



CONTROLLED SUBSTANCES COMPLIANCE CONSIDERATIONS

A White Paper for Public Safety Professionals

Controlled Substances Compliance Considerations

When evaluating your controlled substance program for compliance with regulatory requirements, agencies should focus on two areas: 1) The administrative requirements and 2) the operational flow. The administrative requirements include registration, security, recordkeeping, and the development and implementation of robust policies and procedures. The operational flow includes areas where controlled medications change hands and move through the organization.

When assessing your controlled substance compliance program, ask the following questions:

- 1** Is the controlled substance compliance program well designed?
- 2** Is the program being applied earnestly and in good faith? Is it being implemented effectively?
- 3** Does the controlled substance compliance program work in practice?

DID YOU KNOW?

According to the U.S. Department of Health and Human Services, 80% of heroin users reported misusing prescription opioids prior to heroin. Public safety agencies can offer support in this public health crisis not only with life-saving procedures, but also by ensuring the appropriate management of controlled substances. The methods your agency use to track records of controlled substances and manage their movement throughout your agency are crucial in the fight against the opioid epidemic. Additionally, your accurate data from opioid-related calls and usage of controlled substances during emergency response offers guidance to national research and prevention strategies.

(Understanding the Opioid Crisis - <https://www.hhs.gov/opioids/about-the-epidemic/>)

Administrative Requirements



Registration

The DEA requires that each site that stores or dispenses controlled substances be registered. In addition to the requirement for DEA registrations, many states impose their own requirements on public safety agencies that handle controlled substances. Although many state requirements closely follow the federal guidelines, some states impose more stringent requirements and may require registration with their own controlled substance regulatory body.



Security

The DEA requires that controlled substances be stored in a "securely locked, substantially constructed cabinet". There are no specific requirements for ambulance services beyond the general requirements, but there are many options available. Additionally, some states require alarm systems or closed-circuit TV monitors, so be sure to know the local requirements.



Recordkeeping

DEA regulations require stringent recordkeeping. Schedule II records must be maintained separately from other schedules and invoices, packing slips, and other ancillary purchase records that also require recordkeeping. Many states require records retention beyond the DEA two-year requirement. To ensure your agency's adherence to these standards, be mindful of additional local requirements.

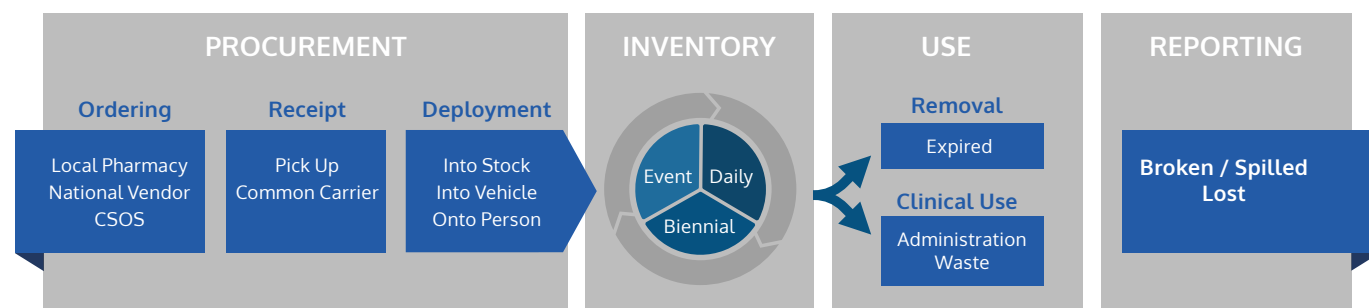


Policy & Procedure

Similar to other regulatory bodies, the DEA will expect your program to have comprehensive policies and procedures related to the administration and operational use of your controlled substances program. Just as important as having the policies and procedures in place, is following them. Be sure to establish an audit schedule to spot check your adherence to your own policies.

Operational Flow

Typically, controlled substances follow the same operational flow through most organizations. This operational flow includes six major transactions. All transactions should be performed by two clinicians, one performing the transaction, the second witnessing the use or handling of controlled substances.



Procurement

Ordering

Whether your agency utilizes a local partner hospital, a national vendor, or the Controlled Substances Ordering System (CSOS), there must exist a mechanism whereby you can procure controlled substances for clinical use.

Receipt

Once you receive your CS from your supplier, you will be required to place them into your inventory. This transaction requires you to complete DEA paperwork or online confirmations and document the amounts in your recordkeeping system. This is where records retention begins with finalized DEA form 222s, packing slips, invoices, and receipts. Schedule II records must be maintained separately from other medication records.

Deployment

Deployment refers to the mechanism by which you introduce controlled substances into operational use. Deploying controlled substances can be unique based on the operating environment and mission profile of the program. Be sure that the integrity of your controls remain intact during this phase.

Inventory

There are three categories of inventory. Daily, where controlled substances are accounted for by the members of the agency that will maintain custody throughout the operational period. Event, when there is a change in custody during the operational period or there is an introduction or removal of CS during this time. Lastly, biennial, where a separate and total inventory inspection is conducted once every two years (required by the DEA) and captures more information than the daily or event inventories.

Use

Removal

There will be occasions when you would need to remove controlled substances from your custody without administering them to a patient. Some examples are when a medication outdates or expires, when a stored vial is accidentally broken or spilled, and when you are transferring between locations (registrant locations).

Clinical Use

The reason we maintain controlled substances at our organizations is to provide care to our patients. We must record any use of the medication for our patients and record any waste of partially used doses drawn for patient use during transportation. Documentation of both the dose and volume must be recorded accurately and consistently.

Reporting

There are occasions when specific action or events must be reported to the myriad of regulatory bodies that monitor and control our use of schedule II controlled substances. Some event reporting that may occur includes theft or loss of controlled substances – or the unaccounted-for status of a controlled substance. Theft or loss of a controlled substance requires very specific DEA reporting and may require state-specific reports as well. Many of these reports are time sensitive. Some states require additional reporting regarding use, patient information, and others. Be sure to learn the requirements of the state you operate in.



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Managing controlled substances is simple and secure with the Vector Check It system for Fire and EMS departments. Using the application, you can track drugs as they move from storage to assigned apparatus to when they are administered to patients.

For more information on this product and other solutions for public safety agencies, contact us at 800.840.8046 or visit www.VectorSolutions.com