

## FAQs for the Revisions to Inventory Reconciliation

The revisions to California Code of Regulations (CCR), Title 16, section 1715.65, Inventory Reconciliation Reports of Controlled Substances took effect January 1, 2023. The regulation text is available [here](#).

Below are questions frequently asked regarding the revisions to CCR §1715.65.

### **General:**

#### **1. With CCR §1715.65 revised, what inventory activities and inventory reconciliation reports are now required for controlled substances?**

Effective January 1, 2023, every pharmacy and every clinic licensed under Business and Professions Code (BPC) §§ 4180 and 4190 must conduct inventory activities and prepare inventory reconciliation reports on the following ongoing basis:

- All federal Schedule II controlled substances, at least once every three months;
- For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months, the following controlled substances: alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls drug product;
- For any controlled substances not listed above, an inventory reconciliation report must also be prepared when a controlled substance loss is identified, no later than three months after discovery of the **reportable loss** of the controlled substance in addition to the timely report of the loss as required;
- For any controlled substance not listed above, inventory activities must be performed at least once every two years from the performance of the last inventory activities.

CCR §§1715.65(a)(1), (a)(2), (a)(3)

However, if you are an inpatient hospital pharmacy, the inventory reconciliation for all federal Schedule II controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls drug product, must be performed quarterly. CCR §1715.65(a)(1), (a)(2), (a)(3)

**2. While reviewing the pharmacy's wholesale invoices, I noticed extra bottles of diazepam 5mg were being ordered when no prescriptions for diazepam 5mg was dispensed in the past 3 months. What time period am I required to audit to determine if there was any loss of diazepam 5mg and am I required to report any losses to the board?**

Yes. When a controlled substance loss is identified, an inventory reconciliation report must be completed. The audit period must cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery. CCR §1715.65(a)(3)(A)

Losses of controlled substances must be reported no later than 30 days after the date of discovery in accordance with CCR 1715.6. If the cause of the losses is related to theft, diversion, or self-use the loss must be reported to the board within 14 days of discovery.

Controlled substance losses can be either mailed to the address of the board or emailed to [DEA106@dca.ca.gov](mailto:DEA106@dca.ca.gov). CCR §1715.65(d), CCR §1715.6, BPC §4104(c)

**3. With the new revisions for inventory reconciliation reports and inventory activities, what is now required to be in the report?**

An inventory reconciliation report must include the following:

- A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the pharmacy or clinic licensed by the board has in inventory, pursuant to BPC §§ 4180 or 4190. If an inpatient hospital pharmacy or licensed correctional pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count.
- The individual(s) who performed the inventory must sign and date the inventory or the report.
- A review of all acquisitions and disposition of each federal controlled substance covered by the report since the last inventory reconciliation report covering that controlled substance.
- A comparison of the physical counts in inventory to all acquisitions and dispositions (since the last inventory reconciliation report) of each federal controlled substance covered by the report.
- Identification of all records used to compile the report, which must be maintained in the pharmacy or clinic.
- The identification of each individual involved in preparing the report.
- The possible causes of overages.
- Identify to the Board, in writing, the losses and known causes. Reportable losses defined in CCR §1715.6, must be reported to the board within 30

days of discovery, unless the cause of the loss is theft, diversion, or self-use in which case the board must be notified within 14 days of discovery.

- The inventory reconciliation report must be dated and signed by the PIC or the professional director of the clinic licensed pursuant to BPC §§4180 or 4190.
- The report and all records used to compile the report must be readily retrievable in the pharmacy or clinic for three years.

CCR §1715.65(c), (d), (e)

#### **4. What type of “inventory activities” does the board require a pharmacy to perform for all other controlled substances that are not mandated to be physically counted quarterly or every 12 months?**

“Inventory activities” are required for each controlled substances that is not already required to be physically counted quarterly or at least every twelve months. Inventory activities for these controlled substances must be performed at least once every two years from the performance of the last inventory activities. “Inventory activities” means inventory and all other functions sufficient to identify loss of controlled substances. The functions that are sufficient to identify loss outside of the inventory reconciliation process must be identified within the pharmacy’s policies and procedures.

CCR §1715.65(a)(1), (a)(2), (a)(3)(B)

#### **5. Can I delegate a staff pharmacist to do the physical count and prepare the inventory reconciliation report for the pharmacy?**

Yes. Any individual involved in preparing the report must be identified in the report. Any individuals who perform the physical count of each federal scheduled controlled substance must sign and date the inventory or the report.

