



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**XX. Proposed Regulations to Add Title 16 California Code of Regulations (CCR) sections 1715.65, Related to Reconciliation and Inventory Report of Controlled Substances**

At the July 2015 Board Meeting, the board approved proposed text to add Section 1715.65 of Title 16 CCR, related to Reconciliation and Inventory of Controlled Substances. The 45 day comment period began on October 16, 2015 and ended November 30, 2015. Additionally, a regulation hearing was held on February 2, 2016.

The Board received several comments during the comment period and at the regulation hearing.

**At this Meeting**

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

1. Adopt the regulation as approved at the July 2015 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 the proposed regulation text as noticed on October 16, 2015 and a copy of each comment received during the 45 day comment period and at the regulation hearing.

**Reconciliation and  
Inventory of Controlled  
Substances**

**1715.65**

**Reconciliation and  
Inventory of Controlled  
Substances  
45-day Comments**

## Martinez, Lori@DCA

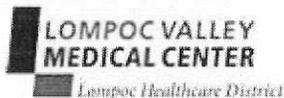
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**From:** Signorelli, Chad Dr <signorec@lompocvmc.com>  
**Sent:** Friday, October 16, 2015 2:53 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Re: Notice of Proposed Action to adopt section 1715.65 of Title 16 of the California Code of Regulations

Is there an allowance or exception allowed for those facilities that keep the entirety of their C-II inventory stock in perpetual inventory machines? In our facility, our C-II stock is in either the Pyxis C-II Safe or a Pyxis ADM with "Blind Count On" thereby allowing an inventory count to be completed every time the medication is removed. If counts are not correct there is an immediate discrepancy created that must be followed up on and acted upon. We therefore inventory our medications much more frequently than every 3 months and asking us to physically inventory the stock every 3 months would be unnecessary and unneeded. I can understand the importance of this process in non-perpetual inventory locations but do not see the need in a location such as ours.

**Chad Signorelli, Pharm.D.**  
*Director of Pharmacy Services*  
*Clinical Pharmacist*

Lompoc Valley Medical Center  
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Lompoc CA 93436  
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**From:** Board of Pharmacy [mailto:pharmacy.subscriberlist@DCA.CA.GOV]  
**Sent:** Friday, October 16, 2015 1:57 PM  
**To:** PHARM-GENERAL@DCALISTS.CA.GOV  
**Subject:** California State Board of Pharmacy Subscriber Alert

The Board of Pharmacy has released a Notice of Proposed Action to adopt section 1715.65 of Title 16 of the California Code of Regulations related to Reconciliation and Inventory Report of Controlled Substances. The Board of Pharmacy will accept written comments to the proposed text until 5:00 p.m. on Monday, November 30, 2015, to the following:

Contact Person: Lori Martinez  
Agency Name: California State Board of Pharmacy  
Address: 1625 North Market Blvd, Suite N 219  
Sacramento, CA 95834  
Email: [Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov)  
Fax: (916) 574-8618

Please click on the link below to view all documents associated with this proposed regulatory action and other pending or newly approved regulations.

[http://www.pharmacy.ca.gov/laws\\_regs/regulations.shtml](http://www.pharmacy.ca.gov/laws_regs/regulations.shtml)

## Martinez, Lori@DCA

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**From:** Ward, Hilary <HWard@TFHD.COM>  
**Sent:** Monday, October 19, 2015 1:18 PM  
**To:** Martinez, Lori@DCA  
**Subject:** RE: California State Board of Pharmacy Subscriber Alert

Hi Lori,

Our humble opinion from Tahoe Forest is that increasing the frequency of narcotic inventory audits is not going to deter diversion effectively. Counts may be off for any number of reasons which are infrequently diversion, yet a diverter can operate in many ways that would never be detected by just looking at inventory counts.

If the Board truly feels more frequent inventory audits will be beneficial, we believe doing every 6 month counts would be operationally feasible, but every 3 months is just excessive.

Thank you for your time and consideration of our comments.

Sincerely,

Hilary S. Ward, Pharm.D., BCOP  
Director of Pharmacy, Tahoe Forest Health System  
Oncology Pharmacist, Gene Upshaw Memorial Tahoe Forest Cancer Center  
[hward@tfhd.com](mailto:hward@tfhd.com)  
(530)582-6372

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**From:** General Board of Pharmacy Subscriber List [mailto:PHARM-GENERAL@DCALISTS.CA.GOV] **On Behalf Of** Board of Pharmacy  
**Sent:** Friday, October 16, 2015 1:57 PM  
**To:** PHARM-GENERAL@DCALISTS.CA.GOV  
**Subject:** California State Board of Pharmacy Subscriber Alert

The Board of Pharmacy has released a Notice of Proposed Action to adopt section 1715.65 of Title 16 of the California Code of Regulations related to Reconciliation and Inventory Report of Controlled Substances. The Board of Pharmacy will accept written comments to the proposed text until 5:00 p.m. on Monday, November 30, 2015, to the following:

Contact Person: Lori Martinez  
Agency Name: California State Board of Pharmacy  
Address: 1625 North Market Blvd, Suite N 219  
Sacramento, CA 95834  
Email: [Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov)  
Fax: (916) 574-8618

Please click on the link below to view all documents associated with this proposed regulatory action and other pending or newly approved regulations.

[http://www.pharmacy.ca.gov/laws\\_regs/regulations.shtml](http://www.pharmacy.ca.gov/laws_regs/regulations.shtml)

**Martinez, Lori@DCA**

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**From:** scott guess <guesses4@msn.com>  
**Sent:** Tuesday, October 20, 2015 12:20 PM  
**To:** Martinez, Lori@DCA  
**Subject:** 1715.65  
**Attachments:** BOP CS Letterhead.pdf; PastedGraphic-8.pdf

Ms. Martinez,

Please accept my public comment on proposed regulation 1715.65.

Thank you,  
Scott

K. Scott Guess Pharm.D., RPh.  
Diplomate, American Academy of Pain Management  
Pain Management Pharmacy, Inc.  
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Santa Maria, CA 93454  
805-928-4700 (work)  
805-714-3908 (cell)

## K. Scott Guess, Pharmacist

Pharm.D., RPh., DAAPM

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Lori Martinez  
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20 October, 2015

Re: CCR Title 16, Division 17, Article 2, §1715.65

The need for a CS inventory monitoring system has been clearly demonstrated by the numbers of lost drug being reported. However, I feel this regulatory requirement will be too stringent, too time consuming, and too overly burdensome to the practice pharmacy, as well as for the Board. Surely the Board does not have the resources to account for every 'lost' tablet in the state? This level of accounting will require the documentation of every dropped pill, every broken tablet found in every bottle, and every over or under fill by a manufacturer. Diversion by internal theft in the retail or outpatient setting does not generally happen in counts of 1-10, but by the bottle, counts of 100, 500 or 1000. The institutional setting is quite different. That setting can and does lose full bottles as well as single doses to internal theft; setting tighter CS inventory controls may be necessary in the institutional setting.

I will respectfully disagree with the Board's financial impact assessment. A full CS physical count using estimated values for C3-5 (as permitted by current rules) is roughly a 3-hour process at my stores. A full manual count of C-2 drugs is also a 3-hour project. Collating that data and comparing it to purchase data can take 10-15 hours. This is a sensitive job and should only be done by the PIC or owner, 13 hours of PIC labor will minimally cost the pharmacy \$1200 in total payroll costs. In our current economic environment with ever-dwindling profit margins and third party reimbursements this is level of scrutiny and labor investment is not cost efficient

For general retail pharmacy a simple In-Out audit is all that is necessary. Compare monthly purchases to monthly dispensing; then look for the discrepancies that are greater than 1 package size (100, 500, 1000) for further research and documentation.

A much more efficient mechanism, and just as capable of detecting diversion, if not more so would be:

- Collect purchase data reports directly from the vendor either as a printed or downloaded report. Do not use invoices; the diverter can destroy invoices.
- Collect sales data directly from the pharmacy software system.
- Compare line items sorted by NDC number (more exacting than drug name).
  - If the difference is greater than 1 package size, documenting the on-hand inventory should balance the equation.
  - If not then a more exacting count and audit process is needed.
- Mandating the use of a perpetual inventory for C-2 drugs is another tool that can be employed to catch inventory discrepancies in timely manner.

It is well documented in the press, Board posted accusations and actions, and Law enforcement investigations the internal retail pharmacy diversion involves full bottles, not random hands full of drug. The full inventories for PIC change must remain as a hard data point for the staffing change. The Biennial inventory is mandated by Federal regulation and currently accepts count estimates for schedules C III-V for packages of 1000 or less.

Retail and institutional pharmacy are vastly different, with different inventory management systems and needs. The above comments are directed towards the retail setting. As the practice of pharmacy becomes more and more specialized it is not unreasonable to develop separated inventory monitoring programs for retail (including institutional out patient) and institutional (inpatient) settings.

Furthermore this regulation **MUST** apply to **EVERY** pharmacy licensed by the California Board of Pharmacy, hospital inpatient, retail (including institutional out-patient), LTC, central fill, **and mail order** (in or out of state).

The Board can fulfill their mission of protecting the public without burdening the practice of pharmacy with down-to-the-tablet accounting.

Thank you for your consideration,  
Scott

## Martinez, Lori@DCA

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**From:** Grace Magedman <gmagedman@CHOC.ORG>  
**Sent:** Thursday, October 22, 2015 11:29 AM  
**To:** Martinez, Lori@DCA  
**Subject:** Inquiry regarding Proposed Regulation 1715.65

Dear Ms. Martinez,

I have a couple questions regarding the proposed text for 1715.65. Reconciliation and Inventory Report of Controlled Substances that I'm hoping you can either clarify or consider for amendment.

