We believe the best way to provide clarity on the types of activities that constitute acquisitions and dispositions would be to define the terms acquisition and disposition within the

regulation; therefore, we provide recommended definitions in the modified proposed text of 16 CCR 1715.65(c)(2)(A) below.

Inpatient hospital pharmacy inventories

We believe that it would be of benefit to clarify that the movement of medications within a pharmacy's inventory, for example from a controlled substance storage vault to an ADDS under the pharmacy's control constitutes neither an acquisition nor a disposition. Because internal transfers of medications between medication storage areas under the pharmacy's control do not constitute acquisitions and dispositions, the regulation does not require separate reconciliation of each medication storage area under the pharmacy's control. Rather the aggregate inventories of all medication storage areas may be reconciled together as long as all *bona fide* acquisitions into and dispositions from the pharmacy's inventory are captured within the aggregate reconciliation report. We recommend clarifying that the inventory counts that are used to prepare an inpatient hospital's inventory reconciliation report or reports must include the aggregate amounts of all federal controlled substances within the pharmacy and each drug storage area under the pharmacy's control. We provide recommended changes to 16 CCR 1715.65(g) in the modified proposed text below.

Investigation to identify causes of identified losses

As it is currently written, the regulation requires a pharmacy that is ***unable to identify the cause*** of a controlled substance loss to engage in "further investigation… to ***identify the cause*** and actions necessary to prevent additional losses". If the pharmacy, and the pharmacist-in-charge, is unable to identify the cause of the loss during the inventory reconciliation process, then it seems unlikely that further investigation will elucidate the reason for the loss. Therefore, for situations in which the pharmacy cannot identify the cause of the loss, we recommend modifying regulation to require further investigation to identify likely vulnerabilities that contributed to the loss. We provide recommended changes to 16 CCR 1715.65(d) in the modified proposed text below.

Recommended modified proposed regulation text

…

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

…

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(A) For the purposes of this subdivision, "acquisitions" means transactions, including but not limited to purchases, that result in obtaining a federal controlled substance into the pharmacy's inventory.

(B) For the purposes of this subdivision, "dispositions" means transactions, including but not limited to dispensing a prescription or an order from the pharmacy or from an ADDS, that result in the removal of a federal controlled substance out of the pharmacy's inventory.

…

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(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~~ likely vulnerabilities that contributed to the loss and actions necessary to prevent additional losses of federal controlled substances.

…

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies, shall prepare an inventory reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The inventory counts described under subdivision (c)(1) that are used to prepare the inventory reconciliation report or reports shall include the aggregate amounts of all federal controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

…

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board's regulations pertaining to inventory activities and inventory reconciliation reports of controlled substances. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully submitted,

John P. Gray, PharmD, MSL
Director, National Pharmacy Regulatory and Legislative Affairs
Kaiser Permanente

Mark Johnston, R.Ph
Senior Director, Pharmacy Regulatory Affairs
One CVS Drive
Woonsocket, RI 02895
401-601-1968
Mark.Johnston@cvshealth.com

