FAQs: Inventory Reconciliation Regulation

On April 1, 2018, a new board regulation took effect – California Code of Regulations, title 16, section 1715.65, "Inventory Reconciliation Report of Controlled Substances."

The board believes this regulation will aid pharmacies and clinics in preventing and identifying losses of controlled drugs earlier than without such measures.

The following information is intended to respond to questions asked of the board regarding this new regulation. As with any regulation, the board seeks compliance at the earliest possible time. For the first few months, the board will focus on education to promote understanding about the regulation. During the transition, any inspection will focus on the pharmacy or clinic's good faith efforts to comply with the regulation.

The regulation text can be found at http://www.pharmacy.ca.gov/laws_regs/1715_65_ooa.pdf.

Here is a summary of CCR section 1715.65 by subsection:

(a) – Requires all pharmacies, and all clinics licensed under Business and Professions Code section 4180 or 4190 ("clinics"), to perform periodic inventory and reconciliation functions for all controlled drugs. (Note: No frequency of these duties is specified in the regulation except for Schedule II drugs.)

(b) – Requires the pharmacist-in-charge (PIC) or the clinic's consultant pharmacist to:
(1) establish and maintain secure methods to prevent losses of controlled drugs;
(2) establish written policies and procedures for performing reconciliation reports; and
(3) review all inventory and reconciliation reports.

(c) – Requires each pharmacy or clinic to prepare a **quarterly** inventory reconciliation report of all federal Schedule II medications, which is based on:
(1) A physical count of all federal Schedule II medications at the time of each inventory;
(2) A review of all acquisition and disposition records since the last inventory;
(3) A comparison of 1 and 2 to identify any differences (losses or overages).
(4) Collection and retention of records to compile each inventory report
(5) Written identification of sources of losses or overages in the report. The report must identify the possible causes of losses or overages.

(d) – Requires a pharmacy or clinic to file a report of losses to the board within 30 days of discovery or within 14 days if theft, self-use or diversion by a board licensee is the cause. If the cause is unknown, requires the pharmacy or clinic to further investigate to identify the causes and to take corrective action to prevent additional losses.

(e) – Requires the inventory reconciliation report to be signed and dated by the individuals performing the inventory, and countersigned by the PIC or professional director (for a clinic).

(f) – Requires a new PIC to complete an inventory reconciliation report within 30 days of becoming PIC. Encourages the outgoing PIC to do an inventory reconciliation report before leaving.

(g) – For INPATIENT HOSPITAL PHARMACIES: Requires a separate quarterly inventory reconciliation report for federal Schedule II drugs stored within the pharmacy and for each of the pharmacy's satellite locations.

(h) – For any pharmacy servicing an AUOMATED DRUG DELIVERY SYSTEM (regardless of location), requires the PIC to:

(1) Ensure that all controlled substances added to any automated drug delivery system are accounted for;

(2) Ensure that access to any automated drug delivery system is limited to authorized facility personnel only;

(3) Ensure that any discrepancy or unusual access to the controlled substances in the automated drug delivery system is evaluated; and

(4) Ensure that confirmed losses are reported to the board timely.

1. **The regulation took effect April 1, 2018. Must I conduct my initial inventory beginning on April 1, 2018?**

   No, the board expects pharmacies and clinics to transition to satisfy the inventory reconciliation requirements over a short period of time, but not necessarily by April 1.

2. **Are there any drugs in addition to federal Schedule II controlled substances affected by the requirement to do a physical count and reconciliation each quarter?**

   No, the regulation requires a quarterly count and reconciliation of only federal Schedule II drugs. California and the federal government have separate controlled substances schedules, although there is much similarity between the two. Nevertheless, the board determined that the federal Schedule II drug list is a more current and complete schedule, as well as the federal list is the reference for reporting dispensing into the Controlled Substances Utilization Review and Evaluation System (CURES) in California.

3. **Can a pharmacy or clinic estimate (instead of physically counting) federal Schedule II medications for the quarterly inventory?**

   No, a physical count of every Schedule II medication is required for the quarterly inventory reconciliation report.

4. **Subsection (a) of the regulation requires a pharmacy or clinic to "periodically" perform inventory and reconciliation functions for controlled substances. Does this mean every quarter I must count and reconcile all controlled substances?**

   No. However, periodically (and under federal law at least every two years) all controlled substances must be inventoried. The board encourages more frequent counting of

controlled medications to prevent losses of Schedule III, IV and V drugs. The regulation only specifies the frequency of reconciliation duties for federal Schedule II drugs; the appropriate frequency for all other controlled drugs should be determined by the standard of practice in the community under the circumstances of the pharmacy.

5. **Does a perpetual inventory system satisfy the requirements of this regulation?**

   No, the use of a perpetual inventory system does not satisfy the regulation. The regulation requires both a physical count and reconciliation with all acquisitions and dispositions must be performed every 90 days.

