CONTROLLED DRUG LOGS: DOCUMENTING THE "INS" AND "OUTS"

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When the practitioner dispenses or administers a controlled substance to a patient, it must be recorded both on the medical record and a "readily retrievable record of each transaction."

Although a perpetual log is not specifically mandated by the Controlled Substance Act, it has been shown to be the most convenient, effective method to manage this program. Perhaps the easiest way to look at the log and the process of controlled substance accountability is to compare it to a checking or savings account register. Just as in the case of tracking money in a bank account, deposits and withdrawals from the controlled substance safe are tracked to know exactly how much is available at any time. Furthermore, the log or register will give an accountability of how and when the drugs were added or removed.

There is no mandated format or design for controlled substance logs. The layout or format of the log is less important than compliance with actually entering the information. No system, regardless of its design will be useful or accurate if the information is not entered!

Whatever the logs look like, they should contain:

- the date of the transaction,
- the client and patient's name (other details for the client such as address and phone number should be available in the medical record),
- the name of the drug (can be at the top or bottom of the log page if all entries on that page are for that drug),
- the quantity of the substance dispensed for administration or prescribing,
- an accurate "balance on hand", and
- the initials of the staff member who removed the drug from the supply."

A long-living myth suggests that controlled substance logs must be in a bound ledger format. It's just not true. There is no federal requirement for the controlled substance log to be a bound book!

Computerized logs are acceptable if the accuracy of the entries is verified periodically and the computer program can produce a report identifying the date, client, patient, drug and amount used or dispensed for every single transaction. The balance on hand portion need not be present on a printed report but should be easily accessible for verification. If using the computer as the primary means of tracking controlled substance use, we recommend the manager or registrant produce and keep regular printed controlled substance reports. In a DEA audit, the agent will want to want to review printed reports and will not be inclined to spend time looking at the practice's computer screen. And although most practices back up computer data regularly, sooner or later, every computer system will fail, or some data will be corrupted. If the information is not maintained in printed form and there is a computer problem, one can bet there will be a citation for failure to maintain the required data for the required time.

Controlled Substance Log

Drug Name & Strength: <u>Díazepam 5mg/ml</u>Bottle Size: <u>10 ml víal</u>Page # <u>4</u>

Date	Transaction Description or Client/Patient ID	Full Bottles	Amount Drawn	Amount Wasted	Open Bottle Balance	Initials
2/1/21	Rec'd from Distributor - Invoice 23418 Bottles Numbered 1-10	10			0	PJS
2/1/21	Opened bottle #1	9	+10.0		10 ml	PJS
2/1/21	Smith "Dog"		1.0		9.0	PJS
2/1/21	Jones "Cat"		1.0		8.0	PJS
2/2/21	Johnson "Another Dog"		2.5		5,5	DEB
2/3/21	Wills "Fido"		.75		4.75	CKL
2/3/21	Sanchez "George"		1.0		3.75	CKL
2/3/21	Eidson "Angus"		2.0		1.75	CKL
2/4/21	Lane "Bo"		1.5		0.25	PJS
2/5/21	Adjustment - Bottle Empty - Phil Seibert		.25		0	PJS
2/5/21	Opened bottle #2	8	+10.0		10 ml	PJS
2/6/21	Snyder "Títan"		1.25		8.75	PJS

Figure 1 - Example of a simple perpetual drug log

For the small operation with a single safe in the treatment room and just a few bottles of drugs on hand at one time, a "Simple Perpetual Log" method may be the best choice. In this method, the receipt, opening and use of all the bottles of a given drug are maintained on a single page. This example shows:

 On 2/1/21, PJS received 10 bottles of Diazepam from the distributor - he logged them in and included the invoice number and numbered the bottles 1-0. That same day, PJS opened bottle 1. He subtracted 1 from the FULL BOTTLE amount and ADDED 10 ml to the OPEN BOTTLE BALANCE amount. He still has the same amount on hand, but simply changed the unit of measure for the bottle that was opened.

- 2) On that day and for the next four days, the practice used the open bottle and recorded each transaction.
- 3) On 2/5/21, the opened bottle was empty and an adjustment entry was made to "zero out" the log (WILL EXPLAIN THIS IN WEEK 3 LESSON!). At the same time, PJS, opened bottle 2. He subtracted 1 from the FULL BOTTLE amount and ADDED 10 ML to the OPEN BOTTLE BALANCE amount.
- 4) The cycle repeats itself.

