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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Allowances for emergency drugs by EMS agencies
Date this document prepared	May 10, 2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Emergency medical services (EMS) providers throughout the Commonwealth have operated uniquely from other states for decades by exchanging partially used drug boxes or "kits" to multiple participating hospital pharmacies, which in turn supply EMS providers with new drug kits to use in EMS vehicles. This exchange has, for years, performed an important part of emergency service provision in Virginia, which ais also uniquely reliant upon volunteer EMS providers, as it allows EMS vehicles to ensure they are fully stocked to provide needed drugs to patients in transport or at accident sites. While seemingly condoned by the Drug Enforcement Administration (DEA), the kit exchange process is not fully compliant with DEA requirements as drugs are not exclusively transferred between DEA registrants or provided to an EMS agency working as an extension of a specific hospital DEA registration. Therefore, the tracking and ownership of controlled substances has historically been challenging and creates potential liability for hospital pharmacies.

Due to federal regulatory changes associated with the Drug Supply Chain Security Act, 21 U.S.C. § 351 *et seq.* (DSCSA), and the Protecting Patient Access to Emergency Medications Act, 21 U.S.C. § 823, hospitals have indicated that they will no longer provide and exchange drug kits with EMS providers as of November 27, 2024, the date the U.S. Food and Drug Administration (FDA) has indicated that it will begin enforcing additional requirements of the DSCSA impacting hospital pharmacies.

Following these federal changes, the Board of Pharmacy and EMS stakeholders have worked together to align regulations with new federal requirements and provide a solution to ensure EMS providers can provide drugs to patients as needed. To do so, many EMS agencies must obtain controlled substance registrations ("CSR") and subsequent registration from the DEA to purchase their own drug stock and transfer to associated EMS stations. The unique nature of emergency medical services requires the Board of Pharmacy to implement regulatory changes to ensure the process of obtaining CSRs and complying with drug requirements is not impractical or overly onerous on EMS entities while conforming to federal allowances for obtaining a DEA registration.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

EMS = emergency medical services
FDA = Food and Drug Administration
DEA = Drug Enforcement Administration
RFID = radio-frequency identification
ADD = automated dispensing device

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

a) Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.
b) Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change.

The following factors have created an emergency situation which requires immediate regulatory amendments:

- FDA enforcement of the Drug Supply Chain Security Act will begin as of November 27, 2024. This will impact the hospital drug kit exchange program.
- The implementation of regulations by the DEA in compliance with the Protecting Patient Access to Emergency Medications Act will impact the hospital drug kit exchange program. The DEA is in the process of adopting final regulations.
- EMS agencies predominantly rely on hospital drug kit exchanges to ensure EMS vehicles have adequate drug stock for emergency needs.

- EMS agencies will need to obtain CSRs and DEA registrations to purchase their own drug stock. Given the expense and practical problems with each individual station obtaining a CSR and DEA registration, a new system must be implemented in regulation for EMS entities obtaining CSRs and DEA registrations.
- Changes must be in place in time for EMS entities to obtain CSRs and DEA registrations, set up the hub-and-spoke model described below, and obtain drugs used to stock drug kits via wholesale distribution.

The Office of Regulatory Management and the Office of the Attorney General have been notified of this action and have agreed with the need to file an emergency action.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts and Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

As stated above, EMS agencies predominantly rely on hospital drug kit exchanges to ensure EMS vehicles have adequate drug stock for emergency needs. This system has been in place in Virginia for decades. Changes to federal regulations, however, will make hospital drug kit exchanges nonexistent, potentially leaving EMS vehicles without reliable sources of drugs to use when transporting patients or responding to emergencies. Therefore, the Board of Pharmacy, in consultation with VDH and stakeholders, has determined that regulatory changes are necessary and imperative to ensure the public can receive adequate emergency care.

These amendments address the need of EMS agencies and regional EMS councils to obtain or operate under controlled substance registrations and DEA registrations while balancing the unique needs and limitations of EMS agencies.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The amendments in these emergency regulations allow EMS agencies and regional EMS councils to apply for controlled substance registrations and use a hub-and-spoke model to service designated

locations of the entity holding the CSR and DEA registration. The regulations lay out requirements for required healthcare practitioners needed to maintain, audit, and dispense drug stock and requirements for prescribers connected to the CSR holder. The amendments provide certain allowances for EMS agencies and regional EMS councils regarding drug storage, alarm systems, and audits of drugs. The amendments also permit transfer of drugs between locations controlled by a hub CSR and between CSR holders.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) The primary advantages to the public are reliability of drug stock on EMS vehicles serving the Commonwealth. There are no disadvantages to the public.
2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system . . . Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title." The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There are no alternatives to regulatory changes. CSR requirements are contained in regulation. To amend those requirements, regulatory amendments must be made.

