California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item V. 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 the Second 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 and, following review by the Board at the January 2022 Board meeting, amended language was released for second 15-day public comment.

The second 15-day public comment period began on January 28, 2022 and ended on February 12, 2022. 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 second 15-day public comment. Several comments were received during the comment period. Attached following this memo are the following:

1. The proposed text released for the second 15-day public comment period.
2. Board staff prepared summarized comments with recommendations
3. 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 January 28, 2022 for comment.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a third 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses and adopt the regulation text as noticed for public comment on January 28, 2022. Additionally, delegate the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

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

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

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

Comment 1: 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. Commenters requested a delay in implementation until further impact on patient safety and financial concerns can be heard.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the comment is outside of the scope of this comment period as the comment appears to apply to existing law. Additionally, Board staff note that the language has been discussed for over a year and at numerous public meetings. Further, Board staff note 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. Board staff further note that the Board has delayed the effective date to 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: 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 the comment appears to apply to existing law. Additionally, Board staff note that the language has been discussed for over a year and at numerous public meetings. Further, Board staff note 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. Board staff further note that the Board has delayed the effective date to January 1, 2023 to allow time for implementation.

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

Comment 3: The commenter requests 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: Board staff have reviewed this comment. Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that controlled substances within an ADDS are considered part of inventory of the pharmacy. Board staff note 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: 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 the comment appears to apply to existing law. Additionally, Board staff note that the language has been discussed for over a year and at numerous public meetings. Further, Board staff note 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. Board staff further note that the Board has delayed the effective date to 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: 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 the comment appears to apply to existing law. Additionally, Board staff note that the language has been discussed for over a year and at numerous public meetings. Further, Board staff note 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. Board staff further note that the Board has delayed the effective date to January 1, 2023 to allow time for implementation.

Written Comments from Martin Iyoya, PharmD.,

Comment 6: The commenter indicates 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: 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 the comment appears to apply to existing law. Additionally, Board staff note that the language has been discussed for over a year and at numerous public meetings. Further, Board staff note 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. Board staff further note that the Board has delayed the effective date to 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 request 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: 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 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 8: The commenters indicate that section 1715.65(a)(3)(A) is unclear and requests further clarification on the Board's intent.

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 "reportable loss" is defined within section 1715.65(a)(3)(A), specifically, "a reportable loss is as specified in section 1715.6" and Board staff do not believe addition clarification is necessary or appropriate.

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

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. Additionally, board staff note 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: 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 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: 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 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: 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 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 recommend 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 states that the requirement to inventory an AUDS would be an administrative burden.

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. Additionally, board staff note 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 recommend 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 state that the requirement to

inventory an AUDS would be an administrative burden. The commenters request that the Board maintain the existing language.

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. Additionally, board staff note 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.

February 11, 2022

Lori Martinez lori.martinez@dca.ca.gov
California State Board of Pharmacy
2720 gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Members of the Board

I appreciate the opportunity to comment on the California Board of Pharmacy's Title 16, California Code of Regulations Section 1715.65.

I would like to add my voice to many others who have already expressed concern for the proposed modified sections of Title 16 Section 1715.65. It leaves me concerned about the level of effort and cost in reconciling controlled substances regularly for each Automated Drug Dispensing System (ADDS) (such as Pyxis®/Omnicell®) in a hospital environment as stated in section (g) of the modified text.

Please allow me to share my personal experience. In the past I attempted to perform this reconciliation for each ADDS using only electronic records and my experience was that it was a massive time commitment. I would like to share some of the details I encountered in practice.

My hospital performs Pyxis level physical counts monthly, so we have a beginning and end count for each drug in a Pyxis machine. We utilize a spreadsheet with programming that can crunch the numbers. It takes time in *Knowledge Portal* (the Pyxis reporting portal where all transactions are tracked, Omnicell has Pandora) for the system to generate a .csv report for Acquisitions and a .csv report for Dispositions for each Pyxis unit. The reports can only be done by date and not by time. One must delete lines with transactions prior to the beginning count and after the end count. Once this is done, in theory the end count should match the calculated count. When these counts don't match, the mismatch must be researched, and an explanation found and documented. These mismatches occur frequently and usually are a result of the reporting or various explainable Pyxis transactions that routinely occurs.

