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XXI. 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 Report 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 immediately following this memo contains the proposed regulation text as noticed on October 16, 2015 and a compilation document of the comments 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/Hearing Comments

Comment Period Closed November 30, 2015

Code Section	Commenter	Comment
1715.65(a)	**BJ Bartleson** **CHA** **and** **Dignity Health**	"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." 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. All hospitals perform the required CMS biennial inventory of controlled substances and a monthly physical inventory of the respective pharmacy vault. 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.
1715.65(a)	**Kaiser**	Section 1715.65 (a} says "Every pharmacy...". This terminology is unclear as it does not differentiate between Community/Retail, Central Fill, Mail Order and other pharmacies licensed as "PHY" pharmacies and Hospital pharmacies that are licensed as "HSP" pharmacies. It does not reflect the discussion at the Board of Pharmacy meetings that the risk and history of diversion of large of amounts of controlled substances was substantially greater by many fold from Community ("PHY") pharmacies than it has been or is likely to be from Hospital ("HSP") licensed pharmacies. This section should be modified to indicate that the regulation only applies to "PHY" licensed pharmacies or to "PHY" pharmacies and controlled substances stored centrally in "HSP" pharmacies. In hospitals only small amounts of controlled substances are stored in each patient care areas away from the pharmacy, e.g. in nursing station,surgery related suites, "crash carts", etc. Storage in patient care areas are inside very secure equipment with sophisticated access and record keeping controls,e.g. "Pyxis" and similar dispensing equipment. Cost Impact: Without a regulatory language change reflecting the differentiation specified above regarding periodic physical inventory requirements in patient care areas vs. within the hospital's pharmacy the Board's predicted cost impact of the regulation on hospitals, including State,County and municipal hospitals,substantially under stated.
1715.65(a)	**Michael Tou** **Providence Health**	"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."

Code Section	Commenter	Comment
1715.65(b)	**BJ Bartleson CHA** **and** **Dignity Health**	"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.
1715.65(b)	**Michael Tou Providence Health**	"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 developed for performing the reconciliation and inventory reports required by this section." 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.
1715.65(b), (c), (e)	**Lauren Berton CVS** **Also provided at Hearing**	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.

Code Section	Commenter	Comment
1715.65(c)	**BJ Bartleson CHA** **and** **Dignity Health**	"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 all quantities of federal Schedule II controlled substances *(within the inpatient pharmacy only if a licensed hospital) 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 (electronic signature acceptable) by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist." 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. 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. 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 technology.

Code Section	Commenter	Comment
1715.65(c)	**BJ Bartleson CHA** **and** **Dignity Health** **(Also provided at Hearing)**	Examples of automated dispensing cabinets (ADCs) inventory practices utilized in various facilities: • Use of biometric identification to access ADCs • Use of "blind counts" when removing controlled substances which eliminates the possibility of confirmation bias in the counting process and automatically records any discrepancies • Use of "blind counts" when restocking the ADCs • Required resolution of any controlled substance discrepancies on a daily basis by the nurses, and verification (oversight) by pharmacy that the process has been completed (including reviewing the rationale documented during the resolution process) • Physical inventory of controlled substances in the ADCs on a regular basis by the nurses utilizing "blind counts." • Daily monitoring ADC overrides to ensure there is a valid prescriber order for the medication that was removed • Regular review of oversight reports, e.g. ADC Users created; Cancelled transactions, to detect suspicious activity and prevent diversion • 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 • Perpetual inventory of all controlled substances in the pharmacy utilizing specialized computer software (C-II Safe). This software also tracks all controlled 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. • Review and approval of all Pharmacy orders for controlled substances from wholesalers/suppliers by a Pharmacy Manager • 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 • Use of "blind counts" when adding and/or dispensing controlled substance from the Pharmacy inventory specialized computer tracking software 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.
1715.65(c)	**Grace Magedman**	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.