The pharmacist-in-charge of a pharmacy or the consulting pharmacist for a clinic licensed by the board pursuant to BPC §§ 4180 or 4190, must review all inventory activities performed and inventory reconciliation reports prepared and establish and maintain secure methods to prevent losses of federal controlled substances, including written policies and procedures for performing the inventory activities and preparing the inventory reconciliation reports.

In addition, the inventory reconciliation report must be dated and signed by the pharmacist-in-charge or the professional director for a clinic licensed by the board pursuant to BPC §§ 4180 or 4190. An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature for this report if, in addition, the individual physically signs a printed statement

confirming the accuracy of the inventory or report. The signature must be dated, and the signed and dated statement must be retained on file in the pharmacy or clinic for three years.

CCR §§1715.65(b), (e)(1), (e)(2)

**6. How long is the pharmacy required to maintain its inventory reconciliation reports?**

All inventory reconciliation reports, and all records used to compile the reports, are required to be readily retrievable in the pharmacy or clinic for three years. CCR §1715.65(e)(2)

**7. I am new PIC and this is my first time doing an inventory reconciliation report. What is required to be included in an inventory reconciliation report?**

As a new PIC of a pharmacy, the PIC must complete an inventory reconciliation report for all federal Schedule II controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg/10mg/5mls drug product within 30 days of becoming the PIC. CCR §1715.65(f)

**8. I notified my employer that I will be resigning as the PIC at the end of the month. Am I required to complete an inventory reconciliation before I leave?**

Whenever possible, the outgoing PIC should complete an inventory reconciliation report for all federal Schedule II controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg/10mg/5mls drug product. CCR §1715.65(f)

Whenever possible, it is also recommended (though not required) the outgoing PIC perform an inventory count of all controlled substances prior to their disassociation as the PIC.

**Hospital Pharmacies and Drug Rooms:**

**9. Are drug rooms required to complete an inventory reconciliation report?**

Yes. Under 22 CCR §70263(a), hospitals having fewer than 100 licensed beds (informally referred to as drug rooms) are required to have a license pursuant to BPC 4029 and 4056, and must comply with CCR §1715.65.

**10. Does a hospital pharmacy need to include the controlled substances stored in the automated drug delivery system (ADDS), if the controlled substances were already removed from the stock inside the hospital pharmacy's narcotic locker?**

Yes. The hospital pharmacy must account for all controlled substances subjected to inventory reconciliation stored inside the licensed pharmacy premise and stored in all the ADDS throughout the hospital, including locations listed on the general acute care hospital license, provided the ADDS were stocked by the hospital pharmacy.

However, if any inpatient hospital pharmacy, or licensed correctional pharmacy, uses an ADDS, only the inventory in the ADDS may be accounted for by using a means other than a physical count. CCR §1715.65(h)

**11. Are the controlled substance removed from the main hospital pharmacy inventory then transferred to the satellite pharmacies, nursing stations, surgical units, clinics, and other locations listed on the general acute care hospital license required to be included in the hospital pharmacy's inventory reconciliation report?**

Yes. The inventory reconciliation reports for an inpatient hospital pharmacy must include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. A physical count of the controlled substances (all federal Schedule II controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine/5mls drug product) is required. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count.

CCR §§1715.65(a), (g), (h)

**12. For federal Schedule II controlled substances stored in an ADDS, are they required to be physically counted?**

No. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count. CCR §1715.65(h)

**13. The inpatient hospital pharmacy operates various ADDS throughout the hospital which includes controlled substances. We plan to generate audit reports through the ADDS report module. Are these reports sufficient to account for the controlled substance since the law allows the inpatient hospital pharmacy to use means other than physical counts for controlled substances stored in an ADDS?**

It depends. Yes, the inpatient hospital pharmacy may use the ADDS audit report programs. However, when using these audit programs, the board recommends the pharmacy should also consider the following:

- A review of the records of acquisition for the controlled substances being audited.
- A review of the records of disposition for the controlled substances being audited, include expired drugs removed, drugs removed due to breakage, etc.
- Review of discrepancy reports and adjustments made for shortages and overages, including all discrepancy reports opened and closed, and unaccounted-for losses.
- The total loss of each controlled substance during the audit period, resulting from shortages, especially when the count is adjusted. If the total loss causes the aggregated amount to equal or exceed the thresholds listed in CCR §1715.6, the losses must be reported to the board.
- All shortages were investigated to determine the cause.
- When there is a shortage, the policies and procedures were reviewed to determine if any changes were needed to prevent the shortage from reoccurring.

