



Virginia Fire Chiefs Association

P.O. Box 699 Blackstone, VA 23824

info@vfca.us

Phone: (888) 818-0983

Virginia Board of Pharmacy
Attn: Caroline Juran

Dear Caroline,

I write this letter as president of the Virginia Fire Chiefs Association (VFCA), which provides leadership, advocacy and education for Fire & EMS based organizations throughout Virginia. These organizations respond to both emergent and non-emergent needs of the 8.6 million residents and visitors. Our concerns are related to the impacts of the FDA's Drug Supply Chain Security Act (DSCSA), DEA's Protecting Patient Access to Emergency Medications Act (PPAEMA) 2017 amended Section 33 of the Controlled Substance Act (CSA), and Virginia's Board of Pharmacy's rules and allowances that will define and guide Fire & EMS agencies to being compliant with each after November 27, 2024.

We specifically ask for favorable considerations with the following:

1. Facilitate regulations that allow for 1:1 exchange of EMS medications at the hospital pharmacy.
 - a. reduces the financial, logistical, and administrative burden on agencies/localities like, compliant storage in buildings, dispensing machines, accounting and reporting, dedicated staff, and competitive purchasing agreements.
 - b. decreases downtime and improves reliability.
 - c. reduces waste of unused medications.
 - d. limits impact on drug shortages
2. Endorse the "Hub & Spoke" method which eliminates the need for separate Controlled Substance Registrations (CSR) for Fire & EMS departments within the same locality.
3. Use separate guidance & regulations of Schedule II-V versus Schedule VI medications.
 - a. Explore alternative approaches to handling and storage.
 - b. Exempt Fire & EMS agencies from Schedule VI regulations.
4. Differentiate between Schedule VI medications and devices.
 - a. Allow regulation to apply only to medications and not devices.

Additionally, Virginia's Fire & EMS needs survey and assessment was concluded in 2023. The survey queried all localities in the state which resulted in an 85% response rate. The top five needs in order of priority are: staffing, facilities/modifications, fire trucks/ambulances, personal protective equipment, and training. This equates to hundreds of millions of dollars that we already fall short of obtaining through our budgetary processes, as well as grants from local, state, and federal opportunities. The demands on the Fire & EMS Service that will ensue November 27th only add to this existing problem and potentially require some of our communities' first response agencies to reduce their medical treatment capabilities to those that rely on it the most.

Please take the time to review the attached letters from our regional membership. They truly speak their specific concerns and provide equitable solutions.

We understand that this is a significant change for Virginia's Healthcare System and are appreciative of the many task forces, advisory boards, teams, meetings, and collaborations that are ongoing to address these concerns. The VFCA's pursuit of worthy goals as opposed to idle criticism, laziness or inaction are held in highest regard; as such, we stand able and willing to help the Board of Pharmacy through these tough decisions.

Respectfully,

A handwritten signature in blue ink, appearing to read "V. Cooper", with a long horizontal flourish extending to the right.

Vance Cooper
President - VFCA



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



CENTRAL VIRGINIA FIRE CHIEFS' ASSOCIATION

April 5, 2024

Member Departments

Counties of:

Amelia
Caroline
Charles City
Chesterfield
Cumberland
Dinwiddie
Goochland
Hanover
Henrico
King and Queen
King William
Louisa
New Kent
Powhatan
Prince George
Richmond Airport
Sussex

Cities of:

Colonial Heights
Hopewell
Petersburg
Richmond

Military Installations:

DLA Richmond
Fort Walker
Fort Gregg-Adams
Fort Barfoot

Affiliated Organizations:

Virginia Department Of:
Fire Programs
Emergency Management
Virginia Office Of:
Emergency Medical Services
Richmond Ambulance Authority

Association Officers:

President: Edward L. Senter, Jr.
Chesterfield County Fire & EMS
P.O. Box 40
Chesterfield, VA 23832
Email: SenterL@chesterfield.gov
Phone: 804-751-4726

Vice President:

