California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Discussion and Consideration of Proposed Regulation to Add Title 16 California Code of Regulations (CCR) Section 1715.65, Related to Inventory Reconciliation Report of Controlled Substances

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Attachment 1

Background:

At the July 2016 Board Meeting, the board approved proposed text to add Section 1715.65 of Title 16 CCR, related to Inventory Reconciliation Reporting. The 45-day comment period began on September 16, 2016 and ended October 31, 2016. At the December 2016 Board Meeting, the board approved a modified text to address concerns expressed by stakeholders and initiated a 15-day comment period.

The 15-day comment period began on December 23, 2016 and ended on January 7, 2017. The board received several comments during the 15-day comment period.

The Board received several comments during the comment period.

At this Meeting
The board will have the opportunity to discuss the regulation, the comments received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the December 2016 Board Meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

The attachment contains:

1. A copy of the noticed text as approved at the December 2016 Board Meeting.
2. A compilation document of the comments received during the 15-day comment period
3. The actual comments received during the 15-day comment period.

Staff recommendations will be provided at the Board Meeting.

Attachment 1

Inventory Reconciliation of Controlled Substances
16 CCR § 1715.65

Board Approved Text

December 14, 2016

Title 16. Board of Pharmacy
Modified Text

Changes made to the originally proposed language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:
    1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
    2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;
    3) A comparison of (1) and (2) to determine if there are any variances; and
    4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
d) A pharmacy or clinic shall report in writing identified ~~L~~ losses and possible causes, ~~shall be identified in writing and reported~~ to the board ~~and, when appropriate, to the Drug Enforcement Administration~~ within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and security improvements necessary to prevent additional losses of controlled substances.
e) ~~Likely~~ Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.
~~e)~~ f) The 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 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)~~ g) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory reconciliation report as required in subdivision (c).

~~g)~~ h) For inpatient hospital pharmacies, a separate quarterly Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

~~h)~~ i) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems 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; ~~and~~
5) ~~A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, 4105.5, 4119.1, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

Inventory Reconciliation of Controlled Substances 16 CCR § 1715.65

15-Day Comment Compilation
Comment Period Closed January 7, 2017

Code Section	Commenter	Comment
1715.65(a)	Kim-Anh Thi Dinh	Commenter requested clarification if the regulation applies to "drug rooms" in an "acute care hospital." Commenter also requested clarification if C2 reconciliation reports are required quarterly for pyxis machines.
1715.65(a)	Bruce Lepley	Commenter expressed concern that this section is vague. They recommend that the term reconciliation be removed and that "inventory functions" be defined.
1715.65(b)	Bruce Lepley	Commenter expressed concern that it is not possible to review all reconciliations as one would need to review what is coming in and what is being used. They recommended that "inventory reconciliation reports taken" be removed. They believe that the invent of the regulation is only to take an inventory and have policies and procedures in place to mitigate the risk of drug losses.
1715.65(c)	Bruce Lepley	Commenter expressed concern that that term "reconciliation" has multiple meanings, which may require the validation of administer medication. Commenter indicated it would not be feasible to validate administrated medication over a three month period. They recommended that a random audit be permitted as the pharmacy would still be aware of the inventory.
1715.65(c)(2)	Bruce Lepley	Commenter expressed concern about the need to review the disposition of waste and administrations by nursing staff. They indicated hospitals would not have the resources necessary to meet this requirement and recommended that (c)(2) be removed or further clarified as to what dispositions records need to be reviewed.
1715.65(c)(3)	Mark Johnston, CVS	Commenter recommends that perpetual inventory systems be specified as compliant in the regulation. Specifically, commenter recommends that this section be modified to read: A pharmacy or clinic shall maintain a perpetual inventory system or compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. ~~This compilation~~ The Inventory Reconciliation Report shall require:

Code Section	Commenter	Comment
1715.65(c)(3)	Elizabeth LaBouyer	Commenter requested clarification on (c)(3). She asked if pharmacists are required to go line by line in the control log to verify usage and compare it with purchases. She indicated that is would requires hours each month and it would change the pharmacist requirements in Board licensed facilities.
1715.65(d)	Bruce Lepley	Commenter expressed concern that the term "losses" is not clear and requested that the term be defined. Additionally, commenter asked which classes of drugs section (d) applied to. Additionally, commenter requested that "security improvements" be removed and replaced with a requirement to review current security and determine if additional steps are necessary as improvements may not always be necessary or able to occur.
1715.65(e)	Mark Johnston, CVS	Commenter recommends that perpetual inventory systems be specified as compliant in the regulation. Specifically, commenter recommends that this section be modified to read: Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report or, if maintaining a perpetual inventory system, in a readily retrievable form.
1715.65(g)	Mark Johnston, CVS	Commenter recommends that perpetual inventory systems be specified as compliant in the regulation. Specifically, commenter recommends that this section be modified to read: A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report or verify the accuracy of all Schedule II controlled substance on-hand quantities within a perpetual inventory system within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory reconciliation report or verify the accuracy of all Schedule II controlled substance on-hand quantities within a perpetual inventory system as required in subdivision (c).
1715.65(g)	Lin Hokana	Commenter recommended that "or interim pharmacist-in-charge" added to this section to require that interim PIC to complete an inventory as well.

