Proper Drug Security for the Fairborn FD

Adam D. Howard

University of Cincinnati

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Author Note

This paper was prepared for the course on EMS Legal FST3093, taught by Professor Lawrence Bennett.
Certification Statement

I hereby certify that this paper constitutes my own product, that where the language of others is set forth, quotation marks so indicate, and that appropriate credit is given where I have used the language, ideas, expressions, or writings of another.

Signed: ____________________________________

Adam D. Howard
Abstract

The Ohio State Board of Pharmacy, the Ohio Revised Code, and the Ohio Administrative Code establish the laws and regulations that EMS organizations must follow if they desire to stock and store drugs, which are used in the delivery of emergency medical care within the community. EMS organizations must apply for and maintain a license, issued by the Pharmacy Board, to acquire and distribute dangerous drugs. The medical director is considered the responsible party for the drug license, however they may delegate the day-to-day tasks to an EMS provider within the organization, who holds an appropriate certification. To maintain the drug license, the EMS organization must ensure that the drugs are securely stored in a tamper-evident setting with limited access, to only certified personnel.

The Fairborn Fire Department’s current drug security and storage system is well established but still has a few deficiencies. The majority of dangerous drugs that are handled by the FFD are inclusive within a hospital based drug bag exchange program. However, the FFD also maintains a number of other dangerous drugs, which are purchased and stored separately. Current challenges within the FFD’s drug security and storage system includes the lack of security of 10mL IV flushes and an inefficient tracking system, which is required to provide drug accountability records. This document explores all of the security and storage requirements, as well as recommendations for the improvement of the FFD’s current system, to ensure full compliance with the state laws and regulations.
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Background

The Ohio State Board of Pharmacy is the single State agency in Ohio responsible for administering and enforcing laws governing the legal distribution of drugs (Ohio State Board of Pharmacy, 2013). The Ohio State Board of Pharmacy is granted such authority by Ohio Revised Code 4729 *Pharmacists: Dangerous Drugs*. From this point forward within this document, I will use the abbreviated and commonly accepted term of the “Pharmacy Board”, in reference to the Ohio State Board of Pharmacy. The Ohio Administrative Code 4729-33-02 states that any emergency medical service (EMS) organization that desires to stock dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs. There are six different categories of terminal distributor of dangerous drugs (TDDD) licenses issued by the Pharmacy Board. EMS organizations only qualify for limited category TDDD licensing, which includes: Limited Category I, Limited Category II, or Limited Category III. A Limited Category III TDDD license is required to handle and distribute any controlled substance, which are classified into schedules as defined within Title 21 United States Code. There are five distinct categories or schedules depending upon the drug’s acceptable medical use and the drug’s abuse or dependency potential (Drug Enforcement Administration, n.d.). Therefore, all EMS organizations that provide advanced life support (ALS) level service will likely require a Limited Category III TDDD license. Each location, headquarters and satellites, must be licensed as a limited terminal distributor of dangerous drugs and must maintain a current terminal distributor of dangerous drugs license and drug addendum. The one location that serves as the main station will be deemed the headquarters location. Any other locations associated with this headquarters where
dangerous drugs will be stored will be licensed as "satellites". A medical director may add or delete dangerous drugs from the drug license and drug addendum by submitting revised, signed and notarized protocols and list of medications (LAWriter Ohio Laws and Rules, n.d.).

Responsibility

There is a multitude of data required within the TDDD license application. One specific requirement is the identification of the responsible person, designated as the person who will maintain supervision and control over the possession and custody of such dangerous drugs that may be acquired and utilized by the licensee (LAWriter Ohio Laws and Rules, 2009). The responsible person must be a physician or pharmacist; for EMS organizations this individual will be their medical director. However, the responsible person may delegate the day-to-day tasks to the EMS organization personnel who hold appropriate certification to access the dangerous drugs for which they are responsible (LAWriter Ohio Laws and Rules, n.d.). Additionally, a list of personnel employed by the EMS organization who may access and administer dangerous drugs, which includes the name of the individual, level of certification, their certification number, and expiration date must also be included with the TDDD license applications. Any change of personnel requires a letter from the organization within thirty days of the change. EMS organizations and personnel that handle and distribute controlled substances and dangerous drugs, must meet the security and storage requirements as defined by Ohio Administrative Code Chapter 4729-33 Emergency Medical Services. Controlled substances were previously defined. Dangerous drugs are loosely defined as essentially any drug intended for administration by injection into the human body other than through a natural orifice of the human body.
Consequently, intravenous (IV) solutions are classified as dangerous drugs, even though they are nothing more than salt water.