11/1/2021

Lori Martinez

2720 Gateway Oaks Drive, Ste. 100

Sacramento, CA 95833

(916) 518-3078

Lori.Martinez@dca.ca.gov

Dear Ms. Martinez,

I am writing to you in my capacity as Senior Director of Regulatory Affairs for CVS Health and its 1,200 community pharmacies located in California in regards to the California Board of Pharmacy's Notice of Proposed Action for Article 2, Division 17 of Title 16, California Code of Regulations, Section 1715.65, entitled Inventory Reconciliation. CVS Health appreciates the Board's dedication to protecting public safety and the State of California for allowing the public to participate freely during the promulgation process. I first commented on this topic during a 2016 Enforcement Committee meeting, explaining CVS Health's sophisticated drug loss prevention programs, and the committee expressed that our program exceeded their expectations for this future regulation. I later presented to the Board's former Executive Director and supervising inspectors who were again satisfied with CVS Heath's inventory activities. While CVS complies with the intent of these pending changes to 1715.65, we find the myopic approach and detail to be overly burdensome. We have already invested considerable capital to make our program, which we believe is superior to what is required in this regulation, compliant with the reporting requirements of this existing regulation, and these pending changes to 1715.65 propose more revisions at a great expense for what appears to mostly be conveniences for the Board without a proven impact to public safety. Please consider our recommendations below, but if even a portion of these pending rules are approved, we request a delayed effective date of one year to build IT compliance. Furthermore, as the only State that has promulgated such burdensome regulations, we request that the Board conduct and report the scientific findings of an impact study of these rules upon public safety.

CVS Health does not believe these pending changes to 1715.65(a)(3)(A) and 1715.65(d) are in harmony with pending changes to 1715.6, entitled Reporting Drug Loss. Therefore, we request the following changes to create harmony and reduce the administrative burden of producing an inventory reconciliation report and reporting the loss of a single tablet.

1715.65(a)(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any reportable loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the

last physical count of the controlled substance before the loss was discovered through the date of discovery.

1715.65(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board in accordance with regulation 1715.6. 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 federal controlled substances.

While CVS Health appreciates the Board not requiring a report in 1715.65.a(3)(B), we suggest the following changes to create a reasonable duty, as no pharmacy can conceivably conduct "all" said functions without sufficient detail in this rule.

1715.65.a(3)(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and ~~all~~ other functions ~~necessary~~ sufficient to identify ~~losses~~ diversion of the controlled substance.

As previously mentioned, CVS Health operates a robust drug loss prevention program, including many activities that are conducted corporately. For cases of diversion, especially by a PIC, it may be inappropriate for the PIC to conduct or even be aware of such inventory activities. Therefore, we request the addition of the following language in order for a corporate entity to satisfy a portion of the required inventory activities, when appropriate. We believe this is best suited for inclusion within 1715.65(b).

Where the pharmacy is owned by a corporate entity, inventory activities may be performed on the pharmacy's behalf by the corporate entity with actionable results communicated to the pharmacist-in-charge, if appropriate.

Electronic signatures are widely accepted throughout California, as regulated by the Secretary of State. Pending changes to 1715.65(e)(1) add an additional requirement for a paper attestation when a pharmacy utilizes an electronic signature. Other regulated businesses in California are not burdened with a paper requirement for an electronic signature, which is counterintuitive. Additionally, the Board has not promulgated a paper requirement for an electronic signature anywhere else in the Pharmacy Practice Act or its regulations. Therefore, we suggest striking the following:

1715.65(e)(1)…An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section. ~~if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).~~

1715.65 was originally promulgated prior to both statute and rule changes which granted the Board the ability to register and regulate ADDS placed by a community pharmacy within skilled nursing facilities and certain other facilities. With this additional level of Board oversight, CVS Health respectfully requests that such community pharmacies enjoy the allowances afforded to

hospitals within 1715.65(h), including expanding the allowance to “a state-licensed facility with the statutory authority to provide pharmaceutical services or in a jail, youth detention facility, or other correctional facility when drugs are administered within the facility under the authority of a medical director”, as Assembly Bill Number 1533, which was signed by the Governor recently, contains a provision for ADDS placement in these expanded facilities.

If a~~n inpatient hospital~~ pharmacy uses an automated drug delivery systems system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count.

Thank you for considering these changes, and I look forward to the pending regulation hearing.

