

Inventory Reconciliation Regulation – Summary and FAQs

California Code of Regulations, title 16, section 1715.65, [Inventory Reconciliation Report of Controlled Substances](#) took effect April 1, 2018.

Each subsection of CCR section 1716.65 is summarized in the table printed here. Below the table are answers to frequently asked questions (FAQs) about the regulation.

Section 1715.65. Inventory Reconciliation Report of Controlled Substances

<p><i>(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.</i></p>	<p>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 <u>all</u> controlled drugs. (Note: No frequency of these duties is specified in the regulation except for Schedule II drugs, which are discussed below.)</p>
<p><i>(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.</i></p>	<p>Subsection (b) requires the pharmacist-in-charge (PIC) or the clinic’s consultant pharmacist to:</p> <ol style="list-style-type: none"> (1) Establish and maintain secure methods to prevent losses of controlled drugs. (2) Establish written policies and procedures for performing reconciliation reports. (3) Review all inventory and reconciliation reports.
<p><i>(c) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:</i></p> <p><i>(1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year</i></p>	<p>Subsection (c) requires each pharmacy or clinic to prepare at least a quarterly inventory reconciliation report of all federal Schedule II medications, which is based on:</p> <ol style="list-style-type: none"> (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.

<p><i>where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;</i></p> <p><i>(2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report;</i></p> <p><i>(3) A comparison of (1) and (2) to determine if there are any variances;</i></p> <p><i>(4) All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and</i></p> <p><i>(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.</i></p>	<p>(3) A comparison of 1 and 2 to identify any differences (losses or overages).</p> <p>Collection and retention of records to compile each inventory report.</p> <p>The report must identify the possible causes of overages.</p>
<p><i>(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances.</i></p>	<p>Subsection (d) requires a pharmacy or clinic to file a report of losses and known causes 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, this section requires the pharmacy or clinic to further investigate to identify the causes and to take corrective action to prevent additional losses.</p>
<p><i>(e) The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.</i></p>	<p>Subsection (e) requires the inventory reconciliation report to be signed and dated by the individual(s) performing the inventory and countersigned by the PIC or professional director (for a clinic).</p>

<p><i>(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).</i></p>	<p>Subsection (f) requires a new PIC to complete an inventory reconciliation report within 30 days of becoming PIC. Encourages the outgoing PIC to do a reconciliation report before leaving.</p>
<p><i>(g) For inpatient hospital pharmacies, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.</i></p>	<p>Subsection (g) requires INPATIENT HOSPITAL PHARMACIES to complete a separate quarterly inventory reconciliation report for federal Schedule II drugs stored within the pharmacy and for each of the pharmacy's satellite locations.</p>
<p><i>(h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:</i></p> <p><i>(1) All controlled substances added to an automated drug delivery system are accounted for;</i></p> <p><i>(2) Access to automated drug delivery systems is limited to authorized facility personnel;</i></p> <p><i>(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and</i></p> <p><i>(4) Confirmed losses of controlled substances are reported to the board.</i></p>	<p>Subsection (h) requires the PIC of any pharmacy servicing an AUTOMATED DRUG DELIVERY SYSTEM (regardless of location) to:</p> <ol style="list-style-type: none"> (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. (4) Ensure that confirmed losses are reported to the board timely.

FAQs about CCR section 1716.65

1. The regulation took effect April 1, 2018. Should I have performed my initial inventory beginning 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. An initial physical count of the Schedule II medications is the first step.

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 more current and complete, and the federal list is the reference for reporting dispensing into the Controlled Substances Utilization Review and Evaluation System (CURES) in California. A pharmacy may on its own add additional drugs to its reconciliation program.

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 identify and 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 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 drugs shall be compiled at least every three months and, in order to complete the 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., July 1, 2018).

Additionally, any new PIC on or after April 1, 2018, is required to prepare a report upon assuming the PIC position. 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 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 three-month period (after April 1), and then begin reconciliation processes after July 1st?

Yes. See the response to question 9.

11. A PIC must complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge. If there is a PIC change on April 1, 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 were 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 if the board 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 reconciliation regulation restates the reporting of drug loss requirements for clarity. A DEA Form 106 may be used to make this report to the board. Also, a separate report is required to the DEA (on a Form 106) of any significant loss of a controlled substance.

13. 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. Check the board's website on [how to report a drug theft or loss](#).

14. 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 be identified later, an additional

report can be made to the board. If the cause 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.

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).

