TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Inventory Reconciliation

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1715.65

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on September 17, 2021 and ended on November 1, 2021. The board's notice indicated that the board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the board during the 45-day comment period.

During the 45-day comment period several comments were received. At its December 2, 2021 board meeting, the board considered the comments and amended the regulation text to further define "inventory activities" and establish minimum criteria to initiate an inventory reconciliation report stemming from a loss. The board voted to amend the regulation text and release the modified text for a 15-day comment period, which commenced on December 3, 2021 and concluded on December 18, 2021.

During the first 15-day comment period several comments were received. At its January 27-28, 2022 board meeting, the board considered the comments and amended the regulation text to add correctional pharmacies for subsection (h) and edit subsection (3)(A) to re-write the section and provide additional clarity on what is considered a reported loss. The board voted to amend the regulation text and release the modified text for a second 15-day comment period, which commenced on January 28, 2022 and concluded on February 12, 2022.

During the second 15-day comment period, the board received several comments. At the March 16, 2022 board meeting, the board considered the comments submitted and determined that no additional modifications to the text were appropriate. The board voted to adopt the second modified text as noticed for public comment on January 28, 2022.

First Modified Text

Subsection (a)(3)(A) was amended to provide clarity as to when an inventory reconciliation report must be completed by adding minimum criteria. The minimum criteria established will allow for identification of a pattern of loss by the pharmacist-in-charge where the pattern of loss is defined by the pharmacy's policies and procedures. The board

determined that a pattern of loss could vary depending on the pharmacy's business practice, so this allows flexibility for the pharmacy to determine what a pattern of loss will look like for their location. Additionally, a reportable loss was identified as being specified in section 1715.6, reporting drug losses. This was added as it clarifies the minimum threshold for losses and removes a single tablet loss, unless there is an identified pattern for those single tablet losses.

Subsection (a)(3)(B) was amended to refine the language and provide clarity as to the meaning of the term "functions" when identifying a loss of controlled substances. The functions completed must be sufficient to identify a drug loss and shall be defined with the pharmacy's policies and procedures. The board determined that the functions could vary depending on the pharmacy's business practice, so this allows flexibility for the pharmacy to determine the process for their location.

Second Modified Text

Subsection (a)(3)(A) was amended to rearrange the wording of the section. The reference to a reportable loss, as specified in section 1715.6, was relocated from the last sentence to following "at a minimum" to provide additional clarity that single tablet losses do not require completion of an inventory reconciliation report, unless there is an identified pattern for those single tablet losses.

Subsection (h) was amended to add "licensed correctional pharmacy" after inpatient hospital pharmacy. The board determined that this change was necessary because an ADDS used in a correctional facility is done so in a manner consistent with those of an inpatient hospital pharmacy.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the board does not have nor does it maintain data to determine if any of its licensees (pharmacies and clinics) are a "small business" as defined in Government Code section 11342.610, the board has determined that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the board concludes that the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant.

Business Reporting Requirements

As described in the original Notice for this action, pharmacies and clinics are currently required to perform an inventory reconciliation and report certain drug losses. This regulatory action does not require businesses to file additional reports with the board, but it does expand the substances that must be inventoried. The board has determined that it is

necessary for the health, safety, or welfare of the people of the State California that the identified controlled substances be inventoried by pharmacies and clinics and losses, as specified, be appropriately reported due to the abuse of opioids nationwide.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The board considered requiring an annual inventory of all controlled substances within Schedules III-V; however, the board determined that a more targeted approach was appropriate. The board determined that focusing on the non-Scheduled II controlled substances with the largest drug losses would have the greatest impact on the health and safety of California residents while also accounting for the pharmacy staff time necessary to complete the inventories.

Objections or Recommendations/Responses to Comments

During the public comment period beginning September 17, 2021 and ending on November 1, 2021, the board received several comments, which were provided in the meeting materials for the December 2, 2021 board meeting, and the board reviewed and considered them.

Summarized 45-day Comments Regarding Inventory Reconciliation:

Written Comments from Valley Children's Hospital

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

Response to Comment 1: The board reviewed this comment and did not make any changes to the text based thereon. The board noted 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." The board noted 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, the board made amendments to the regulatory text to further define "inventory activities."

