Congress of the United States
House of Representatives
Washington, DC 20515

September 12, 2024

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

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

Dear Commissioner Califf and Administrator Milgram:

Emergency Medical Services (EMS) agencies in many counties across Virginia have shared concerns with our offices about pending changes from the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) that will discontinue the Old Dominion EMS Alliance Regional Medication Box (Drug Box) Exchange Program later this year.

The changes will shift new administrative and budgetary responsibilities onto each county, putting a strain on the most rural areas. We echo the concerns recently expressed by the Virginia Association of Counties[1] and foresee significant disruptions to the administration of emergency drugs to Virginians if your agencies fail to provide more time for counties to acquire the relevant licenses they will need to run the program on their own. Further, we believe that your agencies could work with Virginia to provide an accommodation for the drug box program that does not require it to be completely upended.

For over 40 years, the Drug Box Exchange Program has operated in Virginia as a partnership between EMS agencies and hospitals. Hospitals have coordinated with EMS agencies to provide drug kits containing medications to treat conditions such as overdose, hypoglycemia, or allergic reactions. This program is built on the trust between hospitals and EMS professionals. Upon administering any of the medications, EMS personnel often accompany the patient to a hospital. As the patient receives treatment, the drug kit is restocked.

[1] https://northern.vaems.org/index.php/regional-medication-kit-transition-2024-info/rescources/554-vaco-usda-medications-letter-08-26-2024/file

On November 27, 2024, this partnership will end when the FDA begins enforcing requirements on hospitals related to tracking and tracing drugs. The *Drug Supply Chain Security Act* (DSCSA) requires the tracking and tracing of regulated products until it reaches the patient. While EMS agencies are exempt from these requirements, hospital and health system pharmacies are not. Because medications from the drugs kits could come from various local hospitals, and one centralized entity does not keep track of every patient who receives a drug, the hospital will be held liable under the law for violating the tracking requirements of DSCSA. Therefore, when enforcement of this law begins in November, hospitals will be forced to either stop providing life-saving drugs to EMS agencies or face stiff penalties from the FDA.

As a result of these forthcoming changes, each EMS agency across the Commonwealth must prepare to procure and maintain the drugs itself in order to continue providing life-saving drugs to Virginians during emergencies. This creates a massive administrative and financial burden for each EMS agency, which will essentially be forced to fully function as a pharmacy. They will be required to obtain both a certificate from the Commonwealth and a DEA registration permitting them to stock and administer controlled substances. This will lead to more stress for already-stretched county budgets to cover the costs of additional technology and personnel to comply with all the protocol of creating a pharmacy. This includes building an infrastructure to receive shipments of medication, providing 24/7 monitoring of such drugs, keeping full records of every item, training staff and volunteers about new protocols, and fully covering the cost of every drug.

Rather than depending on the expertise of hospital pharmacies for these services, small localities are being asked to unnecessarily reinvent a program over a period of a few months even though it has operated efficiently for 40 years. As the November deadline draws near, many counties are still working to obtain the required state license and therefore have not been able to start the process with the DEA. As a result, many areas will face a lapse in drug access while EMS agencies struggle with compliance. This is extremely concerning for the health and well-being of our constituents.

Virginia's drug box program is distinct from other states' and will face serious disruption without prompt federal action. We urge your swift response to this letter by September 26, 2024.

Sincerely,

Bob Good, Member of Congress, VA-05

Jen Kiggans, Member of Congress, VA-02

Ben Cline, Member of Congress, VA-06

Rob Wittman, Member of Congress, VA-01

H. Morgan Griffith, Member of Congress, VA-09