

Virginia Association of Counties

Connecting County Governments since 1934

**President**

Ann H. Mallek
Albemarle County

President-Elect

Ruth Larson
James City County

First Vice President

William M. McCarty
Isle of Wight County

Second Vice President

Victor S. Angry
Prince William County

Secretary-Treasurer

Donald L. Hart, Jr.
Accomack County

Immediate Past President

Jason D. Bellows
Lancaster County

Executive Director

Dean A. Lynch, CAE

General Counsel

Phyllis A. Errico, Esq., CAE

August 23, 2024

Robert M. Califf

Commissioner

U.S. Food and Drug Administration

10903 New Hampshire Ave

Silver Spring, MD 20993-0002

Anne Milgram

Administrator

U.S. Drug Enforcement Administration

8701 Morrisette Drive

Springfield, VA 22152

Dear Commissioner Califf and Administrator Milgram,

I am writing on behalf of the Virginia Association of Counties (VACo) to express serious concerns about the impending regulatory changes under the Drug Supply Chain Security Act (DSCSA) and the Protecting Patient Access to Emergency Medications Act. These changes, set to take effect on November 27, 2024, threaten to impose significant unfunded mandates on local governments in Virginia, particularly impacting our Emergency Medical Service (EMS) providers.

The Prescription Drug Box Program, unique to Virginia, has long played a vital role in ensuring that EMS vehicles are fully stocked with necessary medications, enabling providers to deliver critical care to patients in transport or at accident sites. The program, however, faces a severe disruption due to the proposed enforcement of new DSCSA requirements on hospital pharmacies, which would prevent hospitals from providing and exchanging drug kits with EMS providers.

As you may be aware, the Virginia Board of Pharmacy has indicated that the current kit exchange process does not fully comply with DEA requirements, which could result in local governments bearing the brunt of these regulatory changes. The burden of obtaining controlled substance registrations (CSRs) and DEA licenses, along with the logistical and financial challenges of managing drug stocks independently, will be onerous for many EMS agencies, particularly those in rural areas that rely heavily on volunteer staff.

The Virginia Regional EMS Medication Kit Transition Workgroup has highlighted the impracticality of the federal regulations, which fail to accommodate the unique nature of our regional drug box exchange system. The guidance provided by this workgroup underscores the need for a more flexible approach that does not disrupt essential emergency services.

We respectfully urge the FDA and DEA to consider the unique circumstances of Virginia's EMS providers and work collaboratively with state and local agencies to develop a regulatory framework that ensures compliance without imposing undue burdens on local governments. Specifically, we request that federal agencies explore

1207 E. Main St., Suite 300
Richmond, Va. 23219-3627

Phone: 804.788.6652

Fax: 804.788.0083

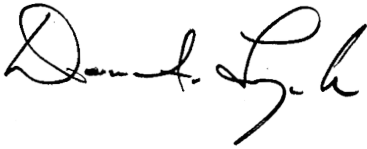
Email: mail@vaco.org

Website: www.vaco.org

options for maintaining the viability of the Prescription Drug Box Program while aligning with federal law.

We appreciate your attention to this critical issue and look forward to working with you to safeguard the health and safety of our communities.

Sincerely,

A handwritten signature in black ink, appearing to read "Dean A. Lynch". The signature is fluid and cursive, with the first name "Dean" and last name "Lynch" clearly distinguishable.

Dean A. Lynch, CAE
Executive Director
Virginia Association of Counties (VACo)

CC:

Senator Mark Warner
Senator Tim Kaine
Representative Rob Wittman
Representative Jen Kiggans
Representative Bobby Scott
Representative Jennifer McClellan
Representative Bob Good
Representative Ben Cline
Representative Abigail Spanberger
Representative Don Beyer
Representative Morgan Griffith
Representative Jennifer Wexton
Representative Gerry Connolly
Virginia Secretary of Public Safety and Homeland Security Terrance C. Cole
VACo Board of Directors