CCR §§1715.65(b), (c), (h), 1715.6

**Clinics licensed pursuant to BPC 4180 and 4190:**

**14. Our surgical center maintains a perpetual inventory for controlled substances. Can we use the counts from the perpetual inventory for the inventory reconciliation report?**

No. The surgical clinic is required to take a physical count, not an estimate, of all quantities of each federal controlled substance covered by the inventory reconciliation report. If the inpatient hospital pharmacy uses an ADDS to stock the controlled substances, the inventory in the ADDS may be accounted for by using a means other than a physical count.

CCR §§1715.65(c)(1), (h)

**15. We are a surgical clinic that is listed on the general acute care license as an approved service. We do not have a separate clinic license pursuant to BPC 4180 or BPC 4190. The hospital pharmacy provides the medications for the surgical clinic used for administration only in an ADDS. Does the board require the surgical clinic to conduct a separate inventory reconciliation?**

No. If the controlled substance in the ADDS is stocked by the inpatient hospital pharmacy, the controlled substances in the ADDS will need to be included in the inpatient hospital pharmacy inventory reconciliation report. CCR §1715.65(a)

**16. I am a consulting pharmacist at an ambulatory surgical center (ASC) that is not licensed with the board pursuant to BPC 4190. Based on the Capen decision in 2013, does an ASC that is not licensed with the board required to perform inventory reconciliation reports?**

No. ASC who are not licensed by the board are not required to comply with CCR §1715.65, since it is not licensed as a pharmacy nor a clinic with the board. The controlled substance acquired for the ASC would be acquired by the licensed prescriber authorized to purchase controlled substances. BPC §§4170, 4059(b)

**17. At a surgical clinic licensed by the board, can a registered nurse perform the physical count of the federal Schedule II controlled substances?**

Yes. CCR §1715.65 does not specify who is required to perform the physical count. However, any individual who performs the required inventory must be authorized to access controlled substances and sign and date the inventory or inventory reconciliation report. CCR §§1715.65(c)(1), (e)(1)

**18. Our surgical clinic verifies the inventory count twice each day. Are we required to do inventory reconciliation quarterly for the federal Schedule II controlled substances?**

Yes. Every clinic licensed with the board must perform periodic inventory activities and prepare inventory reconciliation reports. CCR § 1715.65(a)

**Correctional Clinics – BPC §4187:**

**19. Our pharmacy stocks federal Schedule II controlled substance in ADDS at each of the correctional clinics at the prison. Are we required to perform a physical count of these controlled substances in the ADDS for the inventory reconciliation?**

No. If the correctional clinic, operated by the California Department of Corrections and Rehabilitation, uses an ADDS to stock the controlled substances, the controlled substance inventory in the ADDS may be accounted by using a means other than a physical count. CCR §1715.65(h)

**20. The county outpatient pharmacy operates ADDS at the county jail. Are we required to perform a physical count of the controlled substances in the ADDS for the inventory reconciliation and inventory activities?**

Yes. A county jail is operated by the county where it is located and not by the California Department of Corrections and Rehabilitation. Therefore, every

pharmacy licensed with the board must perform periodic inventory activities and prepare inventory reconciliation reports. CCR § 1715.65(a)

**Compounding Pharmacies:**

**21. We have hydromorphone powder used for compounding. We are concerned, each time the powder is weighed, drug loss may occur with each transfer in and out of the bottle. Is the pharmacy required to physically count the powder by weighing out the powder by emptying the contents and recording the weight of the powder?**

No. The board recommends that when the pharmacy receives a new bottle of a powder for a federal Schedule II controlled substance and when a physical count is required for the inventory reconciliation, the pharmacy records the weight of the bottle with the powder remaining in the bottle. CCR §1715.65(c)(1)

**Long Term Care (LTC) Pharmacies:**

**22. We are a LTC pharmacy and provide the long-term care facilities with emergency kits stored in secured containers which contain federal Schedule II controlled substances. Are the federal Schedule II controlled substances in the emergency kits required to be physically counted for the inventory reconciliation?**

Yes. A physical count is required. CCR §1715.65(c)(1)

**23. Our LTC pharmacy operates ADDS at various long term care facilities, and these ADDS include federal Schedule II controlled substances. Are the federal Schedule II controlled substances stored in the ADDS required to be physically counted for the inventory reconciliation?**

Yes. Only inpatient hospital pharmacies and licensed correctional pharmacies that uses an ADDS may account for the inventory in the ADDS using means other than a physical count. CCR §§1715.65(c)(1), (h).