This method gives an accurate picture of the total number of unopened bottled and the amount in the opened bottle in the safe at any one time all on one page. When the page is full, a new page is started by carrying forward the balances from the end of the previous page. The completed page is filed. And of course, each drug will have its own sheet.

For a larger or more active veterinary practice, the best controlled drug documentation program seems to be the Central Pharmacy-Department User system. In this system, all drugs are received into a central pharmacy and then "issued" to the various sections of the hospital where they are actually used in operations. What makes the Central Pharmacy - Department User system different from the traditional method of storing and logging all drugs in one safe is the presence of multiple drug logs maintained where the drugs are actually used or dispensed. Here's an explanation of how a central pharmacy - department user system works.

0	Controlled Substances Log				Page				
Date	Drug & Strength →	Ketamine Injection 100mg/ml	Morphine Injection 50mg/ml	Euthasol Solution	Diazepam Injection 5mg/ml	Tramadol 50mg Tablet	Hydrocodone Syrup	Phenobarb ¼ grain Tablet	Drug
	Received/Transferred/ Initials↓	10 ml btl	20 ml btl	100 ml btl	10 ml btl	1000 tab btl	473 ml btl	1000 tab btl	Unit
1/31/19	Balance Forward PJS								Qty
		12	8	5	7	0	1	1	Bal
2/1/19	Transfer to	1			1				Qty
	Surgery ~ PS	11			6				Bal
2/3/19	Transfer to Dr. Jone's Truck -CKL			2					Qty
				3					Bal
2/4/19	Rec'd from MWI~ 00281722 ~ CKL					2			Qty
						2			Bal
2/4/19	Moved to pharmacy - GF					1			Qty
						1			Bal
	Transferred to Surgery ~ PS				1				Qty
2/5/19					5				Bal
									Qty
									Bal
									Qty
									Bal
									Qty
									Bal

Controlled Substance Log									
Drug Name	Drug Name & Strength: <u>Díazepam 5mg/ml 10 ml Víal</u> Bottle # <u>12</u>								
Date	Client/Patient ID or transfer location	Amount Drawn	Amount Wasted	Balance on Hand	Initials				
2/5/19	Rec'd new bottle from safe			10.0	PJS				
2/5/19	Smith "Dog"	1		9.0	PJS				
2/5/19	Jones"Cat"	1		8.0	₽JS				
2/6/19	Johnson "Another Dog"	2.5	1.0	5.5	DEB				
2/7/19	Wills "Fido"	.75		4.75	CKL				
2/7/19	Sanchez "George"	1.0		3.75	CKL				

Figure 3 - Example of a Department User log that corresponds to the Central Pharmacy Log.

- When a bottle of a controlled substance is received from the supplier, the unopened bottle is placed in the central pharmacy safe and logged (in full bottle quantities) as received on the central pharmacy log. The invoice number and supplier are entered in the "client ID" section of that "central supply" log. The balance on hand is updated to reflect the new quantity and the actual amount of the drug in the safe should match the new balance on hand (see the 2/4/19 entry in Figure 2).
- 2) When needed, a single bottle is taken out of the safe for use in another area of the practice, such as the surgery department or maybe an ambulatory truck. The central pharmacy log is annotated with the place where the drug is being "issued" (e.g., surgery or truck #1.) The balance on hand is updated and the actual quantity of the drug in the safe is verified to match the balance on hand (see the 2/5/19 entry for diazepam in Figure 2).
- 3) A single page log for that bottle is generated and the transfer from the central pharmacy is noted. The single page log and the bottle is then taken to the appropriate activity center's safe or lock box (see figure 3). As the drug is used, each patient's dose is recorded on the single page log. When the bottle is empty, the log's balance on hand should be zero or adjusted accordingly. The completed log is returned to a designated person for review, then a new bottle and log sheet are obtained from the central pharmacy.

This process can take place for several activity centers simultaneously. For instance, on a single day, the central pharmacy may issue a bottle of diazepam to the surgery

department, a bottle of phenobarbital to the outpatient pharmacy and a bottle of euthanasia solution the ambulatory unit. Each of those activity centers will keep track of their individual activities on their single page log. Each activity center's log will reflect the use and current status of just that bottle while the central pharmacy log gives a picture of the entire operation's status.

