



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

Karen Shelton, MD
State Health Commissioner

Office of Emergency Medical Services

1041 Technology Park Drive
Glen Allen, VA 23059-4500

1-800-523-6019 (VA only)
804-888-9100
FAX: 804-371-3108

Rachel Stradling
Interim Director

April 2, 2024

Virginia's Office of Emergency Medical Services (OEMS), in coordination with leadership of the Virginia Department of Health (VDH), have been actively working to advocate for Virginia's EMS providers and agencies throughout the current discussion on the state's drug box exchange program. This memo is meant to inform you on the current status of drug box exchange in the Commonwealth, provide solutions for your consideration, and to assure you that we at OEMS are continuing to stay abreast of the changes to keep you properly informed.

Due to Federal regulatory changes, the existing Virginia EMS agency hospital drug box exchange program will end, possibly as early as November 27th, 2024. This is not the fault of any state or private entity; it is due to compliance with regulations under the Drug Supply Chain Security Act (DSCSA) under section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act. This new regulatory requirement went into effect on November 27, 2023, and is scheduled to be enforced by the Food and Drug Administration (FDA) starting November 27, 2024. The DSCSA regulations, also known as "Track and Trace," provide a carve-out for EMS agencies regarding mandated tracking and reporting, but as interpreted, does not give hospitals the same allowance. The act also requires a "transfer" of ownership, which does not occur with the drug box exchange process today. Since hospital pharmacies are the entities providing medications to an EMS agency, they have difficulty demonstrating transfer of ownership to a single entity and provide transaction information, transaction histories, and transaction statements upon request for medications provided in the drug box exchange program.

In addition to the FDA regulatory changes, the Drug Enforcement Administration (DEA) is reviewing the final rule for the Protecting Patient Access to Emergency Medications Act (PPAEMA) of 2017. This will likely impact the handling of Schedule II-V controlled substances and will likely have an effect on the drug box program as well.

In anticipation of these regulatory changes, OEMS has been working with leadership from the state Board of Pharmacy and others to discuss emergency regulations which will make implementation of new processes easier to move forward.

Additionally, in response to these Federal regulatory changes, the Regional EMS Councils assembled a workgroup comprised of representatives from OEMS, Regional EMS Councils, the Virginia Society of Health Systems Pharmacists, the Virginia Hospital and Healthcare Association, the State Medical Direction Committee, the Virginia Fire Chiefs Association, the Virginia Association of Volunteer Rescue Squads, and the Virginia Association of Governmental EMS Administrators. The work group met on several occasions to develop recommendations for EMS agencies across the Commonwealth.

The workgroup has released the following recommendations:

1. EMS Agencies that plan to store drugs in their stations will likely need to obtain a Virginia Board of Pharmacy Controlled Substances Registration Certificate (CSRC) for Schedule II through VI medications. A registration from the DEA may also be required in some instances following the issuance of the CSRC (see recommendation #2). The Board of Pharmacy is currently amending the requirements for a CSRC in response to the DEA's proposed regulations for EMS agencies. The Board intends to clarify which type of activities will require a CSRC, who is eligible to serve as responsible party and access the medications, and if an alarm system is required. The Board is scheduled to adopt these final requirements on May 2nd. OEMS will work collaboratively with the Board to immediately communicate these requirements following the meeting. EMS agencies should be prepared to promptly submit an application for a CSRC if required under the amended requirements. Please be on the lookout for communication following the May 2nd meeting that will require timely action on your part.
2. EMS Agencies must obtain a registration under the Controlled Substances Act (CSA) with the DEA if you intend to carry Federal schedule II-V medications. Based on the anticipated final rule, the DEA does allow for a single registered location for an EMS agency. Other locations within the agency must be listed as non-registered locations with the DEA.
3. Regional EMS Councils are encouraged to explore options in collaboration with their pharmacy committees, including the feasibility of a 1:1 Schedule VI medication exchange program between hospitals and EMS agencies, as an intermediate step if such a practice would be compliant with FDA DSCSA and can be operationalized with current DSCSA software capabilities. Such a program could provide 1:1 Schedule VI medication exchange when patients are treated and transported to the hospital.
4. EMS Agencies should develop the processes to purchase Schedule II-VI medications as applicable. This would allow EMS Agencies to replace medications when needed.

The workgroup has also assembled teams to create tools to assist EMS agencies in this transition. These tools will include:

- Detailed step-by-step instructions for how to obtain CSRC and DEA licensure.
- Developing 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.
- Developing options for EMS agency access to group or contract pricing for medications, storage, dispensing, inventory, and disposal services.

When created, the tools will be located on the OEMS website at the following URL:

<https://www.vdh.virginia.gov/emergency-medical-services/other-ems-programs-and-links/virginia-ems-drug-box-exchange-program-updates/>

OEMS is researching opportunities for funding to support EMS agencies as they transition away from the current drug box exchange practice. More information will become available as it is developed.

OEMS understands that the enforcement of the updated Federal regulation presents challenges for EMS Agencies in the Commonwealth. **We strongly encourage the EMS Agencies to work with each other, their Regional EMS Councils and healthcare coalitions, as well as reaching out to the Virginia Office of EMS for technical assistance.** We will continue work closely with the Regional EMS Councils to make sure everyone has the latest information and updates.