Sincerely,

Mark Johnston, R.Ph

CVS Health, Senior Director, Pharmacy Regulatory Affairs

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 28, 2021

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
via email: Lori.Martinez@dca.ca.go

Re: Proposed Rule Changes to 16 CCR §1715.65; Inventory Activities and Inventory Reconciliation Reports of Controlled Substances

Ms. Martinez,

On behalf of our members operating chain pharmacies in the state of California, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment to the California State Board of Pharmacy on the proposed rule revising inventory reconciliation requirements for controlled substances under 16 CCR §1715.65. Although NACDS understands that the Board's stated intent with this rulemaking is to curb diversion of controlled substance medications, we are concerned that the proposed expansion of inventory reconciliation activities to apply to all controlled substances would be a misguided attempt to do so.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org

As frontline healthcare providers confronted daily with the issues of prescription drug abuse facing our nation, chain pharmacy is strongly committed to combatting the problems of abuse that challenge the communities we serve. To that end, NACDS members remain steadfast in their dedication to pursuing and implementing targeted and workable policy solutions to prevent the misuse, abuse and diversion of prescription medications. With respect to issues of diversion, our members have implemented robust internal programs, policies and strategies to root out and prevent this occurrence.

As the Board is likely aware, the federal Drug Enforcement Administration (DEA), which has been given Congressional authority and responsibility for protecting Americans from the dangers of controlled prescription drug diversion and abuse, does not require

pharmacies to perform inventory reconciliation activities. Even as DEA amended its own regulations related to inventory requirements over the years, the agency never imposed requirements as burdensome as those being proposed by the Board when DEA amended its inventory regulations in 1997, 2003, and as recently as 2014. *See DEA regulations at 21 CFR §1304.11, and regulation amendments at 62 FR 13959 (Mar. 24, 1997), at 68 FR 41228 (July 11, 2003) and at 79 FR 53562 (Sept. 9, 2014).* Accordingly, we believe that the Board should look to the authority and leadership of DEA.

We are further concerned that expanding the inventory reconciliation requirements to apply to all controlled substances would have negligible impacts on reducing prescription drug abuse and diversion, while establishing a tremendously cumbersome new process for pharmacies that would require significant resources to accommodate. Accordingly, NACDS urges the Board to reject the proposed rule expansion of the existing inventory reconciliation requirement, and instead continue to apply this requirement only to Schedule II controlled substances.

Additionally, with respect to the inventory reconciliation reports, the Board has proposed hard copy attestation log requirements as a redundancy to certain electronic records. Given the movement in recent years to adopt and implement electronic record practices that are arguably more accurate and harder to alter, such a requirement would be misguided. Accordingly, we recommend revising the language to eliminate the proposed hard copy "physical signature" requirement from the rule language. Please see NACDS' proposed in-text edits on the next page to address these issues.

Lastly, the extensive new inventory reconciliation requirements proposed by the Board will require time and resource intensive updates to pharmacy systems and processes. To accommodate this, we ask the Board to delay implementation of the proposed rule changes for at least one year.

NACDS thanks the Board for considering our feedback on the proposed rule. We appreciate the Board's efforts to ensure that appropriate anti-diversion policies and measures are implemented to protect Californians and enhance the delivery of patient care. If we can provide further assistance, please contact NACDS' Sandra Guckian at SGuckian@NACDS.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

NACDS Suggested Edits to § 1715.65

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports 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 activities and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports **for federal schedule II controlled substances shall be prepared at least once every three months.** ~~**shall be prepared on the following ongoing basis:**~~

~~**(1) For federal Schedule II controlled substances, at least once every three months.**~~

~~**(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:**~~

~~**(A) Alprazolam, 1 milligram/unit.**~~

~~**(B) Alprazolam, 2 milligrams/unit.**~~

~~**(C) Tramadol, 50 milligrams/unit.**~~

~~**(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.**~~

~~**(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery.**~~

~~**(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance.**~~

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

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ ~~**each**~~ federal **schedule II** controlled ~~substances~~ ~~**substance substances covered by the report that the pharmacy or clinic has in inventory**~~, except as provided in

subdivision (h). 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. ~~**An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);**~~

(2) A review of all acquisitions and dispositions of ~~**each**~~ federal ~~Schedule II~~ **Schedule II** controlled ~~substances~~ ~~**substance**~~ **substances** covered by the report since the last inventory reconciliation report ~~**covering that controlled substance**~~;

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

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) 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 federal controlled substances.