Dillard E. Ferguson, Jr.
Goochland Fire-Rescue Chief
P.O. Box 247
Goochland, VA 23063
Email: cferguson@goochlandva.us
Phone: 804-556-5304

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

Dear Virginia Board of Pharmacy Members:

I write this letter as President of the Central Virginia Fire Chiefs Association (CVFCA), a professional organization that represents the interests of Fire & EMS chiefs who lead departments that collectively serve over 2 million residents. On behalf of the CVFCA and its members, we would like to ask that you give consideration to various issues related to the rapidly changing landscape of pharmaceutical management in EMS agencies in the Commonwealth of Virginia.

CVFCA is appreciative of the focus on EMS and the efforts being put forth to develop regulations that support the mission of the agencies. We recognize the need for change is being driven by external factors such as the Drug Supply Chain Security Act (DSCSA) and Protecting Patient Access to Emergency Medications Act (PPAEMA). We further appreciate the efforts underway to create reasonable Virginia Board of Pharmacy (BoP) regulations for EMS agencies. Regulations that are too intensive may create administrative and logistical challenges for both career and volunteer EMS agencies, which can lead to worsening health care disparities and overall reduction in the level of services provided.

CVFCA offers the following comments for your consideration:

- Under current BoP regulations, there are provisions for a 1:1 exchange of medications for EMS. The DSCSA and PPAEMA proposed rule allows the transfer of hospital owned medications to EMS agencies. We encourage the BoP to continue regulations that facilitate the ability for hospitals to exchange medications.
- EMS system designs vary among regions and must be tailored to the need of the locality. Likewise, EMS supply chains vary. It would be ideal if BoP regulations allowed several models for EMS agencies to obtain medications.
 - Hospital provided medications as described in first bullet point
 - Agency provided medications for sole use within agency
 - Central agency purchases medications but allows transfer to other EMS agencies within political subdivision/jurisdiction
 - Central agency purchases medications but allows transfer to other EMS agency, via MOU or other written agreement

- Under current BoP regulations, any location which stores medication kits outside of the licensed EMS vehicle will need a Controlled Substance Registration (CSR). Likewise, any location that stores schedule VI medications outside of the medication kit will require a CSR. This would be quite burdensome for EMS agencies. We encourage the BoP to continue promulgating regulations that facilitate a single CSR for an EMS agency and designated locations (stationhouses).
- Under current regulations, storage of schedule VI medications requires a CSR. We ask for the consideration that the BoP investigate the possibility of exempting licensed EMS agencies for the CSR requirement for storing schedule VI medications. If not possible for all schedule VI medications, BoP should consider exemption for limited medications (e.g., albuterol, ipratropium, Epipen, naloxone) that could be used in first response models.
- EMS agencies have a differing definition of “staffed 24-hours”. We ask the BoP to consider modifying their definition of “staffed 24-hours” as it applies to licensed EMS agencies.
- Office of EMS, BoP, and EMS agencies may have differing interpretations of “EMS vehicle”. We suggest that BoP consider mirroring proposed DEA PPAEMA language.
- Office of EMS, BoP, and EMS agencies may have differing interpretations of who is allowed to manage, store, and deliver EMS medications to stationhouses (schedule II-VI). We suggest that the BoP consider mirroring proposed DEA PPAEMA language, in which the Operational Medical Director decides who has authority to access medications, regardless of legal authorization to administer such medication.
- Record requirements for Schedule II -V medications are significant, but understandable. The CVFCA is requesting that the BoP not mirror DEA reporting requirements for schedule VI medications. For the administration of schedule VI medications, it is reasonable to report the medication name, dose, and individual who administered the medication.
- EMS providers operate under the patient care guidelines (PCGs), or protocols authorized by the agency Operational Medical Director (OMD). When using PCGs, instead of requiring the initials of the OMD on each recorded medication administration, it would be a reasonable alternative to require that the agency has a signed copy of the PCG, in lieu of the initials. The signed PCG would be made available to BoP upon request.
- In Virginia, medical devices that require a physician order are also considered under schedule VI. In the BoP regulations, it should be made clear that the regulations apply only to medications and not to devices.

