EMS Drug Kit Update

Panelists/Presenters

Michael Player
PEMS Executive Director, Co-Chair of Regional EMS Medication Kit Transition Workgroup

David Long
TEMS Executive Director, Member of Regional EMS Medication Kit Transition Workgroup

Brian Frankel
Stafford County Assistant Chief of Operations, VFCA Representative on State EMS Advisory Board, VFCA Representative on Regional EMS Medication Kit Transition Workgroup, Chair of Purchasing Tool Team

Ryan Ashe
James City County Fire Chief, VFCA Representative on Regional EMS Medication Kit Transition Workgroup, Chair of Policy and Procedures Tool Team

Cindy Williams
Chief Pharmacy Officer of Riverside Health System and Co-Chair of the Regional EMS Medication Kit Transition Workgroup.

Regulatory Background

Protecting Patient Access to Emergency Medications Act (PPAEMA) of 2017 (DEA)

Amends Section 33 of the Controlled Substance Act (CSA) to include EMS requirements

An EMS agency must adhere to 3 regulations to stay compliant with federal law:

- The storage of these controlled substances must be at a registered agency or in a designated vehicle from the agency.
- During delivery, an agency with a DEA registration must deliver the controlled substances to EMS.
- Record keeping for these controlled substances can be done either electronically or on paper, but the approach must be specified and the records kept in a designated area.

DEA published proposed regulations per the Act in 2020

Final rule is still pending. Per Caroline Juran, Executive Director Virginia Board of Pharmacy, rule has been finalized andwaiting authorization to publish. Does not anticipate major language/content change.

Protecting Patient Access to Emergency Medications Act (PPAEMA) - Tenants

1. Allows EMS agencies to receive their own DEA registration to administer controlled substances.

- A. Hospital-based emergency medical services agency registered under may use the registration of the hospital to administer controlled substances without requiring the agency to acquire a separate registration

2. EMS agencies that service multiple states will need DEA registrations for each of those states

3. Allows EMS agencies to administer medications with a standing order

4. EMS agencies may store controlled substances in the agency location registered with the DEA, unregistered locations, and in EMS vehicles used by the agency.

- Allows for “hub and spoke” model with a single DEA for the primary location.

Virginia EMS Kit Exchange and Proposed DEA Regulation Impact

Proposed DEA Regulations:

A private emergency medical service may enter into a formal written agreement with *one specific hospital* to supply the EMS unit with a prepared emergency kit and replenish the kit as necessary *only at that hospital.*

- Example: York County can enter into a formal written agreement with Sentara Williamsburg Hospital and can only exchange the box at that location, regardless of where the patient is transported.
- Feedback from several EMS agencies that model would result in lost response time due to the need to travel for box exchange, therefore not seen as a viable option
- Feedback from hospitals that they lack the storage and resources to accommodate individual boxes for each EMS agency with which they contract if more than one.

Protecting Patient Access to Emergency Medications Act (PPAEMA) of 2017 (DEA): 1:1 Replenishment

Following an emergency response where controlled substances were administered,**EMS personnel may not have enough time to return to their stationhouse** to restock their EMS vehicle with controlled substances.

Thus, the Act allows non-hospital based EMS agencies to receive controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response (1:1 replenishment)

- **Still requires the agency to hold a DEA license since considered a "transfer" of ownership**
- **1:1 replenishment of CII-V medications not currently allowed under Virginia Board of Pharmacy regulation, but could be requested**
- Designated locations of an **EMS agency must notify the registered location of their EMS agency within 72 hours of receiving controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response.**
- **Unclear of additional record keeping requirements/reporting to the DEA for EMS agency or hospital**
- **Does not remove FDA DSCSA track and trace requirements for dispenser (Hospital)**

FDA Drug Supply Chain Security Act (DSCSA) Considerations for Ambulance Restocking

Approved in 2013

Enforcement date = 11/27/24

FDA does not intend to take action against a dispenser (pharmacy) who **transfers ownership** of product directly to a first responder where the dispenser does not provide the first responder with product tracing information (i.e., a transaction information, transaction history, and transaction statement) provided that:

- The **dispenser captures and maintains** the product tracing information for such transaction (including the creation of the product tracing information, prior to, at the time of transaction, or, if necessary shortly thereafter) for not less than **six years** after the transaction
- The dispenser **provides such product tracing information** to the first responder or Secretary, if requested, **not later than two business days after receiving the request** or in such other reasonable time as determined by the Secretary, based on the circumstances of the request.