(e) (1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-incharge or professional director (if a clinic) ~~and~~~~**, in addition to any signature required by subdivision (c)(1)**~~. An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section ~~**if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).**~~

(2) The report, and all records used to compile the report, shall 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)~~ for ~~**all**~~ federal **Schedule II** controlled substances ~~**described in paragraphs (1) and (2) of subdivision (a)**~~ 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)~~ for ~~**those**~~ **federal Schedule II** controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory

reconciliation report ~~or reports covering the~~ **for** federal **Schedule II** controlled substances **described in paragraphs (1) and (2) of subdivision (a)** on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

(h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~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.~~

November 1, 2021

Lori Martinez
California Board of Pharmacy
2720 Gateway Oaks Drive
Sacramento, CA 95814
Via Email: Lori.Martinez@dca.ca.gov

Re: CRA Comments re: Proposed Inventory Reconciliation Regulations

Dear Ms. Martinez,

The California Retailers Association (CRA) appreciates the opportunity to comment on the California Board of Pharmacy's proposed regulation related to inventory reconciliation.

Our members are committed to curbing prescription drug misuse in the communities we serve and work diligently to mitigate diversion of medications within our pharmacies. We acknowledge the Board's stated goal to prevent diversion and stop drug losses before they occur and we appreciated the opportunity to engage with the Board after the 2018 regulations establishing a requirement for pharmacies to perform inventory reconciliation activities to mitigate drug losses (16 Title, CCR Sec. 1715.65) were adopted.

However, we do have concerns with the current proposal to modify the inventory reconciliation regulations to apply to all controlled substances. This will impose a significant administrative burden on our pharmacies at a time when pharmacy teams can least afford it. In this unprecedented time, our members and their pharmacy teams have risen to the challenge and provided millions of COVID-19 tests and vaccinations to patients throughout the country. CRA has advocated to remove barriers to care and assist our pharmacy teams during and beyond the current Public Health Emergency. Adding a new burdensome and costly requirement will only distract from these critical services our members are providing.

The proposed regulation also requires that all individuals involved in completing the inventory or preparing the report be identified, and that the individual who performs the inventory to sign and date it. We respectfully urge the Board to remove the physical signature requirement given that electronic record practices are more commonplace, more difficult to tamper with and more accurate.

As healthcare providers on the front lines of the opioid epidemic, the chain pharmacy community is strongly committed to combatting the scourge of prescription drug abuse plaguing the communities we serve. We are steadfast in our dedication to pursuing and implementing targeted and workable policy solutions to prevent misuse and diversion of prescription drugs. However, we are concerned that while well-intended, the proposed modifications to the inventory reconciliation requirements will not achieve this goal. For this

reason, we urge the current inventory reconciliation requirements to continue to apply only to Schedule II controlled substances. We also request that the physical signature requirement be removed.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, restaurants, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware and home stores. CRA works on behalf of California's retail industry, which prior to the Pandemic operated over 400,000 retail establishments with a gross domestic product of billions of dollars annually and employs millions of Californians.

Thank you for your work on these regulations and your consideration of our comments. Please do not hesitate to contact Lindsay Gullahorn with Capitol Advocacy at (916) 221-8708 or lgullahorn@capitoladvocacy.com if you have any questions.

Sincerely,

Rachel Michelin, President
California Retailers Association

cc: The Honorable Seung Oh, President, Board of Pharmacy
Members, Board of Pharmacy
Anne Sodergren, Executive Officer, Board of Pharmacy

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SANTA BARBARA • SANTA CRUZ

OFFICE OF THE CHIEF PHARMACY OFFICER

OFFICE OF THE PRESIDENT
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Lori Martinez
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
(916) 518-3078
Lori.Martinez@dca.ca.gov

Dear Ms. Martinez,

On behalf of the University of California Medical Center Pharmacy Departments at UCD, UCI, UCLA, UCSD and UCSF, I am submitting the following questions intended to clarify the changes being proposed to the Board's regulation, 16 Title, California Code of Regulations (CCR) section 1715.65.

