



March 26, 2024

Virginia Board of Pharmacy
Office of Emergency Medical Services
9960 Mayland Dr #300
Henrico, VA 23233-1463

Attention: Written Impact Statement for the proposed Virginia Board of Pharmacy regulations amendment -
March 28, 2024

Dear Virginia Board of Pharmacy Members,

On behalf of the 15 Northern Virginia Fire Department Chiefs, 10 NoVA regional Operational Medical Directors, and the Northern Virginia EMS Council, we thank you for the opportunity to provide feedback on the proposed regulations. As background, the Fire/EMS agencies in Northern Virginia responded to 323,476 emergency responses in 2023. Through collaboration with our local hospitals, the Northern Virginia EMS Council, and multiple regional committees and groups, including the NoVA Fire Chiefs group, the regional medical directors committee, and the regional EMS Chiefs group, we are proud of our reputation and ability to provide some of the leading front-line field-based emergency medicine in the country. Our collective primary mission is to continue to provide the 911 response services that our communities rely on and be allowed to do so as efficiently as possible within existing (and proposed) regulatory and compliance mandates.

This group understands the need for and supports greater controlled substance accountability through the Drug Supply Chain Security Act (DSCSA). It is the responsibility of all medical practitioners, including emergency medical services (EMS) providers and agencies, to ensure medications are stored safely, securely, and within regulatory guidelines. EMS agencies must make adjustments to legacy practices to ensure industry best practices are integrated into our services. However, there must be consideration and exceptions for the unique environment EMS agencies conduct their care delivery and the challenges and hardships the current legislation and proposed changes would create for EMS agencies in the Commonwealth.

The Federal Drug Administration (FDA) DSCSA included various exclusions and exemptions for EMS services, and we strongly encourage that the Virginia Board of Pharmacy leverage similar considerations when evaluating controlled substance regulations impacting EMS. Controlled substance regulations that are too intensive to ensure adherence and compliance may create administrative and logistical challenges for both career and volunteer EMS agencies leading to considerations for reductions of service level and quality.

We openly recognize and appreciate the efforts put forth by the Virginia Department of Health, Virginia Office of EMS, and Virginia Board of Pharmacy to alter its existing regulations to accomplish the goals of the DSCSA

while considering the different working environment and challenges compliance with these regulations pose on EMS agencies in the Commonwealth.

We are also appreciative and supportive of the Virginia Board of Pharmacy's proposed amendments to regulations to allow a "hub" model which would require an EMS agency to only possess a single controlled substance registration (CSR) for its agency as opposed to requiring a separate CSR for each station.

The current amendment to regulation 18VAC110-20-690 Section H. references Schedule VI medications and it is recommended that the board considers extending this amendment to specifically include Schedule II-V medications being temporarily stored in sealed drug kits within an EMS building. These medications should be temporarily stored in an appropriate, safe manner within the EMS facility, but due to the limited access to a sealed kit and the limited quantity of the Schedule II-V controlled substance, it would be reasonable to allow temporary storage to occur with less extensive security measures.

We continue to advocate and urge the Virginia Board of Pharmacy and our regional hospital partners to continue the long-standing practice of a 1:1 exchange of medications. Departure from this successful, established model could lead to the following complications:

- The inability of ambulances to restock pharmaceuticals at receiving facilities would create extended turnaround time for units and negatively impact unit reliability and availability for its communities. As our Commonwealth experiences the impact of a nationwide shortage of advanced life support (ALS) providers, ensuring the timely turnaround of these units is paramount. Increases in turn-around time would create a negative impact on unit availability and our patients receiving needed ALS resources.
- Most EMS agencies do not currently have compliant, dedicated storage locations or automated dispensing devices within each station or logistics staff prepared to manage the accountability and delivery of controlled substances. This implementation would create an immediate financial impact on agencies with little reflex time to plan for this adjustment. This immediate funding need would be unable to be absorbed by some organizations and require most agencies to adjust their funding priorities and delay other beneficial EMS initiatives.
- Smaller jurisdictions lack the competitive purchasing power to reduce the cost-of-service delivery and the ability to maintain stock during medication shortages.
- Less frequently administered medications stored at each jurisdiction would be less cost effective than the current model and many medications may expire before use. Additionally, many agencies would need to increase their medication allotments to each operational unit to allow these units to remain in service while traveling to an identified restocking location.

The additional medication allotments increase operational costs, exacerbate potential drug shortages, and lead to increased medication waste due to expiration. Our regional goal is to utilize collaboration and regionalization initiatives to deliver the highest quality service in the most cost-effective method for our communities. Continued partnerships with our regional receiving facilities for 1:1 medication exchanges allow us to continue to achieve this goal.

We recognize and understand the hesitation and concern of our regional hospital systems regarding proposed product tracing requirements in the FDA's DSCSA regulations. However, the DSCSA includes exclusions for first responders and notes that pharmacies can consider EMS an "endpoint" for tracking medications. It is encouraged that regional receiving facilities continue to collaborate and partner with their local EMS agencies

to modify the existing 1:1 medication exchange model as opposed to choosing to eliminate EMS medication restocking options. The continued partnership between EMS agencies and hospitals is believed to be the best model for our regional system of healthcare and ensures our community continues receiving the most efficient, cost-effective care.

We urge the Virginia Board of Pharmacy to further evaluate opportunities to separate guidance and regulations of Schedule II-V versus Schedule VI medications. Although both groups of medications need to be handled appropriately by practitioners, the potential for theft, abuse, and harm is different between Schedule II-V and Schedule VI medications. Enacting similar measures to address all schedules of medications equally creates a burdensome hardship for EMS agencies. The Virginia Board of Pharmacy should explore alternative approaches to handling different schedules of medications.

We, the undersigned, understand the difficulty and challenge presented to the Virginia Board of Pharmacy board members in establishing regulations that adhere to changing national regulations and balancing the need for improved safety and accountability while accounting for the unique needs of each service industry possessing controlled substances in the Commonwealth. Any consideration given to the viewpoints shared within this letter when evaluating decisions to create or modify controlled substance regulations for the betterment of EMS service delivery is appreciated.

Sincerely,



Joseph A. Cardello, Chief, Stafford County Fire and Rescue Department
Chair, Northern Virginia Fire Chiefs Committee

Sincerely,



Laura Vandegrift, Interim Executive Director, Northern Virginia EMS Council, Inc.

Sincerely,



Kari L. Scantlebury, Operational Medical Director, Fairfax County Police Department
Chair, Northern Virginia Operational Medical Directors Committee