Comment 2: The commenter indicated 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 recommended that the language be amended to add "periodic review" of all the records.

Response to Comment 2: The board reviewed this comment and did not make any changes to the text based thereon. The board noted 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 requested clarification on the meaning of "in writing" and if electronic communication (email) is acceptable.

Response to Comment 3: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the language does not prohibit email notification. Additionally, the board noted that there is a specific email designated for licensees to report drug theft, drug losses and impaired licensees (DEA106@dca.ca.gov).

Comment 4: The commenter requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board noted 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 recommended 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: The board reviewed this comment and did not make any changes to the text based thereon. The board believes that the terms "acquisition" and "disposition" are well known and understood and adding the definitions to the regulation is

not necessary. The board noted that varying levels of technology exist within ADDS systems utilized and such variances further emphasize the importance of maintaining the board's requirements.

Comment 6: The commenter requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board disagreed 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 requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board believes, 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 recommended 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: The board reviewed this comment and amended the regulation language to establish minimum criteria to initiate an inventory reconciliation report stemming from a loss.

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

Response to Comment 9: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that subsection (d) is existing regulation language and did 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 recommended that the language be amended to read "other functions sufficient to identify diversion."

Response to Comment 10: The board reviewed this comment and did not make any changes to the text based thereon; however, the board amended the regulatory text to further define "inventory activities." The board believes 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 requested 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 stated that if the PIC is diverting, the PIC should not be aware that the audit is occurring.

Response to Comment 11: The board reviewed this comment and did not make 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, the board noted that the regulation does not prohibit a corporate entity from conducting separate inventory activities and/or reconciliation reports.

Comment 12: The commenter requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board noted 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 requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board noted 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 requested a one-year implementation delay for IT changes.

Response to Comment 14: The board reviewed this comment and did not make any changes to the text based thereon. The board determined that an effective date of January 1, 2023, is sufficient to allow for implementation.

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

Comment 15: The commenter requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board did 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. The board noted 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 requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board 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 requested a one-year implementation delay for IT changes.

Response to Comment 17: The board reviewed this comment and did not make any changes to the text based thereon. The board determined that an effective date of January 1, 2023, is sufficient to allow for implementation.

Written Comments from Rachel Michelin, California Retailers Association

Comment 18: The commenter requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board did 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. The board notes 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 requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board noted 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 requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the language identifies that the inventory is specific to “that controlled substance.” The board amended the regulatory language to establish minimum criteria to initiate an inventory reconciliation report stemming from a loss.

Comment 21: The commenter requested 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: The board reviewed this comment and did not make any changes to the text based thereon. The board did not believe enough information

regarding the blind count and review of discrepancy reports was provided to provide a specific answer to the commenter's question 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 recommended 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: The board reviewed this comment and did not make any changes to the text based thereon; however, the board recommended that the language be amended to establish minimum criteria to initiate an inventory reconciliation report stemming from a loss.

Comment 23: The commenter recommended that subsection (g) be amended to add the phrase "outside of an automated drug delivery system (ADDS)." Commenter stated the addition of a quarterly report specific to each ADDS location could have significant operational impact for inpatient pharmacies.

Response to Comment 23: The board reviewed this comment and did not make any changes to the text based thereon. The board noted 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).

Summarized First 15-day Comments Regarding Inventory Reconciliation:

During the public comment period from December 3, 2021 and ended on December 18, 2021, the board received several comments, which were provided in the meeting materials for the January 27-28, 2022 board meeting, and the board reviewed and considered them.

Written Comments from Greg Doe, PharmD., CA Correctional Health Care Service

Comment 1: The commenter requested that licensed correctional pharmacies be regulated consistent with licensed hospital pharmacies due to the single entity ownership and oversight. Commenter stated that Correctional Pharmacies average 12 ADDS per pharmacy, with 480 ADDS across 34 institutions. Commenter requested that "licensed correctional pharmacy" be added to subsection (h) following "inpatient hospital pharmacy."

Response to Comment 1: The board reviewed this comment. While the board noted that this comment was outside the scope of the comment period, the board believed that the change was necessary and recommended that subsection (h) text be amended to add

“licensed correctional pharmacy” after inpatient hospital pharmacy. The board noted that ADDS used in a correctional facility are utilized in a manner consistent with those of an inpatient hospital pharmacy.