Code Section	Commenter	Comment
1715.65(h)	John Teague	Commenter indicated that the standard of practice in a hospital is to conduct an annual controlled substance inventory and a perpetual inventory with a monthly physical count. He indicated that reviewing the acquisitions and dispositions for 20 automated dispensing machines would divert clinical resources and impede patient care. Commenter recommends that section (h) be removed from the regulation and on require the inventory as noted in section (c).
1715.65(h)	Bruce Lepley	Commenter expressed concern that this section is vague. They recommend that the term "reconciliation" be defined to eliminate confusion. Additionally, commenter requested that an example be provided in the regulation.
1715.65(h)	Gregory Tertes	Commenter expressed concern that ambulatory surgery centers are not required to be licensed by the Board and tracking the medication for each procedure would include the tracking on thousands of transactions. Commenter expressed concern that the regulation, as written, will be a deterrent for centers to become licensed with the Board.
1715.65(i)(1)	Bruce Lepley	Commenter expressed concern that they are unsure which schedule of drugs this section applies to. Additionally, commenter expressed concern about what this section is requiring and asked for examples to be provided.
1715.65(i)(4) ** Incorrectly Identified as (h)(4)	Bruce Lepley	Commenter expressed concern that the term "losses" is not clear and requested that the term be defined. Additionally, commenter asked which classes of drugs this section applies to.
Overall	Mark Johnston, CVS	Commenter recommends that perpetual inventory systems be specified as compliant in the regulation. Specifically, commenter recommends that a definition of perpetual inventory system be added and read as follows: For the purposes of this section a “perpetual inventory system” means program whereby at least every three months every schedule II controlled substance in stock is physically counted and the remaining quantity is verified against a running total of the difference of all acquisitions and dispositions.

Code Section	Commenter	Comment
Overall	Ellis	Commenter stated that conducting a quarterly inventory is a hassle and will require him to work on Sunday's. He stated that there are two many regulations that make owning a pharmacy stressful. Commenter provided information on the regulation regarding controlled substance refills and asked for clarification as to why refills are limited to 120 days.
Overall	Brian Rucker	Commenter indicated that requiring a quarterly inventory without a complete accountability audit will not prevent diversion and will not provide sufficient information to detect thefts. Additionally, only requiring the inventory of schedule II will allow the theft of schedule III-V to go undected. Commenter also indicated that quarterly inventories will be an undue burden on pharmacists and it is likely that the audits will be filed and not reviewed. He recommends that inventories be done twice a year and be a complete audit of all schedule II-V.
Overall	Noelle Smith	Commenter requested an exemption for Automated Dispensing Cabinets. She indicated that these have just in time inventory and a quarterly physical count should not be required.
Overall	Therese Helser	Commenter agreed with the comments submitted by Noelle Smith. She indicated that counting controlled substances quarterly would be cumbersome and they already have a perpetual inventory in place.

Inventory Reconciliation of Controlled Substances
16 CCR § 1715.65

15-Day Comments Comment Period Closed
January 7, 2017

Martinez, Lori@DCA

From: Beth LaBouyer <blabouyer@casurgery.org>
Sent: Wednesday, January 04, 2017 8:58 AM
To: Sodergren, Anne@DCA; Martinez, Lori@DCA
Subject: Board of Pharmacy Proposed Regulations
Attachments: image003.jpg

Hi Anne and Lori,

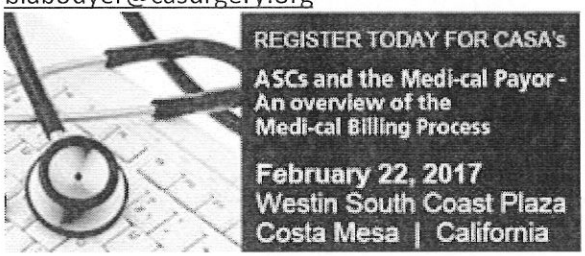
I'm hoping you can provide me some guidance on the proposed pharmacy regulations- Inventory Reconciliation Report of Controlled Substances

I've had some pharmacy consultants concerned and reaching out to me particularly regarding item number 3 and the comparison for variances. Does this mean that the pharmacists would be required to go line by line in the control log verifying the usage and comparing it to the purchasing? This would require hours each month. I understand the direction of this, but based on that interpretation it would completely change the pharmacist requirement to facilities licensed by the Board of Pharmacy, and increase the time required.