In subsection (c), it states that a physical count must be done of all Schedule II controlled substances (CS) during this quarterly inventory. In our organization, the charge nurse and another nurse witness do a *weekly* physical count of the CS in their automated dispensing cabinets (Pyxis). This is a blind count, so it would force a physical count of the CS. Would this suffice as part of the required quarterly physical count for the Schedule IIs stored outside of the pharmacy department when compiling information? It would also be electronically "signed" and timed/dated, as access details are typically captured when this activity occurs and could then be countersigned by the PIC after review.

In regards to subdivision (c)(1) and (e), will electronic copies of the signed CS inventory report as well as other records used in reconciliation be acceptable? It would be much more readily retrievable and it would cut down on the costs of increasing document storage requirements and retrieval.

Thank you for your time and clarification.

Best,  
Grace

Grace Magedman, PharmD  
Director of Pharmacy



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**Martinez, Lori@DCA**

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**From:** John Gallegos <jgallegosysandoval@outlook.com>  
**Sent:** Wednesday, October 21, 2015 10:26 AM  
**To:** Martinez, Lori@DCA  
**Subject:** RE: Proposed Amendments to Title 16 CABOP Rules and Regulations

Lori thank you for your clarification of the proposed law.

As the pharmacy consultant, other than verification that the DEA schedule II count is done twice daily and that there is no shrinkage involved, am I responsible for more than documenting due diligence on the part of the surgery clinic staff as a result of my quarterly audits?

I generate a multi-page report every quarter that covers my responsibilities listed under surgical clinic consultant pharmacist.

My question was do I have any additional responsibilities under the proposed regulation as it applies to the quarterly controlled substances audit?

Thank you for your time.

Regards,

**John H. Gallegos**  
**Beaumont, CA**

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**From:** Lori.Martinez@dca.ca.gov  
**To:** jgallegosysandoval@outlook.com  
**Subject:** RE: Proposed Amendments to Title 16 CABOP Rules and Regulations  
**Date:** Wed, 21 Oct 2015 14:39:31 +0000

If the clinic is doing a twice a day physical count of all schedule II's, then it meets the quarterly requirement.

Can you provide additional information on what verbiage they want clarified?

Lori Martinez  
Administration and Regulations Manager  
California Board of Pharmacy  
1625 N Market Blvd., Ste. N219  
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**From:** John Gallegos [mailto:jgallegosysandoval@outlook.com]  
**Sent:** Tuesday, October 20, 2015 4:00 PM

**To:** Martinez, Lori@DCA

**Subject:** Proposed Amendments to Title 16 CABOP Rules and Regulations

Good afternoon Ms. Martinez.

I recently had the opportunity to read the text of the proposed amendment of Title 16 relating to the proposal to conduct quarterly inventory audits of controlled substances in pharmacies and clinics.

I do consultant pharmacist work for various surgical center clinics.

Controlled substances are inventoried twice daily (at the beginning of the nursing shift and at the close of the shift after records reconciliation has occurred) every business day.

This this new proposed amendment relate to surgical clinics where daily controlled substances inventory is protocol?

The directors of nursing wish to have this verbiage clarified.

Thank you for your time addressing this inquiry.

Regards,

**John H. Gallegos**  
**Beaumont, CA**

## Martinez, Lori@DCA

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**From:** Jeremiah Joson <josonone@mac.com>  
**Sent:** Monday, November 02, 2015 1:04 AM  
**To:** Martinez, Lori@DCA  
**Subject:** Reconciliation and Inventory Report of Controlled Substances

To Whom It May Concern,

This is another "reactive" action by the Board that does not solve the problem but further burdens already burdened pharmacists and their staff. This has happened with the New England Compounding Center debacle; the Board became overzealous with their regulations to the point that mixing three ingredients to make Magic Mouthwash was considered compounding. This level of bureaucratic insanity does nothing to protect the public (please, explain to me how preventing me from mixing 3 ingredients and letting the patient do it themselves is supposed to protect them) but only further complicates an already complicated and stressed profession.

For one, opioids are just **one class** of abused prescription drugs (<http://www.pdmpexcellence.org/drug-abuse-epidemic>). According to the PDMP Center of Excellence, the "rise in the misuse and abuse of prescription drugs, opiates in particular, has been attributed to their increased availability over the last decade, **a result of increased prescribing.**" Many deaths are due to heroin, due to its low cost, easy availability, and the fact that it can be smoked or snorted. Compounding the profession with excessive, ineffective regulations will only lead to increased robberies, threatening our livelihoods, as is also referenced by the PDMP.

According to Okie, NEJM 2010, "**more than 40% of opioid prescriptions are written by general or family practitioners, osteopaths or internists...**" As studies by the State Departments of Health for Florida, Kentucky, and Ohio have shown, **the vast majority of deaths were due to pain clinic over prescribing** and oxycodone. When Kentucky and Florida decided to go after these "pill mills," their death rates were reduced drastically. They also increased drug abuse programs.

Dr. Frieden of the CDC, published a report in 2014 stating that the drug abuse epidemic is **caused largely by prescribers.** His study, along with an LA Times investigation, showed that physician prescribing was a key contributor to the crisis of addiction (<http://www.latimes.com/local/la-me-rx-source-20140304-story.html#axzz2v0MEW9Sh>).

Why are we asked to count all our Schedule II medications every three months when we are, by law, required to keep a perpetual inventory maintained daily? Furthermore, we are required to have policies & procedures in place addressing diversion. Furthermore, we are required to report theft or loss to the Board as well as the DEA via form 106. **This is another attempt by the Board to "brown nose" the public, to put on a performance so as to assure them that it is doing everything in its power to protect the public from the drug epidemic, when in fact, it is just forcing its pharmacists to exercise futile maneuvers and to collect payment from them for "gotcha" non-compliance. Drug diversion within pharmacies is already well regulated and plays a minor part in the overall scheme of drug overdose deaths.** As mentioned in many reports and studies (something the Board should undertake before jumping to conclusive actions), the greatest problem to the epidemic is **PHYSICIAN PRESCRIBING.**

Thanks to the Board, and case law, *State of California v. Thang Tran*, **pharmacists are already burdened with filling controlled substances**, checking CURES, and acting as gate-keepers, fighting with patients and sometimes their prescribers. **The burden of liability rests solely on pharmacists** and *nothing* is being done to address the real problem, physician over-prescribing and/or inappropriate prescribing. This has opened up more

paperwork, time spent filling prescriptions, hostility from patients toward pharmacists, and as has been already reported, increased gun-point robberies. Physicians should be required to staple a current CURES report with each opioid prescription they write before a patient leaves their office.

It is my professional opinion that if the Board truly believes that the "protection of the public shall be the highest priority," it would work with the California Medical Association, CDPH, and the State DEA to conduct a study and set forth recommendations as did the states of Florida, Kentucky, Ohio, and Tennessee, all of whom were successful in reducing drug deaths. As a matter of fact, none of those states required their pharmacists to count their Schedule II prescriptions every 3 months. Also, counting every Schedule II (e.g., Adderall, Concerta, Vyvanse, Duragesic), a vast majority of which are not implicated in the epidemic, is another waste of time and energy.

In addition, the Board should remove penalties of any kind for the self-reporting of controlled substance losses unless those losses were deemed intentional or have already been addressed in a previous infraction. Getting pharmacists and pharmacies to feel more comfortable with reporting diversion requires removing punishment the Board hands out to its pharmacists-in-charge. As has been known for a long time by the Institutes of Medicine, medication error reporting dramatically increases when employees know that no punitive action will be taken against them (<https://www.ismp.org/Tools/whitepapers/concept.asp>). It is ridiculous for the Board to make examples of its pharmacists and it does not help in the protection of the public, much like medication underreporting does not either.

In summary:

1. No, do not require a Schedule II inventory every 3 months with more burdensome paperwork to fill out
2. Understand the true nature of the problem before creating a useless, ill-advised regulation that does not protect the public or address the problem. Create a taskforce with other key-institutions and come up with real solutions.
3. Physicians should be required to print a current CURES report and attach it to any controlled substance prescription they write
4. Codify that pharmacists-in-charge will not be punished by the Board for any reports of diversion or missing pills, within reason

Respectfully submitted,

**Jeremiah (Jay) Josen, PharmD, CGP, BCPS, BC-ADM**  
Senior Outpatient & Clinical Pharmacist,  
Kern Medical Center Outpatient Pharmacies /  
Adjunct Professor of Pharmacy Practice,  
UOP School of Pharmacy & Health Sciences  
(F) 661-215-5115

**Martinez, Lori@DCA**

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**From:** Costantino, Dale <dcostantino@maderahospital.org>  
**Sent:** Thursday, November 12, 2015 12:04 PM  
**To:** Martinez, Lori@DCA  
**Subject:** comment on 1715.65

Ms Martinez,

I would like to comment on the proposed changes to 1715.65. My comments are specific to paragraph "g" below. Hundreds and sometimes thousands of doses of controlled substances are removed from automated drug delivery systems daily at many California hospitals for patients administration. This obligation to review each record would be overwhelming if not impossible. One person, a PIC in this case, may be able to review approximately 50 records a day.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy.

I believe that oversight and audits are needed. However, please consider revising this proposed text.

If you have any questions or comments, please feel free to call or write.

Thanks  
Dale

Dale Costantino Pharm.D.  
Pharmacy Director  
Madera Community Hospital  
(559) 675-5543

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**Martinez, Lori@DCA**

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**From:** Youmbi, Karen V <Karen.Youmbi@cshs.org>  
**Sent:** Monday, November 23, 2015 9:18 AM  
**To:** Martinez, Lori@DCA  
**Cc:** Youmbi, Karen V  
**Subject:** Proposed regulations for pharmacy reconciliation and inventory report of controlled substances  
**Attachments:** Pharmacy Reconciliation and Inventory REport of Controlled Substances 11....pdf

Dear Lori,

Thank you for the opportunity to provide feedback on the board's proposed regulations related to the reconciliation and inventory of controlled substances. We have attached our recommendations and comments. These have also been sent to you via FedEx.