FDA also does not intend to take action against a trading partner that transfers ownership of a product to a first responder who is not “authorized” as a dispenser

Drug Supply Chain Security Act (DSCSA) Considerations for Ambulance Restocking

FDA does not intend to take action against a first responder who:

- Accepts ownership of product without first receiving the product tracing information, and does not capture and maintain product tracing information as required by section
- Does not have systems in place to enable the verification of suspect and illegitimate product

- If a first responder believes it has received suspect or illegitimate product, FDA strongly recommends that the first responder take steps to protect patients from receiving illegitimate product, which includes quarantine and investigation of such product, contacting appropriate authorities, and working with the previous owner to prevent further distribution of such product.
- This compliance policy does not extend to the other requirements, including the requirement that the first responder conduct business only with authorized trading partners.

The Anti-Kickback Statute and Ambulance Restocking

Anti-Kickback Statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce the referral of business by a federal health care program.

Ambulance restocking arrangements implicate the anti-kickback statute because the receiving hospital gives something of value (drugs or medical supplies) to a potential source of Federal health care program business – ambulance providers that deliver patients to the hospital.

The Anti-Kickback Statute and Ambulance Restocking

Department of Health and Human Services (HHS) published a final rule in the December 4, 2001 issue of the Federal Register, describing safe-harbor protections for ambulance restocking

- The receiving facility must restock drugs or supplies on an equal basis for ambulance providers in one or more of three categories: all ambulance providers; all non-profit and governmental providers or all non-charging providers (typically volunteer and municipal providers)
- The restocking must be conducted publicly.
  - To be considered conducted publicly the arrangement is memorialized in a conspicuously posted writing that outlines the terms of the restocking program or the restocking program operates in accordance with a plan or protocol of general application by an EMS council.
  - The first condition may be achieved by posting a written disclosure notice at the receiving facility, with copies available to the public upon request.
- If drugs are **sold** to the ambulance authority, it must be at fair market value
- A written agreement between the two parties must be in place

The Anti-Kickback Statute and Ambulance Restocking

There are four conditions that apply to all three of the categories:

1. The ambulance provider and the hospital may not both bill for the same restocked drug or supply.
2. Either the hospital or the ambulance provider may generate the necessary documentation, so long as the other party receives and maintains a copy for 5 years which is consistent with the recordkeeping requirements of the CMS)
    1. This document is usually referred to as a trip or run sheet, where patient care during the transport is recorded. This information must include patient information, drugs and supplies used on the patient.
3. No ties to referrals.
4. Compliance with all other Federal, State and local laws, including the handling of controlled substances.

Future options for EMS drug kit replenishment to meet DEA/FDA/BOP

1. The current full box exchange would meet FDA DSCSA and DEA requirements only if an EMS agency solely transfers with a single hospital – based on feedback, this does not seem feasible for either agencies or hospitals.

2. 1:1 replenishment of medications used in emergency transport of patient to receiving facility. This concept is acceptable under both FDA DSCSA and DEA final rule, but is subject to hospitals being able to maintain required records for 6 years and supply within 2 business days of request OR receive waiver/exception/exemption from FDA. Process will still require EMS agency to obtain CSR/DEA and to potentially obtain and supply medications (expired, etc). Willingness to participate in 1:1 replenishment will be a hospital decision.