The time it takes to generate reports and research the mathematical differences for each ADDS comes to an average of 1 hour per unit. In my hospital, we have 15 ADDS's which would equate to almost 2 full working days of work for a pharmacy staff member. Over time we established that performing the reconciliation monthly keeps data limited and is more manageable. Kindly keep in mind that this is two days that takes a staff member away from being involved with the care of hospital patients. Given this average time commitment, I am also concerned for large hospitals in California which ultimately will need one staff member to do this full time. This will put a burden in terms of removing staff from their patient care functions and increase labor cost on inpatient pharmacy departments. The level of effort required to do this while we are already ensuring high accountability in our processes seems disproportionate. Kindly keep in mind that hospitals already have systems and processes in place that ensure accountability for all staff members throughout the drug distribution process.

ADDS's have a valuable tool in drug diversion prevention in requiring a 'blind count'. What this entails is that every user removing a controlled substance (CS) from the ADDS first need to count the CS before removing the dose. The count is considered 'blind' because the user does not know in advance whether the quantity physically counted matches with what the machine tracking of the quantity on hand should

be. If the count does not match, a 'discrepancy' is created which is reported on the ADDS and also in the pharmacy department. Nursing staff will resolve the discrepancy if there is a logical explanation for the discrepancy and pharmacy staff will audit the resolution to ensure appropriateness. If the discrepancy cannot be resolved, nursing and pharmacy leadership partner to thoroughly investigate the issue.

Another practice that is in place is the 'waste witness' requirement built in the ADDS system. If a user removes a vial containing CS and only part of the dose will be used, another user must witness the waste of the partial dose and enter their credentials in the ADDS verifying that they witnessed the waste.

Also consider that the ADDS's in a hospital are linked to the controlled substance ADDS in the pharmacy department. If a quantity is removed from the pharmacy ADDS and then delivered to the ADDS on the care unit, this quantity must match the quantity stocked in the ADDS on the care unit. If a drug dose goes missing in the transport and replenishment process between the pharmacy and the care unit, the ADDS on the care unit will recognize the discrepancy and a report is automatically created and sent to pharmacy management for investigation and resolution.

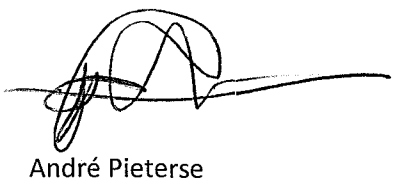
These are just a few examples of systems already in place at hospitals that helps us ensure tight controls over the drug distribution process in hospitals. Due to all these controls already being in place and within the capability of the ADDS's in hospitals, there is very little value in performing regular inventory reconciliations at the ADDS level in a hospital.

Kindly consider that pharmacists in hospitals take our role as the stewards of medications very serious and we are already ensuring high accountability from anyone who handles not only controlled substance medications, but all medications. We are aligned with the BOP and other agencies in that we want to prevent drug diversion.

The assessment and assumption that this regulation has negligible cost impact, is not correct in the case of hospitals. Please know that if this regulation is enacted and implemented, it will take licensed pharmacy staff member/s away from the care of patients and it will add the cost of the time and salary of these staff members to the overall cost of care in a hospital while negatively impacting patient safety.

I would like to respectfully request that the Board of Pharmacy delay further progression towards the implementation of these changes in Section 1715.65 until it had the opportunity to hear from stakeholders about the impact on patient safety and financial repercussions.

Sincerely,



André Pieterse

Registered Pharmacist #53374

PO Box 482, Pioneer CA 95666

From: Sisodiya, Deepak
To: Martinez, Lori@DCA; Damoth, Debbie@DCA
Subject: BOP Title 16, Regs 1715.65 Feedback
Date: Friday, February 11, 2022 10:09:15 AM
Attachments:

Good Morning Ms. Martinez and Ms. Damoth,

I hope this email finds you both well. I am reaching out to share my thoughts on California Board of Pharmacy's Title 16, California Code of Regulations Section 1715.65.

I am concerned the proposed modifications will present an unnecessary burden on hospitals and health systems. Stanford already have processes in place for oversight through the use of our Automated Dispensing System (ADDS) platform, Omnicell, which is further supplemented with Diversion Analytics software BlueSight. All transactions are monitored electronically with processes to explore and resolve any discrepancies should one arise. Stanford has ~ 200 Omnicell units which we estimate would require up towards > 120 hours per month to perform a full reconciliation based on the proposed modification. Given we are very strapped on resources and facing record patient volumes, these are valuable hours that would be much better served towards advancing patient care medication activities (e.g., Medication Reconciliation, Patient Education).