Sincerely,

**Karen V. Youmbi, PharmD, BCPS**

Compliance and Performance Improvement Pharmacist  
Cedars-Sinai Medical Center  
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CEDARS-SINAI®

November 20, 2015

Lori Martinez

Administration & Regulations Manager

California State Board of Pharmacy

1625 North Market Blvd, Suite N 219

Sacramento, CA 95834

[Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov)

**Re:** Proposed regulations for pharmacy reconciliation and inventory report of controlled substances

Dear Lori,

Thank you for the opportunity to provide feedback on the board's proposed regulations related to the reconciliation and inventory of controlled substances. We have attached our recommendations and comments.

Should you have any questions, please feel free to contact me directly.

Sincerely,

Rita Shane, PharmD, FASHP, FCSHP

Chief Pharmacy Officer

Asst Dean, Clinical Pharmacy

UCSF School of Pharmacy

Office: 310-423-5611

Email: [shane@cshs.org](mailto:shane@cshs.org)

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Los Angeles, CA 90048



**California State Board of Pharmacy Reconciliation and Inventory Report of Controlled Substances  
Proposed Regulations – Comments**

Institution/Contact	Cedars-Sinai Medical Center Department of Pharmacy Services 310-423-5611 Rita Shane, Pharm.D., Chief Pharmacy Officer; shane@cshs.org
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Subdivision <b>1715.65</b>	Proposed Language	Recommendations/ Comments
c	<p>Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.</p>	<p><b><u>Recommendation:</u></b> Revise proposed regulations to: “Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist. <u>Alternatively, a pharmacy or clinic may utilize automated drug delivery systems in lieu of performing a periodic inventory.”</u></p> <p><b><u>Comments:</u></b> As defined under 4186 (h), automated drug delivery systems (ADDs) 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. Since ADDs provide perpetual inventory of controlled substances, pharmacies should be allowed to utilize these systems to fulfill the requirements of the proposed regulation.</p>



**California State Board of Pharmacy Reconciliation and Inventory Report of Controlled Substances  
Proposed Regulations – Comments**

e	Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.	<p><b><u>Recommendation</u></b> Revise proposed regulations to add: “Alternatively, organizations may use Automated Drug Delivery systems (ADDs) to perform ongoing perpetual inventory of all controlled medications that includes reconciliation of acquisitions and dispositions.</p> <p><b><u>Comments:</u></b> As defined under 4186 (h), automated drug delivery (ADDs) systems 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. Organizations which utilize these systems perform reconciliation on an ongoing basis which meets the intent of this section and therefore should be included in the regulations as recommended above.</p>
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**California State Board of Pharmacy Reconciliation and Inventory Report of Controlled Substances  
Proposed Regulations – Comments**

<p>g.</p>	<p>The pharmacist-in-charge of a hospital pharmacy or of pharmacy servicing skilled nursing homes wherever an automated drug delivery system is used shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.</p>	<p><b>Recommendations:</b> Revise proposed regulations as follows: “The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where automated drug delivery systems (ADDs) are used shall ensure that:</p> <ul style="list-style-type: none"> <li>a) All controlled substances added to an automated drug delivery system are accounted for;</li> <li>b) Access to automated drug delivery systems is limited to authorized facility personnel;</li> <li>c) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and</li> <li>d) Confirmed losses of controlled substances are reported to the board.”</li> </ul> <p><b>Comments:</b></p> <ol style="list-style-type: none"> <li>1. The intent of the proposed regulations is to identify losses of controlled substances. Performing a monthly review of all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy will not meet this goal. Having policies in place to ensure effective use of ADDs and leveraging the capabilities of these systems to identify discrepancies/unusual access and investigating them in real time allow pharmacies to identify and follow up on discrepancies or unusual access. Of note, larger institutions such as Cedars Sinai Medical Center add and remove approximately 80,000 controlled substance doses each month.</li> <li>2. Inappropriate access or removal of controlled substances does not always result in loss of controlled substances. A thorough investigation needs to be performed to confirm loss of controlled medications before reports are submitted to the board. This will minimize the number of false positive reports submitted to the board and provide a more accurate estimate of the number of controlled substances lost due to employee pilferage.</li> </ol>
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**California State Board of Pharmacy Reconciliation and Inventory Report of Controlled Substances  
Proposed Regulations – Comments**

h	<p>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, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.</p>	<p><b><u>Recommendation:</u></b> Revise proposed regulations to: “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, which may include installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.</p> <p><b><u>Comments:</u></b> The pharmacist- in- charge should evaluate and determine which strategy will prevent further loss of controlled medications.</p>
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## Martinez, Lori@DCA

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**From:** WILLIAM MAGUIRE <william.maguire@omnicell.com>  
**Sent:** Tuesday, November 24, 2015 12:08 PM  
**To:** Martinez, Lori@DCA  
**Subject:** re: proposed Ca reg 1715.65 sect (g)

Lori,  
I am writing to ask for clarification on Ca. code of Regulations in section 1715.65(g) and also some comments. According to the proposed regulation, it states either the PIC or pharmacy consultant shall review at least once a month all controlled substances removed or added to the ADC.

Questions;

- a. Can this function be delegated to another pharmacist or than the PIC or consultant pharmacist-like an assistant Mgr or lead pharmacist? Seems very onerous.
- b. Is this rule only for institutions with ADC's? It clearly states for those sites with ADC's so does that mean it is not mandatory for non-automated sites? If not mandated for non-automated sites-why? There are more chances of diversion without automation.

Thank you for your time.

Regards,  
Bill

William C. Maguire, RPh | Pharmacy Consultant, Professional Affairs | Post-Acute Care Division  
m: (404) 422 2718 | e: [william.maguire@omnicell.com](mailto:william.maguire@omnicell.com)



**Martinez, Lori@DCA**

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**From:** Berton, Lauren N. <Lauren.Berton@CVSHealth.com>  
**Sent:** Monday, November 30, 2015 8:43 AM  
**To:** Martinez, Lori@DCA  
**Subject:** CVS Health Comments in Reference to Addition of § 1715.65 Reconciliation and Inventory Report of Controlled Substances in Article 2 of Division 17 of Title 16 of the California Code  
**Attachments:** CVS Health Comments to Proposed Addition of Section 1715.65.pdf

Good Morning Lori,

Please find attached CVS comments in reference to addition of § 1715.65 Reconciliation and Inventory Report of Controlled Substances in Article 2 of Division 17 of Title 16 of the California Code. Please feel free to reach out to me with any additional questions on the attached comments.

Thank you,



**Lauren Berton, PharmD** | Director, Pharmacy Regulatory Affairs  
c 540-604-3661 | f 401-733-0479  
**CVS Health** | One CVS Drive, Mail Code 2325, Woonsocket, RI 02895

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Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

November 30, 2015

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

**Re: Proposed addition of Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations**

Dear Ms. Martinez:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. CVS Health appreciates the opportunity to submit comments on the proposed addition of Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations regarding Reconciliation and Inventory Report of Controlled Substances. We would like to thank the Board for their continued vigilance to continuously improve the laws and rules that guide pharmacists serving California patients.

We appreciate the Board's continued focus on combating prescription drug abuse in California with a focus on decreasing and preventing employee diversion, preventing excessive drug losses from occurring and attempting to reduce the supply of controlled substances available to those who misuse and abuse.

CVS Health maintains a perpetual inventory for all Schedule II controlled substances and also completes a physical count of these medications once a month. By maintaining the perpetual inventory, we are able to identify potential losses and investigate discrepancies on a regular basis. We strongly urge the board to consider adding language for pharmacies that maintain a perpetual inventory of Schedule II controlled substances to be deemed compliant with 1715.65(b), (c), and (e). Full reconciliations, as required by 1715.6(e) will take a substantial amount of time and focus for the pharmacist to complete by reviewing all acquisition invoices and dispensing records to determine the expected stock and then comparing to the balance on hand. Also, Pharmacists may not be able to perform cognitive services such as MTM or furnishing of hormonal contraceptives as well as experiencing difficulty to perform mandatory counseling as they will be focused on completing these reconciliations if maintaining a perpetual inventory is not deemed compliant.

We also request that the board limit the additional controlled substance identified in 1715.65(c) to be inventoried to one additional controlled substance. The current language leaves this open to the board adding on an infinite number of controlled substances to be inventoried, which can become very onerous for the pharmacies to complete. Current discussion includes Alprazolam and Promethazine with Codeine as the additional controlled substances. Alprazolam has multiple strengths and a pharmacy could possibly stock more than one manufacture, so this already requires at least 5 additional medications to be included in the count.

**Suggested Language:** (c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of Schedule II controlled substances and ~~at least~~ one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year.



Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

Current proposed language in 1715.65(c)(2)(A) indicates that the biennial inventory of controlled substances required by federal law may serve as one of the periodic inventories, provided that a physical count of *all* controlled substances is performed. This is more stringent than DEA regulation 21 CFR 1304.11(e)(6)(i) and (ii) which allows for a registrant to estimate Schedule III to V, unless the container holds more than 1,000 tablets or capsules. We request that the board clarify this section that requires only an exact physical count for the additional controlled substance identified by the board as opposed to all controlled substances.

**Suggested Language:** (A) A physical count of controlled substances in Schedule II and the additional controlled substance identified by the board to be inventoried periodically is performed, with an estimated count of all other Schedule III to V controlled substances as allowed by 21 CFR 1304.11

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 540-604-3661.

Sincerely,

A handwritten signature in black ink that reads "Lauren Berton PharmD". The signature is written in a cursive, slightly slanted style.

Lauren Berton, PharmD.  
Director, Pharmacy Regulatory Affairs  
CVS Health

**Martinez, Lori@DCA**

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**From:** Mary Staples <mstaples@NACDS.org>  
**Sent:** Monday, November 30, 2015 9:00 AM  
**To:** Martinez, Lori@DCA  
**Cc:** Herold, Virginia@DCA; Angie Manetti (amanetti@calretailers.com); Brian Warren; Jennifer Snyder; Jon Roth  
**Subject:** NACDS Comments on Proposed Rule Section 1715.65, Reconciliation and Inventory Report of Controlled Substances  
**Attachments:** CA NACDS CMTS Controlled\_Substance\_Prop\_Rule 11-30-2015.pdf

Please accept the attached comment letter for the record.

