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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, Title 16, California Code of Regulations Section 1715.65, Inventory Reconciliation, Including Consideration of Public Comments Received During 15-Day Comment Period

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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 and, following review by the Board at the December 2021 Board meeting, amended language was released for 15-day public comment. The 15-day public comment period began on December 3, 2021 and ended on December 18, 2021. Several comments were received during the comment period. Attached following this memo are the following:

1. The proposed text released for 15-day public comment.
2. Board staff prepared summarized comments with recommendations
3. Board staff recommended modified text
4. Comments received during the 15-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 December 3, 2021 for 15-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 15-Day Comment

Title 16. Board of Pharmacy
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 substance~~s~~. 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 Board Staff Comment Recommendations

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Business, Consumer Services and Housing Agency
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Proposed Regulation to Amend Title 16 CCR Section 1715.65, Inventory Reconciliation

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Summarized 15-day Comments Regarding Inventory Reconciliation with Board Staff Recommendations:

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

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

Response to Comment 1: Board staff have reviewed this comment. While Board staff note that this comment is outside the scope of the comment period, Board staff believe that the change is necessary and recommend that subsection (h) text be amended to add "licensed correctional pharmacy" after inpatient hospital pharmacy. Staff note 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 requests 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: Board staff have reviewed this comment. Board staff note 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. Board staff are recommending clarifying language subsection (a)(3)(A).

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

Comment 3: The commenter requests 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. Additionally, Board staff note that the Board previously determined that these products are 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 requests that "inventory activities" be defined if the Board is requiring specific documents. Additionally, the commenter requests that the Board provide an FAQ with additional information.

Response to Comment 4: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note "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, Board staff note that an FAQ is currently available on the Board's website https://www.pharmacy.ca.gov/licensees/faqs.shtml for inventory reconciliation 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. Additionally, Board staff note 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. Additionally, Board staff note 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. Additionally, Board staff note 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 recommends that subsection (g) be amended to specifically exclude AUDS from inventory reconciliation counts because they are significant controls in place to prevent diversion. Commenter states that the requirement to inventory an AUDS would be an administrative burden.

Response to Comment 8: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. Additionally, Board staff note 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, Board staff note 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 recommends 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 states that the requirement to inventory an AUDS would be an administrative burden. Commenter requests that the Board maintain the existing language.

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 the comment is outside of the scope of this comment period. Board staff also note 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. Board staff note 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, which is available on the Board website: https://www.pharmacy.ca.gov/laws_regs/1715_65_isr.pdf. Finally, Board staff note 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 requests 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. Additionally, Board staff note 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 requests clarification on the minimum criteria to initiate an inventory reconciliation report stemming from a loss as the commenter does not believe the language establishes a minimum criteria. Commenter believes the language requires an inventory reconciliation of a single pill.

Response to Comment 12: Board staff have reviewed this comment and are recommending clarifying language subsection (a)(3)(A).

Comment 13: The commenter requests 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period. 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 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. Additionally, the commenter indicates 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 states 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note 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, Board staff note 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. Board staff believe 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 requests a one-year implementation delay for IT changes.

Response to Comment 15: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff recommend a January 1, 2023 effective date.

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.

Additional changes to the modified regulation language are shown by ~~*italic double strikethrough*~~ for deleted language and wave underline for added language. [These amendments are specific to subsections (a)(3)(A) and (h).]

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~~ reportable 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, a reportable loss is as specified in section 1715.6, or any pattern(s) of loss(es) identified by the pharmacist in charge, as defined by the pharmacy's policies and procedures. A reportable loss 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 reconcilliation 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 substance~~s~~. 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 report~~s 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 licensed correctional 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 15-Day Public Comment

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December 9, 2021

Lori Martinez
California State Board of Pharmacy
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Members of the Board,

California Correctional Health Care Services (CCHCS) appreciates the opportunity to provide comment in response to the proposed modified text for California Code of Regulations §1715.65 Inventory Activities and Inventory Reconciliation Reports of Controlled Substances. CCHCS operates approximately 40 licensed Correctional Pharmacies, 320 licensed Correctional Clinics and 480 Automated Drug Dispensing Systems (ADDS) across 34 Institutions. Therefore, the CCHCS Correctional Pharmacies average 12 automated drug dispensing systems per pharmacy.