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

Comment 2: The commenter requested clarification if an inventory reconciliation report for a device where a loss occurred is sufficient or is an inventory reconciliation required across the entire hospital.

Response to Comment 2: The board reviewed this comment. The board noted that an inventory reconciliation report would only be required for the ADDS with the drug loss, not the entire hospital, unless there is a pattern identified or reason for concern identified by the pharmacist/pharmacy where a more extensive inventory is necessary. The board added clarifying language in subsection (a)(3)(A) to address this question.

Written Comments from Stanley Hill, PharmD., Orange Coast Medical Center

Comment 3: The commenter requested that the addition of the 4 drugs in subsection (a)(2) be removed as abused drugs change over time and subsection (a)(3) would require a reconciliation for them.

Response to Comment 3: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that it previously determined that these products were appropriate as they are the four non-Schedule II products with the highest reported drug losses to the board (See January 2020 Board Meeting Materials). These products are also subject to abuse and misuse, which make them a target for diversion within the pharmacy. The board determined that by requiring at least a yearly inventory of these four non-Schedule II-controlled substances, pharmacists, pharmacies, and clinics will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring.

Comment 4: The commenter requested that “inventory activities” be defined if the board is requiring specific documents. Additionally, the commenter requested that the Board provide an FAQ with additional information.

Response to Comment 4: The board reviewed this comment and did not make any changes to the text based thereon. The board noted “inventory activities” is defined within subsection (a)(3)(B) and shall be further defined by the pharmacy within their policies and procedures based on the functions sufficient to identify loss outside the inventory reconciliation process that meet the operational practice of the pharmacy. Additionally, the board noted that an FAQ is currently available on the board’s website https://www.pharmacy.ca.gov/licensees/faqs.shtml for inventory reconciliation (which was provided as Underlying Data in this rulemaking) and that the FAQ will be updated upon completion of this rulemaking process and approval by OAL.

Comment 5: The commenter believes subsection 1715.65(c)(1) conflicts with 1715.65(a), 1715.65(a)(1), and 1715.65(a)(2) as it states “each federal controlled substance,” which would include all controlled substances.

Response to Comment 5: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that the language in subsection (c)(1) states “An inventory reconciliation report prepared pursuant to this section shall....,” which identifies the controlled substances for which the inventory reconciliation report must be completed. The regulation does not state “all federal controlled substances.” The regulation refers to the federal schedules of controlled substances and not the state schedules of controlled substances as the schedules are different.

Comment 6: The commenter believes subsection 1715.65(c)(2) conflicts with 1715.65(a), 1715.65(a)(1), and 1715.65(a)(2) as it states “each federal controlled substance” which would include all controlled substances.

Response to Comment 6: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that the language in subsection (c)(2) states “each federal controlled substance covered by the report....” which identifies the controlled substances for which the records review must be completed. The regulation does not state “all federal controlled substances.” The regulation refers to the federal schedules of controlled substances and not the state schedules of controlled substances as the schedules are different.

Comment 7: The commenter believes subsection 1715.65(f) conflicts with 1715.65(a), 1715.65(a)(1), and 1715.65(a)(2) as it states “each federal controlled substance” which would include all controlled substances.

Response to Comment 7: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that the language in subsection (f) states “for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a)....” which identifies the controlled substances for which the records review must be completed. The regulation does not state “all federal controlled substances” or limit it to Schedule-II only. The regulation refers to the federal schedules of controlled substances and not the state schedules of controlled substances as the schedules are different.

Comment 8: The commenter recommended that subsection (g) be amended to specifically exclude AUDS from inventory reconciliation counts because they are significant controls in place to prevent diversion. Commenter stated that the requirement to inventory an AUDS would be an administrative burden.

Response to Comment 8: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that an inpatient hospital would follow subsection (h) for the inventory of an AUDS, which allows for inventory to be accounted for using a means other than a physical count. Further, the board noted that the board previously determined that as a pharmacy is responsible for the security of the drugs within its control (CCR 1714), and because inpatient hospitals maintain multiple drug storage areas, it is appropriate to include all drug storage areas within the hospital under the pharmacy's control in the regulation (See November 2019 and January 2020 Committee and Board Meeting Materials/Minutes).