17. How do I physically count liquid Schedule II medications for the reconciliation report?

The board does not expect a count or measurement of every liquid you have as part of the quarterly reconciliation. Instead, the board recommends:

- **Where there is a unit of use container**, a pharmacist should accept the measurement printed on the container and include it in the physical count. However, if the unit of use container looks damaged or altered in some manner, treat the item as quarantined.
- **Where multidose containers are used**, a pharmacist should subtract the amount dispensed from the measurement printed on the container. Subsequently, the pharmacist should document the remaining amount on the container itself. Example: A pharmacist dispensed 240ml from a 473ml stock bottle. The pharmacist would subtract 240ml from 473ml and document the difference of 233ml on the stock bottle. The remaining amount of 233ml would be used as the physical count for the reconciliation report.

18. Can unlicensed personnel (e.g., clerks) perform the inventory necessary to complete the inventory reconciliation report?

As identified in CCR section 1793.2, the counting of pharmaceuticals is considered a “nondiscretionary task” – a duty a pharmacy technician may perform. Accordingly, unlicensed personnel cannot complete the inventory function.

19. How does a reconciliation report help detect drug diversion?

A reconciliation report aids in the identification of controlled substance inventory discrepancies. Pharmacies can respond to inventory shortages or overages by initiating a close

review, which may aid in detection of drug diversion. Recording of an inventory alone lacks review and analysis of acquisition and disposition information.

20. Wouldn't a perpetual inventory identify diversion?

A perpetual inventory is a beneficial tool and may aid in identification of drug diversion. However, a perpetual inventory with no discrepancies is not evidence of a lack of diversion. A perpetual inventory may only account for known drug acquisitions and dispositions. If acquisition invoices are destroyed or fraudulent prescriptions are processed and later deleted, a perpetual inventory may show no discrepancies. Further, all categories of drug acquisition and disposition may not be entered into a perpetual inventory.

21. The computer already counts acquisitions and dispositions of Schedule II controlled substances for the perpetual inventory. Is the count in the computer sufficient for the reconciliation report?

No. Electronic records can be used to aid in calculation of total acquisition and disposition information for the reconciliation report, but this information must be used in conjunction with an initial physical count and a final physical count to complete the requirement of CCR 1715.65. Any electronic records used should be reviewed for unauthorized manipulation and evaluated against other available records for consistency. Other records may include hard copy drug acquisition invoices, purchase orders, signatures for dangerous drug deliveries, drug acquisition summaries from wholesalers, reverse distribution documents, return to wholesaler for credit documents, drug destruction documents and/or hard copy prescription documents.

22. In an inpatient pharmacy, would "disposition" of Schedule II drugs refer to drugs that are 1) supplied into an ADDS (Pyxis, Omnicell, etc.) or as floor stock; or 2) dispensed to the patient?

In an inpatient pharmacy, disposition would refer to medications dispensed directly to the patient. Please see additional requirements for inpatient hospital pharmacies found in 1715.65(g)-(h).

23. Does the regulation require a reconciliation of all controlled substances or only Schedule II controlled substances?

As referenced in 1715.65(c), the compilation of a quarterly inventory reconciliation report is required only for all federal Schedule II controlled substances. However, as referenced in 1715.65(a), every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, still must perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. Additionally, other sections of pharmacy law (BPC 4081 and CCR 1718) require a pharmacy to have complete accountability of all dangerous drugs handled by every licensee.

24. Could you provide more guidance on periodic reconciliations of Schedule III – V drugs? For example, can Schedule III-V counts be estimates – as allowed for biennial inventories – or must they also be exact counts? Should Schedule III-V reconciliations be done more frequently?

CCR 1715.65(c)(1) requires a physical count, not an estimate of, of all quantities of federal Schedule II controlled substances. The regulation is silent regarding estimation of Schedule III – V counts; however, because BPC 4081 and CCR 1718 require licensees, including a pharmacy, to have complete accountability of all dangerous drugs, it is recommended Schedule III – V drugs be exact counts.

25. 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 identify and prevent losses of Schedule III, IV and V drugs. But the regulation only specifies the 90-day 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 and under the circumstances of the pharmacy.

26. I am the PIC of a pharmacy that is so small there are no other staff. Do I still have to complete a reconciliation report, or is the perpetual inventory sufficient?

Yes. All pharmacies, regardless of size or staff, that stock federal Schedule II controlled substances must comply with CCR 1715.65.

27. I work in a chain pharmacy, where we store the data used to perform the reconciliation at the corporate level and keep a signed face sheet in the pharmacy. Are the acquisition and disposition records used to complete the reconciliation report required to be attached to the reconciliation/signature page?

Attachment is not mentioned in the regulation, but as referenced in 1715.65(c)(4), all records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form. The board recommends all documents related to compilation of an inventory reconciliation report be stored together.