Any clarification you can provide would be greatly appreciated.

Beth

Elizabeth LaBouyer RN CNOR CASC
Executive Director
California Ambulatory Surgery Association
530.790.7990-office
530.701.0604 – cell
blabouyer@casurgery.org



Martinez, Lori@DCA

From: LauraBeth Antone <LAntone@communitymedical.org>
Sent: Thursday, January 05, 2017 3:00 PM
To: Martinez, Lori@DCA
Cc: Bruce Lepley; Timothy Lopez
Subject: CRMC Pharmacy_BOP Proposal of Controlled Substance Inventory_January 2017
Attachments: CRMC Pharmacy_BOP Proposal of Controlled Substance Inventory_January 2017.docx

Good afternoon Lori,

Please find our documents attached for review regarding proposed modifications. If there are any further questions, please feel free to let me know.

Thank you.

LauraBeth Antone
Executive Secretary to:
Bruce Lepley, RPh
Director of Pharmacy

Community Regional Medical Center
2823 Fresno Street
Fresno, CA 93721
Office: 559-459-2101; ext52101
Cell: 559-287-0984
lantone@communitymedical.org

Community Regional Medical Center **Bruce Lepley, Director of Pharmacy**		
Section, Subdivision	**Proposed Language**	**Recommendation/Comments**
Section 1715.65. paragraph (a) Pharmacy must perform inventory of controlled substances	"Every pharmacy... shall perform... **inventory reconciliation functions...**"	**Reason for Concern:** The section is vague regarding the term reconciliation. The true definition of the word means to include nursing drug administration transactions. In a facility such as ours we have close to 500,000 drug administration transactions per month that would need to be accounted for to perform a true reconciliation which is just not feasible in the way this section implies. Clinical pharmacists performing patient care activities would have to be repurposed for perform medication inventory reconciliation. **Solution:** Remove the term reconciliation and more clearly define what is meant by "inventory functions". Define the word reconciliation to include true meaning of what is being asked.
Section 1715.65. paragraph (b) Review of inventory reconciliation report	"The pharmacist-in-charge of a pharmacy...**shall review all...inventory reconciliation reports taken...**"	**Reason for Concern:** It would not be feasible for someone or even a small team of people to review all reconciliations. True reconciliation means to review not only medications coming in but also medication that is being used (i.e. nursing drug administrations). **Solution:** Remove "inventory reconciliation reports taken" from this paragraph. We believe that this would still achieve the intent of this proposal which is for a facility to take inventory and develop policies and procedures that describe how a facility mitigates the risk of preventing losses of controlled substances.
Section 1715.65. paragraph (c) Inventory report requirements	"A pharmacy.....shall compile an Inventory reconciliation report of **all Schedule II controlled substances....**"	Reason for Concern: The term "reconciliation" is used throughout the entire proposed section. Again, this word has multiple meanings which may include validating the documented transaction of medication administration. With a facility that has over 500,000 medication administration transactions it would not be feasible to compile and validate a report that has each Schedule II medication administration that has occurred over a period of three months. It seems as if this part of the proposed regulation would be better suited for smaller clinics where the number of medication administrations would be more manageable to review.

		Solution: There needs to be a clear definition of the term "reconciliation" in order to mitigate the risk of confusion. In addition, we believe that if a pharmacy would be allowed to audit a certain proportion of inventory transactions that this would accomplish the original intent of this entire proposed rewording of this section which is to have the pharmacy be aware of inventory transactions in order to establish and maintain secure methods to prevent losses of controlled substances.
Section 1715.65. paragraph (c) part (2) Pharmacist-in-charge shall review acquisitions	"A review **of all acquisitions and dispositions of Schedule II controlled substances**..."	**Reason for Concern:** Reviewing dispositions of controlled substances includes reviewing medications that are not only wasted or sent to automated dispensing cabinets, but it also means reviewing drug administrations performed by nursing. Again, a facility such as ours has approximately 500,000 drug administrations per month that would need to be included in a disposition review. Pharmacy administrations that operate large hospital facilities would not be able to maintain the resources necessary to fulfill these proposed requirements. **Solution:** Clarify the expectation for disposition review and all transactions that would be included in the expectation and/or remove part (2) of paragraph c entirely.
Section 1715.65. paragraph (d) Reporting losses	"A pharmacy or clinic shall report.....**losses** and possible causes....." If the pharmacy or clinic is unable to identify...**security improvements necessary to prevent additional losses of controlled substances."**	**Reason for Concern:** It could be interpreted that "losses" mean that after completing an investigation that it is uncertain where the controlled substance went. Some times after investigations it is determined that a controlled substance was accidentally thrown in the trash or was put in a place that renders it non-usable. It is also not clear this is specific to Schedule II controlled substances or all controlled substances. In addition, the recourses described for taking "security improvements" each time a loss occurs are limited after periods of time that go by. A good system could continue to exist without having the exact requirement of making it mandatory to provide security improvements each time a loss is reported. When you look at the number of transactions that occur in large hospital

