

AN INTRODUCTION TO CONTROLLED SUBSTANCE COMPLIANCE

Why your drug diversion prevention efforts begin here.

The first thing that comes to mind when talking about drug diversion is typically how to detect and monitor for it. However, diversion detection is only a fraction of the equation. In order to successfully detect and prevent drug diversion, one must also consider compliance. Both the Drug Enforcement Agency (DEA) and State agencies have strict regulations on controlled substance handling. In addition to assessing your diversion detection efforts, consider assessing your controlled substance compliance.

Before understanding what compliance looks like, it is essential to understand why compliance is important for your practice. Studies show that one out of every ten nurses will face some sort of drug or alcohol abuse disorder during their career¹. Physicians, Pharmacists, and other healthcare workers face similar realities due to the stressful nature of their profession and the ease of access to controlled substances. Realistically, it is not a matter of *if* you will detect diversion, but *when*. When diversion does occur, the extent in which you are compliant with federal and state regulations will directly impact the potential fines and penalties levied against your institution. Newsworthy diversion cases with large settlements are almost always coupled with non-compliance. Whether it was failure to maintain records appropriately, or not reporting theft/loss to the DEA in a timely manner, sanctions levied against the institution stretch far beyond just lapses in diversion monitoring efforts. The diverter is also liable to face civil penalties for their crimes, but those penalties are most often restricted to drug theft itself. Unless the diverter is the registrant, they are not responsible for controlled substance compliance and therefore not subject to the fines and sanctions associated with being non-compliant. To make matters worse, those seeking to divert drugs exploit the non-compliant practices as potential avenues of diversion. Diversion is inevitable in healthcare. Maintaining compliance, however, is completely within your control.

THE 3 R'S

Begin by reviewing the Code of Federal Regulations, Title 21, Chapter 2². Your state agency will also have statutes and regulations regarding controlled substance compliance. Keep in mind that the stricter rule always applies. For example, if your state agency requires five years of record keeping and the DEA only requires two, you are required to maintain five years of records².

Generally speaking, controlled substance compliance can be broken down into 3 R's; **Registration, Reporting, and Record Keeping**. The 3 R's are not all encompassing, but a great place to start your compliance journey.

REGISTRATION

Depending upon your practice setting (pharmacy, hospital, provider, etc.) there are different registration requirements. To lawfully purchase, dispense, and administer controlled substances you or your practice must be registered with the state and DEA. Each practice site is required to have its own registration for the specified business activity. Your business activity is going to be determined by the primary role of your business (retail pharmacy, distributor, manufacturing, research, etc.). Requirements of the registrant, including security against drug diversion, also fall within this category.

REPORTING

Reporting comes in the form of ordering (form 222), theft/loss (form 106), and destruction (form 41).

DEA Form 222: Executed order forms for schedule II controlled substances must be shared with the DEA on a monthly basis

DEA Form 106: Theft/Loss Reporting

Whenever theft or significant loss of controlled substances occurs, the registrant must report it to the DEA. Your state agency likely has requirements on reporting theft and loss to them as well. No matter how much was stolen, it must be reported. Defining significant loss is left open to interpretation and involves controlled substances that are unaccounted for but **not** stolen. Each registrant should have a policy that defines significant loss for their practice.

DEA Form 41: Disposal/Destruction of unwanted controlled substances

Defining 'unwanted' controlled substances is going to depend on the practice setting. Consider the following three scenarios you may encounter:

1. Dispensed by a pharmacy via a valid prescription to an ultimate user
2. Dispensed in a healthcare setting via a provider order for the purposes of direct administration
3. Inventory that was not dispensed to a patient and is unwanted (expired, recalled, etc.)

Each scenario has different requirements and only the last scenario is subject to a DEA Form 41. However, many registrants prefer to transfer unwanted inventory to a reverse distributor instead of filing a Form 41 with the DEA.

RECORD KEEPING

Every registrant shall maintain a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of (21 CFR § 1304.21). All records must be kept for at least two years per the DEA, although the state in which you are registered in may require longer. Violations of the recordkeeping requirements can result in penalties of up to \$15,040 for **each** violation³. This includes:

- DEA form 222 order forms
- Power of attorney authorizations and revocations
- Receipts and/or invoices
- Inventory records – every two years per DEA (state may require more frequently)
- Records of distribution
- Dispenses – via prescription or order
- Reports of theft or significant loss (DEA Form 106)
- Reports of destruction (DEA Form 41)
- DEA registration certificate
- Self-certification certificate and logbook as required under the Combat Methamphetamine Epidemic Act of 2005 (21 CFR § 1314.30)²

Now that the fundamental elements of controlled substance compliance have been identified, the next step is to determine *how* you are going to become and maintain compliant. From implementing policies and procedures, to

establishing systematic audits, compliance must be considered as an everyday priority. Contact a Trexin Advisor to see how we can help assess and improve your controlled substance compliance.

References

1. Kunk, D. (2015). Substance use disorders among registered nurses: prevalence, risks and perceptions in a disciplinary jurisdiction. *Journal of Nursing Management*, 22(1), 54–64.
2. Drug Enforcement Administration, Department of Justice, 21 C.F.R. § 1300- (2022).
3. Drug Abuse Prevention and Control, Prohibited Acts B, 21 U.S.C. 842 (2022).



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