

BUREAU OF NARCOTICS & DANGEROUS DRUGS



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WHAT IS REPORTED AND WHEN?

State Law & Federal Law Do Not Match

DEA Federal Regulation 21 CFR 1301.76(b)

- Thefts or significant losses are reported;
- Use a DEA 106 form;
- Report in writing, within one (1) business day, upon discovery of the loss or theft;
- Report to the local DEA Division Office.



DEA—Determining What is Significant

- (1) The actual quantity of controlled substances lost in relation to the type of business.
- (2) The specific controlled substances lost.
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals or whether the loss can be attributed to unique activities that may take place involving the controlled substances.
- (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses, and, if known.
- (5) Whether the specific controlled substances are likely candidates for diversion.
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

important

MISSOURI BNDD REPORTING LAW

19 CSR 30-1.034(2)(B)

- Requires reporting of **ALL** losses, thefts, & **diversions**.
- Notify the BNDD immediately upon discovery.
- Submit a report form and summary within seven (7) business days.
- BNDD report form available on the website.
- Initial notification can be a telephone call, email or fax.
- Registrant may ask for an extension if more than seven (7) days is needed.
- Insignificant losses do not get reported – “insignificant” is defined and described.
- The BNDD loss report form asks questions that are from the DEA 106 Form.



BNDD DEFINITIONS

Loss: Controlled substances are missing and you don't know where they went.

Theft: Stolen, taking property of another unlawfully, not paid for and their possession is not legal.

Diversion: Controlled substances were not necessarily lost or stolen, but drugs left their normal and legal channels, and entered into a path not authorized by law.

A tech created false prescriptions and had a friend come in and pay cash for them. The drugs were not lost because the pharmacy knows where the drugs went.

The drugs were not stolen-- they were paid for. There was “diversion” because of the illegal acts.



BNDD—Insignificant Losses

1. The drugs are not lost—you know where they went.
2. The drugs were not stolen.
3. The drugs were not diverted to unauthorized channels.
4. An explanation of the “insignificant event” needs to be documented and to balance your records. Example are:
 - Drugs dropped on floor and spilled;
 - Mistake made during preparation or mixture;
 - Spillage, breakage and leaks;
 - Trace amounts lost during compounding, mixtures sticking to sides of containers, etc.
5. In all these insignificant events, legal activities were taking place but there needs to be a documented explanation to balance your records.
6. The documentation of the insignificant events should be stapled to your annual inventory document.



DIFFERENCES

DEA

- Losses & thefts
- You determine “significance”
- Report within one (1) business day
- Asks value of drugs



MO BNDD

- * Losses, thefts & diversion
- * Significance is defined
- * Notify immediately
- * Form due in seven (7) days
- * Can request an extension
- * Does not ask for value
- * Asks who did it?
- * Requires written summary of your investigation



BNDD LOSS/THEFT REPORT STATISTICS

Five (5) years of data from 2011—2016

BNDD has 30,095 registrants—1,362 are pharmacies (4½%)

Why BNDD and DEA statistics won't match:

1. BNDD registers LTCFs and DEA does not.
2. BNDD schedules pseudoephedrine and DEA does not.
3. BNDD fiscal year is July 1 to June 30, and the DEA year is from October 1 to September 30, so the reporting periods are different.
4. BNDD requires reporting of ALL losses and also any diversions, even if not stolen.



ALL BNDD REGISTRANTS—30,095

27 Different Registration Types

ANNUAL LOSS/THEFT REPORTS

2011.....	646
2012.....	668
2013.....	939
2014.....	1,181
2015.....	1,432
2016.....	1,532



DIFFERENCES IN TYPES OF THEFT

BURGLARY: (Business is closed/empty)

Unlawfully entering or remaining within a structure for the purpose of committing a crime therein.

ROBBERY:

Suspect uses force or threat of force to effectuate the theft of property.

- Without displaying a weapon could be “strong-armed robbery”
- With a weapon is “armed robbery.” (knife, gun, chainsaw...)



MO PHARMACY LOSSES/THEFTS

1,362 Pharmacies
Does not include hospital inpatient

2011.....	552
2012.....	510
2013.....	823
2014.....	1,004
2015.....	1,213
2016.....	1,354



BURGLARIES & ARMED ROBBERIES

<u>YEAR</u>	<u>BURGLARIES</u>	<u>ROBBERY</u>
2011.....	24.....	8
2012.....	23.....	8
2013.....	18.....	12
2014.....	22.....	11
2015.....	16.....	10
2016.....	22.....	22

PERCENTAGES

<u>YEAR</u>	<u>ALL LOSSES</u>	<u>PHARMACIES</u>	<u>%</u>
2011.....	646.....	552.....	85%
2012.....	668.....	510.....	76%
2013.....	939.....	823.....	88%
2014.....	1,181.....	1,004.....	85%
2015.....	1,432.....	1,213.....	85%
2016.....	1,532.....	1,354.....	88%

MOST COMMONLY DIVERTED DRUGS

hydrocodone (*when CIII*)
 oxycodone
 amphetamines
 alprazolam
 diazepam
 lorazepam
 clonazepam
 zolpidem



Why is This Happening?