		facilities, even a 0.00001% occurrence rate of loss would translate to possibly more than one discrepancy in a given year. Therefore to mandate that each time that an additional measure is taken when a loss occurs would mean that the facility would run out of additional steps to take after one year of evaluating. **Solution:** Provide a definition of loss. For example "Losses are defined as circumstances where a discrepancy is created in the inventory and the whereabouts of the Schedule II controlled substance in question is unknown after an investigation performed by the pharmacist in charge." Also, please clarify which classes of controlled substances paragraph (d) is referring to. Lastly, remove the requirement of reporting security improvements each time a loss is reported and replace the verbiage with the facility having to defend/explain the current measures that are in place and to explain the rationale if additional measures are not taken or put into place.
Section 1715.65. paragraph (h) Separate Inventory Reconciliation Report	"For inpatient hospital pharmacies, a **separate quarterly Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location**."	Reason for Concern: The section is vague regarding the term reconciliation. The true definition of the word means to include nursing drug administration transactions. In a facility such as ours we have close to 500,000 drug administration transactions per month and of these approximately 10% are CII drug administration's that would need to be accounted for to perform a true reconciliation which is just not feasible in the way this section implies. Pharmacy administrations that operate large hospital facilities would not be able to maintain the resources necessary to fulfill these proposed requirements. Clinical pharmacists performing patient care activities would have to be repurposed for perform medication inventory reconciliation. Solution: Provide a clear definition of the term "reconciliation". In addition, provide an example in the section that would make it clear what the

		expectations are for hospitals to fulfill this requirement. Most of us Pharmacy Directors believe that hospitals generally operate in the same general manner so providing an example in this proposed section would help make it clear of the expectation in this paragraph.
Section 1715.65. paragraph (i) part (1) Accounting for automated drug delivery systems	"The pharmacist-in-charge of an inpatient hospital pharmacy...shall ensure that:...**All controlled substances added to an automated drug delivery system are accounted for;**"	**Reason for Concern:** We are not sure if this section is referring to all schedule classes of controlled substances. In addition, there are innate measures in place when using automated dispensing cabinets to account for controlled substance inventories. Uncertain if this section is referring to those inherit measures already in place when using automated dispensing cabinets. Depending upon what is being asked could lead to more comments from hospital pharmacies. **Solution:** Most Hospital Pharmacy Directors agree that in terms of automated dispensing machines there is a general/common workflow that is used in hospitals. Therefore, it would be extremely beneficial for this section to provide some specific examples of what is meant to meet the expectation in this paragraph (i) part (1). This would mitigate the risk of misinterpreting of what is being requested.
Section 1715.65. paragraph (h) part (4) Confirming Losses of Controlled Substances	"**Confirmed losses** of controlled substances are reported to the board"	**Reason for Concern:** It could be interpreted that "losses" mean that after completing an investigation that it is uncertain where the controlled substance went. Some times after investigations it is determined that a controlled substance was accidentally thrown in the trash or was put in a place that renders it non-usable. In these instances we know what happened to the medication and at times we actually have the medication but it is no longer usable and has to be placed out of service. Lastly, in this section, it is also not clear if this is specific to Schedule II controlled substances or all controlled substances. **Solution:** Provide a definition of loss and which controlled substances this applies to. For example "Losses are defined as circumstances where a

		discrepancy is created in the inventory and the whereabouts of the controlled substance in question is unknown after an investigation performed by the pharmacist in charge." This part could also be combined with paragraph (d).

Martinez, Lori@DCA

From:	Brian and Michele Rucker <ruckerbm@gmail.com>
Sent:	Saturday, January 07, 2017 8:11 AM
To:	Sodergren, Anne@DCA; Martinez, Lori@DCA
Cc:	Tboragno@usa.com
Subject:	Proposal to add and adopt Section 1715.65 of Article 2 of Division 17 of Title 16
Attachments:	BOP Response.docx

Ms. Martinez,

Please see the attached comments on the Boards proposed modifications to Section 1715.65 of Title 16.