**Drug Security & Storage Regulations**

Ohio EMS organizations are tasked with the responsibility of maintaining proper security and storage of all dangerous drugs, which encompasses the entire scale from schedule II narcotics, such as morphine, to normal saline IV solutions. The Ohio Administrative Code 4729-33 *Emergency Medical Services* states that “all dangerous drugs must be secured in a tamper-evident setting with access limited to EMS personnel based on their certification status except for sealed, tamper-evident solutions labeled for irrigation use. All registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs”. Tamper-evident is defined, by the Ohio Administrative Code, as the package being sealed in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made. Any dangerous drug showing evidence of damage or tampering shall be removed from stock and replaced immediately. Any loss or theft of dangerous drugs must be reported upon discovery, by telephone, to the Pharmacy Board, local law enforcement and, if controlled substances are involved, to the Drug Enforcement Administration (DEA). In addition to maintaining proper security and storage of dangerous drugs, the EMS organization must also keep complete and accurate records for at least three years of receipt, use, administration, destruction, and waste of dangerous drugs. These records must be readily available for inspection by Pharmacy Board agents or inspectors (LAWriter Ohio Laws and Rules, n.d.). Over recent time, Ohio EMS organizations have received unannounced visits from Pharmacy Board field agents, who have attempted to gain unauthorized access to
dangerous drugs located in unlocked ambulances and fixed EMS facilities. These dangerous drug are essential to core functions of EMS delivery, to provide proper medical treatment to the community in which they serve. Therefore, EMS organizations must protect and maintain their TDDD license, so that they can continue to acquire and distribute these dangerous drugs. To do so, they must establish effective internal systems to meet the security and storage requirements, set forth by the Ohio Administrative Code and as enforce by the Pharmacy Board. Such internal systems must be routinely monitored and revised to ensure continued compliance.

FFD Current Drug Security & Storage System

The Fairborn Fire Department’s (FFD) current drug security and storage system has evolved over time, with minor updates and changes being made along the way. The majority of dangerous drugs that are handled by the FFD are inclusive within the Greater Miami Valley EMS Council’s (GMVEMSC) drug bag exchange program. This is a regional 1:1 drug exchange system that has been coordinated with the Greater Dayton Area Hospital Association (GDAHA). The GMVEMSC purchased standard compartmentalized bags to carry all the drugs required by the regional EMS protocols, at all provider levels. The bags were stocked and distributed to all participating EMS organizations within the region. The drugs are specifically arranged to limit access to providers who hold the appropriate certification necessary. For example, drugs permitted to be administered by EMT-Basics are stocked within a separate compartment from those limited to administration by providers with higher certification levels and so on. Once any compartment of the drug bag is accessed in the field, by the EMS providers, the entire bag is exchanged at the receiving hospital. Each separate compartment of the drug bag is sealed with a tamper-evident tag, which includes a label that identifies the soonest expiration date of the drug
within and identifying information from the pharmacy that last stocked the compartment. Blue colored tags are used for drug bag compartments that have been stocked and ready for use. Red colored tags are used by the EMS provider after they access the drugs that they need from the compartment, to ensure the security of the remaining contents. When the EMS provider exchanges the drug bag with the hospital, they complete a paper report which requires documentation which generally includes the following information: the drugs used, date, patient name, EMS provider name, EMS agency affiliation, and certification level. If a controlled substance was administered or accessed there are some additional reporting requirements on the report. Once completed the paper report is attached to the sealed drug bag and forwarded to the hospital pharmacy for restocking.

With the FFD, these GMVEMSC drug bags are secured and stored utilizing a couple of different methods, depending upon the apparatus. All front-line medic units and fire apparatus are ALS equipped and therefore each carry a drug bag. The older medic units and the fire apparatus simply use a combination bicycle cable lock as a means to secure the bag to the vehicle. The cable lock is passed through a substantial mount, such as an eyebolt, and then through the attached carrying handles of the drug bag. However, newer medic units have been specifically designed to include a locking cabinet within the interior patient care compartment, to security store the drug bag. These locking cabinets are most recently equipped with remote electronic key pad locking systems. All of the locking cabinets and cable locks share a common security code among all members of the organization.