3. EMS agency takes responsibility for purchase, fill and maintenance of all medications contained in kit.

Update from 3/28/24 Board of Pharmacy Meeting

- Board published draft Emergency Regulation prior to meeting
- Both written and public comments provided by stakeholders, with majority from EMS providers
- Board voted as below
  - Confirmed need for emergency regulations to provide clarity and reduce burden of Virginia Board of Pharmacy regulations regarding EMS providers and Controlled Substance Registration
  - Due to time critical nature of situation, will convert May 2, 2024 Legislative committee into full board meeting.
  - Draft language for emergency regulations to be available prior to the meeting to allow for review and submission of written (requested by April 30, 2024) and verbal public comment
  - Goal to finalize emergency regulation at May 2, 2024 meeting
  - Emergency regulations in place for 18 months with ability to extend
  - Full Notice of Intent for Regulatory Action to be issued prior to final regulations being adopted

Regional EMS Medication Kit Transition Workgroup/ PEMS Initiatives

MICHAEL PLAYER

Regional EMS Medication Kit Transition Workgroup

- Virginia EMS Councils
- Virginia Department of Health, Office of EMS
- State EMS Advisory Board
- Virginia Board of Pharmacy
- Virginia Hospital and Healthcare Association
- Virginia Association of Volunteers Rescue Squads
- Virginia Fire Chiefs Association
- Virginia Association of Government EMS Administrators

Goal of the Workgroup

Multi-Agency/Stakeholder Workgroup

- Collaborative process to develop information and tools to assist EMS agencies transition to a future state with their medication kits that will meet regulatory requirements, recognizing that there will probably not be a “one-size fits all” solution.
- Focus is to maintain the integrity of EMS services and access to medications throughout the Commonwealth

Workgroup Progress

- Discussed Current, Pending and as Yet Unknown Regulatory Environment forcing Change
  - BOP
  - DEA – Protecting Patient Access to Emergency Medications Act (PPAEMA)
  - FDA – Drug Supply Chain Security Act (DSCSA)
  - CMS – Anti-Kickback Statute (AKS)
- Discussed Challenges of Compliance Timeline with regard to Funding and Change Program Development and Implementation
- Discussed Potential Impacts to established Patient Care standards/Regional Patient Care Delivery Systems if Change Process Not Managed Well
- Explored Virginia Health Systems to Participate in a Transition Program (Y/N, 1-2 or More Years)
- Discussed Current EMS Medication Kit Programs and Variations of EMS Medication Procurement
- Discussed Compliant Program Options/Timeline for Workgroup
  - Recommendations/Tools as soon as possible to allow time for implementation
  - May - Absolute Deadline

Workgroup Progress

- Discussed Options for a Compliant Hospital 1:1 Exchange Program of Class VI Medications as a 1-2 Year Transition to full EMS ownership of medication procurement/restocking
- Discussed Options for group purchasing of medications by EMS agencies.
- Developed and Disseminated Recommendation
  - EMS Agencies obtain CSR/EMS Agency DEA
  - Regional Councils Develop a 1:1 CVI Medication Exchange Program between hospitals and EMS Agencies as an intermediate step if such a practice can be in compliance with FDA DSCSA and can be operationalized with current DSCSA software capabilities. Hospitals Provide 1:1 CVI Medication Exchange for Patients Treated and Transported to the Hospital
  - EMS Agencies Purchase CII-V, VI Medications
    - EMS Agencies Replace CVI Medications for Patients Treated/ and Not Transported
    - EMS Agencies Replace CVI Medications expired in kits/storage
    - EMS Agencies Replace CII-V Medications

Workgroup Progress

- The workgroup has also assembled toolkit teams to create tools to assist EMS agencies in the transition. The toolkit teams include:
  - **CSRC and DEA Licensure** - to develop detailed step-by-step instruction for how to obtain CSRC and DEA EMS Agency Licensure with an estimated timeline, and training on how to prepare for inspection, understanding of requirements for purchasing and management of medications, record keeping, etc.
  - **Policies and Procedures** - to develop best practice model templates for small and large EMS agencies for the management of medications, to include purchasing, storage and inventory management, dispensing, operational resupply, security and accountability, record keeping, diversions and disposal.
  - **Purchasing** - to develop multiple options that will allow EMS Agencies in Virginia to benefit from larger contract pricing when purchasing medications, medication storage/dispensing/inventory hardware and software, and disposal services.
  - **Financial Assistance** - to develop some funding options to assist EMS agencies with initial transition costs.

