FIXING PROBLEMS IN THE CONTROLLED DRUG PROGRAM

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Defining "Loss"

Whether it's noticed during an inventory or an end of container management check, there will come a time when the log does not match the actual amounts on hand. In some cases, there will be a small shortage and in others there may be an overage. What the registrant does about a shortage depends on the amount of the shortage and whether it's because of "operational losses" or whether it's because of a theft or diversion.

If the shortage is a "significant amount" or the result of theft (of any kind, including employee theft), notification to the DEA is required within one business day of **discovery of the loss**.

In a 2005 rule clarification, the DEA says, *"there is no single objective standard that can be applied to all registrants--what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. Any unexplained loss or discrepancy must be reviewed within the context of a registrant's business activity and environment."*[i]

So, what determines a "significant loss" for us? Since there is no specific quantity amount, it depends on the circumstances, including the type of activity taking place. For example, in a manufacturing process, loss of 100 milliliters of substance from a 10,000 bottle batch is not significant and may be from a counting error or a bottle filling error. On the other hand, the loss of a single 100ml bottle of substance from a veterinary practice that uses just four or five bottles of that substance per year would be a significant loss. In the past, veterinarians often relied on the standard of 10% of the volume to determine significance. That number appears nowhere in the federal regulation, but many believe it to still be a good "rule of thumb."

A report of loss or theft of controlled substances is made to the DEA Regional office responsible for the practice location using a DEA Form 106. The location of the office can be found on the DEA's web site. A report to local law enforcement is not a substitute for the registrant's report to the DEA.

Aside from theft, shortages can be from accidental breaking of a glass vial, human error by the hospital staff or because of "operational losses." A small amount of residual drug in syringes and less than perfect measurements are a fact of life in any operation and they impact the balance on hand, so no one will have perfect logs without any errors, corrections or adjustments. If the logs always come out perfectly balanced, most DEA agents suspect that the logs are being manipulated instead of reflecting the actual

operation. In other words, they EXPECT to see corrections and adjustments in the logs as a sign that the registrant is managing the program.

Documenting Losses

So, when those shortages do happen, they must be documented properly. If the shortage is because of an accident that resulted in the breaking of a bottle or spilling of the drug in an unrecoverable manner, follow these steps:

1) **Take pictures** of the broken bottles or the spill. Everyone has a camera on their phone so this one should be easy.

2) **Write a statement** on a piece of paper explaining what happened. Identify any witnesses that observed the accident. SIGN the statement and have any witnesses sign. If there were no witnesses, tell a supervisor of the incident immediately and ask them to view the accident before cleaning it up. Have them sign the statement. Keep a copy of the statement attached to or with the log.

3) **Clean up the spill** and dispose of any liquid collected in the same manner as a wasted dose (see Chapter 8 – Disposal).

4) **Make an entry** on the log that says "Accident-Bottle Broken. See written memo"

5) Subtract the lost amount from the balance on hand in the log.

6) There is no need to notify the DEA unless there is suspicion that the incident was an attempt to steal the drugs and substitute another substance in its place.

When it comes to people making mistakes on logs, the three most common are:
1) Arithmetic errors on the log,
2) Entering the transaction on the wrong page or in the wrong column on the log or using the wrong code on the computerized invoice, and
3) Failing to enter the transaction on the log.

All three mistakes can be corrected but should only be isolated instances. If they are happening on a regular basis, it's a compliance problem, not a mistake and the registrant must take corrective action to correct the reasons for the errors.

When making any correction to a log, **DO NOT REWRITE, OBLITERATE or COVER UP ANY PREVIOUS ENTRIES! Always simply highlight the error and make a NEW entry to explain and adjust the balance.**

When an arithmetic error is found, even days later, highlight the incorrect math error to draw attention to it. Do not change the entry and do not change any following entries. On the next blank line:

1. Enter the current date.
2. In the patient ID section enter "Correction for math error" with the date of the error and the patient ID.
   In the Amount column, enter the amount of the correction as a positive or negative amount.
   Adjust the Balance on Hand amount up or down by the amount in step 3.

If the entry was made on the wrong log sheet:

1. Draw a single line through the incorrect entry,
2. Explain the mistake and indicate the log on which the entry should have been made,
3. Initial or sign the entry,
4. Make the correct entry on the correct page using the current date.

5. Make a note on the correct entry referencing the incorrect entry (to tie them together).

If the errors are the result of staff "forgetting" to enter the transaction on the log in the first place, the solution is a three-step process:

1) **Evaluate** the number of people with access to the drugs and revoke the access of anyone not essential to the process. Also evaluate the recordkeeping process to see if it can be simplified. For example, something as simple as moving the log from one location in the treatment room to more accessible location may be enough to solve the problem.

2) **Retrain** and remind the staff on the rules. Stress the need for recording EVERY transaction, no matter how busy we get. There must be no flexibility in that requirement.

3) Although the first two steps will solve most of the "I forgot" problems, there will still be some staff members who need the third step…**discipline**. If a particular staff member is always "forgetting" or finding excuses for failing to record each and every transaction on the log, the only solution to the problem is to use the same discipline methods that would be used if they kept making mistakes when handling cash or other sensitive items. If the problem persists, that staff member's access to the controlled substance program should be revoked.