Code Section	Commenter	Comment
1715.65(c)	**John Gallegos**	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
1715.65(c)	**John Grubbs** **UC Davis**	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 11 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 1 33 hours to complete.
1715.65(c)	**Kaiser**	Section 1715.65 (c) again does not differentiate between hospital pharmacies,which have much stronger controlled substance inventory control procedures than other categories of pharmacies. Thus,this section's proposed requirement for physical inventories of Schedule II and other controlled substances specified by the Board, is unclear as it does not differentiate between controlled substances maintained in the pharmacy vs.controlled substances distributed throughout the patient care areas of a hospital,as specified above. The proposed regulation would place a disproportionate burden on hospitals in relation to the history and future risk of major controlled substance diversion from hospitals vs non-hospital licensed facilities. Hospital pharmacies are also governed by the California Department of Public Health {CDPH} and inspected by CDPH for compliance with CDPH regulations and all other California and federal law, including proper accounting for and security of,controlled substances. CDPH also inspects hospitals for compliance with federal CMS Conditions of Participation. Hospitals are also accredited by several deemed status organizations, such as The Joint Commission, on behalf of government and other payers for compliance,quality and safety. Because of these standards and the standards of practice for hospitals, much more strict procedures are employed by hospitals to secure controlled substances and usually include not only daily perpetual physical inventory counts of controlled substances in patient care areas, but the majority hospitals perform such counts several times per day upon nursing shift changes.

Code Section	Commenter	Comment
1715.65(c)	**Kaiser**	Section 1715.65(c) also does not reflect the difference in preponderance of use of different non- Schedule II controlled substances between Hospital (HSP) and Community (PHY) licensed pharmacies. Hospitals administer very few controlled substances intended for symptomatic relief, such as benzodiazepines and codeine containing cough preparations than do Community pharmacies. Therefore,the substantially diminished diversion risk for such "outpatient" controlled substances should be recognized in the regulation by language that indicates that the additional non-Schedule II inventory control requirements may not apply to Hospitals, as determined by the Board.
1715.65(c)	**Kaweah Delta**	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.
1715.65(c)	**Lauren Berton CVS** **Also provided at Hearing**	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.

Code Section	Commenter	Comment
1715.65(c)	**Mary Staples** **NACDS**	In Section 1715.65, the Board seeks to require pharmacies to provide quarterly inventories of Schedule II drugs and "at least one additional controlled substance which may be specified by the board every year based upon loss reports." While we have no objection to the Schedule II drug inventories, we have concerns regarding the scope of the latter provision. More specifically, our members will have difficulty meeting the inventory requirements for non-Schedule II drugs if the state does not provide enough notice of the specific "additional controlled substances" to be inventoried or does not effectively communicate which non-Schedule II drug or drugs will require quarterly inventories. In addition to this lack of specificity in the Proposed Rule, we are concerned that this provision could be used to overburden pharmacies and their inventory capabilities. While we understand the need to curb diversion and abuse of controlled substances, we believe that overly burdensome and time consuming quarterly inventories of non-Scheduled II controlled substances hinders the ability for pharmacists to focus on other needed patient care activities. We believe and have full confidence in other mechanisms that are currently in place to monitor and inventory these substances, which ultimately allows pharmacists to devote adequate time to patient care activities such as counseling patients, performing medication therapy management, providing disease management programs, engaging in other important pharmaceutical patient care services and conferring with other health care professionals, thus permitting a higher level of service to patients that ultimately improve patient outcomes. In light of the lack of specificity discussed above and the potential for a wide scope of non-Schedule II drugs subject to inventory, we ask the Board to adopt one of the following proposals. First, and our strongest preference, is for the Board to remove the provision for "at least one additional [non-Schedule II] controlled substance" to be inventoried. Second, as an alternative, in order to prevent undue inventory burdens on pharmacies, we ask the Board to limit how many non-Schedule II controlled substances can be identified each year. As a third alternative approach, we request that, with regard to non-Schedule II drugs, only pharmacies that have reported a theft or loss of the Board identified drug be required to do the quarterly audit and to do so for only one year following the reported loss. In conclusion, at a minimum, we are asking for more parameters regarding inventories of non-Schedule II drugs and we would prefer that such drugs not be subject to quarterly inventories.
1715.65(c)	**Rita Shane** **Cedars-Sinai**	Recommendation: 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. Alternatively, a pharmacy or clinic may utilize automated drug delivery systems in lieu of performing a periodic inventory." 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.