6. **If I use a perpetual inventory, can I use the physical counts made for the perpetual inventory instead of physically counting the drugs specifically for the inventory reconciliation report?**

   It depends. The regulation requires a physical count of each Schedule II medication every quarter, which is then used as part of the inventory reconciliation analysis and report. If, for example, the pharmacy or clinic physically counts the specific drug stock each time a Schedule II drug is dispensed or acquired, that count might be used to fulfill the physical count required by the inventory reconciliation regulation, but the PIC or consultant will need additional data. For any drug where there were no dispositions or acquisitions during the quarterly reconciliation period (and therefore no physical count through the perpetual inventory system), a physical count of the Schedule II drug must be made because each drug must be physically counted at least quarterly.

7. **I have a recent physical count for each Schedule II drug. What do I compare that to? What do I do with that information?**

   For each medication, the PIC or consultant would start with the physical count of the medication from the last inventory reconciliation report and:
   1. Add all acquisitions, and subtract all dispositions, that occurred during the reconciliation period (no greater than 90 days) to identify the amount of drug stock that should be on hand (expected drug stock).
   2. Compare the expected drug stock to the actual physical inventory count.
   3. If there is a difference, attempt to identify the source of overage or shortage. **NOTE:** If there is a discrepancy and the recent physical count is from a perpetual inventory system, the board urges the facility to initiate a supplementary physical count of the medication. Determine if the facility needs to take corrective action, including modify its policies and procedures, conduct an investigation, institute additional security or modify its practices.
   4. Whether or not there is a discrepancy, the results must be recorded in your inventory reconciliation report.

8. **Does an inpatient hospital pharmacy or a pharmacy servicing onsite or offsite emergency kits (e-kits) have to complete an inventory reconciliation report for the Schedule II controlled substances contained within the e-kits?**

   There is no specific reconciliation report for the kits themselves, although a pharmacy's replenishment of Schedule II drugs removed from the emergency kits would be part of a pharmacy's disposition of medication.

9. **An inventory reconciliation report of all Schedule II controlled substances shall be compiled at least every 3 months, and in order to complete such a report the inventory must be compared with a review of drugs that entered and left the pharmacy since the previous inventory reconciliation. Since no reconciliation report exists before April 1, 2018, does that mean that the first inventory reconciliation report will not be due before July 1, 2018?**

   To initiate the reconciliation process and establish a baseline for future inventory reconciliation reports, a physical count of all Schedule II medications must be undertaken. The board would generally expect a pharmacy to perform this count on or after April 1, 2018. To allow time to develop meaningful written policies and procedures for the inventory reconciliation process, the board recommends a pharmacy or clinic perform the inventory counts within the first 90 days after April 1 (i.e., August 1, 2018).

   Additionally, any new PIC on or after April 1, 2018, is required to prepare a report. Within the first three months after April 1, 2018, the board would expect the new PIC, within 30 days, to have performed an inventory count of all Schedule II medications consistent with to the requirements to prepare an inventory reconciliation report.

10. **An initial inventory does not appear to be required as part of this rule change. Since a reconciliation report cannot be compiled without an initial reference count, would it be appropriate for pharmacies or clinics to perform a physical count of all Schedule II drugs during the initial 3-month period (after April 1st), and then begin reconciliation processes after July 1st?**

    Yes. See the response above.

11. **A new PIC must complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge. If there is a PIC change on April 1st, 2018, how can the PIC create a reconciliation report, given there may not be a recent inventory or reconciliation report to refer to?**

    In this specific case, if prior data was unavailable because of the implementation date of the regulation, the board would expect the PIC to at least perform an inventory of all Schedule II medications consistent with the requirements to prepare the reconciliation report within 30 days (May 1, 2018).

12. **Should the inventory reconciliation report encompass only significant losses, as defined by the DEA, or should the report encompass any discrepancy? If the former, doesn't a pharmacy's or clinic's filing of DEA Form 106 with the DEA already provide the requested information to the Board of Pharmacy, if the Board of Pharmacy receives a copy of that report?**

    California law requires that any loss of controlled substances be reported to the board within 30 days, and reported within 14 days where drug theft, self-use or diversion have been committed by a board licensee. These are existing requirements, predating the inventory reconciliation requirements. The regulation restates the reporting of drug loss requirements for clarity. A DEA Form 106 may be used to make this report to the board.

13. **If my pharmacy or clinic is unable to identify the cause of the loss, should we wait to report the loss to the board until the cause is determined?**

    No, reporting is required for any loss of controlled substances within, at most, 30 days regardless if a cause of the loss was identified. Should a cause of the loss be identified later, an additional report can be made to the board. If the cause of the loss is theft, diversion or self-use by a board licensee, the report must be made within 14 days.

    However, the regulation also directs that "further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substance" where the source of a loss cannot be readily identified.

14. **Will the board create a new process for reporting Schedule II controlled substances drug losses? Is there a standard form or email address to submit this information?**

    The board will not create a new or additional process for reporting the loss of controlled substances. A DEA Form 106 or a written statement containing specified details of the loss is sufficient. The current processes are detailed at http://www.pharmacy.ca.gov/licensees/facility/dea106.shtml

15. **Does a pharmacy have to maintain actual paper documents of the records used to compile each inventory reconciliation report? Are electronic records acceptable?**

    All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form. Provided the records are readily retrievable, electronic records are acceptable.

16. **Can the inventory reconciliation report be completed by multiple persons?**

    Yes, all persons involved in performing the inventory must sign and date the report, which also must be countersigned by the PIC or professional director (if a clinic).