Warmest Regards,

Brian Rucker
609-722-1861

Ms. Lori Martinez
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Martinez,

I am the Director of DEA Compliance for a wholesale distributor, with over 1,000 independent pharmacy customers in California. In addition, I am a retired United States Drug Enforcement Administration Diversion Supervisor and would like to provide comments on the board's proposal to modify Section 1715.65 of Article 2 of Division 17 of Title 16 to require pharmacies to perform quarterly physical inventories of Schedule II medications.

Although it is generally recognized that drug diversion and abuse is a growing problem throughout California, this proposal does not adequately address the issue on how to properly prevent diversion. Your proposal to require quarterly inventories of Schedule II controlled substances will not detect shortages unless a complete accountability audit is completed along with the proposed inventory. When working as a DEA field investigator, I was required to obtain the following records in order to determine possible shortages in a pharmacy: a biennial or annual inventory; a total of drugs purchased; a closing inventory; a total of drugs dispensed; a total of theft/losses and destructions; and any drugs that were returned to suppliers or reverse distributors. Completing just an inventory every quarter would not provide the pharmacist sufficient information to detect thefts or losses and essentially is a waste of time. In addition, completing an audit of just Schedule II drugs will allow the theft/losses of Schedule III-V drugs to go totally undetected. As you know, carisoprodol and alprazolam, Schedule III and IV controlled substances, are highly abused in combination with hydrocodone and oxycodone, which is known as the holy trinity or trinity combination on the street. Codeine cough syrup, a Schedule V controlled substance is also highly abused in California and is often mixed with soft drinks.

I would also like to address the periodicity for the inventory. You are proposing a quarterly inventory which I feel will be considered an undue burden on pharmacy owners. A business colleague of mine is a former California pharmacy owner. He practiced as a pharmacist for 36 years and a multiple store owner of 30 years, who currently performs Controlled Substance audits of California pharmacies. It is his opinion that these quarterly audits will likely be filed and not referenced by most PIC's and store owners because they will view them as another requirement on their time that does not serve the intended purpose.

Accordingly, I recommend changing your proposal to require inventories to be taken two times a year along with a complete audit of ALL Schedule II-V controlled substances. Along with the inventory, a complete audit should be completed so any shortages or overages can be detected. Completing an inventory/audit two times a year also prepares the pharmacy for a probable DEA inspection and accountability audit. Approximately 3 years ago, DEA added pharmacies to its required inspection list, so all pharmacies in California will eventually be inspected by DEA. Since DEA audit periods begin with the date of the last inventory, conducting inventories more frequently would allow for shorter audit periods, which would be a benefit to all concerned.

I would be glad to consult with you on this proposed change to the regulation to achieve the best outcome.

Professionally yours,

Brian Rucker
13745 N. Goldfield Road
Fort McDowell, AZ 85264
609-722-1861

Martinez, Lori@DCA

From: Ellis <eherz@earthlink.net>
Sent: Saturday, December 24, 2016 11:27 AM
To: Martinez, Lori@DCA
Subject: New rule

Hi Lori,

Regarding the new proposed regulations on CII inventory

Having to do a CII inventory every 3 months is so much of a hassle.

It takes hours to do and that means I have to go in on a Sunday when I am closed and spend 3 to 4 hours doing the inventory.

I think this is way to often.

There are too many rules and regulations which are making the business of owning a pharmacy very stressful and honestly making many of us want to quit and sell.

Just look at the regulation regarding refills on CIII and CIV drugs

The Federal rule says a doctor can write the RX with 5 refills

We can fill it 6 times withing the 6 month allowance.

BUT the California Board of Pharmacy only allows us to fill 120 days of refills.
So we can only really enter 4 refills not 5 to ensure we are following the California law.

The insurance companies love it because they can nail us on that ONLY CALIFORNIA regulation to take back the money for the RX if we did fill it for the extra month.

Who comes up with these regulations that make no sense. I talked to 20 other pharmacist at a meeting and non of them were aware of this crazy law.

I talked to the head of the California Pharmacy Association who said the Law was written so poorly in the law book no one understood it.
They got a lawyer who to basically translate it so we could all understand it.

EVERYONE wants to know what the reason behind changing the law for refilling these meds to be only allow to fill it once with 120 days of refills instead of the 5 refills or 6 months that was always the law?

Honestly, I am waiting for the day when I flush the toilet I have to sign in a log book that I was in the bathroom for x amount of time and sign it.

