

November 22, 2024

Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Anne Milgram
Administrator
U.S. Drug Enforcement Administration
8701 Morrisett Drive
Springfield, VA 22152

U.S. Drug Enforcement Administration
Diversion Control Division
Attn: Policy Section
8701 Morrisette Drive
Springfield, VA 22152

Re: Virginia EMS Drug Box Exchange Program

Dear Commissioner Califf and Administrator Milgram,

We are aware that you have received correspondence from members of Virginia's Congressional delegation, the Virginia Association of Counties, and other parties expressing concerns about the impact of impending regulatory changes under the Drug Supply Chain Security Act (DSCSA) and Protecting Patient Access to Emergency Medication Act (PPAEMA) on the Drug Box Exchange Program that has been in place in Virginia for many years.

In response to these laws, Virginia Hospital & Healthcare Association (VHHA) has been actively engaged with representatives from the Virginia Department of Health, Virginia Board of Pharmacy, and Emergency Medical Services (EMS) agencies across the state to take steps to discontinue the Drug Box Exchange Program and safely transition toward EMS agencies maintaining and administering their own supply of medications to treat patients in the prehospital environment.

VHHA previously released a statement on April 16, 2024, informing statewide partners that the Drug Box Exchange Program would be discontinued November 27, 2024, the effective date of FDA regulations under the DSCSA. Subsequently on October 30, 2024, VHHA authorized a revised statement informing statewide partners that the Drug Box Exchange Program could be extended through the earlier of April 15, 2025, or the date the Drug Enforcement Administration (DEA) publishes the final rule for implementing applicable provisions of the PPAEMA with an enforcement date prior to April 15, 2025. Copies of both statements are enclosed for your reference.

The decision to extend this deadline was made necessary due to multiple reported delays in obtaining Controlled Substances Registration, DEA Registration, and required budget approvals or acquisition of funds through sources such as the Rescue Squad Assistance Fund. The extension was undertaken in consultation with state agencies and is conditioned upon (1) Food and Drug Administration (FDA) issuance of an exemption from the enhanced drug distribution security requirements of the DSCSA for eligible trading partners to November 27, 2025, and (2) indications from DEA officials that the PPAEMA final rule would not likely be promulgated until 2025.

Notwithstanding the need for this delay, VHHA continues to encourage all regions to move forward with full transition by the previous November 27, 2024, deadline and the extension is not intended to disrupt those efforts.

We recognize that in the event that the FDA changes its decision to exempt certain eligible trading partners from the enhanced drug distribution security requirements of the DSCSA, or the DEA final rule on the PPAEMA becomes effective prior to April 15, 2025, it will be necessary to immediately discontinue the Drug Box Exchange Program.

It is our goal to accurately and completely inform our members of the requirements for compliance with the DSCSA and PPAEMA and corresponding regulations in a manner that provides consistency across the Commonwealth. It is our understanding based upon available information and the status of current and pending law and regulation that the extension is permissible by FDA and DEA, respectively, and neither the FDA nor DEA will initiate enforcement action asserting that the Drug Box Exchange Program is a violation of the relevant provisions of the DSCSA or the PPAEMA/Controlled Substances Act, for so long as the arrangement qualifies for an exemption from the enhanced drug distribution security requirements of the DSCSA and the DEA final rule on the PPAEMA has not taken effect. Please notify us immediately if this is not correct or if there are additional measures that need to be taken in order for this extension to comply with applicable FDA or DEA law and regulation.

Thank you for your willingness to work with Virginia's hospitals to ensure that we are maintaining compliance with applicable federal laws and regulations and safeguarding the health and safety of our communities.

Sincerely,



R. Brent Rawlings
Senior Vice President & General Counsel

cc: Karen Shelton, M.D., State Commissioner of Health
Caroline Juran, Executive Director, State Board of Pharmacy

Enclosures



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.

Contact Information:

Virginia Society of Health-System Pharmacists vshppres@vshp.org
Virginia Hospital & Healthcare Association <https://vhha.com/contact/>



EMS Drug Kit Transition Plan Update

October 30, 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. As was previously communicated on April 16, 2024, there are multiple recent and pending regulatory changes underway by the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) that will require discontinuation of these practices. To ensure a safe transition to the new regulatory environment, the Virginia Society of Health-System Pharmacists (VSHSP) and Virginia Hospital & Healthcare Association (VHHA) have been participating in the Virginia Regional EMS Medication Kit Transition Workgroup.

At the time the April 16, 2024, statement was released, the consensus of the Workgroup was that the pending DEA and FDA regulations would require the discontinuation of hospital and health system provided pre-filled drug kit exchanges and single drug replenishment as of November 27, 2024.

Due to multiple reported delays in obtaining Controlled Substances Registration, DEA License Registration, and required budget approvals or acquisition of funds through sources such as the Rescue Squad Assistance Fund, EMS agencies and Regional EMS Councils have highlighted concerns for the ability to meet the current November 27, 2024, timeline for EMS medication kit ownership transition.

In response to these concerns, VSHSP, in collaboration with VHHA, is recommending an extension for the transition timeline to no later than April 15, 2025, with the following considerations:

Transition Date:

1. If the DEA publishes the final rule for Protecting Patient Access to Emergency Medications Act (PPAEMA) with an enforcement date prior to April 15, 2025, the transition date will be the earlier of the two dates.
2. For agencies that are ready to transition, it is encouraged that they work with their Regional EMS Council and local hospitals to transition earlier than April 15, 2025. This may allow agencies to have a "soft" launch to ensure that all processes work as designed prior to the full transition.
3. For agencies that are challenged with meeting the April 15, 2025, transition date, work with Regional EMS Council leadership to address any obstacles and determine solutions.

Readiness Updates and Ongoing Actions to Take:

1. Progress Reports: EMS Agencies and Regional EMS Councils provide a monthly update on status for each agency CSR, DEA, and transition readiness to hospital leadership for hospitals to understand progress toward transition readiness and implementation.
2. CSR is Established: EMS Agencies should continue to work towards readiness. For those that have received their CSR and are awaiting DEA, it is recommended to move forward with establishing Group Purchasing Organization (GPO) and Wholesaler accounts to the extent possible to reduce the overall timeline for implementation.



3. DEA License Registration is Established: While the DEA Controlled Substances Ordering System (CSOS) is the preferred method of ordering CII medications, it is not required for transition. Agencies should request DEA222 forms when obtaining their DEA License Registration as a bridge.

This extension is made possible by (1) FDA issuance of an exemption from the enhanced drug distribution security requirements of the Drug Supply Chain Security Act (DSCSA) for eligible trading partners to November 27, 2025ⁱ (2) assurances from DEA officials that the PPAEMA final rule would not likely be promulgated until 2025. At the same time, this extension acknowledges that there are many regions that are already moving forward with full transition by the previous November 27, 2024, deadline and is not intended to disrupt those efforts.

Virginia's hospitals and health systems and health systems pharmacists continue to recognize that this change is requiring some EMS agencies to develop new systems and supply chains and incur new costs as part of their operations. As we have stated previously, 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.

Contact Information:

Virginia Society of Health-System Pharmacists vshppres@vshp.org
Virginia Hospital & Healthcare Association <https://vhha.com/contact/>

ⁱ U.S. Food & Drug Administration, Waivers and Exemptions Beyond the Stabilization Period, October 9, 2024, available online at: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/waivers-and-exemptions-beyond-stabilization-period>.