

**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 Morrissette 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

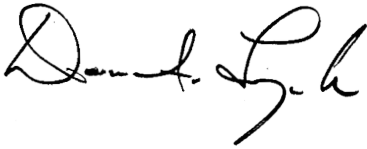
Email: [mail@vaco.org](mailto:mail@vaco.org)

Website: [www.vaco.org](http://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