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Feature Article

Controlled Substances Compliance for Transport Programs

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A B S T R A C T

Transport programs are highly regulated health care organizations. Of the many imposers of regulations, those controlled by the Drug Enforcement Administration are some of the least understood by transport programs. This article serves to lift the regulatory fog surrounding controlled substances and to provide clear and actionable guidance to transport programs. Storage, security, and recordkeeping requirements for emergency medical service organizations can be confusing given that there are no specific regulations for emergency medical services. Transport programs are subject to all the current regulations, and nonadherence can result in significant fines and loss of public trust for any transport program found to be in violation.

President Nixon created the Drug Enforcement Administration (DEA) in 1973 as the agency tasked with regulating controlled substances that have a high potential for abuse.[1] Despite several revisions, the Controlled Substances Act[2] has no specific guidance directed at emergency medical services (EMS) organizations. The DEA recognizes practitioners and pharmacies and guides transactions associated with controlled substances for these entities. Because of the lack of specific regulation governing the use of controlled substances by EMS agencies,[3] many states have chosen to include EMS under the existing regulatory agencies within their own structures.

In a 2011 letter written to a Kentucky paramedic, the DEA asserted that the Controlled Substances Act did not allow for the dispensing of controlled substances under a standing order.[4] In 2014, DEA representatives announced that they would be imposing regulations that would effectively ban the use of standing orders. Transport providers regularly use controlled substances during our patient encounters and routinely under standing orders.[5] This interpretation would have significantly impacted our practice.

In 2017, the Protecting Patient Access to Emergency Medications Act (PPAEMA)[6] was passed into law. The PPAEMA materially changes EMS administration of controlled substances programs in the areas of registration, standing orders, storage, restocking, recordkeeping, and liability.

The PPAEMA was passed as an amendment to the Controlled Substances Act (21 U.S.C. 823).[7] The DEA has not yet adopted this law into their regulations. Under current White House Administration, every new federal regulation introduced must be accompanied by 2 regulations to be rescinded.[8] At the time of writing, it is expected that the DEA will release proposed rules based on the PPAEMA during March 2019. Many states maintain authorities having jurisdiction over EMS use of controlled substances, and changes to the federal statutes do not directly affect state law. Transport programs must adhere to both state and federal law when operating controlled substance programs.

Regardless of the enactment of new regulations, many of the monitoring and control mechanisms discussed in this article remain relevant. Current regulations and other useful guidance can be found at https://www.deadiversion.usdoj.gov/index.html. Transport programs wishing to store and dispense controlled substances must register with the DEA and state authorities (if applicable) to store and dispense controlled substances on behalf of their programs.[9] You can learn more about state-controlled substances authorities by visiting http://www.nascsa.org/.

Under DEA regulations, programs may register as a “midlevel practitioner–ambulance service” or “practitioner” by completing the online DEA 224 form. Some states restrict the use of “midlevel practitioner–ambulance service,” so be sure to consult the midlevel practitioners authorization by state[10] to ensure compliance in your state of

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operations. If a transport program elects to obtain a practitioner registration, then the medical director of the program registers an additional practice at the physical location of the program. A DEA registrant may designate agents to operate that program on his or her behalf. For an EMS service, this includes procuring medication, performing inventory, administering medications, and wasting leftover portions of drugs. Depending on the implementation of a particular transport program, leadership staff may fulfill some of these functions. Clinical staff (both nurses and paramedics) are then operating as the agent of the medical director when administering controlled medications to patients. All levels of practitioner using controlled substances are responsible for the storage, security, and recordkeeping of the medications entrusted to them.[11]

Transport programs are required to store scheduled medications in a securely locked, substantially constructed cabinet.[12] There are no specific manufacturer or physical property requirements described by the DEA, but there are multiple vendors that transport programs can use to ensure compliance. The adequacy of security controls is determined by the following factors[13]:

- The quantity of controlled substances handled
- The type of vault, safe, and secure enclosures or other storage systems
- The adequacy of key control systems and/or combination lock control systems
- The adequacy of supervision over employees having access to storage areas
- The adequacy of the registrant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations

Given the vague nature of "adequate controls," the DEA generally relies on current approved policy at the operations location when determining if controls are being followed. This practice is based on the assumption that the registrant (often the medical director) has reviewed and approved the policies and procedures governing a program. Operational and clinical leaders must ensure that the medical director is involved with developing, reviewing, and enforcing control practices.