California Correctional Health Care Services provides medical and pharmacy services across all 34 institutions. Each institution has a series of licensed correctional clinics and may have inpatient beds licensed by California Department of Public Health all of which are located at one physical address and are overseen by one Chief Executive Officer. Therefore, the ownership and operation of each institution falls under a single entity as does an inpatient hospital.

Controlled substances are stored in ADDS which are comprised of a series of locked compartments that can't be opened without recording access. The inventory count is maintained by blind count back prior to removal of a dose, guided cycle counts on a daily basis, discrepancy reporting and a monthly cycle count of all controlled substances by a pharmacist for each ADDS machine. For the purposes of controlled substance inventory management, CCHCS manages its ADDS pursuant to its system-wide policy similar to an "inpatient" hospital pharmacy.

In consideration of: single entity ownership and oversight, the average number of ADDS that each licensed correctional pharmacy would be required to "physically count" pursuant to the proposed regulation, and policies and procedures essentially the same as those for a licensed hospital pharmacy, CCHCS is requesting that "licensed correctional pharmacy" be added to "subsection h)" so that it reads as follows:

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§ 1715.65. Inventory Activities and Inventory Reconciliation Reports of Controlled Substances.

. . .

h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy **or licensed correctional 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~~ §1715.65

~~(4) Confirmed losses of controlled substances are reported to the board.~~

Respectfully,

DocuSigned by:
Greg Doe
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December 14, 2021

Lori Martinez
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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.

> *Regarding the proposed text amendment to 1715.65 subdivision a (3)(A):*
> *In an inpatient hospital setting, is the completion of an inventory reconciliation report for the device (ex. ADCs on nursing units or narcotic vault) where the loss occurred sufficient to satisfy this requirement? Or is there a need to submit a report of the full inventory of the medication activity across the entire hospital?*

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

From: Stanley E Hill III <SHill@memorialcare.org>
Sent: Thursday, December 16, 2021 2:51 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Cc: Stanley E Hill III <SHill@memorialcare.org>; Jill Chang (4) <JChang4@memorialcare.org>; Jennifer Chang (2) <JChang2@memorialcare.org>; Ed Wong <ESWong@memorialcare.org>; Willis Shu <WShu@memorialcare.org>; Brian Stuckman <BStuckman@memorialcare.org>; Kristen Pugh <KPugh@memorialcare.org>
Subject: CCR 1715.65 Modified Text Comments
Importance: High

Ms. Martinez

I appreciate the opportunity to comment on the California Board of Pharmacy's (BOP) December 2, 2021 modified Regulation text for Inventory Activities and Inventory Reconciliation Reports of Controlled Substances by modifying CCR Section 1715.65. A link to the Proposed Regulations is provided below: https://www.pharmacy.ca.gov/laws_regs/1715_65_mod_text.pdf

Drug diversion is a serious issue that requires continuous and detailed management and oversight at all levels. The current CCR 1715.65 text has been in place for several years to help identify and combat controlled substance loss. I hope that the Board of Pharmacy has studied the impact of the current regulations along with the proposed modified text on current rates of diversion in comparison to the operational impacts on pharmacies and its personnel. This regulation requires a significant amount of resources to meet. It requires significant labor resources redirected from patient care or management activities, IT resources for report generations, analyst time to review and analyze data, and labor resources for any investigations and report writing. Please consider this overall impact to pharmacies in considering the modified text and my subsequent comments.

1715.65(a)(2)

(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.

Comment: The inclusion of the 4 drug preparations listed under 1715.65(a)(2) are too specific for continuous review. Though alprazolam and promethazine with codeine are currently well known abused drugs, preferences for these drugs will change over time. The unfortunately effect is all pharmacies will continue to perform these reconciliation practices when the risk has moved to a different drug. In

addition, the main wholesalers (McKesson, ABC, Cardinal) currently have processing in place to limit controlled substance ordering based on historical patterns. Finally, 1715.65(a)(3)(A) provides guidance to perform a reconciliation of a controlled substance. This would seem sufficient for these targeted drugs over continuous review based on available resources.