Code Section	Commenter	Comment
1715.65(c)(1)	**Grace Magedman**	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.
1715.65(c)(1)	**Kaiser**	Section 1715.65 (c) (1) regarding record retention for "three years" "in the...pharmacy" without mention of the current ability for pharmacies to store records outside the pharmacy on the premises, and, with the Board's permission, offsite for the balance ofthe three years is vague and confusing. Historical storage of such records as allowed outside a hospital or community pharmacy space has not been discussed by the Board as being a significant problem or risk that would justify the additional space allocation and expense for storage inside the pharmacy.
1715.65(c)(1)	**Michael Tou Providence Health**	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.
1715.65(c)(2)(A)	**Lauren Berton CVS** **Also provided at Hearing**	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.
1715.65(d)	**Kaiser**	Section 1715.65 (d) is vague as it does not reflect whether the requirement for a "new pharmacist-in-charge" to complete and inventory applies to an "interim pharmacist-in-charge", as specified in B&P Code section 4113(e). Further, for hospitals, is the required physical count limited to only what is stored inside the hospital pharmacy. Again, if the physical inventory is required for every patient care area storage unit,the burden is understated.

Code Section	Commenter	Comment
1715.65(e)	**BJ Bartleson CHA** **and** **Dignity Health**	"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 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." 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. 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).
1715.65(e)	**John Grubbs UC Davis**	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.
1715.65(e)	**Kaiser**	Section 1715.65 (e) is vague or incomplete because it does not reflect the discussion by staff and Board members of the problem found that reconciliation processes were not well understood by pharmacists. Further it does not reflect the Board's discussion that reconciliation should and be performed against Accounts Payable records rather than just relying on packing lists or invoices to determine what the actual total amounts of a controlled substances acquired by the pharmacy during the starting and ending physical count period. The Board's discussion indicated the entity (pharmacy or hospital) would be held responsible for what was "paid for" (or otherwise acquired) not just what was listed on packing lists or invoices that reached the pharmacist-in-charge.
1715.65(e)	**Michael Tou Providence Health**	Providence requests clarification from the Board on the following issues: Does this requirement take into account stock fluctuations based on demand, as well as facilities that ramp up purchases due to anticipated shortages? Does the language need to specify that this inventory report is meant to determine expected stock on hand? If the stock on hand has doubled for a legitimate reason, does it conflict with the proposed requirement?

Code Section	Commenter	Comment
1715.65(e)	**Rita Shane** **Cedars-Sinai**	Recommendation 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. Comments: 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.
1715.65(e)(2)	**Michael Tou** **Providence Health**	Providence requests clarification from the Board on the following issues: Should overages be documented in the inventory report? Does this require dual- signature by the pharmacist- in-charge and another licensed pharmacist/technician?
1715.65(e)(3)	**BJ Bartleson** **CHA** **and** **Dignity Health**	"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(e)(3)	**Kaweah Delta**	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, and there is no matching disposition, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances.
1715.65(e)(3)	**Michael Tou** **Providence Health**	"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."

Code Section	Commenter	Comment
1715.65(g)	**BJ Bartleson CHA** **and** **Dignity Health**	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. 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.
1715.65(g)	**Candace Fong (Hearing)**	Allow the pharmacist-in-charge to delegate the reconciliation and inventory.
1715.65(g)	**Dale Costantino**	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.

Code Section	Commenter	Comment
1715.65(g)	**John Grubbs UC Davis**	Subd ivision (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 remova l is appropriate. All inappropriate accesses or removals identified by these processes would be reported to the Board. Additionally, some hospitals have formed multi-disciplinary commi ttees 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 requ irements. 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)
1715.65(g)	**Kaiser**	Section 1715.65 (g) is vague as it applies to hospital pharmacies in that it uses a term "review" for the duties of the pharmacist-in-charge regarding records of controlled substances "removed from or added into each automated drug delivery machine". It is unclear:1)because it is not clear whether this monthly task could serve as substitute for the tri-monthly physical inventory and reconciliation of such controlled substance in such secure storage devices as is implied by Sections 1715.65 (a)&(c) above,2) because it is not clear whether the reporting of "inappropriately accessed or removed" means would only be required if the removal resulted in a "loss" or diversion from the hospital,and 3) how this reporting responsibility corresponds to reporting a loss within 30 days in Regulation 1715.6. Allow the pharmacist to delegate to another staff person the inventory requirement.