I would like to propose the Board of Pharmacy re-consider implementing these changes or allow time to solicit more feedback from our peers.

Respectfully,

Deepak Sisodiya
Administrative Director – Pharmacy Services
Stanford Health Care
300 Pasteur Dr, Room HO301 MC 5616 • Stanford, CA 94305
dsisodiya@stanfordhealthcare.org | **O:** 650.725.5801 **C: 925.895.1350**
Administrative Assistant: Denise Ramirez 650.725.5802 | dramirez@stanfordhealthcare.org

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February 11, 2022

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

Dear Members of the Board,

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

1. Regarding the proposed text amendment to 1715.65 subdivision (g), we would like to seek clarification on the phrase "... within each drug storage area in the hospital under the pharmacy's control". Specifically, we would appreciate if the board could either confirm or deny that controlled substances stored within automated drug delivery systems (ADDS) are to be included in the quarterly inventory reconciliation report compiled by the inpatient hospital pharmacy.

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: kenfukushima84@gmail.com
To: Martinez, Lori@DCA
Cc: Damoth, Debbie@DCA
Subject: Modified Title 16 Section 1715.65 Inventory Reconciliation
Date: Saturday, February 12, 2022 8:03:13 AM

February 11, 2022

Ms. Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Members of the Board,

I appreciate the opportunity to comment on the California Board of Pharmacy's Title 16, California Code of Regulations Section 1715.65.

I'd like to express my concern over the proposed modified sections of Title 16 Section 1715.65. Based on my review of our current controlled substances inventory reconciliation processes, I feel that such modifications will only unnecessarily burden resource strapped hospital and health system pharmacies while not adding value to programs with strong diversion mitigation and monitoring programs already in place.

Our controlled substance inventory, particularly that stored in our Automated Drug Dispensing Systems(ADDS), Pyxis and Omnicell (depending upon the site) are closely monitored real time through a system of programs (Diversion analytics) along with daily nursing activities such as blind counts and waste witnessing. Daily Discrepancy review results in investigation and resolution of any mismatch. Inventory in our ADDS is linked to our inventory system in the pharmacy system and monitored with each withdrawal and transaction on the nursing unit. In fact, discrepancies in controlled drugs are reported out during daily Leadership safety huddles and resolved shortly after they are discovered.

Our large and small hospitals in totality maintains, stocks and supplies over 300 Pyxis/Omnicell devices throughout our facilities. During a recent assessment, we estimated that it would take the equivalent of 40 or more staff(pharmacist/pharmacy technician/nursing combination) hours per week to conduct a full reconciliation of these devices as required by the aforementioned modification. As stated previously, a combination of the demands of the pandemic and tightening budget controls has left us with little room in staffing flexibility. Reconciling each ADDS Unit would negatively impact our labor force and patient safety and force us to limit the expansion of truly valuable services.

As I've heard concerns over the changes in Section 1715.65 discussed in a number of pharmacy leadership forums, I would like to respectfully request that the Board of Pharmacy consider delaying implementation of these changes until it has the opportunity to hear from my colleagues and counterparts on this matter.

Respectfully submitted,
Ken Fukushima, PharmD
RPH 38906
Ken
909-292-7233

February 10, 2022

Lori Martinez lori.martinez@dca.ca.gov
California State Board of Pharmacy
2720 gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Members of the Board

I appreciate the opportunity to comment on the California Board of Pharmacy's Title 16, California Code of Regulations Section 1715.65.

I would like to add my voice to many others who have already expressed concern for the proposed modified sections of Title 16 Section 1715.65. It leaves me concerned about the level of effort and cost in reconciling controlled substances regularly for each Automated Drug Dispensing System (ADDS) (such as Pyxis®/Omnicell®) in a hospital environment as stated in section (g) of the modified text.

Please allow me to share my personal experience. In the past I attempted to perform this reconciliation for each ADDS using only electronic records and my experience was that it was a massive time commitment. I would like to share some of the details I encountered in practice.