Comment 9: The commenter recommended that subsection (h) not be amended as an AUDS and an APDS are different types of ADDS with different diversion prevention methods in place. Commenter stated that the requirement to inventory an AUDS would be an administrative burden. Commenter requested that the board maintain the existing language.

Response to Comment 9: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. The board also noted that the comment is unclear, and the intent of the language change is to provide increased flexibility to specified licensees.

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

Comment 10: The commenter expressed concern that the board has not accounted for economic impact to businesses.

Response to Comment 10: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. The board noted that the addition of the four non-Schedule II controlled substances was discussed at several committee and board meetings. The board selected these products as they are the four non-Schedule II products with the highest reported drug losses to the board (see January 2020 Board Meeting Materials). Additionally, the regulation text requires the inventory to be completed on an additional four non-Schedule II-controlled substances once a year (instead of once every two years) and that the economic impact to businesses was examined, calculated, and identified within the Initial Statement of Reasons. Finally, the board noted that because these products are also subject to abuse and misuse, making them a target for diversion within the pharmacy, California residents benefit from a more frequent inventory of these products as drug losses will be identified sooner, which reduces the amount of controlled substances diverted and the amount of drugs available for misuse and abuse.

Comment 11: The commenter requested that the regulation language be returned to committee for further discussion on the necessity for the regulation changes and possible alternatives.

Response to Comment 11: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that the language was discussed over several months and numerous public meetings and alternatives were considered, including requiring an annual inventory of all controlled substances; however, the board determined a targeted approach would have a larger impact on the health and safety of California residents while also accounting for the pharmacy staff time necessary to complete the inventories (please refer to the Underlying Data for the rulemaking, specifically, July and November 2019 Committee and Board Meeting Materials and Minutes and January 2020 Committee and Board Meeting Materials Minutes).

Comment 12: The commenter requested clarification on the minimum criteria to initiate an inventory reconciliation report stemming from a loss as the commenter does not believe the language establishes minimum criteria. Commenter believes the language requires an inventory reconciliation of a single pill.

Response to Comment 12: The board reviewed this comment and amended the regulation language to subsection (a)(3)(A) for clarity.

Comment 13: The commenter requested that pharmacies with operating systems with sufficient electronic record keeping be exempt from the wet signature requirement of 1715.65(e)(1).

Response to Comment 13: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the commenter previously submitted this comment during the 45-day comment period. As stated during the response to comment during the 45-day comment period, 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. (See 45-day comments, comment number 12).

Comment 14: The commenter requested 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. Additionally, the commenter indicated that “a single pharmacy may oversee many ADDS’ at variable distances from the pharmacy” and this is more complex than within a hospital, so these pharmacies should be able to rely on electronic reports as well. Commenter stated “an ADDS with scientific data proving the accuracy of its contents is valid that is stocked by authorized pharmacy personnel should enjoy the relief to administrative burden that hospitals enjoy.”

Response to Comment 14: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. As stated during the response to comment during the 45-day comment period, the board noted that technology varies based on the ADDS machine and the board is not requiring the use of a specific device. Additionally, as the commenter

points out, a pharmacy may not always be the one loading the ADDS and the pharmacy is responsible for devices outside the walls of a hospital. The board determined that the commenter's point about ADDS being varying distances from the pharmacy clearly illustrates why a physical count of the ADDS is more important for these machines. Without a physical count, the pharmacy would be unable to identify a loss for drugs under their control, but outside of their walls. Additionally, see the response to comment 1.

Comment 15: The commenter requested a one-year implementation delay for IT changes.

Response to Comment 15: The board reviewed this comment and did not make any changes to the text based thereon. The board determined that an effective date of January 1, 2023, is sufficient to allow for implementation.

Summarized Second 15-day Comments Regarding Inventory Reconciliation:

During the public comment period from January 28, 2022 and ended on February 12, 2022, the board received several comments, which were provided in the meeting materials for the March 16, 2022 board meeting, and the board reviewed and considered them.