I am sorry but I am so frustrated at what is happening

Ellis

Martinez, Lori@DCA

From: Gregory Tertes <gregory@safemedicationsolutions.com>
Sent: Saturday, January 07, 2017 1:01 PM
To: Martinez, Lori@DCA
Subject: Comments on Pending Regulation Inventory Reconciliation Report of Controlled Substances

Dear Lori Martinez,
I am writing to comment on the proposed regulations, "Inventory Reconciliation Report of Controlled Substances"

I am a licensed pharmacist in California, and I specialize in consulting to Ambulatory Surgery Centers (ASCs). Many of these facilities are licensed with the California Board of Pharmacy as Clinics under section 4190. ASCs perform safe surgical procedures in locations separate from hospitals.

Background information:
1) I recognize this pending regulation to be a "part of the Board's efforts to combat drug loss and diversion from within pharmacies and prescription drug abuse within California", and I completely agree with the intent. Since ASCs are a very small subset of the Board's oversight, I am concerned that this regulation is using one language to cover different types of operations.
2) ASCs perform twice daily counts of all of their DEA Controlled Substances, not just Schedule II, as required by their accrediting organizations, and keep a perpetual inventory of all acquisitions and dispositions.
3) ASCs are more similar to hospital ORs than to pharmacy departments.

Comments:
1) My interpretation of this pending regulation as it pertains to a hospital is that the reconciliation report would count up to the point that the medication is in the hands of the OR staff. As quoted from the pending regulation, "h) For inpatient hospital pharmacies, a separate quarterly Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location." and automated drug delivery systems are included, which again cover up until an OR staff member removes it.

2) My interpretation of this pending regulation for ASCs notes that ASCs do not have a "Pharmacy department" so the tracking in ASCs would start at the point where the tracking in hospitals stops. ASCs would then have to track Schedule II use for each procedure and administration to each patient in order to complete this Reconciliation Report. In many ASCs, this tracking would encompass thousands of transactions. Since ASCs do not have pharmacy departments, they hire a Consultant Pharmacist to come quarterly, and not be on site.

Separate comments:
1) ASCs are not required to be licensed by the California Board of Pharmacy.
2) I do believe there is benefit to being licensed by the Board.
3) I am concerned that this regulation, as I interpret it, will prove to be a deterrent for ASCs to license with the Board.

My primary desire for writing is to bring your attention to the affect that may occur for Ambulatory Surgery Centers licensed by this pending regulation. I am also requesting to contact someone at the Board that I can discuss my interpretation to see if it is accurate.

Thank you for your time and attention.

Gregory Tertes, R.Ph.

Consultant Pharmacist, President
Safe Medication Management for Ambulatory Surgery Centers

ASC Pharmacist Consultants, Inc.
248 3rd Street, Suite 606
Oakland, CA 94607
510-710-3640
gregory@SafeMedicationSolutions.com
www.SafeMedicationSolutions.com

The current modified text is,
"c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:

1.
    1. 1) A physical count, not an estimate, of all quantities of Schedule II controlled substances.

       The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

    2. 2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;
    3. 3) A comparison of (1) and (2) to determine if there are any variances; and
    4. 4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form. "

Martinez, Lori@DCA

From: John P Teague <JTeague@pmhd.org>
Sent: Friday, January 06, 2017 5:42 PM
To: Martinez, Lori@DCA
Cc: John P Teague
Subject: 1715.65 comment
Attachments: image001.jpg

Board of Pharmacy,

Currently standard of practice in the hospital setting is to complete an entire physical count of Facility wide Controlled Substance inventory annually. Furthermore, it is also quite common to maintain a very strict policy of perpetual inventory of Controlled Substances with a monthly physical count of the hospital pharmacy inventory. In section (h) of the modified text the board proposes a separate quarterly "inventory reconciliation report" which will be completed within the pharmacy and all satellite locations, the issue here is that an inventory reconciliation report for a small hospital of 100 beds or so would encompass at least 20 Automated Dispensing Machines (located in satellites). If we follow the letter of the proposed regulation and complete the 4 items the board has noted as "inventory reconciliation report" we would be completing a review of all acquisition and dispositions from at least 20 Automated Dispensing Machines, the acquisitions would be the inventory sent from our hospital pharmacy to the satellite/automated dispensing machine and the dispositions would be every single transaction or dispensation removed for administration to patients. I'm not sure if this truly was the intent of the board, but it would make more sense to require the "inventory reconciliation report" as noted in section (c) and remove what is in section (h); it may be more prudent to require an annual inventory (physical count) of all Controlled Substances stored within the pharmacy and for each satellite location if desired as a modification to section (h). Monitoring every single dispensation and administration done in the clinical setting to patients is an impossible task and doing so would divert critical clinical resources and impede time spent on patient care.