Recommendation:

1. Remove the language in 1715.65(a)(2) and allow 1715.65(a)(3)(A) to require a reconciliation for identified losses.

1715.65(a)(3)(B)

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

Comment: The definition "inventory activities" is nebulous. If the Board of Pharmacy is looking for specific items which could be favored based on size and practice setting it will be difficult to determine those standard activities.

Recommendation:

1. Further define "inventory activities" if the Board of Pharmacy has specific ones in mind
2. Provide an FAQ to pharmacies with the appropriate information

1715.65(c)(1)

(c) An inventory reconciliation report prepared pursuant to this section shall include all of the following:

(1) A physical count, not an estimate, of all quantities of each federal controlled 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)

Comment: This section does not specifically correlate with 1715.65(a). This section indicated each federal controlled substances. This could imply all schedules including C-II through C-V. I believe the intent was all federal schedule II drugs as defined in 1715.65(a)(1). In addition, it does not correlate with 1715.65(a)(2) since alprazolam and promethazine with codeine are not C-II.

Recommendation:

1. Modify the text as follows
   (1) A physical count, not an estimate, of all quantities of each federal controlled ***II*** 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)

1715.65(c)(2)

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

Comment: This section does not specifically correlate with 1715.65(a). This section indicated each federal controlled substances. This could imply all schedules including C-II through C-V. I believe the intent was all federal schedule II drugs as defined in 1715.65(a)(1). In addition, it does not correlate with 1715.65(a)(2) since alprazolam and promethazine with codeine are not C-II.

Recommendation:

1. Modify the text as follows
   (2) A review of all acquisitions and dispositions of each federal controlled ***II*** substance covered by the report since the last inventory reconciliation report covering that controlled substance;

1715.65(f)

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report 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 for those controlled substances.

Comment: This section does not specifically correlate with 1715.65(a). This section indicated each federal controlled substances. This could imply all schedules including C-II through C-V. I believe the intent was all federal schedule II drugs as defined in 1715.65(a)(1). In addition, it does not correlate with 1715.65(a)(2) since alprazolam and promethazine with codeine are not C-II.

Recommendation:

1. Modify the text as follows
   (f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report 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 for those ***federal*** controlled ***II*** substances.

1715.65(g)

(g) 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 quarterly basis. The report or reports shall include controlled substances stored within the pharmacy within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

Comment: The addition of the phrase "…and within each drug storage in the hospital under the pharmacy's control.", is unclear. I would request the Board of Pharmacy clarifies this since this be floor stock, medication trays, automated dispensing stations, etc. The automated dispensing stations are AUDS and have significant controls in place for diversion prevention. The inclusion of AUDS in this regulation astronomical increases the amount of resources and time needed to complete these

activities. In performing the inventory reconciliation process quarterly in the main inpatient pharmacy ADDS yields 6100 lines of transactions that need to be analyzed. Including each AUDS site at most facilities will increase this analysis by the number of AUDS present at each facility. Personally, I would go from analyzing 6,100 lines to ~180,000 lines of data quarterly. This amount of data becomes untenable especially when numerous accountability activities are in place.

Recommendation:

1. Modify the language to exclude AUDS from here.
   "…and within each drug storage in the hospital under the pharmacy's control ***excluding AUDS***."
2. Modify the language to indicated areas not under AUDS control
   "…and within each ***non-AUDS*** drug storage in the hospital under the pharmacy's control.",

1715.65(h)

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

Comment: According to the Board of Pharmacy lawbook, an "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions. An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

The term ADDS is an umbrella term that is covering AUDS and APDS. Both AUDS and APDS are unique solutions for the storage and control of medications. A AUDS, such as Pyxis or Omnicell, is typically used in the inpatient setting. There are numerous control in place for diversion prevention in the inpatient setting. The previous language that ensures tight management of controlled substance in these machines. These mechanism are sufficient to identified potential diversion. In performing the inventory reconciliation process quarterly in the main inpatient pharmacy ADDS yields 6100 lines of transactions that need to be analyzed. Including each AUDS site at most facilities will increase this analysis by the number of AUDS present at each facility. Personally, I would go from analyzing 6,100 lines to ~180,000 lines of data quarterly. This amount of data becomes untenable especially when numerous accountability activities are in place.