Workgroup Progress

- Messaging/Presentations/Q and A
- Assisting BOP with EMS informed Draft Emergency Regulations
- Dissemination of the Draft Emergency Regulations and Facilitating EMS comments and system participation in the March 28, 2024 BOP Meeting

PEMS Initiatives

- Development of Workgroup (Presentation to RDG with White Paper authored by Cynthia Williams)
- Messaging/Presentations/Q and A/Information Sharing
  - Urgent Message
  - Workgroup Recommendation
  - Medication Kit Notice
  - Website for Tools/Resources
- PEMS Committees (EMS Operations/Pharmacy) – Combining with Medical Advisory Committee to a PEMS Transition Task Force
- Active Agency Outreach/Change Advocacy/Resource
- Development of Program Assistance
  - PEMS EMS Medication Kits (Custom Modified
  - Vizient Access
  - npp/gov Access – National Procurement Partners/Government and LifeAssist Access
  - PEMS Pharmacy (Class VI medication stocking (Alternative to Hospital 1:1 Exchange)/Safety-Net for Agencies

PEMS Initiatives

- Consulted in development of Draft BOP Emergency Regulations
- Provided Formal Written Comments on Draft Emergency Regulations on the Record - March 28, 2024 BOP Meeting
- Participation in Regional EMS Medication Kit Transition Workgroup/EMS Advisory Board Next Steps Workgroup
- PEMS Metrics – 43 EMS Agencies with CSR and DEA License appropriate for their level of service by August 1, 2024

