



## EMS Drug Kit Transition Plan Update

April 16, 2024

Virginia's hospitals and health systems and health system pharmacists have historically provided various forms of community support to emergency medical service (EMS) agencies to ensure that they have access to a supply of medications needed to treat patients in a prehospital environment. This has included providing EMS agencies with pre-filled drug kit exchange systems, as well as, single replenishment of used or expired drugs contained within drug kits.

There are multiple recent and pending regulatory changes underway by the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) that, combined, will result in the discontinuation of these practices:

FDA regulations under the Drug Supply Chain Security Act (DSCSA), to be enforced beginning November 27, 2024, will require the tracking and tracing of regulated products through each step in the chain to the patient. While EMS agencies are exempt from these requirements, hospital and health system pharmacies are not, and these requirements would apply to any pre-filled drug kit exchange or single drug replenishment model.

Pending DEA regulations under the Protecting Patient Access to Emergency Medication Act (PPAEMA) direct EMS agencies that administer controlled substances schedule II-V to obtain a state controlled substances and DEA registration and be responsible for the maintenance and administration of their own controlled substances. This regulation is pending final publication, but is anticipated to be in effect 30 days after publication.

Members of the Virginia Society of Health-System Pharmacists and Virginia Hospital & Healthcare Association have actively participated in the Virginia Regional EMS Medication Kit Transition Workgroup along with representatives of the Virginia Board of Pharmacy and Office of Emergency Medical Services and the EMS community over the past several months to ensure a safe transition as these regulatory changes are implemented.

Implementation of the FDA regulations will require the discontinuation of the current model of hospital and health system provided pre-filled drug kit exchanges as of November 27, 2024. Following implementation of both FDA and impending DEA regulations, different models will need to be employed to support the medication emergency response need for different regions. Agencies should strive to provide a consistent medication restocking process within each council. It is recommended for EMS agencies to take all required steps to ensure that they have in place the capability to maintain and administer their own supply of medications to treat patients in the prehospital environment beginning November 27, 2024. Single drug replenishment may be possible in limited avenues that are able to support the resource heavy and complex infrastructure under the FDA and DEA expectations. We are aware that many hospitals and health systems have begun communicating this change to EMS agencies serving their regions and are working with those agencies to bridge this transition over the next several months.

Virginia's hospitals and health systems and health systems pharmacists recognize that this change may require some EMS agencies to develop new systems and supply chains and incur new costs as part of their operations. We are committed as your community partners to provide assistance at a local or regional level that may be available to ease the transition to a compliant model for all EMS agencies across the state.

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