In addition to the GMVEMSC drug bags, the FFD also maintains a number of other dangerous drugs, which are stored separately. These other drugs include: rapid sequence intubation (RSI) drugs, Dextrose 10%, normal saline irrigation bottles, normal saline IV flushes,
and normal saline fluid bags in various sizes. RSI is not an inclusive procedure within the regional EMS protocol. Therefore, the drugs required to perform this procedure are not included within the GMVEMSC drug bags. So the FFD purchases these drugs separately from a third-party distributor, which include three separate drugs: Etomidate, Succinylcholine, and Vecuronium. These drugs are currently only carried on the front-line medic units, within a difficult airway bag. Inside the difficult airway bag we securely store these three drugs in a clear Otter Box case that is sealed with a tamper-evident tag. The FFD also purchases Dextrose 10% from a third-party distributor. While Dextrose 10% is included within the region protocol and GMVEMSC drug bags, it is common for crews to treat patients with it and release them without transport to a hospital. Therefore, by stocking our own supply we can keep our EMS crews in service more often by reducing trips to the hospital simply to exchange drug bags due to the usage of Dextrose 10%. The Dextrose 10% is carried on all front-line apparatus and is stored in a rear compartment of our first-in bag. This compartment is also sealed with a tamper-evident tag.

Normal saline is carried by the FFD in a number of different forms, which include: 500mL irrigation bottles, 10mL prepackaged IV flushes, 250mL bags, 500mL bags, normal temperature 1000mL bags, and cold 1000mL bags. The irrigation saline bottles are carried on all medic units and stored in an unlocked compartment, which is permissible by the Ohio Administrative Code because they are tamper-evident sealed by the manufacturer and labeled for irrigation use. The 10mL prepackaged IV flushes are carried on all medic units and front-line fire apparatus. These flushes are currently stored in an unsecured fashion in an IV slide out cabinet within the patient care compartment of the medic units and inside a front compartment of the first-in bags. The Ohio Administrative Code does require these 10mL prepackaged IV flushes to
be secured like any other dangerous drug, with a tamper-evident system. However, the current FFD drug security and storage system is deficient in meeting this requirement.

The FFD maintains a number of 250mL and 1000mL bags of normal saline stored at room temperature. These saline bags are carried on all front-line medic units and fire apparatus. There is one 1000mL bag inside the same sealed compartment as the Dextrose 10%, within the first-in bags. Each medic unit carries additional 250mL and 1000mL bags inside an IV fluid bag that is sealed with tamper-evident tags. The IV fluid bag also has separate compartments for the two different sized bags, which are sealed separately. These IV fluid bags are also stored in the same locking cabinet as the GMVEMSC drug bag, within the patient care compartment of the medic units. The FFD also carries a 500mL bag of normal saline in the top compartment of the pediatric bag, which is sealed with a tamper-evident tag. These pediatric bags are carried on all front-line medic units and fire apparatus. The pediatric bags are not locked or secured to the apparatus, as they are not required to be. Lastly, the FFD also carries two or more bags of cold 1000mL bags of normal saline. These are used primarily for a newer protocol designed to induce hypothermia in a cardiac arrest patient. Originally these bags were simply placed in an Igloo cooler along with ice bricks to keep them cold. Due to the constant requirement to rotate out the ice bricks and fluid bags to keep them at the proper temperature, these coolers were not locked or sealed. However, this was a violation of the Ohio Administrative Code regarding security of dangerous drugs. Newer medic units are now being specifically designed to include an onboard refrigerator for this purpose. However, two of the older front-line medics had to be upgraded with portable electronic cooler systems, manufactured by Engel. These onboard refrigerators and portable coolers were modified with hasp locks so that they could be sealed with tamper-evident tags. Securing these systems with a lock and seal is much more practical because the fluid bags
are maintained at a constant temperature and access is only required for use, rather than on a routine basis to maintain the temperature.

The FFD uses a paper and three-ring binder system, called a drug log, in the attempt to maintain the required complete and accurate records of receipt, use, administration, destruction, and waste of dangerous drugs. There are specific tracking sheets for each of the dangerous drugs carried, which are not included within the GMVEMSC drug bag exchange system and purchased directly through third-party distributors (Appendix A). While this system works in theory, there have been several challenges discovered. One challenge is that these paper documents are susceptible to damaged and occasionally become lost. Another challenge is that data input can be time consuming and difficult for the EMS provider to perform accurately. During a medical emergency it is not uncommon to have multiple providers accessing different drugs from different locations. The EMS provider tasked with restocking the equipment after the incident has concluded is required to complete the drug log. Unfortunately, this provider is commonly left with incomplete information and missing tamper-evident tags to accurately document the access of the drugs. On occasion the pages from the drug logs are cleared out and collected, which are then filed and retained in the Battalion Chief’s office for a three year period, as required by the Pharmacy Board.