Mary Staples  
Director, State Government Affairs

NACDS  
1560 E. Southlake Blvd., Suite 230  
Southlake, TX 76092  
817.442.1155  
817.442.1140 Fax  
817.308.2103 Cell  
[mstaples@nacds.org](mailto:mstaples@nacds.org)

## Martinez, Lori@DCA

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**From:** TerryC <tcater@comcast.net>  
**Sent:** Monday, November 30, 2015 9:33 AM  
**To:** Martinez, Lori@DCA; Sodergren, Anne@DCA  
**Subject:** Comment on proposed adoption of Section 1715.65

I am commenting on the proposed adoption of Section 1715.65 of Article 2 of Division 17 of Title 16 of the CCR (requirements for reconciliation and inventory of controlled substances) which, among other requirements, would require pharmacies to perform a physical inventory count of all Schedule II controlled substances every 3 months.

This proposed regulation does not increase the protection of the public. It may actually take away from the public safety. This is one more non-patient centered activity that takes pharmacist's time and attention away from patient medication safety.

The DEA currently requires a complete CS inventory every two years. The State of California regulations should either "mirror" the federal requirement or consider amending the current proposal from taking an inventory every three months to once a year.

Thank you.

Terry Cater, R.Ph., M.B.A.  
Pharmacy Executive  
One Hawthorne Street 15G  
San Francisco, CA 94105  
925.895.1506 cell  
415-358-4502 fax

## Martinez, Lori@DCA

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**From:** Tou, Michael P <Michael.Tou@providence.org>  
**Sent:** Monday, November 30, 2015 10:12 AM  
**To:** Martinez, Lori@DCA  
**Subject:** Providence comments on reconciliation and inventory reporting of controlled substances rule  
**Attachments:** 11-30-15 Providence Comments on Reconciliation & Inventory Report of Controlled Substances.pdf

Good morning Lori,

On behalf of Providence Health & Services, I am submitting our comments in response to the proposed regulations for reconciliation and inventory reporting of controlled substances.

Please let me know if you have any questions about the comment letter.

Best regards,

Michael

**Michael Tou, MPA** | Director, Government Relations | Providence Health & Services, Southern California |  
Office: (310) 793-8093 | Mobile: (818) 512-4837 | 20555 Earl Street, Torrance CA 90503



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November 30, 2015

California State Board of Pharmacy  
 Attn: Ms. Lori Martinez  
 1625 N. Market Blvd., Suite N219  
 Sacramento, CA 95834

**RE: Reconciliation and Inventory Report of Controlled Substances, Notice of Proposed Action, Articles 2 of Division 17 of Title 16 of the California Code of Regulations, Section 1715.65. Comment Period: October 16, 2015 to November 30, 2015.**

Dear Ms. Martinez:

Providence Health & Services in Southern California appreciates the opportunity to submit comments on the proposed regulations for reconciliation and inventory report of controlled substances.

Providence Southern California is a not-for-profit organization dedicated to providing quality and compassionate health care and reaching out to the poor and vulnerable in the communities it serves. Providence operates six award-winning acute-care medical centers in the Los Angeles area, providing a full continuum of health care services: Providence Holy Cross Medical Center in Mission Hills, Providence Little Company of Mary Medical Centers in Torrance and San Pedro, Providence Saint John’s Health Center in Santa Monica, Providence Saint Joseph Medical Center in Burbank, and Providence Tarzana Medical Center. Providence operates pharmacies at each of our six medical centers and another pharmacy at the Disney Family Cancer Center in Burbank.

**DETAILED RECOMMENDATIONS AND COMMENTS**

For ease of reference, we have organized our detailed comments in a matrix. On the left is the location of the language as proposed in the rule; in the center column is the language contained in that section. On the right, we propose new language either by tracked deletions or by additions in red italics.

Section	Proposed Language	Providence Health & Services Comments/Recommendations
1715.65(a)	“Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.”	<i>“Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions to prevent the loss of controlled substances.”</i>
1715.65(b)	“The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.”	<i>“The pharmacist-in-charge or designee of a pharmacy or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be</i>

		<p><i>developed for performing the reconciliation and inventory reports required by this section.</i></p> <p>Providence believes this section may also apply to unresolved orders for overrides of controlled substances. Pharmacists-in-charge are caught between end-users, such as nurses and physicians, of whom PICs do not have supervision over.</p>
1715.65(c)(1)	<p>"The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years."</p>	<p>Providence requests clarification from the Board as to whether records can be stored off-site for licensed facilities that inventory more frequently than every 90 days.</p>
1715.65(e)	<p>"Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form."</p>	<p>Providence requests clarification from the Board on the following issues:</p> <ul style="list-style-type: none"> <li>• Does this requirement take into account stock fluctuations based on demand, as well as facilities that ramp up purchases due to anticipated shortages?</li> <li>• Does the language need to specify that this inventory report is meant to determine expected stock on hand?</li> <li>• If the stock on hand has doubled for a legitimate reason, does it conflict with the proposed requirement?</li> </ul>
1715.65(e)(2)	<p>"Likely causes of overages shall be identified in writing and retained."</p>	<p>Providence requests clarification from the Board on the following issues:</p> <ul style="list-style-type: none"> <li>• Should overages be documented in the inventory report?</li> <li>• Does this require dual-signature by the pharmacist-in-charge and another licensed pharmacist/technician?</li> </ul>
1715.65(e)(3)	<p>"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has</p>	<p><i>"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and,</i></p>

	<p>been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.”</p>	<p><i>if the pharmacist-in-charge or consultant pharmacist determines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1.”</i></p>
<p>1715.65(g)</p>	<p>“The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the Board within 14 days.”</p>	<p><i>“The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine system operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery drug system shall be reported to the Board within 14 30 days.”</i></p> <p>California regulations currently require pharmacies to report losses associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days.</p> <p>Automated Dispensing Systems (ADS), which are located in a hospital or nursing home, would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. Nursing and medical personnel access the machines to remove doses of controlled substances on a more frequent basis than the pharmacy personnel, who access the inventory to restock or replenish the supply.</p> <p>Additionally as the actions of these non-pharmacy personnel are not under the direct supervision of the pharmacy or pharmacist-in-charge, it may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. Many occurrences may be resolved satisfactorily upon investigation. It</p>

		<p>may be discovered that the access or removal was not actually “inappropriate” after all.</p> <p>The timeframe required by the Board should allow sufficient time for investigation first, and then, unresolved inappropriate access or removals should be reported.</p> <p>Pharmacies are being prompted to report every discrepancy to the Board prior to performing a diligent investigation in order to make that 14-day time period. This could create over-reporting and difficulty identifying actual events versus miscounts and typographical errors.</p> <p>The timeframe of 14 days for an inappropriate access or removal does not seem proportionate to the 30-day timeframe allowed for an actual irreconcilable loss of controlled drugs, as stated in Section 1715.65(h).</p> <p>Providence urges the Board to provide further clarification as to the definition of “inappropriately access or removed” in the proposed rule. Errors on the patient’s medication record may not be the result of an actual loss or diversion.</p> <p>Providence requests clarification from the Board as to how it plans to take action against non-pharmacy personnel associated with a reported loss or discrepancy.</p> <ul style="list-style-type: none"> <li>• Has the Board engaged with the Medical Board of California and Board of Registered Nursing on the proposed rule to ensure effective compliance with the requirements across disciplines?</li> </ul>
1715.65(h)	“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, including	<i>“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</i>

	<p>installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.”</p>	<p><i>origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing, until the cause is identified and resolved.”</i></p>
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Thank you for this important opportunity to comment on the proposed regulations. Providence asks the Board of Pharmacy to give full and careful consideration to our comments and recommendations.

Sincerely,



Michael Tou  
Director, Government Relations

**Martinez, Lori@DCA**

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**From:** John Grubbs <jgrubbs@ucdavis.edu>  
**Sent:** Monday, November 30, 2015 10:21 AM  
**To:** Martinez, Lori@DCA  
**Cc:** Paula K Peterson  
**Subject:** Comments on proposed changes to 1715.65  
**Attachments:** Comments on CCR 1715.65.pdf

Thank you.

John H. Grubbs, MS, MBA, RPh  
Chief Pharmacist  
UC Davis Medical Center  
916-734-3305 (office)  
916-734-5668 (fax)

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PHARMACY DEPARTMENT  
(916) 734-3305

UC DAVIS MEDICAL CENTER  
2315 Stockton Boulevard  
SACRAMENTO, CALIFORNIA 95817

November 23, 2015

Lori Martinez  
1625 North Market Boulevard, N219  
Sacramento, CA 95834

Dear Ms. Martinez:

I am in full support of efforts to prevent the abuse and diversion of controlled substances in California, particularly by healthcare workers. However, I'm concerned that some of the proposed additions to CCR 1715.65 will only add extra administrative costs to California hospitals, without helping to prevent the problem of controlled substance abuse.

As worded, Subdivision (c) would require my staff to complete an inventory of all Schedule II controlled substances plus one other Schedule III-V controlled substance every three months and for me as the Pharmacist-in-Charge to sign these inventories. At my hospital we have more than two thousand (2,000) locations where Schedule II controlled substances are stored, including all of the automated dispensing machines. Using a conservative estimate of two minutes per location, this inventory would take at least 133 hours to complete.

Subdivision (e) requires reconciliation between the on-hand inventory and all acquisitions and dispositions of controlled substances. At my hospital, we dispense approximately 50,000 CII doses per month. In addition, we perform approximately 5,000 refills. It would be difficult to estimate the time required to reconcile the acquisitions and dispenses against the inventory, but it's likely to be at least a full time job.