P.S. sorry for the poor grammar, but thank you for the opportunity to comment

Thank you,

John P. Teague, Pharm.D.
Director of Pharmacy
Pioneers Memorial Healthcare District
207 West Legion Rd.
Brawley, CA 92227
760-351-3367
jteague@pmhd.org

PIONEERS
MEMORIAL HEALTHCARE DISTRICT

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Martinez, Lori@DCA

From: Dinh, Kim <Kim.Dinh@Hoag.org>
Sent: Thursday, January 05, 2017 11:04 AM
To: Martinez, Lori@DCA
Subject: Question regarding propose law 1715.65 Inventory Reconciliation Report of Controlled Substances

Good morning Lori,
I have a few questions regarding the proposal of this new law.

(1) The law specifically applies to the PIC of a "pharmacy" and consultant pharmacist for a "clinic"—I am a Consultant Pharmacist for a "drug room" in an "acute care hospital". Would I be exempt? Although we don't have a full pharmacy, I try to follow the laws that apply to the full pharmacy and already do the biennial narcotic inventory for my C2 Pyxis Safe.
(2) The law also states that inpatient hospital pharmacies require separate quarterly inventory reconciliation reports for the pharmacy and for each pharmacy satellite location. Again, I don't have a pharmacy and only have a drug room so would this quarterly inventory reconciliation report apply to the drug room.
(3) All of our controlled substances are Received into our C2 Pyxis Safe and then loaded into the different nursing unit pyxis machines. Blind count is turned on for the pyxis machines and pyxis discrepancies as well as a C2 safe variance report is reviewed daily. Our pyxis activities/transactions are tightly controlled –are C2 inventories/inventory reconciliation reports required quarterly for the pyxis machines?

Thank you,

Kim-Anh Thi Dinh, PharmD | Manager and Consultant Pharmacist
Hoag Orthopedic Institute | 16250 Sand Canyon Ave., Irvine, CA 92618
Office (949)727-5252 | Cell (949)929-2672 | Kim.Dinh@hoag.org

Martinez, Lori@DCA

From: Hokana, Lin@DCA
Sent: Friday, December 23, 2016 11:21 AM
To: Martinez, Lori@DCA
Subject: Modifications to the text of Title 16 CCR § 1715.65
Attachments: image001.png; image003.png

Hi Lori,
I would like to suggest the following addition to the text of 1715.65, subdivision (g):

g) A new pharmacist-in-charge, or interim pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory reconciliation report as required in subdivision (c).

Lin Hokana, R.Ph., Inspector
California State Board of Pharmacy
(209) 245-3207(w) | (530) 663-3395 (c) | FAX (209) 245-3207 | www.pharmacy.ca.gov
Be Aware and Take Care: Talk to your Pharmacist!

Martinez, Lori@DCA

From: Johnston, Mark D. <Mark.Johnston@CVSHealth.com>
Sent: Saturday, January 07, 2017 9:31 AM
To: Martinez, Lori@DCA
Cc: Herold, Virginia@DCA
Subject: Public comment
Attachments: CACSCommennts.docx

Dear Ms Martinez,

Thank you for the opportunity to comment on the controlled substance inventory proposed rules. Please see the attached.

Sincerely
Mark Johnston
Senior Director, Pharmacy Regulatory Affairs
CVS Health

CVSHealth

1/6/2016

Lori Martinez
Administration and Regulations Manager
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Via email

Re: Title 16 CCR § 1715.65, related to Inventory Reconciliation Report of Controlled Substances

Dear Ms. Martinez:

I am writing to you in my capacity as Senior Director of Regulatory Affairs for CVS Health and its family of pharmacies, subsidiaries and affiliates located throughout the State of California. CVS Health appreciates the opportunity to submit comments on Title 16 CCR § 1715.65, related to Inventory Reconciliation Report of Controlled Substances. We would like to thank the Board for their continued vigilance to improve the laws and rules that guide pharmacists serving California patients and the Board's efforts to combat prescription drug abuse for greater public safety.

At the December 14, 2016 meeting of the Board in Burbank, I explained CVS Health's perpetual inventory system and asked if such a system would satisfy these proposed requirements. The Board asked me several pertinent questions and agreed with my request. While the Board agrees that CVS Health's perpetual inventory system should satisfy these proposed requirements, as I review the proposed language, it does not appear to allow such a system as currently written. Therefore, I respectfully submit the following edits, so that the proposed rule would clearly allow a perpetual inventory system to be compliant. Along with providing clarity to pharmacies and pharmacists, I believe this would also positively impact Board staff by reducing the administrative burden of processing waivers for each compliant perpetual inventory system utilized in California.