We understand the difficulty and challenge presented to the Virginia Board of Pharmacy in developing regulations that comply with the DEA and FDA, while balancing the needs of clinicians and agencies. 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,



Edward L. Senter Jr.
Fire & EMS Chief, Chesterfield County
President, Central Virginia Fire Chiefs Association



HAMPTON ROADS FIRE CHIEFS ASSOCIATION

• CAMP PEARY • CHESAPEAKE • CURRITUCK • FORT EUSTIS • FRANKLIN • HAMPTON • ISLE OF WIGHT COUNTY • JAMES CITY COUNTY • LANGLEY AFB • NAVY REGION MID-ATLANTIC • NEWPORT NEWS • NORFOLK • NORFOLK INTERNATIONAL AIRPORT • POQUOSON • PORTSMOUTH • SUFFOLK • SURRY • VIRGINIA BEACH • WILLIAMSBURG • YORK COUNTY

April 4, 2024

Virginia Board of Pharmacy
9960 Mayland Drive #300
Henrico, VA 23233-1463

Dear Virginia Board of Pharmacy Members:

The Hampton Roads Fire Chiefs Association (HRFCA) is aware of the need for regulation changes associated with the Federal Drug Administration (FDA) Drug Supply Chain Security Act (DSCSA) and pending Drug Enforcement Agency (DEA) regulations for emergency medical services agencies. Our organization understands the need for greater accountability of controlled substances and supports a collaborative approach to ensure our agencies as well as the hospital systems are compliant with federal regulations. We would like to recognize the collaboration that is already happening between Virginia Board of Pharmacy staff and the state workgroup in developing the draft regulation changes.

We recognize our current practice of regional medication kit exchange will need to be modified however we request consideration for the unique environment in which EMS agencies operate and the challenges these regulatory changes will have on our agencies. We are committed to ensure our agencies implement recognized best practices into our operations and we request the Virginia Board of Pharmacy leverage the exclusions and exemptions for EMS agencies allowed by the federal regulations. The short time frame for implementation of these changes in our operations are creating logistical, financial, and administrative challenges for our career and volunteer agencies. Reducing some of the regulatory burden will help agencies implement the necessary measures to meet the controlled substance registration (CSR) and DEA regulations.

We are supportive and appreciative of the draft regulation that allows for a "hub and spoke" model for CSR to eliminate the need for separate CSR for each station or EMS agency operating within a jurisdiction. We hope that your final emergency regulations will also reduce the security measures for Schedule II-V controlled substances in sealed kits that are temporarily stored in stations that are operated 24 hours per day and secured when staff are out of the building. In addition, we are supportive of separate regulations and requirements for the storage of Schedule VI medications since the potential for theft and abuse is less of a concern.

In addition, we encourage the regulations to still allow for a 1:1 medication exchange with the hospital systems, that is allowed by the DCSA regulations. We understand the concerns that our hospital systems have with their ability to fully comply with the FDA regulations in November 2024 however we are optimistic that a collaborative solution can be developed since EMS agencies are seen as the end point. Implementing a 1:1 medication exchange program can significantly reduce the financial, logistical and administrative burden on agencies that have not had time to or are unable to prepare for the change.

We appreciate the opportunity to provide feedback to the Virginia Board of Pharmacy on behalf of the Hampton Roads Fire Chiefs Association and appreciate your efforts to ensure the Commonwealth is able to meet the national regulations. Your consideration of the impact to EMS agencies will be critical in ensuring we meet the regulatory requirements but also continue to provide our critical services in an efficient way.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. Barakey".

Michael J. Barakey
Chair, Hampton Road Fire Chiefs Association
Fire Chief, City of Suffolk



March 20, 2024

To Whom It May Concern:

We are writing to address a critical concern regarding the recent imposition of unfunded financial and regulatory mandates on EMS drug exchange within our community. As an integral member of this community and a stakeholder in its well-being, we feel compelled to express the significant burden these mandates place on both our EMS providers and our budgetary processes.