Subdivision (g) requires monthly reviews of all removals and additions of controlled substances to automated drug delivery systems and investigation and reporting of unusual accesses or discrepancies. Does this review supersede the inventory and reconciliation requirements of Subdivisions (c) and (e)? Also, what would constitute acceptable proof of this review?

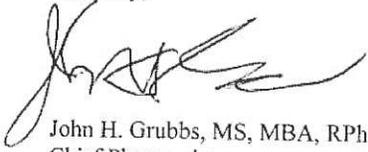
I suggest that the Board allow hospitals utilizing automated drug delivery systems to implement alternative processes to identify and prevent controlled substance diversion. Some examples of such processes would include monthly analysis of staff who are removing more controlled substances than their peers, daily investigation of all discrepancies in the inventories of controlled substances, and review of all removals of controlled substances that were made on "override" (ie emergent situation when physician's order has not been verified by pharmacist) to ensure the removal is appropriate. All inappropriate accesses or removals identified by these processes would be reported to the Board.

Additionally, some hospitals have formed multi-disciplinary committees charged with reviewing all audits of controlled substance use, for overseeing investigations into potentially inappropriate use, for ensuring appropriate reporting when theft or diversion has occurred and for implementing changes to prevent future occurrences. This would be another alternative process that hospitals could use instead of the requirements of Subdivisions (c) and (e).

I feel that the alternative processes that I've described above would be much more effective at preventing controlled substance diversion than the requirements of Subdivision (c) and (e). Hospitals that implement such alternative processes should not be subject to these new requirements. The language in Subdivision (g) should be modified to allow for such alternative processes and should specify that hospitals that have these processes in place are exempt from the requirements of Subdivisions (c) and (e).

Thank you for allowing me to comment on these proposed changes to CCR 1715.65. I would be happy to discuss this in more detail if needed.

Sincerely,

A handwritten signature in black ink, appearing to read 'John H. Grubbs', written in a cursive style.

John H. Grubbs, MS, MBA, RPh  
Chief Pharmacist

## Martinez, Lori@DCA

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**From:** Ronda Fricke <rfricke@calhospital.org> on behalf of BJ Bartleson <BJbartleson@calhospital.org>  
**Sent:** Monday, November 30, 2015 3:28 PM  
**To:** Martinez, Lori@DCA  
**Cc:** BJ Bartleson; Ronda Fricke  
**Subject:** Reconciliation and Inventory Report of Controlled Substances, Notice of Proposed Regulations to Adopt Section 1715.65 of Article 2 of Division 17 of Title 16, California Code of Regulations  
**Attachments:** CCR 1715.65 Recon and Inven of Controlled Substances DO Comments112015 DRAFT.docx; CHAboPreconinventory.docx

Dear Ms. Martinez:

Attached please find California Hospital Association's Letter and Comments for consideration to the proposed regulations and adoption of Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR).

Please let us know if you need anything else from us. Thank you.

### **Ronda Fricke**

ASSISTANT TO  
BJ BARTLESON, VICE PRESIDENT NURSING AND CLINICAL SERVICES  
DEBBY ROGERS, VICE PRESIDENT CLINICAL PERFORMANCE & TRANSFORMATION  
CALIFORNIA HOSPITAL ASSOCIATION | 1215 K STREET SUITE 800 | SACRAMENTO CA 95814 | MAIN 916.443.7401  
DIR 916.552.7616 FAX 916.554.2212 | [RFRICKE@CALHOSPITAL.ORG](mailto:RFRICKE@CALHOSPITAL.ORG)



**CALIFORNIA  
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*Providing Leadership in  
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November 30, 2015

California State Board of Pharmacy  
Attn: Lori Martinez  
Lori.Martinez@dca.ca.gov  
1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834

BY ELECTRONIC CORRESPONDENCE

**RE: Reconciliation and Inventory Report of Controlled Substances, Notice of Proposed Regulations to Adopt Section 1715.65 of Article 2 of Division 17 of Title 16, California Code of Regulations**

Dear Ms. Martinez:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments for consideration to the proposed regulations and adoption of Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR). The Board of Pharmacy (Board) has added these specific requirements for reconciliation and inventory reporting of controlled substances as part of their effort to combat drug loss and diversion from within pharmacies and prescription drug abuse within California.

The Board proposes to add specific requirements for periodic reconciliation and inventory at least every three months of all Schedule II controlled substances and at least one additional controlled substance as identified by the Board based on drug loss reports. According to the Board, by conducting a physical count inventory, pharmacists, pharmacies, and clinics will have more accountability and monitoring of controlled substances. The Board cites the availability of opioids is partly the cause of epidemic misuse of prescription medication. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. According to the Board, this will reduce the supply of controlled substances available for misuse and abuse without denying pain relief for those who need it.

CHA agrees with the underlying premise that comprehensive safeguards and highly reliable systems need to be in place to prevent controlled substance misuse, particularly with the high rate of opioid deaths across the nation and within the state. And while we agree with the need for comprehensive controls of opioid acquisition and distribution, we acknowledge the stringent hospital regulations and standards of practice presently in place, along with rigorous practices used by hospital pharmacists to secure all medications specifically to prevent misuse and

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enhance appropriate use with patients. Presently, all hospital pharmacists undergo the “biennial inventory” of controlled substances required by federal law and agree that periodic inspection is necessary. In addition, each hospital, health system and clinic has a specific process in place for storage and security of controlled substances. The CHA Medication Safety Committee has developed the “Reducing Controlled Substances Diversion in Hospitals” tool to provide recommendations to hospitals on actions they could take to assess their resources and technology to develop an individualized diversion and prevention plan that protects organizations from substance diversion. The tool outlines recommendations utilizing present state and federal laws and regulations, as well as, stating best practice recommendations as goals for ongoing process improvement and high reliability performance. A section on storage and security of controlled substances identifies the numerous different ways controlled substances are securely stored within institutions, and therefore, how individualized plans for inventory and reconciliation must be utilized, especially as it pertains to narcotic storage outside of the main pharmacy, particularly in Administration Dispensing Cabinets (ADC’s).

CHA and its members agree that physical inventory of the pharmacy vault every three months is reasonable, and most hospitals perform this activity monthly. The area of greatest concern with the proposed regulations revolve around the hospital’s inventory of ADC’s and the variable type and level of safety and security systems, necessitating a well-designed policy specific to that institution’s resource capability. A periodic physical inventory every three months is not necessarily the best method to identify or limit diversion, depending on other technology and methods available to the organization. Systems in place and used by many organizations include biometric identification, blind counts, use of specific controlled substance software, etc. Hospitals need to provide the highest level of security within existing resources. Many of these alternative processes are far superior than a physical inventory, and the addition of labor intensive activity, as proposed in these regulations when other successful systems are in place, are wasteful and unnecessary.

CHA’s specific comments are outlined in the attached grid. As mentioned in previous comments, our main concern is the fiscal impact incurred by hospitals across the state to comply with this regulation when there is no evidence to support its efficacy. One hospital system reports the need for additional \$300,000 annually to provide ADC physical inventory. Extrapolated across 400 hospitals, this number would conservatively increase to over \$3 million dollars for hospitals to deploy. While ADC physical inventory is one of several methods to identify and limit diversion, it is not the most effective method and should not be mandated.

In section 1715.65 (a), CHA agrees with the BOP that periodic reconciliation and inventory functions defined by hospital policy should prevail. We agree that periodic physical inventory of the pharmacy vault is appropriate, however, physical inventory of the ADC’s should not be mandated due to the fiscal impact and availability of other equivalent, if not more successful methods such as biometric identification, blind counts, controlled substance software, etc.

In section 1715.65(b), CHA proposes to add designee status as all hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over

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providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy.

In Section 1715.65(c) CHA specifically discusses our biggest concern with the proposed regulations on physical inventory count of ADC's. CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy vault is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do "blind counts" to verify they match the total in their software systems, if computerized software tracking software systems are in place.

If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue resource burden would occur. A California health care system with over 30 hospitals and 700 ADC's would need four hours of labor per machine to count all Schedule II controlled substances at an annual cost of \$300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over \$3 million annually. The physical inventory of ADC's should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion.

As discussed, this is an unnecessary financial burden, as other safeguards listed in the grid are examples of activities implemented in hospitals that utilize ADC's e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADC's by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation technology.

In section 1715.65(e) CHA offers the same perspective as per section 1715.65(c). CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC's or other mechanisms for narcotic administrative practice.

In section 1715.65(e)(3), CHA offers clarification language.

In section 1715.65(g), CHA would suggest that California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the Board within 30 days. ADC's located in hospitals or nursing homes would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggests changing the time frame to 30 days presently allowed for an actual irreconcilable loss of controlled drugs.

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In section 1715.65(h), CHA agrees that additional measures should be implemented in response to unidentified controlled substance drug loss. However, we disagree that those measures should be specifically determined as presently proposed. Strike, “including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing”, and replace with “take additional steps to improve the security of the controlled substances to prevent losses”. Hospitals need to have flexibility in what resources are used to address narcotic loss.

In summary, hospitals and health systems are fully committed to combating drug loss and diversion from within hospital pharmacies. Each hospital has specific standardized policies and practices in place to mitigate diversion. We agree that robust systems need to be in place, however, we need to recognize the extreme resource variability, in particularly with ADC’s, and allow hospitals to develop plans and policies based on evidence and present resource capability. We are in full agreement that periodic, every three month physical inventory of the inpatient pharmacy vault is appropriate, and most hospitals are already performing this more often. Our main concerns, as discussed in depth, center around the physical inventory requirement for the ADC’s. This requirement is an unnecessary financial burden without appropriate evidence or rationale, particularly when other more stringent measures are present.

Once these regulations are finalized, the CHA Medication Safety Committee will update the medication safety tool, “Reducing Controlled Substances Diversion in Hospitals”, distribute, and continue to educate and foster improved narcotic administration practices that protect patients and lessens theft, diversion or other controlled substance untoward activities.