1. *Regarding the proposed text amendment to 1715.65 subdivision a (3)(A), upon discovery of loss, is this amendment requiring the inventory of all controlled substances or only the controlled substance involved in the loss?*

2. *Regarding the proposed text amendment to 1716.65 subdivision h, we had previously received guidance that maintaining a blind count and regularly scheduled discrepancy reports for controlled substances stored in automated drug delivery systems would meet the requirements of the current iteration of 1716.65 subdivision h. With these proposed changes, will these processes still meet the expectations of "using means other than a physical count"?*

If there are any questions please contact me at john.grubbs@ucop.edu or 916-719-8557.

Sincerely,

John H. Grubbs, MS, MBA, RPh
Chief Pharmacy Officer, University of California Health

Cedars Sinai

October 12, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Email: Lori.Martinez@dca.ca.gov

Re: 16 CCR § 1715.65. Inventory Activities and Inventory Reconciliation Reports of Controlled Substances - Proposed Regulations Comments

Dear Madam:

Cedars-Sinai Medical Center is submitting the attached comments concerning the proposed regulations.

Should you have additional questions or concerns regarding this correspondence, please do not hesitate to contact me.

Sincerely,

V Patel

Pharmacist-In-Charge Signature
Vipul Patel, Pharm.D.
Cedars-Sinai Medical Center
8700 Beverly Blvd, Room ST PL 2800
Los Angeles, CA 90048

VIPUL PATEL

Pharmacist-In-Charge Printed Name

Cedars Sinai

California State Board of Pharmacy § 1715.65. Inventory Activities and Inventory Reconciliation Reports of Controlled Substances Proposed Regulations – Comments

Institution/Contact	**Cedars-Sinai Medical Center** Department of Pharmacy Services 310-423-5611 **Rita Shane**, PharmD, Vice President & Chief Pharmacy Officer; shane@cshs.org **Vipul Patel**, PharmD, Executive Director, Pharmacist-In-Charge (Hospital Pharmacy); Vipul.patel@cshs.org

Subdivision	Proposed Language	Recommendation/Comments:
1715.65.a.3	(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery. (B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance.	**Recommendation**: Revise 1715.65.a.3.A to: "For any controlled substance not covered by paragraph (1) or (2), no later than three months after any significant loss reported to the Drug Enforcement Administration of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery. **Comments:** Based on the current definition of drug loss under 1715.6, the proposed regulation would require inventory activities following the loss of even 1 dosage form which would have an operational impact and add undue burden to pharmacies/clinics with minimal yield. The proposed recommendation would ensure that inventory activities are reserved for losses that truly impact the pharmacy/clinic.
1715.65.g	~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies, shall prepare an inventory reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each	Recommendation: Revise to: ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies, shall prepare an inventory reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area

	pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.	outside of an automated drug delivery system (ADDS) in the hospital under the pharmacy's control. **Comments:** Controlled substances stored within hospital ADDS are subject to added security and diversion detection/prevention functionality/measures including perpetual inventory that allow hospital pharmacies to reconcile acquisitions (drug additions to the ADDS) and dispositions (drug removals from the ADDS) in real time. The addition of a quarterly report specific to each ADDS location could have significant operational impact especially since inpatient pharmacies may several to over a hundred ADDS with minimal yield in preventing/detecting drug diversion. Furthermore, inpatient hospital pharmacies currently leverage diversion detection software to ensure controlled substance accountability and detect diversion based on ADDS information, which would appear to meet the intent of the proposed regulations. Also, for hospital pharmacies that perform complete inventory of all controlled substances on a periodic basis (as often as quarterly), the intent of the proposed regulations would be met with discrepancies identified in a timely fashion.