Beyond maintaining "adequate controls," each transport program is responsible for the execution of 5 transactions involving controlled substances:

- Procurement
- Inventory
- Clinical administration and waste
- Reverse distribution and removal from inventory
- Report of loss or theft

Procurement

For this article, we will define procurement as the process by which controlled substances are obtained for clinical use. There are several options available to transport programs to procure scheduled medications. Here, we will discuss 3 of the most common.

Local Pharmacy Procurement

The transport program uses a local inpatient pharmacy from a health system to provide scheduled medications. For hospital-based programs, the transport program is treated like any other clinical unit in the hospital. For those programs storing and deploying medications from an off-campus location (ie, remote base away from the hospital campus), a separate DEA registration listing the physical address of the off-site base is required, even if the base is a property owned by the health system. The distribution of medications from a DEA-registered location to an unregistered site constitutes a violation of DEA regulation and could expose the program to fines.[14]

Community-based programs partnered with a health system are a separate legal entity and must maintain separate DEA registration documents even when colocated at the same physical address of the hospital. For community-based models that procure medications from a health system, DEA 222 forms (Fig. 1) must be completed for all schedule II medication transactions and thorough recordkeeping must accompany all other scheduled medication purchased. Community programs are also responsible for meeting the requirements for storage, security, and recordkeeping. Each location must maintain a DEA registration for the physical address where scheduled medications are stored and deployed.

For programs with multiple locations, each location is required to maintain its own DEA registration certificate. DEA 222 forms are specific to the registration number and are used to order *only* for the address listed on the certificate. This means registered sites can only order scheduled medications for their location. The transfer of scheduled medications between registrant locations is highly restricted, and transfers that exceed the restrictions are considered illegal distribution of controlled substances; this violation carries the risk of significant fines.

Distributor Procurement: 222 Forms

Procurement can also occur by using a number of national distributors of controlled medications. Each distributor will have a unique process of validation before they supply scheduled medications. For programs that do not have a local pharmacy partner to procure scheduled medications, this is the next best option. This option requires that the DEA 222 form be completed, mailed to the distributor, reviewed and validated, and the order filled and shipped. This can cause delays in delivery that should be considered.

Distributor Procurement: Controlled Substances Ordering System

The third option for procurement is the use of the Controlled Substances Ordering System (CSOS), which allows the program to communicate an order directly to a registered distributor via a secure paperless system. CSOS allows for electronic ordering, error reduction, data integrity, and recordkeeping through a DEA-supported program. CSOS may also expedite the arrival of controlled substances by reducing or eliminating many of the delays inherent in the 222 process.

Procurement includes the mechanisms by which a service obtains medications and how the medication is entered into recordkeeping systems. Procured medications should be entered into inventory as soon as possible after receipt. All transactions involving controlled substances should be conducted by 2 employees. When entering

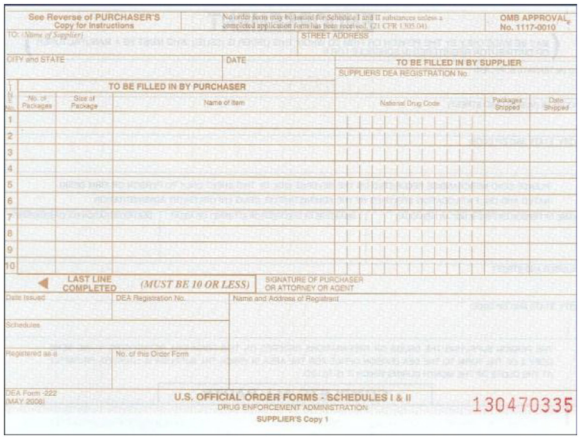

Figure 1. DEA Form 222.