Respectfully Submitted:



BJ Bartleson, RN, MS, NEA-BS  
Vice President, Nursing and Clinical Services

BJB:rf

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(a)	<p>“Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.”</p> <p>This is added to ensure all Board licensees that dispense controlled substances are required to perform the inventory defined under this proposal.</p>	<p>“Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions, defined by policy, to prevent the loss of controlled substances.”</p>	<p>California hospitals and health system pharmacies have stringent individualized standardized practices in place to prevent, detect, and mitigate controlled substance diversion. Because of the broad variability in types of facilities, and, medication administration resources, hospitals each define their individualized system in specific policies, as well as, perform periodic controlled substance inventory.</p> <p>All hospitals perform the required CMS biennial inventory of controlled substances and a monthly physical inventory of the respective pharmacy vault.</p> <p>While most hospitals have automated dispensing cabinets (ADC's), the types and utilization are variable, depending on available resources. Thus the most important aspect of this regulation should be the requirement for periodic reconciliation based on individualized hospital policy that defines the specific controlled substance procurement and administration process inventory and reconciliation process.</p>
1715.65(b)	<p>“The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.”</p> <p>This is added to ensure the licensee responsible for the pharmacy operations is reviewing the reconciliations and inventories. Additionally, the facility needs to develop policies and procedures to ensure that each reconciliation and inventory is completed following the same</p>	<p>“The pharmacist-in-charge or designee, or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled substances. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.”</p>	<p>All hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy,</p>

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(c)	<p>methods to prevent inaccurate collection of data. Finally, the Board reviews policies and procedures while performing site inspections and will be able to confirm if the policies and procedures implemented by the pharmacy or clinic meet the regulatory requirements.</p> <p>“Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be <b><u>dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.</u></b>”</p> <p>This subdivision specifies the required time frame of at least every three months. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. While the Board is requiring the inventory to be completed quarterly, the term “at least” allows for the pharmacist-in-charge to use their professional judgment should they wish to perform the inventory more frequently. The additional requirement of at least one additional controlled substance based of drug loss reports allows the Board to utilize drug</p>	<p>“Perform a Periodic Inventory: An Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of <u>all</u> quantities of federal <u>Schedule II</u> controlled substances *(within the inpatient pharmacy only if a licensed hospital) and at least <u>one additional</u> controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be <b><u>dated and signed (electronic signature acceptable) by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.</u></b>”</p>	<p>CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do “blind counts” to verify they match the total in their software systems, if computerized software tracking software systems are in place.</p> <p>If a physical inventory count was required of all dispensing cabinets throughout the hospital by the Inpatient Pharmacy, an undue burden of resources would be incurred. A California health care system with over 30 hospitals and 700 ADC’s would need four hours of labor per machine to count all schedule II controlled substances at an annual cost of \$300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over \$3 million annually. The physical inventory of ADC’s should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion.</p> <p>As discussed, this is an unnecessary financial burden, as other safeguards listed below are examples of activities implemented in hospitals that utilize ADC’s e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADCs by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation</p>

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	<p>loss reports and alert pharmacies and clinics of high theft controlled substances that may not be Schedule II. As regular inventory is being completed on Schedule II controlled substances, those wishing to divert controlled substances may change their focus to non-Schedule II in order to avoid detection, an example of this is Promethazine with Codeine cough syrup. Promethazine with Codeine has a high potential for abuse, but it is not Schedule II. By requiring an inventory of at least one non-schedule II, the Board will be able to reduce the theft and misuse of an additional controlled substance. Finally, as the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that those who performed the inventory sign and date the Inventory Report, and that it be countersigned by the pharmacist-in-charge or consultant pharmacist to ensure they are aware and accountable for the inventory. By requiring the signing and countersigning of the Inventory Report, Board inspectors will know who completed the inventory during an inspection.</p>		<p>technology.</p> <p>Examples of automated dispensing cabinets (ADCs) inventory practices utilized in various facilities:</p> <ul style="list-style-type: none"> <li>• Use of biometric identification to access ADCs</li> <li>• Use of “blind counts” when removing controlled substances which eliminates the possibility of confirmation bias in the counting process and automatically records any discrepancies</li> <li>• Use of “blind counts” when restocking the ADCs</li> <li>• Required resolution of any controlled substance discrepancies on a daily basis by the nurses, and verification (oversight) by the pharmacy that the process has been completed (including reviewing the rationale documented during the resolution process)</li> <li>• Physical inventory of controlled substances in the ADCs on a regular basis by the nurses utilizing “blind counts.”</li> <li>• Daily monitoring ADC overrides to ensure there is a valid prescriber order for the medication that was removed</li> <li>• Regular review of oversight reports, e.g. ADC Users created; Cancelled transactions, to detect suspicious activity and prevent diversion</li> <li>• Use of specialized computer software (Pandora) to analyze patterns of controlled substances removal from ADCs and identify suspicious activity and/or users to prevent diversion</li> <li>• Perpetual inventory of all controlled substances in the pharmacy utilizing specialized computer software (C-II Safe). This software also tracks all controlled</li> </ul>

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
			<p>substances removed from the pharmacy and stocked in the ADCs and communicates with the ADCs to verify the controlled substances that left the pharmacy were subsequently stocked in the ADCs.</p> <ul style="list-style-type: none"> <li>• Review and approval of all Pharmacy orders for controlled substances from wholesalers/suppliers by a Pharmacy Manager</li> <li>• Verification by a Pharmacy Manager that all controlled substances received in the Pharmacy from a wholesaler/supplier are entered in to the specialized tracking software</li> <li>• Use of "blind counts" when adding and/or dispensing controlled substance from the Pharmacy inventory specialized computer tracking software</li> </ul> <p>As evidenced by the aforementioned numerous examples, each hospital, depending on size and resource availability must devise its individualized policy and plans for controlled substance reconciliation and inventory outside the inpatient pharmacy vault.</p>
1715.65(c)(1)	<p>"The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be <b>readily retrievable for three years.</b>"</p> <p>This requirement is added so that the Inventory Report will be readily available for review by Board inspectors as defined in Business and Professions Code (B&amp;P) section 4105(a). The three year time frame is defined in B&amp;P section 4105(c) and is maintained in this proposal.</p>	No Comment	
1715.65(c)(2)	<p>"The biennial inventory of controlled substances required by federal law may</p>	No Comment	

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	<p>serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided.”</p> <p>This subdivision allows for the use of the federally required biennial inventory to be used as one of the proposals quarterly inventories. This specification will eliminate the need for repetitive inventories to meet state and federal Requirements.</p>		
1715.65(c)(2)(A)	<p>“A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.”</p> <p>This subdivision specifies that, in order to use the biennial inventory, it must have been a physical count inventory and not an estimate. The federally required biennial inventory does not specify a physical count as required in subdivision (c) of this proposal, so this specification is necessary to ensure a physical count inventory is completed.</p>	No Comment	
1715.65(c)(2)(B)	<p>“The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.”</p> <p>This subdivision specifies that in order to utilize the federally required biennial inventory, it must be no older than 90 days from the last physical inventory completed. This subdivision ensures that an inventory is completed at least once every three months.</p>	No Comment	

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(d)	<p>“A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).”</p> <p>This subdivision requires a new pharmacist-in-charge to complete an inventory. While this is currently recommended, it is not required. Requiring a new pharmacist-in-charge to complete an inventory within 30 days of becoming pharmacist-in-charge will familiarize the pharmacist with the pharmacies policies and procedures and will hold them accountable for the drug inventory and drug losses that may occur after they become pharmacist-in-charge. The Board selected the 30 day time frame to allow the new pharmacist-in-charge time to acclimate to their new position and to allow time to address day to day operations. While not being mandated, the Board is also recommending that the outgoing pharmacist-in-charge should complete an inventory upon their departure. Completing an inventory upon departing will reduce or eliminate suspicion and possible disciplinary action against the departing Pharmacist-in-Charge should a drug loss be discovered by the new Pharmacist-in-Charge.</p>	<p>No Comment</p>	
1715.65(e)	<p>“Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand,</p>	<p>“Reconciliation with Inventory Report: The pharmacy or clinic shall review, based on policy, all acquisitions and dispositions of controlled substances as part of the inventory process (within</p>	<p>As per section 1715.65(c), CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC’s or other mechanisms for</p>

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	<p>based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.”</p> <p>This subdivision requires that the acquisition and disposition reports be reconciled with the inventory report. This reconciliation is necessary to ensure that controlled substances are not being ordered and diverted upon arrival without the knowledge of the pharmacist-in-charge. This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&amp;P section 4105(a). The three year time frame is defined in B&amp;P section 4105(c) and is maintained in this proposal.</p>	<p>other inpatient pharmacy only if a licensed hospital or clinic) as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.”</p>	<p>narcotic administrative practice.</p> <p>If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue burden of resources would be incurred. This is unnecessary as other individualized stringent safeguards are implemented, such as, blind counts; robust discrepancy resolution process, review of ADC overrides, periodic inventory of the ADCs by nurses, etc. (See more specific examples in section 1715.65(c)).</p>
1715.65(e)(1)	<p>“Losses shall be identified in writing and reported to the Board and, when appropriate, to the Drug Enforcement Administration.”</p> <p>This subdivision specifies what the licensee is required to do if a loss of controlled substances is discovered. If a drug loss is discovered, it is necessary for the Board to be informed from a regulatory stance to determine if there is an issue with security at the pharmacy or clinic.</p>	No Comment	
1715.65(e)(2)	<p>“Likely causes of overages shall be identified in writing and retained.</p> <p>This subdivision specifies what the licensee is required to do if an overage of controlled substances is discovered. The Board does not need to be informed of the overage; however, it is necessary to</p>	No Comment	