Written Comments from Andre Pieterse, Pharmacist and Kevin Kaneko, PharmD.,

Comment 1: The commenters expressed concern about the requirements to complete inventory reconciliation in a hospital due to the blind counts and security controls currently in place for ADDS. Commenters requested a delay in implementation until further impact on patient safety and financial concerns can be heard.

Response to Comment 1: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period as the comment appears to apply to existing law. Additionally, the board note that the language has been discussed for over a year and at numerous public meetings. Further, the board noted that the language requiring an inventory reconciliation of an ADDS device within an inpatient hospital is an existing requirement and that amended language allows for a count to be completed by a means other than a physical count. The board is amending the regulation to allow additional flexibility to hospital using ADDS devices. It is not creating a new inventory reconciliation requirement. The board further noted that the effective date has been delayed until January 1, 2023, to allow time for implementation.

Written Comments from Deepak Sisodiya, Stanford Health Care

Comment 2: The commenter expressed concern about the requirements to complete inventory reconciliation in a hospital as the ADDS are monitored electronically. Commenter requested a delay in implementation until further feedback can be obtained.

Response to Comment 2: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period as the comment appears to apply to existing law.

Additionally, the board note that the language has been discussed for over a year and at numerous public meetings. Further, the board noted that the language requiring an inventory reconciliation of an ADDS device within an inpatient hospital is an existing requirement and that amended language allows for a count to be completed by a means other than a physical count. The board is amending the regulation to allow additional flexibility to hospital using ADDS devices. It is not creating a new inventory reconciliation requirement. The board further noted that the effective date has been delayed until January 1, 2023, to allow time for implementation.

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

Comment 3: The commenter requested clarification on whether "controlled substances stored within an ADDS are included in the quarterly inventory reconciliation report compiled by the inpatient hospital pharmacy."

Response to Comment 3: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that controlled substances within an ADDS are considered part of inventory of the pharmacy. The board noted that Business and Professions Code section 4427.4(d) provides that drugs and devices stored in an ADDS shall be deemed part of the inventory of the responsible pharmacy.

Written Comments from Ken Fukushima, PharmD.,

Comment 4: The commenter expressed concern about the requirements to complete inventory reconciliation in a hospital as the ADDS are monitored in real time through a variety of programs. Commenter requested a delay in implementation until further feedback can be obtained.

Response to Comment 4: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period as the comment appears to apply to existing law. Additionally, the board note that the language has been discussed for over a year and at numerous public meetings. Further, the board noted that the language requiring an inventory reconciliation of an ADDS device within an inpatient hospital is an existing requirement and that amended language allows for a count to be completed by a means other than a physical count. The board is amending the regulation to allow additional flexibility to hospitals using ADDS devices. It is not creating a new inventory reconciliation requirement. The board further noted that the effective date has been delayed until January 1, 2023, to allow time for implementation.

Written Comments from Robert Jackson, PharmD.,

Comment 5: The commenter expressed concern about the requirements to complete inventory reconciliation in a hospital due to the blind counts and security controls currently in place for ADDS. Commenter requested a delay in implementation until further feedback can be obtained.

Response to Comment 5: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period as the comment appears to apply to existing law. Additionally, the board note that the language has been discussed for over a year and at numerous public meetings. Further, the board noted that the language requiring an inventory reconciliation of an ADDS device within an inpatient hospital is an existing requirement and that amended language allows for a count to be completed by a means other than a physical count. The board is amending the regulation to allow additional flexibility to hospital using ADDS devices. It is not creating a new inventory reconciliation requirement. The board further noted that the effective date has been delayed until January 1, 2023, to allow time for implementation.

Written Comments from Martin Iyoya, PharmD.,

Comment 6: The commenter indicated that reconciling each ADDS unit would limit the expansion of valuable services due to additional burden on existing resources. Additionally, the commenter indicated that they had heard concerns about the proposed modifications and requested a delay in implementation until further feedback can be obtained.

Response to Comment 6: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period as the comment appears to apply to existing law. Additionally, the board note that the language has been discussed for over a year and at numerous public meetings. Further, the board noted that the language requiring an inventory reconciliation of an ADDS device within an inpatient hospital is an existing requirement and that amended language allows for a count to be completed by a means other than a physical count. The board is amending the regulation to allow additional flexibility to hospital using ADDS devices. It is not creating a new inventory reconciliation requirement. The board further noted that the effective date has been delayed until January 1, 2023, to allow time for implementation.