controlled medications into inventory, the transport program must retain all associated documents. These documents include DEA Form 222 (do not forget to finalize the 222 by completing the number of packages and the date received sections on copy 3 of the form), any vendor packing slips, and order forms for non–schedule II medications. These records should be dated, initialed, and placed into secure storage available for inspection by any regulator that may ask for them. Schedule II records must be stored separately from those pertaining to schedule III-V as well as the business records of the service. Ideally, records will indicate what was ordered, what was shipped, and what was received.

Transport programs must examine their environment when deciding which method of procurement works best. As programs grow in complexity and geographic distribution, movement toward centralized DEA-approved systems becomes increasingly attractive for monitoring and control over controlled substance systems.

Inventory

Inventory is the recording of controlled substances on hand at a registered location. Transport program clinicians are used to recording inventory once per shift. The DEA does not stipulate how often you will conduct inventory counts, except to require a biennial on-hand inventory of scheduled medications.[15] This is separate from daily count and must document schedule II medications independently. This on-hand inventory may be performed electronically but must be printed and signed before being filed. Inventory, like every other transaction, should be completed with a second person serving as a witness. Inventory should specifically include those crewmembers who are receiving the medications, as well as those who are relinquishing custody. Programs must determine whether there is a specific crewmember by discipline (registered nurse, registered respiratory therapist, or nationally registered paramedic (NRP)) who is responsible for the custody of controlled substances. There may be a more stringent requirement imposed by a state authority in the operating area. Each transport program must understand state requirements for controlled substance use by EMS.

Administration and Waste

Administration should be documented in a log indicating the medication used, dose, and any medication wasted during patient care. Waste documentation should include both the dose and the volume wasted. State requirements may dictate maintenance of additional data fields such as patient name, address, and social security number.

The log serves as a ledger of all transactions involving scheduled medications, including the addition of stock, daily and biennial inventory counts, clinical administration, removal of stock from inventory (including breakage and spillage, reverse distribution, and transfer), and, finally, the report of loss and theft. All transactions should be performed with 2 program clinicians present, and both should sign the log. Be sure to include clinical credentials after each signature in the log.

Reverse Distribution and Removal From Inventory

Reverse distribution and removing stock from inventory require the completion of specific DEA forms depending on the circumstances under which the medication is being removed. Remember the scheduled medication is assigned to the DEA registered location, not an individual or program. The most common reason a program would remove medications from inventory would be outdating or expiration. Some medications are required to be discarded after a time-out of refrigeration regardless of the expiration date. Expired medications are relinquished to a reverse distributor licensed by the DEA.[16] There are many vendors available to choose from, and they have made the reverse distribution process exceptionally easy.

There may be occasions when a vial(s) of a scheduled medication suffers inadvertent destruction. Vials and ampules that are dropped can break and spill. After breaking a vial, the medication cannot be retrieved for reverse distribution but must be accounted for in inventory. The DEA requires that scheduled destroyed medications, including those inadvertently broken, be accounted for on a DEA Form 41 (Fig. 2). It should be noted that a DEA Form 41 should not be used for reverse distributed medications and is not required for the waste of unused portions of controlled medication left over after patient administration.[17]

The transfer of scheduled medication between DEA registrant locations is highly regulated and significantly restricted. The DEA allows for no more than 5% of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.[18] Transfers of schedule II medications require the completion of DEA Form 222.[19] Transport programs must ensure that they are in compliance with state regulations regarding the transfer of controlled substances.

