

## **OLD DOMINION EMERGENCY MEDICAL SERVICES ALLIANCE**

## MEMORANDUM

то	EMS Agency Administration and Leadership
FROM	Heidi M. Hooker, Executive Director
DATE	January 24, 2024
SUBJECT	Urgent Update on Changes to the Regional Medication Kit Exchange Program

It is with a sense of urgency that we bring to your attention significant changes in the Regional Medication Box Exchange Program, affecting all licensed EMS agencies across the Commonwealth. 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, all at no cost. However, recent federal law changes and subsequent regulatory updates demand a thorough reevaluation of the existing regional medication kit systems to ensure compliance.

The 11 Virginia Regional EMS Councils have been aware of impending regulations that could affect the regional medication kit exchange programs. We anticipated the 2017, "Protecting Patient Access to Emergency Medications Act" (PPAEMA) would result in new U.S. Drug Enforcement Administration (DEA) regulations, with a hopeful one to two-year grace period prior to enforcement. However, no such regulations have materialized within the past six years.

Surprisingly, during the Virginia Regional Council Executive Directors meeting on November 15, 2023, we learned that the Drug Supply Chain Security Act by the U.S. Food and Drug Administration (FDA), would impact the regional medication kit systems and force a transition much sooner. The FDA regulation has an enforcement date of November 1, 2024.

In response to this unanticipated development, the Regional EMS Councils initiated a statewide effort to assemble a workgroup comprising representatives from the Virginia Regional EMS Councils, the Virginia Office of EMS, the Virginia Society of Health Systems Pharmacists, the Virginia Hospital and Healthcare Association, the State Medical Direction Committee, and EMS Agency stakeholder groups. This workgroup has already met and is actively exploring alternative solutions to ensure a smooth transition for EMS agencies statewide.

In addition, all 11 Regional EMS Councils are collaborating with their respective Pharmacy Committees to address this challenge collectively. The goal is to present viable solutions to agencies by May 1, 2024, allowing a six-month window for implementation.

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It now appears that regardless of what ultimate solutions are recommended, the Virginia Board of Pharmacy Regulations, the FDA's Drug Supply Chain Security Act, and whatever DEA regulations are delivered, every licensed ALS agency must **obtain a Controlled Substance Registration (CSR)**. Obtaining a CSR is relatively straightforward and cost-effective. In the coming days, we will provide further information to help guide you through the CSR application process should your agency not already have a CSR.

At this time, we advise against developing stand-alone solutions prematurely. Please exercise patience as we engage with our state and federal agency partners, hospital pharmacies, and regional leaders to determine the most effective solutions. For instance, acquiring medication boxes independently may be premature, given ongoing discussions about potentially surrendering council boxes. Similarly, purchasing your own medications might be premature, given ongoing discussions about purchasing coalitions and central warehousing to reduce the cost of medications for EMS agencies.

We appreciate your understanding and cooperation during this transitional period. We understand the importance of maintaining seamless operations and minimizing disruption to your services. Rest assured, the same Regional EMS Councils that have been supporting your EMS agencies for the past five decades continue to work to help ensure your medication supply needs are met in a manner that minimizes cost and operational challenges. We will inform you about the progress and any interim measures that may be implemented.

Sincerely,

Hart M. Hocher