Code Section	Commenter	Comment
1715.65(g)	**Kaweah Delta**	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. 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 discovery. 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.
1715.65(g)	**Lauren Berton CVS (Hearing)**	Allow some delegation of the inventory review and investigation of automated delivery systems. Is quarterly review mandatory of the machines.
1715.65(g)	**Michael Tou Providence Health**	"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." 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. 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. 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 may be discovered that the access or removal was not actually "inappropriate" after all.

Code Section	Commenter	Comment
1715.65(g)	**Michael Tou** **Providence Health**	The timeframe required by the Board should allow sufficient time for investigation first, and then, unresolved inappropriate access or removals should be reported. 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. 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). 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. 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. 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?
1715.65(g)	**Rita Shane** **Cedars-Sinai**	Recommendations: Revise proposed regulations as follows: "The pharmacist-incharge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where automated drug delivery systems (ADDs) are used shall ensure that: a) All controlled substances added to an automated drug delivery system are accounted for; b) Access to automated drug delivery systems is limited to authorized facility personnel; c) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and d) Confirmed losses of controlled substances are reported to the board." Comments: 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. 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 offalse positive reports submitted to the board and provide a more accurate estimate of the number of controlled substances lost due to employee pilferage.

Code Section	Commenter	Comment
1715.65(g)	**William Mcguire**	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.
1715.65(h)	**BJ Bartleson CHA** **and** **Dignity Health**	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.
1715.65(h)	**Kaiser**	Section is vague as it does not indicate which action or actions have priority. The installation of cameras is mentioned first and seems to indicate that should be tried first before the "relocation of the controlled substance to a more secure location" or the implementation of "daily inventory counts". It is likely that the delay for the camera installation and the capture of good identification may result in further significant or substantial losses/diversions. Conversely, the implementation of a storage change or additional physical counts may alert the individual or individuals to the hospital's or pharmacy's awareness of the losses and thus prevent the identification of the individuals responsible for,or the methods employed, that resulted in the loss. The Board should provide guidance as to which is more important - apprehending the responsible individual{s) or protecting the public and patients immediately from further diversion. The Board's guidance has not been consistent on this point historically. Perhaps the Board's guidance on this point could be related to the US Drug Enforcement Administration's (DEA) multi-faceted guidance on when a loss is considered "significant" for reporting.
1715.65(h)	**Michael Tou Providence Health**	"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, until the cause is identified and resolved."

Code Section	Commenter	Comment
1715.65(h)	**Rita Shane Cedars-Sinai**	Recommendation: 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. Comments: The pharmacist- in- charge should evaluate and determine which strategy will prevent further loss of controlled medications .
Overall	**Chad Signorelli**	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.
Overall	**Hilary Ward**	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.

Code Section	Commenter	Comment
Overall	**Jeremish Joson**	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.

Code Section	Commenter	Comment
Overall	**Jeremish Joson**	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

Code Section	Commenter	Comment
Overall	**K. Scott Guess**	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 loose 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.
Overall	**K. Scott Guess**	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). o If the difference is greater than 1 package size, documenting the on-hand inventory should balance the equation. o 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.

Code Section	Commenter	Comment
Overall	**Kaiser Doug O'Brien (Hearing)**	Large losses unusual in California because of oversight by the Board and CDPH. Lots of controls in Hospitals with automated dispensing machines. Realtime discrepancy detection, blind counts, biometric ID access, and tracers. Hospitals have the tightest controls in California. Hospitals experience little loss of controlled substances. Target outpatient / community pharmacies as that is where most of the drug loss occurs. This regulation will not improve oversight in Hospitals. Do a Risk Based Approach.
Overall	**Robert Shmaeff Joyce E. Keefer Med Center**	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
Overall	**Terry Cater**	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.

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.