Please note that CVS Health's proposed changes are highlighted, as to separate from the Board's own changes to the proposed language that was printed on December 23, 2016. Additionally, the Board may wish to define a perpetual inventory program, so CVS Health respectfully submits such a definition as well.

> For the purposes of this section a "perpetual inventory system" means program whereby at least every three months every schedule II controlled substance in stock is physically

counted and the remaining quantity is verified against a running total of the difference of all acquisitions and dispositions.

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

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

c) A pharmacy or clinic shall maintain a perpetual inventory system or compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. ~~This compilation~~ The Inventory Reconciliation Report shall require:

1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;

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

4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.

d) A pharmacy or clinic shall report in writing identified ~~L~~ losses and possible causes, ~~shall be identified in writing and reported~~ to the board ~~and, when appropriate, to the Drug Enforcement Administration~~ within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and security improvements necessary to prevent additional losses of controlled substances.

e) ~~Likely~~ Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report or, if maintaining a perpetual inventory system, in a readily retrievable form.

~~e)~~ f) The 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 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)~~ g) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report or verify the accuracy of all Schedule II controlled substance on-hand quantities within a perpetual inventory system within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory reconciliation report or verify the accuracy of all Schedule II controlled substance on-hand quantities within a perpetual inventory system as required in subdivision (c).

~~g)~~ h) For inpatient hospital pharmacies, a separate quarterly Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

~~h)~~ i) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems 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; ~~and~~

~~5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

CVS Health appreciates the opportunity to submit comments for the proposed addition of these regulations. If you have any questions, please contact me directly at 401-601-1968.

CVSHealth

Sincerely,

Mark Johnston, PharmD

Senior Director, Pharmacy Regulatory Affairs
CVS Health

Martinez, Lori@DCA

From: NSmith1@NorthBay.org
Sent: Tuesday, December 27, 2016 12:12 PM
To: Martinez, Lori@DCA
Cc: Therese.Helser@NorthBay.org
Subject: change in Title 16 CCR § 1715.65, related to Inventory Reconciliation Report of Controlled Substances

I would like to recommend that an addendum be added to exclude all institutions that maintain controlled substances in automated Dispensing Cabinets. These institutions should be exempt from the quarterly physical count and maintain the bi-annual regulations already in place due to the fact that an automated dispensing cabinet maintains just in time inventory for controlled substances.

Thank you

Noelle Smith, CPhT, RPhT | Technician Support specialist Buyer | Northbay Healthcare Group | PH: (707) 646-5364 FAX: (707) 646-5156 | Nsmith1@northbay.org

Martinez, Lori@DCA

From: Therese.Helser@NorthBay.org
Sent: Tuesday, December 27, 2016 5:48 PM
To: Martinez, Lori@DCA
Cc: NSmith1@NorthBay.org
Subject: RE: change in Title 16 CCR § 1715.65, related to Inventory Reconciliation Report of Controlled Substances
Attachments: image001.jpg

I concur with Noelle's recommendation. Counting all Controlled substances quarterly would be cumbersome to our institution, since they are already on a perpetual count with the automated dispensing systems in place.
I would ask for an exception to this recommendation for inpatient facilities with automated dispensing cabinets in place. Recommend keeping with the biannual controlled substance inventory instead.

Thank you for your consideration.

Therese Helser, R.Ph.
Pharmacy Manager
Medication Safety Pharmacist
NorthBay Healthcare
1200 B. Gale Wilson Blvd. Fairfield, CA 94533
PH 707-646-5151 | FX 707-646-5156 | Email Therese.Helser@Northbay.org

NORTHBAY HEALTHCARE

From: Smith, Noelle
Sent: Tuesday, December 27, 2016 12:12 PM
To: 'Lori.Martinez@dca.ca.gov'
Cc: Helser, Therese
Subject: change in Title 16 CCR § 1715.65, related to Inventory Reconciliation Report of Controlled Substances

I would like to recommend that an addendum be added to exclude all institutions that maintain controlled substances in automated Dispensing Cabinets. These institutions should be exempt from the quarterly physical count and maintain the bi-annual regulations already in place due to the fact that an automated dispensing cabinet maintains just in time inventory for controlled substances.

Thank you

Noelle Smith, CPhT, RPhT | Technician Support specialist Buyer | Northbay Healthcare Group | PH: (707) 646-5364 FAX: (707) 646-5156 | Nsmith1@northbay.org