It's crucial to recognize that these mandates not only further strain the resources of our EMS services but also impose unnecessary financial hardships on the community as a whole. With our budgets in process of being finalized, the sudden introduction of additional financial obligations presents a substantial challenge that threatens to undermine the effectiveness of our emergency medical services.

The burden imposed by unfunded mandates extends beyond mere financial considerations. It disrupts the efficient functioning of our EMS systems, diverting resources away from essential services and hampering our ability to respond effectively to emergencies. Furthermore, these mandates introduce regulatory complexities that demand additional time and effort from our already stretched EMS personnel, potentially compromising the quality of care they provide to our community.

As responsible stewards of our community's resources, we must advocate for a more equitable approach to implementing regulatory requirements. It is imperative that any mandates imposed on EMS drug exchange be accompanied by sufficient funding to ensure their effective implementation without placing undue strain on our already limited resources.

We urge you to consider the broader implications of these mandates and work towards finding viable solutions that alleviate the burden on our EMS services and the community at large. Collaboration between stakeholders, including local government officials, regulatory agencies, and EMS providers, is essential to developing sustainable policies that prioritize both the safety and financial well-being of our community.

Thank you for your attention to this matter. We are hopeful that through constructive dialogue and cooperation, we can find mutually beneficial solutions that uphold the integrity of our EMS services while safeguarding the fiscal health of our community.



Gregory Wormser
Fire Chief, Lynchburg Fire Department



Janet Blankenship
Fire Chief, Bedford County Fire & Rescue



Bradley Beam
Amherst County Public Safety Director

Michael L. Thomas

Michael Thomas, Fire Chief
Charlottesville Fire Department

Tracy Fairchild

Tracy Fairchild
Campbell County Public Safety Director

April 5, 2024

To Whom It May Concern,

This letter is written on behalf of representatives of Emergency Medical Services (EMS) agencies across Region 6 for the Commonwealth of Virginia. The intent is to express our deep concern regarding the significant burden anticipated being placed on EMS services and systems due to the discontinuation of hospital-based drug box exchange programs in November 2024.

Hospital based drug box exchange program, which has been in place prior to 1980, provide a vital service for EMS by ensuring a reliable and efficient restocking of medications carried on State licensed ambulances. In order for ambulances (career, volunteer and private transport services) to return to service quickly in the communities they serve hospitals currently maintain an inventory of stocked EMS drug boxes which can be exchanged one-for-one of used and expired drugs. We anticipate the elimination of hospital-based drug box exchange that will occur in the fall to result in a significant budgetary strain on localities as they move to provide a secure pharmacy location within their department, to compensate full time personnel trained as pharmacy staff and purchase pharmaceuticals on their own. In addition we anticipate these challenges:

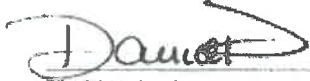
- **Increased Time Commitment:** Crews will now contend with inventory management coordination with vendors, internal pharmacies that may not be staffed 24/7, slow turn-around times which can have serious consequences to patients in need in the community.
- **Risk of Medication Errors:** Increased responsibility for medication management raises concerns about potential stocking errors. EMS agencies do not have trained pharmacists on hand, and the added complexity of restocking medications increases the cost to agencies for employing such personnel and increases the risk of mistakes occurring since no pharmacist will be directly onsite overseeing a technician.
- **Agencies Giving Up Advanced Life Support Care:** Due to the projected cost to localities it is anticipated that many agencies both career and volunteer will not be able to afford the ongoing cost of in house pharmacy and drug-box filling which will result in agencies forfeiting their right to practice at the ALS level.