Operational losses are commonly noticed when a drug bottle is empty. If the discrepancy is small and "expected" as is the case with drugs that are used in very small doses, it is known as an operational shortage. In those situations, a simple entry on the log adjusting the balance on hand is appropriate. For example, if the log indicates a 10 milliliter bottle should have 0.25 milliliters left, but the bottle is actually empty, the final entry for that bottle would be "adjustment – bottle empty"

and -0.25 milliliters would be subtracted from the total to bring it to zero. (see Figure 1)

Controlled Substance Log

Drug Name & Strength: Diazepam 5mg/ml 10 ml vial **Bottle #** 12

Date	Client/Patient ID or transfer location	Amount Drawn	Amount Wasted	Balance on Hand	Initials
2/1/19	Rec'd new bottle from safe			10.0	PJS
2/1/19	Smith "Dog"	1		9.0	PJS
2/1/19	Jones "Cat"	1		8.0	PJS
2/2/19	Johnson "Another Dog"	2.5		5.5	DEB
2/3/19	Wills "Fido"	.75		4.75	CKL
2/3/19	Sanchez "George"	1.0		3.75	CKL
2/3/19	Eidson "Angus"	2.0		1.75	CKL
2/4/19	Lane "Bo"	1.5		0.25	PJS
2/4/19	Adjustment - Bottle Empty Signed: Philip J Seibert	.25		0	PJS

Figure 1 - Example of an entry to adjust the balance on hand at the end of an empty bottle.

Disposal of Unwanted or Expired Controlled Rugs

When it comes to disposing of any controlled substances, the DEA has specific rules that must be followed. There are separate procedures for expired or unused supplies and for wasted doses.

Unused stocks or supplies are quantities of controlled substances that have been purchased for general use in the practice but have never been "dispensed or removed for a particular patient."

When unused stocks of controlled substances are no longer needed or wanted, contact the original supplier of the drug to inquire about returning it for credit or disposal. Often, drug manufacturers and distributors will replace outdated (or nearly outdated) drugs with fresh supplies or issue a credit and accept them as a return. Ask the distributor about their policy and keep track of expiration dates!

If returning the drugs to the original vendor is not an option, the DEA may authorize local destruction but generally they will rely on the use of licensed private companies called "Reverse Distributors". These companies receive controlled substances that are expired or no longer wanted and destroy them according to DEA rules. This Reverse Distributor process greatly streamlines this necessary part of material management. Because they are private companies and not part of the DEA, reverse distributors charge a fee for the service. There is a wide range of fees for such a service so be sure to shop around. A list of reverse distributors is available from the DEA or by conducting an internet search for "reverse distributor." We've also compiled a select list of reverse distributors on our web site[ii]. There is no regulation that requires the use of a reverse distributor in the state where the practice is located, so it is acceptable to use a licensed reverse distributor in any state.

The regional DEA office may authorize an alternative form of destruction, but all such requests must be in writing directed to the Agent in Charge of the DEA office serving the practices location. DO NOT accept any verbal approvals for alternative destruction; verbal authorizations are VERY, VERY difficult to prove!

Security and accountability for the drugs should be maintained until they are destroyed or shipped, and confirmation is received from the reverse distributor.

Local drug take-back events are not an acceptable method of disposing of unused stocks of controlled substances by a registrant. Those disposal events are only authorized for consumers.

A wasted dose is the amount of controlled substance that was removed from the supply for a particular patient but was not actually administered to the patient and is not able to be returned to the supply system for reuse. In the past, we could simply squirt a wasted dose into absorbent material then discard it in the regular trash. However, recent clarification by the DEA requires wasted doses to be disposed of in a way that alters the substance to prevent the possibility of recovery. Fortunately, that's still easy to accomplish; the most practical answer is the use of a chemical pharmaceutical destruction process. Some brand names include Rx Destroyer™[iii] and DETERRA®[iv]. Both products are simple containers filled with a chemical substance that absorbs and binds with the drugs to make them non-retrievable. Both are readily available on the internet and through distributors.

When destroying a wasted dose, be sure to log the entire amount of the drug removed from the supply and note the wasted amount on the medical record and the log.

In the past, very small amounts of unused schedule III through V substances (such as minute amounts of Telazol®[v] that has been reconstituted and has now expired) were also disposed of locally in the same manner as a wasted dose. In recent years, more and more DEA inspectors have insisted that ALL unused stock be disposed of through a reverse distributor.

Accepting Returns from Clients

Controlled substances that have been dispensed pursuant to a prescription (sent home) to a client cannot be used again nor can they be taken back for disposal by the practice. There is no provision in the regulations for a registrant to accept controlled substances from any source other than a licensed distributor or manufacturer for any reason. There is a separate registration category for drug collectors who are authorized to accept unwanted consumer drugs, but PRACTITIONERS are not eligible for such a registration.

The client must dispose of unwanted controlled substances using a local drug take-back program or according to the FDA/EPA recommendations. The FDA has produced a helpful client brochure which can be downloaded from their web site[vi].

Summary

If your controlled drug records are perfect, the DEA knows you're not being honest because things happen! The secret when something unexpected happens is to explain as clearly as possible what happened. Don't cover up mistakes – highlight and explain them!

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[i] www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0812.htm

[ii] www.safetyvet.com/images/RevDist.pdf

[iii] Rx Destroyer ™ is a trademark of C2R Global Manufacturing Inc., Burlington, WI 53105, www.rxdestroyer.com/

[iv] DETERRA® is a registered trademark of Verde Technologies, www.deterrasystem.com

[v] Telazol® is a registered trademark of Zoetis, Parsippany, NJ 07054, www.zoetisus.com

[vi] www.fda.gov/media/111887/download