Ensure Solutions Maintain Regional EMS Standard of Care/ TEMS Initiatives

DAVID LONG

Prior EMS Pharmacy Experience/ Purchasing Tool Team Update

BRIAN FRANKEL

EMS INVENTORY MANAGEMENT

45 FIRE/EMS STATIONS

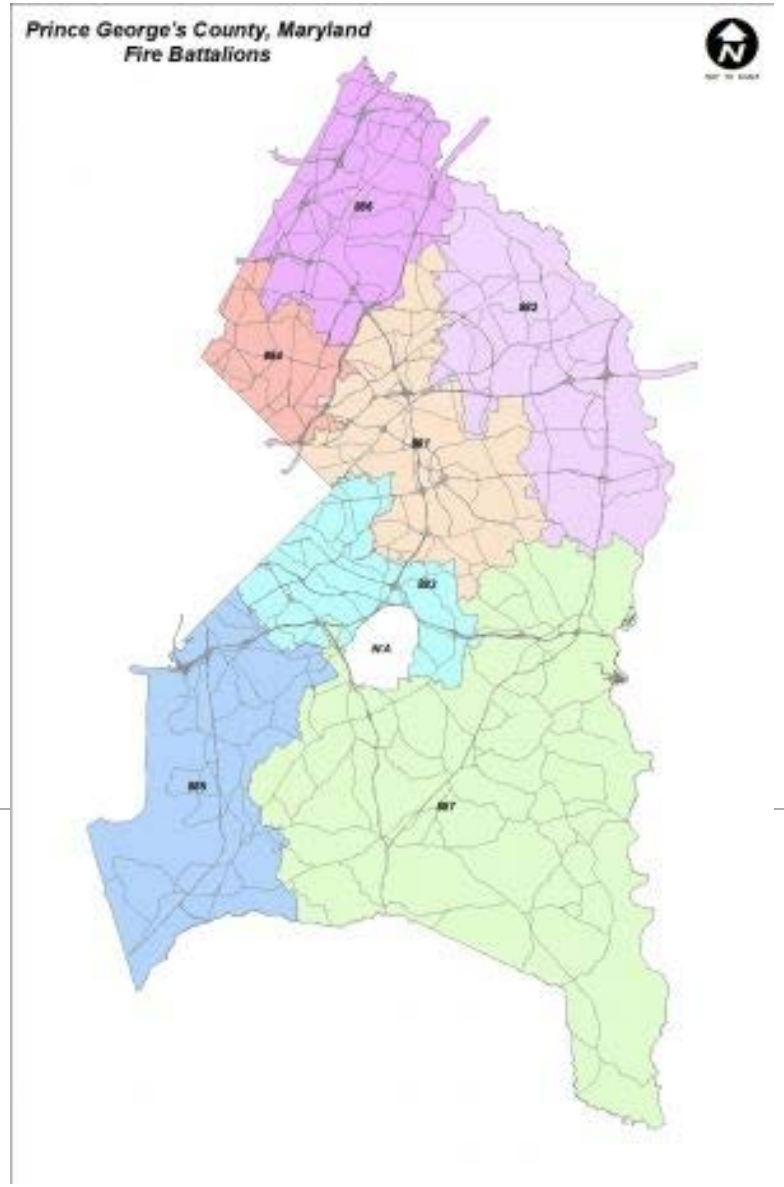
60 EMS TRANSPORT UNITS

20 ALS ENGINE COMPANIES

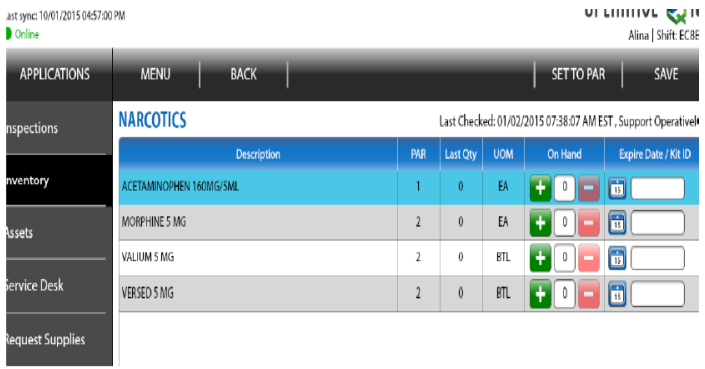
163,000 INCIDENTS

90,000 PATIENT TRANSPORTS

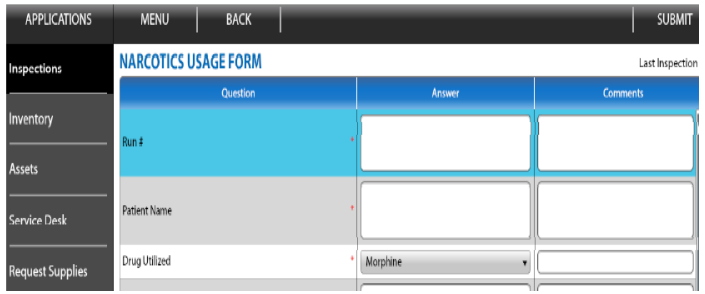
500 SQ MILES



Narcotics Tracking and Control



Example of a Narcotics Usage Form on Check Sheet:



Automated Dispensing Machines

Security-

- Dispensed based on authority
- Controlled access

Single dispensing

- Assigned to incident number
- Expired medications (with collection)
- Asset management/accountability

Purchasing Tool box

GROUP PURCHASING ORGANIZATIONS

Vizient – Available through some Regional Councils

MMCAP – Available for any government or public safety agency

NPPGov – Available to all government agencies

All are free

TOOL BOX WILL INCLUDE:

Access to whole sale or discounted medications, expired medication disposal contracts, equipment (drug storage), automated dispensing cabinets,