My hospital performs Pyxis level physical counts monthly, so we have a beginning and end count for each drug in a Pyxis machine. We utilize a spreadsheet with programming that can crunch the numbers. It takes time in *Knowledge Portal* (the Pyxis reporting portal where all transactions are tracked, Omnicell has Pandora) for the system to generate a .csv report for Acquisitions and a .csv report for Dispositions for each Pyxis unit. A shortcoming of the Knowledge Portal is that reports are only done by date and not by time. One must delete lines with transactions prior to the beginning count and after the end count. Once this is done, in theory the end count should match the calculated count. When these counts don't match, the mismatch must be researched, and an explanation found and documented. These mismatches occur frequently and usually are a result of the reporting or various explainable Pyxis transactions that routinely occurs.

The time it takes to generate reports and research the mathematical differences for each ADDS comes to an average of 1 hour per unit. In my hospital, we have 15 ADDS's which would equate to almost 2 full working days of work for a pharmacy staff member. Over time we established that performing the reconciliation monthly keeps data limited and is more manageable. Kindly keep in mind that this is two days that takes a staff member away from being involved with the care of hospital patients. Given this average time commitment, I am also concerned for large hospitals in California that ultimately will need one staff member to do this full time. This will put a burden in terms of removing staff from their patient care functions and increase labor cost on inpatient pharmacy departments. The level of effort required to do this while we are already ensuring high accountability in our processes seems disproportionate. Kindly keep in mind that hospitals already have systems and processes in place that ensure accountability for all staff members throughout the drug distribution process.

ADDS's have a valuable tool in drug diversion prevention in requiring a 'blind count'. What this entails is that every user removing a controlled substance (CS) from the ADDS first need to count the CS before removing the dose. If the count does not match, a 'discrepancy' is created which is reported on the

ADDS and also in the pharmacy department. Nursing staff will resolve the discrepancy if there is a logical explanation for the discrepancy and pharmacy staff will audit the resolution to ensure appropriateness. If the discrepancy cannot be resolved, nursing and pharmacy leadership partner to thoroughly investigate the issue.

Another practice that is in place is the 'waste witness' requirement built in the ADDS system. If a user removes a vial containing CS and only part of the dose will be used, another user must witness the waste of the partial dose and enter their credentials in the ADDS verifying that they witnessed the waste.

Also consider that the ADDS's in a hospital are linked to the controlled substance ADDS in the pharmacy department. If a quantity is removed from the pharmacy ADDS and then delivered to the ADDS on the care unit, this quantity must match the quantity stocked in the ADDS on the care unit. If a drug dose goes missing in the transport and replenishment process between the pharmacy and the care unit, the ADDS on the care unit will recognize the discrepancy and a report is automatically created and sent to pharmacy management for investigation and resolution.

These are just a few examples of systems already in place at hospitals that helps us ensure tight controls over the drug distribution process in hospitals. Due to all these controls already being in place and within the capability of the ADDS's in hospitals, there is very little value in performing regular inventory reconciliations at the ADDS level in a hospital.

Kindly consider that pharmacists in hospitals take our role as the stewards of medications very serious and we are already ensuring high accountability from anyone who handles not only controlled substance medications, but all medications. We are aligned with the BOP and other agencies in that we want to prevent drug diversion.

The assessment and assumption that this regulation has negligible cost impact, is not correct in the case of hospitals. Please know that if this regulation is enacted and implemented, it will take licensed pharmacy staff member/s away from the care of patients and it will add the cost of the time and salary of these staff members to the overall cost of care in a hospital while negatively impacting patient safety.

I would like to respectfully request that the Board of Pharmacy delay further progression towards the implementation of these changes in Section 1715.65 until it had the opportunity to hear from stakeholders about the impact on patient safety and financial repercussions.

Sincerely,

Kevin C. Kaneko, Pharm.D.
Director of Pharmacy
Memorial Hospital of Gardena & Coast Plaza Hospital
612-219-3376 cell

Department of Pharmacy
John Muir Medical Center
1601 Ygnacio Valley Road
Walnut Creek, California 94598

February 10, 2022

Ms. Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Esteemed Members of the Board,

I appreciate the opportunity to comment on the California Board of Pharmacy's Title 16, California Code of Regulations Section 1715.65.

