

Virginia Regional EMS Medication Kit Transition Workgroup Report

February 2023

Over the past five decades, the Regional EMS Councils have played a vital role in facilitating the exchange of medications at hospital pharmacies for licensed EMS agencies through the development and management of Regional EMS Medication Kit exchange programs in cooperation with local hospital systems. However, recent federal law changes and subsequent regulatory updates has required a reevaluation of the existing regional medication kit systems to ensure compliance.

Although allowed by Virginia Board of Pharmacy regulations for many years, the Regional EMS Councils have been aware of impending federal regulations that could affect the regional medication kit exchange programs. We anticipated the Protecting Patient Access to Emergency Medications Act (PPAEMA) of 2017 would result in new **DEA** regulations, and that we would have a one or two-year grace period prior to enforcement; however, although we saw draft in 2020, we have still not seen the final version.

In November, we were surprised to learn that a different federal regulation, the **FDA's** Drug Supply Chain Security Act or (DSCSA), would impact the regional medication kit systems and force a transition much sooner. The DSCSA has an enforcement date of November 27, 2024. We shared that information with the Virginia Regional Council Executive Directors at our meeting on November 15, 2023.

The DSCSA regulations also known as "Track and Trace" provides a carve out for EMS agencies regarding mandated tracking and reporting. Hospitals can provide medications to an EMS agency if they can transfer ownership and provide transaction information, transaction histories and transaction statements upon request. Compliance is not possible with the current regional drug box exchange system utilized in by many EMS councils where a box is not owned by/transferred to any single agency or hospital, the medications in the box have originated from multiple hospitals, and where there is no origin information accompanying any of the medications in the box.

In response to this unanticipated development, the Regional EMS Councils initiated a statewide workgroup to develop transition options and tools for EMS agencies. The Workgroup includes representatives from the Virginia Regional EMS Councils, the Virginia Board of Pharmacy, the Virginia Office of EMS, the EMS Advisory Board's State Medical Direction Committee, the Virginia Society of Health Systems Pharmacists, the Virginia Hospital and Healthcare Association, the Virginia Fire Chiefs Association, the Virginia Association of Volunteer Rescue Squads and the Virginia Governmental EMS Administrators.

The workgroup has met multiple times since December and has conducted an in-depth evaluation of the regulatory environment impacting EMS medications (including those promulgated by the Virginia BOP, the DEA, the FDA and CMS (Safe Harbor/Anti-kickback regulations), evaluated hospital system willingness to participate in an EMS Medication Kit Transition program, compliant program transition options and timelines for moving EMS agencies from Regional

Medication Kits to full EMS ownership of medication procurement and restocking, and defining the tools such options would need to assist EMS agencies in the transition. The goal of the workgroup was to present viable solutions to agencies no later than May 1, 2024, to allow a minimum six-month window for implementation.

At our last meeting on February 12, 2024, the workgroup approved a recommendation:

It is recommended that EMS Agencies obtain Virginia Board of Pharmacy Controlled Substance Registry Certification for Class II-Class VI Medications storage and an EMS Agency DEA License.

It is recommended that the Regional Councils work with their pharmacy committees to explore the feasibility of a 1:1 Class VI 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. Such a program would provide 1:1 Class VI medication exchange when patients are treated and transported to the hospital.

Finally, it is recommended that EMS Agencies develop the capability to purchase Class II-V and Class VI medications. This would allow EMS agencies to replace all Class II-V medications and Class VI medications when patients are treated and not transported, and when medications expire in kits/storage.

Once the recommendation was finalized, the workgroup then assembled 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/Disposal Contract Options - 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 members have been meeting with stakeholder groups across the state to report out on the recommendation. The next workgroup meeting is March 11, 2024.

In addition, all 11 Regional EMS Councils are collaborating with their respective Pharmacy Committees to determine if they will provide a Class VI 1:1 medication exchange program in their regions, and how they will implement it.

Regardless of whether individual hospitals participate in a Class VI 1:1 exchange program, the Virginia Board of Pharmacy Regulations, the FDA's Drug Supply Chain Security Act and whatever the new DEA regulations are, will require **every licensed ALS agency obtain a Controlled Substance Certificate (CSR) and EMS Agency DEA License.** Obtaining the CSRC and DEA license is relatively straightforward. The Regional EMS Councils will also provide information to help guide their EMS Agencies through the CSRC and DEA License application processes.