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(e)(3)	<p>educate and ensure that the pharmacy or clinic maintains better records of their controlled substances.</p> <p>“Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.”</p> <p>This subdivision specifies that a controlled substance is deemed to be a loss if it is unaccounted for after being in the inventory during the previous six-months. This subdivision will ensure that all controlled substances that are unaccounted for are deemed a loss and are reported as such. Reviewing the data for the prior six-month period will also catch counting and mathematical errors that may occur during the inventory process.</p>	<p>“Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and, if the pharmacist-in-charge or consultant pharmacist determines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1.”</p>	<p>Suggestions for language clarification</p>
1715.65(f)	<p>“Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.”</p> <p>This subdivision is added to balance the inventory. Once the overages and/or losses have been reported, adjustments are made to the inventory so there is a stock on hand starting point for the next inventory period. This will ensure that each inventory period is looking at three months of data at a time in an effort to quickly</p>	<p>No Comment</p>	

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(f)(1)	<p>determine when drug losses occur.</p> <p>“Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.”</p> <p>This subdivision adds documentation requirements to the stock on hand adjustments. When reviewing the inventory reports, it is necessary to know who made the adjustment and when to hold staff accountable for the inventory.</p>	No Comment	
1715.65(f)(2)	<p>“The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.”</p> <p>As the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that they countersign the adjusted inventory report to ensure they are aware and accountable for the adjustments.</p>	No Comment	
1715.65(f)(3)	<p>“The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.”</p> <p>This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&amp;P section 4105(a). The three year time frame is defined in B&amp;P Section 4105(c) and is maintained in this proposal.</p>	No Comment	
1715.65(g)		Language clarification and change of	

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
		<p>14 to 30 days per title 16, Division 17 section 1715.6, Reporting Drug Loss</p> <p>California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days. ADC's located in hospital or nursing home would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggest changing the time frame to 30 days as allowed for an actual irreconcilable loss of controlled drugs as presently in regulations.</p>	
1715.65(h)		Strike," including installation of cameras, relocation of the controlled drugs to a more secure location within	

# 16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
		<p>the pharmacy, or daily inventory counts of the drugs where shortages are continuing”, and replace with “take additional steps to improve the security of the controlled substances to prevent losses”. Hospitals need to have flexibility in what resources are used to address narcotic loss.</p>	

## **Martinez, Lori@DCA**

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**From:** Evans, Clara - SAC <Clara.Evans@dignityhealth.org>  
**Sent:** Monday, November 30, 2015 4:57 PM  
**To:** Martinez, Lori@DCA  
**Cc:** Fong, Candace - SAC  
**Subject:** Controlled Substances I Inventory Reconciliation  
**Attachments:** DignityHealth\_Controlled Substance Inventory Reconciliation.pdf

Dear Ms. Martinez-

On behalf of Dignity Health, I respectfully submit the attached comment.

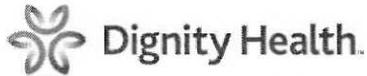
My best,  
Clara

**Clara Evans**  
Director, Public Policy & Fiscal Advocacy

**Dignity Health**  
3400 Data Drive  
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916.851.2007 (O)  
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November 30, 2015

Ms. Lori Martinez  
California State Board of Pharmacy  
1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834  
*Delivered via email: [Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov)*

***RE: Reconciliation and Inventory Report of Controlled Substances, Notice of Proposed Regulations to Adopt Section 1715.65 of Article 2 of Division 17 of Title 16, California Code of Regulations***

Dear Ms. Martinez:

On behalf of Dignity Health and our 30 hospital-based and thirteen infusion center-based pharmacies, we appreciate the opportunity to comment on the proposed regulations and adoption of Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR). The Board of Pharmacy (Board) has added specific requirements for reconciliation and inventory reporting of controlled substances as part of an effort to combat drug loss and diversion from within pharmacies and prescription drug abuse within California. Dignity Health collaborates with the California Hospital Association (CHA) and pharmacy leaders to develop a thoughtful response to the proposed regulations.

Dignity Health is the fifth largest healthcare system in America, with a 21-state network of nearly 9,000 physicians, 55,000 employees, and more than 380 care centers, including hospitals, urgent and occupational care centers, imaging centers, home health and primary care clinics. Dignity Health is dedicated to providing compassionate, high-quality and affordable patient-centered care with special attention to the poor and underserved. Central to our healing mission, Dignity Health is committed to patient and employee safety and is dedicated to continuous improvement to the quality of care, including pharmaceutical care.

**RECONCILIATION AND INVENTORY**

The Board proposes to add specific requirements for periodic reconciliation and inventory at least every three months of all Schedule II controlled substances and at least one additional controlled substance as identified by the Board based on drug loss reports. According to the Board, by conducting a physical count

inventory, pharmacists, pharmacies, and clinics will have more accountability and monitoring of controlled substances. The Board cites the availability of opioids is partly the cause of epidemic misuse of prescription medication. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. The Board believes this will reduce the supply of controlled substances available for misuse and abuse without denying pain relief to those who need it.

Dignity Health agrees comprehensive safeguards and highly reliable systems need to be in place to prevent controlled substance misuse, particularly with the high rate of opioid deaths across the nation and within the state. There already exist stringent hospital regulations and standards of practice, of which Dignity Health has adopted and implemented, along with rigorous practices used by hospital pharmacists to secure all medications specifically to prevent misuse and enhance appropriate use with patients. For example, all hospital pharmacies undergo the “biennial inventory” of controlled substances, as required by federal law. Each hospital, health system and clinic also is required to have specific processes in place for storage and security of controlled substances. In fact, the CHA Medication Safety Committee has developed the “Reducing Controlled Substances Diversion in Hospitals” tool to provide recommendations to hospitals on actions they could take to assess their resources and technology to develop an individualized diversion and prevention plan that protects organizations from substance diversion. The tool outlines recommendations utilizing present state and federal laws and regulations, as well as sharing best practice recommendations for ongoing process improvement and high reliability performance. The tool also contains a section on storage and security of controlled substances, which identifies ways controlled substances are securely stored within institutions, and how individualized plans for inventory and reconciliation must be utilized, especially for narcotic storage outside of the main pharmacy, particularly in automated dispensing cabinets (ADCs).

**While Dignity Health agrees physical inventory of the pharmacy vault every three months is reasonable, we have significant concerns about the proposal to require a hospital’s inventory of ADCs.** Dignity Health already performs a monthly physical inventory of hospital pharmacy vaults, as well as full retail pharmacy inventories. In 2013, Dignity Health implemented strict standardized policies and practices within the hospital and retail settings, which include record keeping accountability, monthly self-audits, standard filing systems, as well as random corporate audits. The standardized policies are also applied to Dignity Health’s more than 800 ADCs with respect to accessing, inventorying and monitoring. All equipment has automated inventory tracking software associated with each cabinet that maintains a perpetual inventory. The majority of the cabinets also utilize biometric identification access, while the remaining few cabinets employ routine individual password access to track each user. User

dispensing practices (anomalous usage) is monitored on a monthly basis. Those exceeding established criteria are further investigated for dispensing practices. The proposed additional quarterly physical inventory of dispensing cabinets, in addition to the practices outlined above, is unnecessary and will not add value given the resource requirements to comply, particularly considering the large volume of machines and manpower required. Dignity Health estimates compliance with this requirement will amount to at least 3,000 additional hours each quarter and a minimum of \$300,000.

**To minimize the impact of this proposal, Dignity Health urges the Board to review provider policies and offer waivers to providers that have existing mitigating policies in place.**

#### **SECTION-BY-SECTION REVIEW**

Dignity Health's specific comments are outlined in the attached grid and are detailed below:

***Section 1715.65 (a):*** Dignity Health agrees that periodic reconciliation and inventory functions defined by hospital policy should prevail and agree that periodic physical inventory of the pharmacy vault is appropriate. Physical inventory of ADCs, however, should not be mandated due to the fiscal impact and availability of more effective control methods, including biometric identification, blind counts, and other controlled substance software.

***Section 1715.65(b):*** Dignity Health urges the Board to add designee status as all hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy.

***Section 1715.65 (c):*** Dignity Health agrees periodic inspection of controlled substances in the inpatient pharmacy vault is necessary and has in place strict standardized policies and practices as described above. The Board should waive the physical inventory of ADCs if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion.

***Section 1715.65(e):*** Dignity Health urges the Board to apply this requirement only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADCs or other mechanisms for narcotic administrative practice.

***Section 1715.65(e)(3):*** Please see clarification language in the attached grid.

***Section 1715.65(g):*** California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are

required to be reported to the Board within 30 days. In addition, ADCs located in hospital or nursing home are generally more susceptible to losses associated with nursing or medical personnel more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists, who routinely restock or replenish the supply. In addition, the actions of non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. Thus, it may take longer than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. In some cases, it may be discovered that the access or removal was not actually "inappropriate" and a provider over reported in an effort to meet the 14 day time period. **Dignity Health urges the Board to change the time frame to 30 days presently allowed for an actual irreconcilable loss of controlled substances.**

**Section 1715.65(h):** Dignity Health agrees additional measures should be implemented in response to unidentified controlled substance drug loss. However, we disagree that those measures should be specifically determined as presently proposed. For example, Dignity Health believes installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are costly and unnecessary. **Thus, Dignity Health urges the Board to replace the proposed language with: "take additional steps to improve the security of the controlled substances to prevent losses."** Hospitals need to have flexibility in what resources are used to address narcotic loss.

#### CONCLUSION

Dignity Health is fully committed to combating drug loss and diversion and has strict standardized policies and practices in place to mitigate diversion. While we agree robust systems need to be in place, existing systems and practices must be leveraged particularly with respect to ADCs. Dignity Health appreciates the opportunity to participate in this regulatory process and hopes our comments are helpful. We look forward to working with the Board to establish a flexible and accommodating approach to developing standards to ensure consistent reconciliation and inventory of controlled substances in California.