EMS Agency Responding to Change/ Policy and Procedure Tool Team Update

RYAN ASHE

Policy and Procedure Tool

Guidance Documents

- Protecting Patient Access to Emergency Medication Act of 2017
- DEA Pharmacist's Manual
- DEA Practitioner's Manual
- Virginia Board of Pharmacy Regulations
  - Emergency Regulations expected May 2, 2024

Examples

- Prince George's County, MD
- Grady EMS, Atlanta, GA
- Palm Coast, Florida
- Rural agency in West Virginia

Policy and Procedure Template

- DEA Registration and CSR Requirements
  - OMD – DEA License
- Purchasing Authority
  - May require Power of Attorney
- Storage, Security and Access Control
  - Central Storage vs Hub – Spoke Model
- Restocking
  - 1:1 exchange at agency, kit for kit, hybrid
- Disposal – waste and expired
- Lost or Damaged
- Emergency Restock or Drug Shortage Procedures
- Transfer of controlled substances
  - DEA 222 process
- Forms – paper, electronic or automated

Supplemental Slides

Protecting Patient Access to Emergency Medications Act (PPAEMA) - Five Tenants

Allows EMS agencies to receive their own DEA registration to administer controlled substances.

The Act creates a new registration category under the CSA for EMS agencies, directing the Attorney General (and thus the Administrator of DEA by delegation) to register such an agency under the CSA if the agency submits an application demonstrating that it is authorized to conduct emergency medical services under the laws of each State in which the agency practices.

The Act authorizes the Attorney General to deny the application of an EMS agency if registering it would be inconsistent with other requirements of or with the public interest

Protecting Patient Access to Emergency Medications Act (PPAEMA) - Five Tenants

EMS agencies that service multiple states will need DEA registrations for each of those states

Second, the Act directs the Attorney General (and thus the Administrator) to allow a registered EMS agency to obtain a single registration for each State in which the agency administers controlled substances, rather than requiring the agency to obtain a separate registration for each location at which it operates within that State

The Act also provides that a hospital-based emergency medical services agency registered under may use the registration of the hospital to administer controlled substances without requiring the agency to acquire a separate registration.

Protecting Patient Access to Emergency Medications Act (PPAEMA) - Five Tenants

Allows EMS agencies to administer medications with a standing order

Subject to certain restrictions, the Act authorizes EMS professionals of a registered EMS agency to administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services.

EMS professionals are only allowed to make such administrations if authorized by State law and pursuant to standing or verbal orders that satisfy a number of statutory conditions.

Protecting Patient Access to Emergency Medications Act (PPAEMA) – Five Tenants

EMS agencies may store controlled substances in the agency location registered with the DEA, unregistered locations, and in EMS vehicles used by the agency.

The Act provides a variety of requirements for how registered EMS agencies must deliver controlled substances from registered to unregistered locations, store controlled substances, restock EMS vehicles at a hospital, maintain records, and otherwise conduct their operations

The Act specifically authorizes the Attorney General (and thus the Administrator) to issue regulations regarding the delivery and storage of controlled substances by EMS agencies.

Record Keeping

Designated locations of an **EMS agency must notify the registered location of their EMS agency within 72 hours of receiving controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response.**

DEA's proposed § 1304.27(c) would codify this requirement in DEA regulations. However, EMS agencies that operate under a hospital-based registration and receive restock of controlled substances from the hospital under which the agency is operating would be exempt from these requirements.

Restocking via EMS-Owned ADC

The second option in proposed § 1301.80(b)(2) would allow an EMS agency to store controlled substances in an automated dispensing system (ADS) machine, under specific conditions.

An ADS is “a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transactions in information.”

Currently, DEA regulations permit retail pharmacies to install and operate ADS machines at long term care facilities as a way of preventing the accumulation of surplus controlled substances at those facilities.

At an EMS agency registered or designated location, an ADS machine effectively would serve as a controlled substance storage locker with advanced capabilities and would provide a mechanism for storing stocks of controlled substances before they are secured in emergency vehicles as well as for monitoring the dissemination of those substances.