Current System Challenges

From the information presented above, you can see that the FFD has some challenges with meeting all drug security and storage requirements, which are established in the Ohio Administrative Code and enforced by the Pharmacy Board. The most significant system deficiency is the lack of security of the 10mL prepackaged normal saline IV flushes. These are
considered a dangerous drug and therefore are required to be secured in a tamper-evident setting with access limited to EMS personnel based on their certification status. However, the Pharmacy Board has created some confusion with a document that they released on July 23, 2012 titled *EMS Frequently Asked Questions*. Within this document the Pharmacy Board states that IV solutions “must be stored and secured with a tamper-evident seal or locked with keys that are only accessible to authorized licensed EMS personnel”. The confusion surrounds the idea of locking the IV solutions with a key. The Ohio Administrative Code requires that all dangerous drugs, which includes IV solutions, must be secured in a tamper-evident setting. They further define tamper-evident, as the package is sealed in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made. Therefore, simply securing the IV solutions with a key lock seems to be in conflict with the requirement for tamper-evident security. An unauthorized person could practically use the key to access the dangerous drug and then simply relock the compartment, leaving no visible proof of such access.

Accurately tracking, monitoring, and documenting the inventory of dangerous drug within the FFD presents another significant challenge. Technically the FFD should be able to produce records from purchase and acceptance of a dangerous drug, all the way through to the administration or waste of that drug. Drugs that are purchased by the FFD through third-party vendors travel an extensive path through the organization with very little oversight or tracking. When the drugs are first received they are stocked into the main supply room, which is located at Fire Station #1 in a secure room. The drugs are then distributed to each of the other fire stations, typically by the Battalion Chief, upon request through an EMS inventory acquisition form. Each fire station has a remote EMS supply room that is locked and secure. As needed, EMS providers
will move the drugs from the station’s EMS supply room and onto the apparatus. Finally, the drugs are either administered to a patient during EMS care or they are wasted after they reach their expiration date. While there are likely some means of tracking the movement of these drugs throughout the organization, documentation of this movement is not clear and obvious.

Recommendations

I recommend that the FFD make two significant updates to the current drug security and storage system, to ensure full compliance with the Ohio Revised Code, Ohio Administrative Code, and the Pharmacy Board. The primary recommendation is to store all of the 10mL prepackaged normal saline IV flushes in a manner that ensures tamper-evident security. In my opinion the best way to achieve this level of security is to compartmentalize the IV flushes so they can be secured separate from other supplies. The current practice within the FFD is to store all IV flushes loosely with other IV supplies. The department should purchase small pouches that have dual zippers or another means to seal with a tamper-evident tag and place all of the IV flushes inside them. Each first-in bag will need an IV flush pouch, as well as each front-line medic unit for the IV slide out cabinet. Then an additional sheet can be created to track the IV flushes and be incorporated into the current drug log. This new system will certainly take more time during the restocking phase, however it will ensure full compliance with the secure storage of the dangerous drug.

The secondary recommendation for the FFD drug security and storage system, is to implement an inventory management system to properly track all drugs as they move throughout the organization. There are information technologies (IT) that could potentially be purchased for direct application or modified to meet the needs of this system. I envision the usage of bar codes
or more modern QR codes for tracking the drugs as inventory. When new drugs are purchase or
placed within the organization they should be tagged with a stick-on code. That code should then
be scanned by the individual that is placing the drug into inventory. Given current technology, I
image the code scanning could potentially be conducted through a devices as simple and
common as smartphone utilizing an app. Each time the drug is moved through the organizations
it would be scanned to update its current location and handling. The inventory management
database should include data for who has handled the drug, status, location tracking, and
expiration date. The database would likely need to be internet cloud-based, to allow for access
and data input from any location. This system should replace the current antiquated three-ring
binder logbooks, for drug tracking. The inventory management system would need the capability
to print reports, including current inventories and other specific reports as requested by the
Pharmacy Board. After a search on the internet I came across a few inventory management
systems that are showing some potential for serving this need. One of those systems is called
eyeKnowTracking and another one was Operative IQ. The challenge will be ensuring that
whatever inventory management system is utilized, that it will meet all of the unique needs of the
organization, be affordable, reliable, quick, and easy to use.
References


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This record must be retained for 3 years.

PROPER DRUG SECURITY FOR THE FAIRBORN FD
## Proper Drug Security for the Fairborn FD

This record must be retained for 3 years.

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RFD Pediatric Drug Log

Howard 20