Sincerely,



Candace Fong, PharmD  
System Director  
Pharmacy & Medication Safety



Clara Evans  
Director  
Public Policy & Fiscal Advocacy

**APPENDIX A  
Dignity Health Comment Matrix**

Section	Proposed Language	Dignity Health Change	Comment
1715.65(a)	Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.	Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions, defined by policy, to prevent the loss of controlled substances.	<p>Hospitals and health system pharmacies have in place strict individualized standardized practices to prevent, detect, and mitigate controlled substance diversion. Broad variability in types of facilities and medication administration resources means hospitals leverage existing resources to define specific policies and perform periodic controlled substance inventory.</p> <p>All hospitals perform the required CMS biennial inventory of controlled substances and monthly physical inventory of the respective pharmacy vault.</p> <p>While most hospitals have automated dispensing cabinets (ADCs), the types and utilization is variable, depending on available resources. Thus, the most important aspect of this regulation should be the requirement for periodic reconciliation based on individualized hospital policy that defines the specific controlled substance procurement and administration process inventory and reconciliation process.</p>

<b>Section</b>	<b>Proposed Language</b>	<b>Dignity Health Change</b>	<b>Comment</b>
1715.65(b)	"The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section."	"The pharmacist-in-charge or designee, or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled substances. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section."	All hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy.

Section	Proposed Language	Dignity Health Change	Comment
1715.65(c)	<p>Perform a Periodic Inventory:  A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of <u>all quantities of federal Schedule II</u> controlled substances and at least <u>one additional controlled substance</u> which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be <b><u>dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.</u></b></p>	<p>Perform a Periodic Inventory:  An Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of <u>all quantities of federal Schedule II</u> controlled substances *(within the inpatient pharmacy only if a licensed hospital) and at least <u>one additional controlled substance</u> which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be <b><u>dated and signed (electronic signature acceptable) by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.</u></b></p>	<p>Dignity Health agrees periodic inspection of controlled substances in the inpatient pharmacy is necessary and already performs a monthly physical inventory of hospital pharmacy vaults as well as full retail pharmacy inventories. Dignity Health has strict standardized policies and practices within the hospital and retail settings, which include record keeping accountability, monthly self-audits, standard filing systems, as well as random corporate audits. The standardized policies are also applied to Dignity Health's 750 ADCs with respect to access, inventory and monitoring. All equipment has automated inventory tracking software associated with each cabinet that maintains a perpetual inventory. The majority of the cabinets also utilize biometric identification access, while the remaining few cabinets employ routine individual password access to track each user. Dignity Health estimates compliance with this requirement on all 750 ADCs will amount to at least 3,000 additional hours each quarter and a minimum of \$300,000.</p>
1715.65(c)(1)	<p>The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be <b><u>readily retrievable for three years.</u></b></p>	No change	No comment

Section	Proposed Language	Dignity Health Change	Comment
1715.65(c)(2)	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	No change	No comment
1715.65(c)(2)(A)	A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.	No change	No comment
1715.65(c)(2)(B)	The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.	No change	No comment
1715.65(d)	A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).	No change	No comment
1715.65(e)	Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.	"Reconciliation with Inventory Report: The pharmacy or clinic shall review, based on policy, all acquisitions and dispositions of controlled substances as part of the inventory process (within the inpatient pharmacy only if a licensed hospital or clinic) as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form."	As per section 1715.65(c), Dignity Health proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADCs or other mechanisms for narcotic administrative practice.

Section	Proposed Language	Dignity Health Change	Comment
1715.65(e)(1)	Losses shall be identified in writing and reported to the Board and, when appropriate, to the Drug Enforcement Administration.	No change	No comment
1715.65(e)(2)	Likely causes of overages shall be identified in writing and retained.	No change	No comment
1715.65(e)(3)	Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.	Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and, if the pharmacist-in-charge or consultant pharmacist determines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1	Suggestions for language clarification.
1715.65(f)	Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.	No change	No comment
1715.65(f)(1)	Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.	No change	No comment
1715.65(f)(2)	The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.	No change	No comment

Section	Proposed Language	Dignity Health Change	Comment
1715.65(f)(3)	The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.	No change	No comment
1715.65(g)	The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the Board within 14 days.	The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month the trends of controlled substances removed from or added into each controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy to detect unusual or suspicious activity. Any discrepancy or unusual/suspicious activity shall be investigated. Any losses of controlled drugs shall be reported to the Board within 30 days.	Language clarification and change of 14 to 30 days per title 16, Division 17 section 1715.6, Reporting Drug Loss.  California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days. ADCs located in hospital or nursing home would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. Dignity Health urges the time frame to reflect existing regulation of 30 days.
1715.65(h)	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, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.	Strike: "...including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing." and replace with: "...take additional steps to improve the security of the controlled substances to prevent losses."	Hospitals need to have flexibility in what resources are used to address narcotic loss.

**Martinez, Lori@DCA**

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**From:** Olson, Katie <KOlson@kdhcd.org>  
**Sent:** Monday, November 30, 2015 5:01 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Comments on Proposed Regulation pertaining to Controlled Substances Inventory and Reconciliation Report  
**Attachments:** CCR 1715 65 Reconciliation and Inventory of CS Public Comment Revised .docx  
**Importance:** High

Dear Ms. Martinez,

Thank you for the opportunity to provide comments and recommendations on the proposed regulations on Reconciliation and Inventory Report of Controlled Substances: adopt Section 1715.65 of Article 2 of Division 17 of Title 16, California Code of Regulations, which are included in the attached document.

If it is not too much trouble, would you mind sending me a quick email in return confirming you successfully received the information I have sent.

Thank you for your time and have a wonderful evening!

Sincerely,

Katie Olson, Pharm.D.  
Lead Pharmacist, Kaweah Delta Medical Center  
Kaweah Delta Health Care District  
400 W. Mineral King Ave.  
Visalia, CA 93291-6263  
Phone: 559.624.5012  
eFax: 559.625.7526  
eMail: [kolson@kdhcd.org](mailto:kolson@kdhcd.org)

Public Comment to Proposed text in Title 16, California Code of Regulations 1715.65 Reconciliation and Inventory Report of Controlled Substances.

<p>Institution: Contact: Section: 1715.65(c)</p>	<p>Kaweah Delta Medical Center  Proposed Language Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be <b><u>dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant</u></b></p>	<p>Recommendations/Comments Please consider the following revisions: Remove requirement that Inventory Reports be signed and dated by the individual performing the inventory and the PIC or consultant pharmacist. Instead allow for a report showing electronic access and remove requirement for countersignature of PIC or consultant pharmacist. At Kaweah Delta Health Care District, an inventory of all controlled substances is performed at each automated drug delivery machine weekly by two registered nurses using an inventory function. Each RN accesses the ADM using their sign on and password. The ADM records the access and this acts as an electronic signature.  Change time frame requirement from every 3 months to quarterly.</p>
<p>1715.65(e)(3)</p>	<p>Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.”</p>	<p>Please consider the following revision: Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, <u>and there is no matching disposition</u>, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances.</p>
<p>1715.65(g)</p>	<p>The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the Board within 14 days.</p>	<p>The text as proposed seems to imply that the pharmacist-in-charge would be required to review all transactions, including removal for a specific patient need, from every automated drug delivery machine. A more effective method to identify diversion would be the use of software to identify anomalous activity. Please consider softening the language to allow for the use of software to identify anomalous activity and change the requirement to state that the pharmacist-in-charge shall review any activity determined to be anomalous. Please consider clarifying if there is required documentation for the review that was performed.</p>

Public Comment to Proposed text in Title 16, California Code of Regulations 1715.65 Reconciliation and Inventory Report of Controlled Substances.

		<p>Additionally, please consider the following revision: Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the Board within 14 days of <u>discovery</u>. If the pharmacist-in charge is reviewing controlled substances removed from or added to each automated drug delivery machine monthly, it is possible that inappropriately accessed or removed medication would not be discovered within 14 days of access or removal. This would place the pharmacy immediately out of compliance.</p>
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## Martinez, Lori@DCA

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**From:** Laurie Manners <Laurie.Manners@jha.org>  
**Sent:** Thursday, December 10, 2015 1:43 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Comment on proposed hospital pharmacy regulations  
**Attachments:** Pharmacy comments on propped regs 12-2015.pdf

Thank you.

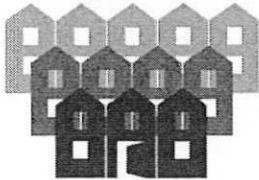
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December 10, 2015

Ms. Lori Martinez  
California State Board of Pharmacy  
1625 N. Market Blvd. Ste N219  
Sacramento, CA 95834  
Sent by email: [Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov)

**RE: Reconciliation and Inventory Report of Controlled Substances, Notice of Proposed Regulations to Adopt Section 1715.65 of Article 2 of Division 17 of Title 16, California Code of Regulations**

Dear Ms. Martinez:

I am the Director of Pharmacy Services of a hospital pharmacy providing services to 239 skilled nursing beds and 10 gero-psychiatric beds. The pharmacy employs two pharmacists, two technicians and a biller.

During my tenure of over eight years we have not had a loss of any controlled substance. It is my belief that hospital pharmacies do not contribute significantly to the diversion problem. Mandating four controlled inventories annually would be over kill. The inventory process here is time consuming and would result in a waste of resources.

It is my considered opinion that four controlled substance inventories per year is not necessary. Thank you for your consideration.

Sincerely,

Robert Shmaeff  
Director of Pharmacy Services  
The Joyce Eisenberg Keefer Medical Center

**Reconciliation and  
Inventory of Controlled  
Substances  
Initial Proposed  
Text**

**Title 16. Board of Pharmacy  
Proposed Text**

**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. Reconciliation and Inventory Report of Controlled Substances**

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
- (b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
- (c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
  - (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
  - (2) 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:
    - (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
    - (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
- (d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
- (e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
  - (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
  - (2) Likely causes of overages shall be identified in writing and retained.

- (3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.
- (f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
- (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.
- (2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.
- (3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.
- (g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.
- (h) 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, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.