Recommendation:

1. Do not modify the current language and continue the same verbiage as currently in place in 1715.65(h).
   (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.

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12/17/2021

Lori Martinez

California State Board of Pharmacy

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Lori.Martinez@dca.ca.gov

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 concerning 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 believes in an evidenced based decision-making process and the "necessity" for the adoption of regulations. This sentiment is shared by the California Legislature whereby the Legislature has declared that substantial time and public funds have been spent in adopting regulations, the necessity for which has not been established. [Cal.Gov.Code § 11340]. The Legislature further defines necessity as to mean the record of the rulemaking proceeding demonstrating by ***substantial evidence*** the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion. [Cal.Gov.Code § 11349]. Recent votes by the California Board of Pharmacy ("The Board"), such as the decision to promulgate rules aimed at decreasing the utilization of auto-refill programs and the decision to not seek a permanent allowance for pharmacy technician immunization administration, raise concerns because the decisions themselves have not been demonstrated by substantial evidence. To the contrary, there is evidence that proves that auto refill programs increase patient adherence and thus public safety[1] and that pharmacy technician administration is safe and effective[2], increasing overall immunization rates and time for pharmacists to dedicate to patient facing activities.

As no other state or the United States Drug Enforcement Administration require inventory reconciliation, as 1715.65 does, the Board has an excellent opportunity to study the results of the effect of 1715.65 upon public safety, which to date has not been done. Without any substantial evidence produced by the Board to prove the rule's necessity, which is a charge by the CA Legislature, the Board proposes substantial changes that require further substantial cost investments by its licensees. The Board is mandated by law to provide facts, evidence, documents, testimony, or other evidence on which the agency relies to support an initial determination that the action will not have a significant adverse economic impact on business. [Cal.Gov.Code § 11346.2(5)(A)]. We believe the Board has not adequately accounted for the cost impact on licensees. Furthermore, the Board is required by law to include a description of reasonable alternatives to the regulation that would lessen any adverse impact on small business and the agency's reasons for rejecting those alternatives. [Cal.Gov.Code § 11346.2(4)(B)]. We don't believe the Board has complied with these statutory mandates.

As I have commented during open, public meetings of the Board many times before, an important component to public safety is access to care[3] and adding administrative burden to pharmacies is going to

continue the trend of pharmacy closure[4]. While much of the nation has embarked upon a campaign to reduce regulation thereby stimulating innovative solutions to healthcare issues, the Board continues to add regulations and burden based upon motives and beliefs that are not founded upon scientific data. ***The Board is engaging in the very activity that the CA Legislature recognized as a significant issue.***

- The Legislature has declared that there has been an unprecedented growth in the number of administrative regulations in recent years.
- The Legislature has declared that the language of many regulations is frequently unclear and unnecessarily complex, even when the complicated and technical nature of the subject matter is taken into account. The language is often confusing to the persons who must comply with the regulations.
- The Legislature has declared that substantial time and public funds have been spent in adopting regulations, the necessity for which has not been established.
- The Legislature has declared that the imposition of prescriptive standards upon private persons and entities through regulations where the establishment of performance standards could reasonably be expected to produce the same result has placed an unnecessary burden on California citizens and discouraged innovation, research, and development of improved means of achieving desirable social goals. [Cal.Gov.Code § 11340(a-d)].

For all the aforementioned reasons, CVS Health respectfully requests that the Board comply with their Legislative charge and prove the rule's necessity based on substantial evidence, starting with sending this rule making back to committee to perform an in-depth study.

Additionally, CVS Health is greatly concerned with confusion stemming from the meeting materials of the 12/2/2021 meeting of the Board and statements made during the 12/2/2021 meeting, which further substantiate the need for this rule making effort to be sent back to committee to resolve these inconsistencies.

- The Board published the following: "**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."