I'd like to express my concern over the proposed modified sections of Title 16 Section 1715.65. Based on my review of our current controlled substances inventory reconciliation processes, I feel that such modifications will only unnecessarily burden resource strapped hospital and health system pharmacies while not adding value to programs with strong diversion mitigation and monitoring programs already in place.

Our controlled substance inventory, particularly that stored in our Automated Drug Diversion System(ADDS), Pyxis, is closely monitored real time through a system of programs(Pyxis Portal and Diversion Analytics) along with daily nursing activities such as blind counts and waste witnessing. Inventory in our ADDS is linked to our inventory system in the pharmacy system and monitored with each withdrawal and transaction on the nursing unit. In fact, discrepancies in controlled drugs are reported out during our Leadership safety huddles and resolved shortly after they are discovered.

John Muir Health maintains, stocks and supplies over 100 Pyxis devices throughout its facilities. During a recent assessment, we estimated that it would take the equivalent of 40 staff(pharmacist/tech combination) hours per week to conduct a full reconciliation of these devices as required by the aforementioned modification. As stated previously, a combination of the demands of the pandemic and tightening budget controls has left us with little room in staffing flexibility. Reconciling each ADDS Unit would force us to limit the expansion of truly valuable services such our technician driven medication reconciliation service and our Transition of Care pharmacist program.

As I've heard concerns over the changes in Section 1715.65 discussed in a number of pharmacy leadership forums, I would like to respectfully request that the Board of

Pharmacy consider delaying implementation of these changes until it has the opportunity to hear from my colleagues and counterparts on this matter.

Respectfully submitted,

Martin Iyoya, Pharm.D. FCSHP
Executive Director of Pharmacy Services
John Muir Health

February 11, 2022

Ms. Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Members of the California Board of Pharmacy,

I appreciate the opportunity to comment on the proposed changes to the California Code of Regulations Section 1715.65, Inventory Reconciliation.

As a licensed pharmacist who handles regulatory compliance for over 20 hospitals in California, I'd like to express my concern over the proposed modified sections of CCR 1715.65, specifically subsections (g) and (h). Multiple Pharmacists-In-Charge have indicated that implementation of these subsection changes will unnecessarily burden already robust diversion programs.

Diversion mitigation and monitoring on the patient care units and at the ADDS level already includes routine nursing activities such as blind counts and waste witnessing. ADDS inventory is tracked through detailed ADDS transaction monitoring by licensed pharmacy technicians and pharmacists. Discrepancy resolution is encouraged immediately but must be done within that nursing shift or 24 hours. These strategies are implemented at every hospital I am aware of and probably can be considered a minimum standard of practice.

These changes appear to add little value for the overwhelming amount of work that they add to an already overloaded pharmacy suffering from Covid pandemic burnout and reduced payer reimbursement. I would like to respectfully request that the Board of Pharmacy consider delaying implementation of these changes until it has had the opportunity to hear more comments from our California pharmacy leaders and colleagues on the matter.

Respectfully submitted,

Robert Jackson, PharmD
Licensed pharmacist RPh 50541
Yorba Linda, CA

From:	Stanley E Hill III
To:	Martinez, Lori@DCA
Cc:	Jill Chang (4); Jennifer Chang (2); Ed Wong; Willis Shu; Brian Stuckman; Kristen Pugh; Stanley E Hill III
Subject:	CCR 1715.65 Second Modified Text Comments
Date:	Friday, February 11, 2022 2:10:52 PM

Ms. Martinez

I appreciate the opportunity to comment on the California Board of Pharmacy's (BOP) second modified 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://pharmacy.ca.gov/laws_regs/1715_65_2mt.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. The current regulation requires a significant amount of resources (time and labor) to meet. It requires significant labor resources redirected from patient care and/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. All pharmacies will need to 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)(A)

The final sentence that was amended, "A reportable loss shall require an inventory reconciliation report for each pattern of loss identified" is not clear. Further clarification is needed on what the Board of Pharmacy's intent with this sentence.

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.

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1. Modify the text as follows

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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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From: Willis Shu
To: Martinez, Lori@DCA
Subject: CCR 1715.65 Second Modified Text Comments
Date: Friday, February 11, 2022 2:35:41 PM

Ms. Martinez

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(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.

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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.

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(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.

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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.

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   (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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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.

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~~(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.