November 20, 2024

Dear Northern Virginia Emergency Medical Service Partners,

Thank you for your continued patience and collaboration as we work through the complexities in this change in provision of medications used to treat patients being transported to our regional hospitals. We appreciate the financial and logistical challenges this transition has created for our local emergency medical service (EMS) partners as a result of forthcoming federal regulatory changes from the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA).

Consistent with the October 31, 2024, announcement (see attached) from the Virginia Hospital & Healthcare Association and the Virginia Society of Health-System Pharmacists, please accept this as formal notice that we, the undersigned Northern Virginia hospitals, will extend the transition timeline to no later than April 15, 2025. As you will recall, our prior communication cited an earlier deadline based on federal guidance and the recommendation of the Virginia Regional EMS Medication Kit Transition Workgroup. We commend the tremendous efforts of you and your colleagues to meet that original timeline, and we share your frustration with delays in licensing that have slowed progress.

In the spirit of continued collaboration, we have a few requests beyond those listed in the VHHA/VSHP update. In addition to the monthly progress reports, which we assume will be coordinated via the Northern Virginia Emergency Response System (NVERS), which is in the process of merging with the Northern Virginia EMS Council, we respectfully request continued meetings with EMS and hospital pharmacy leaders in December, February, and March, coordinated by NVERS, to discuss any ongoing transition issues and updates. As this extended deadline will create a rolling transition with EMS agencies, we will want to coordinate the communication of those handoffs with both of our teams.

A bulk supply of Controlled Substances Kits was previously offered so agencies would not be struggling with drug provision over the holiday period. The extension to 2025 eliminates that need and plan. Further, a question was raised as to whether existing hospital-supplied drugs would be returned to hospitals. No return of existing drug supply is needed; you may use those for patient care. Once the agency transition to self-supply, expired or unusable drug should be returned to a reverse distributor (required for controlled substances). See the state task force purchasing team notes for options.

We are eager to hear from you and your colleagues if there are any further outstanding challenges that we can collectively address. We are proud of our longstanding relationship with our region's EMS providers, and we remain committed to ensuring a seamless and successful transition that does not affect the care of our shared patients.

Respectfully,

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Capital Division President, HCA Healthcare

John J. Moynihan, MD, FACS
Inova Health System, Chief, Clinical Enterprise, President, Inova Surgical Services

Jeff Joyner, MHA, FACHE
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EMS Drug Kit Transition Plan Update **October 31, 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 (VSHP) 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, VSHP, 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, 2025[i] (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.