  However, the published amendments to (a)(3)(A) do not establish a minimum criteria and still require that a single dosage unit loss trigger an inventory reconciliation report. CVS Health believes that the published materials are inaccurate and were not adequately vetted at the 12/2/2021 meeting of the Board.

- The Board states in their "**Response to Comment 12**" that "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."

  This indicates that operating systems with sufficient electronic record keeping, as most pharmacies have developed, should be exempt from "wet signatures", however no such amendment to the pending language was published.

- The Chair of the Enforcement Committee explained that it is not feasible for a hospital to inventory every ADDS under its control at the exact same time, therefore 1715.65 allows hospitals to rely upon electronic reporting for controlled substances contained within said ADDS.

  CVS Health believes that inventorying every ADDS under the control of a pharmacy that services long term care facilities is more challenging than ADDS' located in a hospital. Due to the 1/1/2022 allowance, that expands the types of facilities that may utilize an ADDS, a single pharmacy may oversee many ADDS' at variable distances from the pharmacy. This is a more complex scenario than those ADDS' contained within the walls of a hospital.

- The 12/2/2021 meeting materials include a "**Response to Comment 13"** that states "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", indicating that 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.

  However, no such amendment to 1715.65 was made at the 12/2/21 meeting.

Lastly, CVS Health believes that the following comment submitted and published in the 12/2/2021 meeting materials was not adequately considered by the Board.

- The pending changes to 1715.65 as published require many IT changes at great cost in order to comply. For example, (a)(3)(A) requires an inventory reconciliation report for any loss of a single dosage unit of any controlled substance, which requires every NDC of every CIII, CIV and CV controlled substance to be added to the program, which is no easy feat to accomplish.

  The Board's Response to comment 14 and 17, which request a one-year delayed implementation date, state that the "Board staff determined that this is a policy decision for the Board". Although the Board's staff defers to the Board, we do not believe that the Board adequately considered this request at the 12/2/2021 meeting, and therefore CVS Health again requests that the Board consider this allowance, which we do not believe would initiate an additional comment period.

In summary, CVS Health is greatly concerned in the proceedings that occurred at the Board's 12/2/2021 meeting. The Board has traditionally partnered with the public on rule making efforts, however the Enforcement Committee Chair's motion to accept the pending rules as amended by the Board's staff prior to any Board discussion raises concerns and gives a perception to the public that the Board was more concerned with simply adopting rules than investing the time and effort to consider all valid comments and concerns. While CVS Health commends the Board for administering virtual meetings during the pandemic, we look forward to in-person meetings where public comments seemingly appear to be considered at an appropriate level. This topic deserved more than two minutes of comment per person and deserved the interactive Board deliberations that we have become accustomed to over the years. Therefore again, we respectfully request that the Board send this effort back to committee, and if the Board is determined to finalize these rules without addressing the public's concerns, we respectfully request that implementation be delayed by one year.

CVSHealth

Sincerely,

Mark Johnston, R.Ph

Senior Director

Board of Pharmacy Regulatory Affairs

1. CVS Health comment letter pertaining to Title 16 Code of Regulations Section 1717.5, regarding pharmacy automatic refill programs dated 8/27/2020.
2. Journal of the American Pharmacists Association, 58 (2018) 174e178, Training Pharmacy Technicians to Administer Immunizations, by Kimberly C. McKeirnan*, Kyle R. Frazier, Maryann Nguyen, and Linda Garrelts MacLean.
3. Journal of the American Medical Association, 2019;2(4):e192606. doi:10.1001/jamanetworkopen.2019.2606, Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults by Dima M. Qato, PharmD, MPH, PhD; G. Caleb Alexander,MD, MS; Apurba Chakraborty, MBBS, MPH; Jenny S. Guadamuz, MS; and JohnW. Jackson, ScD.
4. Journal of the American Medical Association, doi:10.1001/jamainternmed.2019.4588, Assessment of Pharmacy Closures in the United States From 2009 Through 2015, by Jenny S. Guadamuz, MS[1]; G. Caleb Alexander, MD, MS[2,3]; Shannon N. Zenk, PhD[4]; and et alDima M. Qato, PharmD, MPH, PhD[1,5]