Written Comments from Stanley Hill, PharmD., Orange Coast Medical Center and Willis Shu, Miller Children's and Women's Hospital

Comment 7: The commenters requested that the addition of the 4 drugs in subsection (a)(2) be removed as abused drugs change over time and subsection (a)(3) would require a reconciliation for them.

Response to Comment 7: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that this comment was previously submitted and reviewed by the board during the January 2022 board meeting. The comment was considered by members and no changes were deemed necessary. The Board Meeting Materials (Agenda Item VI) are available on the board's website: https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jan_bd_mat.shtml.

Comment 8: The commenters indicated that section 1715.65(a)(3)(A) is unclear and requests further clarification on the board's intent.

Response to Comment 8: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that "reportable loss" is defined within section 1715.65(a)(3)(A), specifically, "a reportable loss is as specified in section 1715.6" and the board did not believe addition clarification was necessary or appropriate.

Comment 9: The commenters requested that "inventory activities" be defined if the board is requiring specific documents. Additionally, the commenters requested that the board provide an FAQ with additional information.

Response to Comment 9: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that this comment was previously submitted and considered by the board during the January 2022 board meeting. The comment was considered by members and no changes were deemed necessary. The Board Meeting Materials (Agenda Item VI) are available on the board's website: https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jan_bd_mat.shtml.

Comment 10: The commenters believe subsection 1715.65(c)(1) conflicts with 1715.65(a), 1715.65(a)(1), and 1715.65(a)(2) as it states "each federal controlled substance," which would include all controlled substances.

Response to Comment 10: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that this comment was previously submitted and considered by the board during the January 2022 board meeting. The comment was considered by members and no changes were deemed necessary. The Board Meeting Materials (Agenda Item VI) are available on the board's website: https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jan_bd_mat.shtml.

Comment 11: The commenters believe subsection 1715.65(c)(2) conflicts with 1715.65(a), 1715.65(a)(1), and 1715.65(a)(2) as it states "each federal controlled substance" which would include all controlled substances.

Response to Comment 11: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that this comment was previously submitted and considered by the board during the January 2022 board meeting. The comment was considered by members and no changes were deemed necessary. The Board Meeting Materials (Agenda Item VI) are available on the board's website: https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jan_bd_mat.shtml.

Comment 12: The commenters believe subsection 1715.65(f) conflicts with 1715.65(a), 1715.65(a)(1), and 1715.65(a)(2) as it states "each federal controlled substance" which would include all controlled substances.

Response to Comment 12: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that this comment was previously submitted and considered by the board during the January 2022 board meeting. The comment was considered by members and no changes were deemed necessary. The Board Meeting Materials (Agenda Item VI) are available on the board's website: https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jan_bd_mat.shtml.

Comment 13: The commenters recommended that subsection (g) be amended to specifically exclude AUDS from inventory reconciliation counts because there are significant controls in place to prevent diversion. The commenters stated that the requirement to inventory an AUDS would be an administrative burden.

Response to Comment 13: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that this comment was previously submitted and considered by the board during the January 2022 board meeting. The comment was considered by members and no changes were deemed necessary. The Board Meeting Materials (Agenda Item VI) are available on the board's website: https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jan_bd_mat.shtml.

Comment 14: The commenters recommended that subsection (h) not be amended as an AUDS and an APDS are different types of ADDS with different diversion prevention methods in place. The commenters stated that the requirement to inventory an AUDS would be an administrative burden. The commenters requested that the board maintain the existing language.

Response to Comment 14: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the comment is outside of the scope of this comment period. Additionally, the board noted that this comment was previously submitted and considered by the board during the January 2022 board meeting. The comment was considered by members and no changes were deemed necessary. The Board Meeting Materials (Agenda Item VI) are available on the board's website: https://www.pharmacy.ca.gov/meetings/agendas/2022/22_jan_bd_mat.shtml.

At its March 16, 2022, meeting, after reviewing and considering all comments in the record, the board voted to adopt the regulation text as noticed for public comment on January 28, 2022. Additionally, the board delegated to the Executive Officer the authority to make technical and nonsubstantive changes as necessary to complete the rulemaking file.