The environment has changed:

- More citizens than ever.....6.2 million in Missouri.
- This means a lot more patients than ever.
- The majority are “baby boomers” now 52 to 70 years old, at a time when they may be taking the most medicine.
- BNDD now has more individual prescribers than ever which is over 25,000.
- BNDD has more pharmacies (1,362) than ever before;
- More new drug products.
- Almost everything is going up...numbers of citizens, patients, prescribers, drug products, and pharmacies.
- At the same time, the regulatory enforcement and oversight has decreased mainly due to budgetary restrictions.

SUPERVISION ISSUES NOTED

- Pharmacies are hiring a lot more technicians, sometimes the ratio of technicians to pharmacist overwhelms the pharmacist.
- Due to volume, pharmacy staff are busier than ever.
- Technicians are hired without completed background checks resulting in an unauthorized person hired as a technician.
- There are store policies—but they are not being enforced:
 - Coats in the pharmacy;
 - Purses in the pharmacy;
 - Techs have access to Schedule II safe;
 - Techs can adjust inventory counts without supervision; and
 - The computer allows for “inventory adjustment”.

SUPERVISION ISSUES (Cont.)

- Audits of commonly diverted drugs are not performed regularly.
- Losses are not initially discovered by the pharmacy, but are revealed by police arrests, DWI or corporate reviews of finances.
- The largest diversion cases involve pharmacies with automated dispensing machines/cells.
- Large overstock supplies in back room—not locked in safe.



Older Methods of Theft

- A chance to place one or two doses in pockets;
- Prepare a false phone-in script to steal;
- Steal a bottle instead of returning it to stock;
- Place a few tablets into a purse or coat; and
- Steal when unpacking a shipment.
- Conceal drugs in lunch containers/cups



Current Trends



- ❖ Pharmacy has automated machines/cells;
- ❖ Many stock bottles are purchased and used;
- ❖ Entire stock bottles are stolen;
- ❖ Stock bottles are stolen several times a week;
- ❖ The theft goes on for a year or more without notice;
- ❖ Pharmacy learns of theft from police or internal financial audit;
- ❖ Pharmacy is so busy filling prescriptions, they just keep buying more drugs and without performing audits;
- ❖ Techs can amend on-hand inventory counts or alter other records without supervision;
- ❖ Store's security policies are not being enforced by pharmacist;
- ❖ BNDD probations on pharmacies—losses range from 10,000 doses up to over 78,000 doses; and
- ❖ Pharmacy manager is usually the last to learn of this.

Sample Employee Theft Cases



A technician admitted to the following:

- Stole entire stock bottles from shelves for a year,
- Twice a week or about 8 bottles per month,
- Placed bottles in her smock near closing time,
- 80 bottles of 100# hydrocodone,
- 7 bottles of 500# hydrocodone,
- Sold bottles for sometimes up to \$900 dollars, and
- Final loss report was 28,174 doses.

Other Sample Loss Reports:

- 78,621 doses
- 38,726 doses
- 37,610 doses



COMMON CHARACTERISTICS

- Technicians;
- 20—28 years of age;
- Stealing entire stock bottles several times per week;
- Drugs are placed in a coat or purse;
- Theft goes on for a year or more;
- Tech can enter computer and adjust inventory counts;
- Drugs are not audited—or amount purchased v. dispensed;
- Discovery is made after a police stop, arrest, or DWI;
- Pharmacy's own policies regarding coats, purses, and not allowing techs to enter Cui safe—are not being enforced;
- Corporate office/finance notes that pharmacy has received 100,000 doses but only dispensed 70,000 doses;
- The pharmacy manager (PIC) is totally SHOCKED !!!



RECOMMENDATIONS

- ✓ Know criminal histories before granting access to drugs;
- ✓ Pay attention to issues pertaining to thefts, lying, and moral turpitude;
- ✓ Information from other store employees that worker is also taking food or items from cosmetics or other parts of store;
- ✓ Try to maintain a manageable pharmacist to tech ratio;
- ✓ Enforce ALL store security policies—coats, purses, etc.;
- ✓ Random drug testing;
- ✓ Food containers in the pharmacy? Clear drink containers?
- ✓ Audit most commonly abused/diverted drugs;
- ✓ Chain store corporate offices compare drugs shipped to drugs dispensed;
- ✓ Never let technicians alter computer records without a supervisor logging in to approve;

RECOMMENDATIONS (Cont.)

- ✓ If "inventory adjustment" is used, documentation should support the adjustment to the record;
- ✓ Have strict policies about refilling cells and machines;
- ✓ One of the most important roles and duties is the role of supervisor. Take a few minutes routinely to stop dispensing, and give your store a self-inspection;
- ✓ Make sure your store is covered completely by CCTV and there are no blind spots. Many technicians learn these blind spots very quickly;
- ✓ Do you allow any employees to fill their own prescriptions?



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