In a perfect system, the central pharmacy and each department or activity center would have a separate safe or lock box. If this isn't practical, use a small box, tray or basket in the central pharmacy safe for each department or activity center so that supplies for each center can be maintained separately to match the department level log sheets.

Medicine for Boarders

When a patient or boarder will be administered controlled substance medication during a boarding stay, it's extremely important to safeguard the drugs and keep the records straight. There are four concerns when using controlled substances for boarding patients:

- 1) Verifying the exact amount and name of the drug accepted from the client,
- 2) Providing proper security for the drugs while in the custody of the practice,
- 3) Ensuring the proper medications are administered to the proper patient at the proper times and documented correctly, and
- 4) Returning unused medication to the client upon discharge or release.

If the practice will supply the drugs during dispense the entire prescription amount from the supply just as one would to send it home with the client. It is easier to make a single entry on the log for the patient for the entire episode rather than numerous small entries for just a couple of tablets or milliliters. When the medication is supplied by the client, have a staff member physically count the quantity of the medication being accepted in the presence of the client. Record that amount on a form which the both the staff member and the client signs or initials. That form is retained during the stay, and then a similar count of any remaining medication is conducted upon discharge.

Medication that has already been dispensed as a prescription must still be secured while in the practice. We recommend every practice have a separate, lockable box to secure those drugs for safeguarding. That box should meet all the physical security requirements for controlled substances.

Mixtures of Controlled Substances

Some practices formulate, or compound a special drug mixture, typically for anesthetic induction or pre-medication. If that compounded product contains a controlled substance, it complicates the requirement to "keep a record of each transaction." When a mixture of drugs contains a controlled substance ingredient, the DEA considers the entire mixture a controlled substance.

Controlled Substance Log								
Drug Name & Strength: Dr. Phil's Magic Elixir (Mixture) Bottle # 6								
Date	Client/Patient ID or transfer location	Amount Drawn	Amount Wasted	Balance on Hand	Initials			
3/1/19	Ingredient 1 - Solution A	3		3	PJS			
3/1/19	Ingredient 2 - Solution B	3		6	PJS			
3/1/19	Ingredient 3 - Solution C	4		10	PJS			
3/1/19	"Fluffy" Smith	0.75		9.25	PJS			

Figure 3 -Example of a log for a compounded mixture.

The most effective method for such a situation is to log out the ingredients for the mixture using a unique bottle number for the finished product. Then create a log to record the administration to each patient. Here's how it works:

- 1) Assign a unique bottle number to the container which will hold the finished product. In this example, we will use Bottle #6.
- Log out the amount of controlled substance A from the central pharmacy or department user log. Use the phrase "ingredient for XYZ Mixture Bottle #6". Do the same for all controlled substances.
- 3) Create a NEW department user log sheet for the new mixture. In the patient ID section, list the ingredients line by line showing the amounts of each (even non-controlled substances or diluents. When the mixing is complete, the Balance on Hand column of the log sheet will reflect the TOTAL volume of Bottle 6.
- 4) When an amount is withdrawn from Bottle 6 for a patient, the patient ID, amounts withdrawn and wasted initials of the person withdrawing and the Balance on Hand are entered just like it is for any other drug.

For example: Let's say "Dr. Phil's Magic Elixir" is a combination of 3 ingredients. The formula is 3 milliliters of solution A, 3 milliliters of solution B and 4 milliliters of solution C. That totals 10 milliliters. It doesn't always have to equal an even number, but it must be an accurate sum of all the ingredient amounts. For the purposes of this example, let's assume solutions A and B are controlled substances but solution C is not a controlled substance. Figure 7 is what that completed log would look like.

Of course, the amounts listed on this log for Solutions A and B would match the removal entries on the individual log for that substance.

Summary

Regardless of the logging method that is chosen, remember that every TRANSACTION must be recorded. As for the old question, "which system is best?", our advice is to follow the old architecture principle of Form Follows Function; design the log or form to serve the purpose and organization of the practice. Don't reconfigure the practice to suit a pre-designed format that doesn't serve the purpose.

ⁱ Title 21, Code of Federal Regulations, Section 1304.03

ⁱⁱ Title 21, Code of Federal Regulations, Section 1304.22(c)