We urge the Virginia Board of Pharmacy to defer the decision to discontinue hospital-based drug box exchange programs to a later date. Allowing localities to properly plan for and fund adequate space and processes to fill their own drug boxes. Or allow enough time for agencies to contract with private vendors for such. We believe continuing the current model, will keep the appropriate safeguards in place, provide efficiency and ensure the continued ALS services in the Commonwealth and ensure safety and the well-being of Virginians in need of emergency medical services. We are

open to discussing solutions that maintain strict medication control while streamlining the restocking process for EMS.

Thank you for your time and consideration. We look forward to working with you on this critical issue.

Sincerely,


David Hoback
City of Roanoke, Fire-EMS Chief


John Prillaman
City of Salem, Fire-EMS Chief


C. Travis Griffith
County of Roanoke, Fire-Rescue Chief


Jason Ferguson
County of Botetourt, Fire-Rescue Chief



Southwest Virginia
Emergency Medical Services Council, Inc.
506 Piedmont Avenue • Bristol, Virginia 24201 • (276) 628-4151



April 8, 2024

Virginia Board of Pharmacy
9960 Mayland Dr #300
Henrico, VA 23233-1463

RE: 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 Southwest Virginia Emergency Medical Services (EMS) Council, Inc., and our regional stakeholders, we thank you for the opportunity to provide feedback on your proposed regulations.

Representing sixteen jurisdictions in southwestern Virginia, we understand the need for and support 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. However, we believe that the unique environment and structures under which EMS agencies provide patient care must be considered. The current legislation and proposed changes would create hardships for EMS agencies in our region and throughout the Commonwealth.

For decades, EMS agencies have been supported by regional medication kit exchange systems. These systems allow for medication kits to be provided by a hospital pharmacy and exchanged when medications are administered to an EMS patient. Hospitals have borne the costs of these medications. In the proposed system, these costs would be transferred directly to EMS agencies with no ability to recoup those costs. Because local government and agency budgets have already been developed or approved at this point in the fiscal year, there is no time to plan for additional costs. This places an undue financial burden on EMS agencies and localities.

While we understand that these changes will impact the entire Commonwealth, there are unique concerns regarding the impacts of these changes in the far southwestern end of the state. Our region is mostly rural, with a majority of patient care provided by volunteer EMS agencies. The economic and geographic environment presents unique service delivery challenges including those noted below:

- The inability of ambulances to restock pharmaceuticals at receiving facilities would create extended turnaround time for units and negatively impact response rates, delaying and negatively impacting patient care.
- Most EMS agencies in the region do not have compliant, dedicated storage locations, automated dispensing devices, or staff to properly manage the accountability and

delivery of controlled substances.

- The overall financial impact on agencies is unknown, and the current implementation leaves no time to plan for this adjustment. Localities did not expect and have not budgeted for the increases in operational costs.
- Multiple agencies have indicated that they will downgrade their licensure from advanced life support to basic life support, delaying the provision of lifesaving interventions only allowed by ALS agencies.

We strongly encourage the Virginia Board of Pharmacy to consider the diverse geographical and demographical variations across Virginia when evaluating controlled substance regulations impacting EMS. Volunteer agencies may be overburdened by administrative and logistical challenges related to adherence and compliance with these regulations. Geographical considerations may make it impossible for patients to receive timely medication administration due to the downgrading of EMS licensure, resulting in poor patient outcomes.

The DSCSA includes a number of provisions for waivers and exemptions, including distribution for emergency medical services. We urge the Board of Pharmacy to obtain a determination as to whether current medication kit exchange programs are exempted as part of emergency medical services. In addition, we ask that the Board of Pharmacy issue guidance to cool plans to suspend current exchange practices until the actual scope of impact of federal regulations can be determined through collaboration and discussion with the relevant federal agencies.

We understand the difficulty and challenge presented to the Virginia Board of Pharmacy board members in establishing regulations that reflect changes in national regulations while supporting the needs of the diverse healthcare industry. As these changes do have the potential to negatively impact the provision of emergency medical services across Virginia, we thank you for your consideration of these concerns in drafting regulations and policies related to EMS agency medication storage and administration.

Sincerely,



John C. Bolling, President
On behalf of Southwest Virginia EMS Council, Inc..