

INSPECTOR DAN NEWSLETTER #1

ISSUE: For those of you who may have forgotten or are a new client of the License Protection Service, Inspector Michael Dan is a California State Board of Pharmacy inspector, and is notorious for visiting pharmacies in your local area. It has been quite some time since he last visited your neighborhood pharmacy that many people thought Inspector Dan might have actually retired. Yet on this hectic Thursday morning, after yet another crazy week due to Covid-19, standing at your in-window of your pharmacy is Inspector Dan wearing a smile on his face like he just won the State lottery. As your hands begin to shake you slowly walk over to the in-window. Taking a deep breath, you try to force yourself to relax.

Inspector Dan was on administrative leave from the Board, but has recently returned back to work inspecting pharmacies. Sadly, your pharmacy was first on his list. Anticipating Inspector Dan to start inspecting your pharmacy yet again, he instead tells you that he is not there to inspect your pharmacy. Instead he is there to offer some guidance on the law that took effect back on April 1, 2018 that many pharmacists still do not understand clearly and that law involves the reconciliation of the Schedule II controlled substances. You are so relieved after hearing this from Inspector Dan that you almost fall over in disbelief.

On April 1, 2018, the Board of Pharmacy enacted a new regulation that is called the "Inventory Reconciliation Report of Controlled Substances". Heck, just the name of the regulation is scary enough. I heard that this report needs to be done, but hey, I am doing C2 inventories every 3 months so I have this figured out – right?? Before Inspector Dan dives right into the report and how to do it, he first gave me some background information on why the Board enacted this regulation.

Sadly, there are many unscrupulous employees that work in pharmacy. Many of these employees will steal scheduled drugs from the pharmacy without anyone ever knowing. Yet with the advancement of CURES, the Board can now monitor a pharmacy "remotely" with respect to what the pharmacy purchases and what they sell when it comes to controlled substances. When the Board discovers that a pharmacy is purchasing more controlled substances than is being sold, it raises a red flag that a potential loss or theft is occurring in that pharmacy. The Board will then visit that pharmacy only to discover that an employee has stolen thousands of controlled substances. This now leaves the owner and the Pharmacist-in-Charge to deal with the consequences from that unscrupulous employee's theft.

This "Inventory Reconciliation Report of Controlled Substances" is simply a reconciliation of a pharmacy's Schedule II controlled substances. Reconciliation is an accounting process that uses two sets of records (two separate Schedule II controlled substance inventory counts) to ensure figures are correct and in agreement. It confirms whether the Schedule II controlled substances leaving the pharmacy matches the amount that's been ordered, and makes sure the two are balanced at the end of the recording period. The purpose of reconciliation is to provide consistency and accuracy for your on-hand Schedule II controlled substances in the pharmacy. Reconciliation is particularly useful for explaining the difference between two inventory balances. Some differences may be acceptable but the unexplained or mysterious discrepancies may be signs of theft.

Let's compare a type of reconciliation that happens in everyday life. At the end of every month, many individuals reconcile their checkbooks and credit card accounts by comparing their canceled checks, debit card receipts, and credit card receipts with their bank and credit card statements. This type of account reconciliation makes it possible to determine whether money is being fraudulently withdrawn. It also makes sure financial institutions have not made any errors with individuals' accounts, and it gives consumers an overall picture of their spending.

Now that we have an understanding of what a reconciliation report is all about, let's now go through the steps of what is required by the Board of Pharmacy when you reconcile your Schedule II controlled substances. The following is a list of items to consider in creating this report:

1. How often: A pharmacy shall compile an inventory reconciliation report of all Schedule II controlled substances at least every three months.
2. Different NDC's for the same Drug/Strength: It is recommended that you combine all the different manufactures for the same drug and strength into one quantity when conducting this reconciliation report. It will make this report much easier.
3. What to do first: The first task at hand is to conduct an initial or baseline physical inventory count for all Schedule II controlled substances in your pharmacy (not an estimate). These inventory counts will be used as your initial inventory when you conduct your first reconciliation report within the next three months. Keep in mind this inventory will also include Schedule II controlled substances that are earmarked for return/destruction or those in your e-kits at your facilities you service. If you have already done this inventory then great, but if not, then conduct this initial physical Schedule II controlled substance inventory ASAP.
4. What to do next: You must have in place a system, or some way to track all acquisitions and dispositions of Schedule II controlled substances since the last reconciliation report inventory was taken.
 - a. Acquisition of Schedule II controlled substances: This means that you must keep track of what you purchased from your wholesaler. There are many ways to keep track of what you purchased and different pharmacies do it different ways. The one flagged with *** is my recommendation. For example:
 - i. Contact your wholesaler(s) for a report of what you purchased over that three-month period***.
 - ii. Organize your CSOS or DEA 222 order forms in such a way you can easily determine what was purchased over that three-month period.
 - iii. Utilize a perpetual inventory to assist you in what was purchased over that three-month period. But keep in mind, fraudulent entries into a perpetual inventory will not be discovered unless you match up each Schedule II controlled substance invoice with each perpetual inventory entry.
 - b. Dispositions of Schedule II controlled substances: This means that you must keep track of what has left your pharmacy. There are many ways to keep track of what has left your pharmacy and different pharmacies do it different ways. The one flagged with *** is my recommendation. Keep in mind that Schedule II controlled substances that have been returned for credit or sent for destruction must also be accounted for as what has left your pharmacy. For example:
 - i. Run a Schedule II controlled substance drug report of what has been dispensed over that three-month period***.
 - ii. File your filled Schedule II controlled substance hard copies in such a way that you can easily determine what was dispensed over that three-month period.
 - iii. Utilize a perpetual inventory to assist you in what was dispensed over that three-month period. But keep in mind, fraudulent entries into a perpetual inventory will not be discovered unless you match up each Schedule II controlled substance hard-copy prescription with each perpetual inventory entry.
5. What to do last: Compile the reconciliation report for EACH Schedule II controlled substance in your pharmacy (Please utilize the log sheet in Chapter 2, page 2-C in your *License Protection Handbook* when completing this report). Here is how to do it:
 - a. First: Select a Schedule II controlled substance you want to reconcile.

- b. Second: Use your baseline Schedule II controlled substance inventory as your beginning inventory for that specific Schedule II controlled substance;
- c. Third: Add to that inventory all acquisitions of that specific Schedule II controlled substance over that three-month period;
- d. Fourth: subtract from line (c) above all dispositions of that specific Schedule II controlled substance over that three-month period. This number represents your "calculated inventory count";
- e. Fifth: Conduct a physical inventory of that specific Schedule II controlled substance. (Keep in mind that this will be your baseline count when you conduct your next reconciliation report three months later).
- f. Lastly: Compare the physical inventory count with what you calculated your inventory to be from line (d) above. The numbers have better match; otherwise you will need to investigate the variance.

The above information should be followed to assist you in conducting your initial baseline Schedule II controlled substance inventory and each subsequent reconciliation report every three months thereafter. Please review the Policy and Procedure that is in Section A (page A-43) of your *License Protection Handbook* for more details and requirements associated with this reconciliation report.

Thefts of Schedule II controlled substances happen quite often. Employee thefts are quite common, and when discovered not only must the theft be reported to both the Board of Pharmacy and the DEA, but later the BOP will investigate and at a minimum will issue a citation and fine to the Pharmacist-in-Charge and the pharmacy. Sadly, at a maximum, revocation of the Pharmacist-in-Charge's personal license and the pharmacy license can occur.

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