Reporting Loss or Theft

When conducting shift inventory and clinicians identify that the count of scheduled medications is incorrect, a discrepancy must be noted and specific actions taken to ensure regulatory compliance. For medication to be considered "lost," it must be unaccounted for. A broken vial does not constitute a loss if its whereabouts are known. A lost medication is unaccounted for and cannot be located. Whether because of inadvertent loss or theft, this requires the transport program to meet several reporting requirements including the completion of a DEA Form 106 (Fig. 3).

Any reasonable suspicion of theft of controlled medications must be reported. A loss of scheduled medication may also require that the program report the loss to their local DEA office. A program

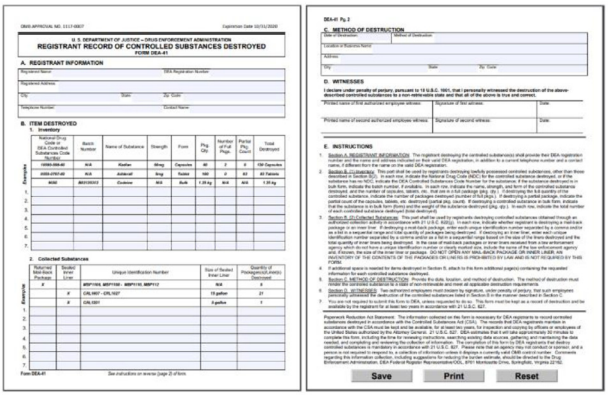

Figure 2. DEA Form 41.

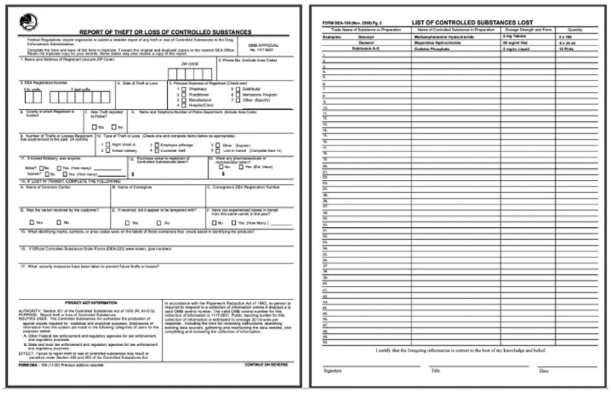

Figure 3. DEA Form 106.

Figure 4. Crew-carried controlled substances.

representative must attempt to speak to someone directly. Be sure to record the date and time of all reporting attempts. This report must occur within 1 business day of determining that a loss occurred. DEA regulations state that the "significance" of the loss is determined by the registrant.[20] In the opinion of the authors, any loss of controlled substances is significant enough to warrant investigative and reporting action, but each registrant will need to weigh this statement against the risk of their interpretation of "significant" differing from that of the local DEA office.

Crew-carried controlled substances (Fig. 4), a routine practice in many areas of the country, can represent a risk to the program. If medical crewmembers carry controlled substances on their person, there exists an elevated risk of diversion. Crew-carried controlled substances, although operationally convenient, create an environment where crewmembers may be able to isolate themselves with their medications. This unaccompanied time presents an opportunity for diversion.

There are many ways to decrease the risk of theft or loss by implementing several controls to your crew-carried containers. These containers should be as follows:

- Rigid on all sides (a rigid container protects the vials from compression forces exerted during carry
- Protect each vial using foam that prevents vial to vial contact (foam separation prevents cap removal or vial destruction from item to item contact)
- Clear to allow for the immediate recognition of missing contents (visual inspection of contents results in timely identification of missing items)
- Sealed using a numbered inventory control tag (creates a recorded number and physical barrier that must be overcome to access the contents)

Controlled substances are a fundamental part of any transport program's operations. Adherence to applicable laws and regulations ensures our programs will have access to controlled substances for our patients for many years to come.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amj.2019.06.007.

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