Failure to amend these regulations may result in failure of EMS agencies to obtain and maintain drug stock as needed to serve citizens of the Commonwealth, which in some cases could be catastrophic.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of the background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at https://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (http://www.townhall.virginia.gov) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the emergency regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-10		Provides definitions used in Chapter 20	The following definitions are added to this section: • designated location • EMS agency

			• emergency medical services provider/EMS provider • emergency medical services vehicle/EMS vehicle • hospital-owned • other EMS vehicle • regional EMS council • registered EMS agency headquarters • registered location • station All new definitions are to clarify usage in the later sections. All definitions have been created with the input of EMS stakeholders and reference to DEA regulations to ensure clarity and consistency of use.
20-500		Provides procedures for hospital pharmacy drug kit exchanges and ability of EMS agencies to obtain CSRs for the purpose of drug kit exchanges	This section is repealed, although the language contained in the section is moved to the new section 591. The language is moved from section 500 to new section 591 because the provision of kits by pharmacies will no longer be limited to hospital pharmacies. Additionally, more changes were made to the provision specific to EMS agencies. Section 500 is currently part of Part IX, Pharmacy Services to Hospitals. Given the broadening of the application of existing provisions and the new provisions specific to EMS agencies, this section requires a new section in a different part. Please see discussion of section 591, below.
20-505		Covers use of radio-frequency identification (RFID)	The existing regulatory language for this section is included in a new subsection A. Subsection A remains unchanged otherwise. A new subsection B is added which permits “registered EMS agency headquarters, regional EMS council, or designated location of the EMS agency or regional EMS council” to use RFID to verify accuracy of drugs placed in drug kits. This is amended to reflect the changes throughout this action regarding EMS entities and designated locations. Most of the provisions in subsection A are repeated in new subsection B with alterations to account for EMS agency use of RFID. The only provision not

			duplicated in subsection B is A 5, which provides pharmacies engaged in RFID tagging of drugs an exemption from certain other requirements in regulation which do not apply to EMS agencies. In general, the changes made to the language of subsection A to account for EMS agency use in subsection B include replacing “pharmacist” with “responsible party” and “pharmacy technician” with “person authorized to administer drugs.” B 4 differs from A 4 in that the EMS responsible party or designee authorized to administer drugs only performs a weekly random check of kits prepared that week rather than a daily random check of kits prepared that day. This reflects the significantly lower volume of kits that will be prepared by an EMS agency as opposed to a hospital pharmacy. The Board felt that daily checks of kits prepared that day would not be efficient or useful.
	20-591	Contains allowances for EMS agencies to obtain drugs	This new section is added to address EMS agencies’ ability to obtain emergency drugs for administration more broadly. The explanations below refer to changes made to the existing language currently found in 18VAC20-110-500. A new section A is added to clarify the purpose of the section as a whole, although much of the section made up the previous section 500, which has been repealed in this action (see above). The changes made by the Board to the previous language of section 500 eliminate the restriction of preparation of kits for EMS agencies to hospital pharmacies. Because the limitation to hospital pharmacies is removed, any pharmacy in the Commonwealth may provide drug kits to EMS agencies. Please note that B 10 refers to hospital pharmacies, but that subsection is specific to allowances for a hospital pharmacy to authorize its emergency department to exchange a drug kit. This language is in the current 500 B 10 and is not included in the expansion noted above.

			Drug kits containing only Schedule VI medications are carved out from certain requirements in the section, including requirements for sealing kits. These allowances apply to both those kits provided by a hospital pharmacy in an exchange and those kits compiled and distributed by an authorized EMS agency. These exceptions are found in B 2, B 4, B 6, B 10, D, E, G 3, G 4, G 6, H, and K. These allowances reflect the lower risk of diversion and misuse of these drugs, which are not federally scheduled controlled substances and are intended to reduce the burden on EMS agencies. Language in current 500 A 3 is not included in 591 because the requirement to maintain standing protocols by the operational medical director is now covered in 20-721 A. B 11 is added to clarify requirements for appropriate storage of drug kits. The provision specifically exempts EMS agencies participating in hospital pharmacy kit exchanges from obtaining a CSR from the Board unless the EMS agency must temporarily store drug kits outside of the secured location on the EMS agency vehicle and the agency does not otherwise serve as the designated location of a current CSR. If an EMS agency must obtain a CSR for temporary storage of drugs away from the EMS vehicle, the EMS building is exempt from the alarm system requirements contained in 20-710. Existing 500 B is not included in section 591. The ability for an EMS agency to obtain a CSR is now covered under 20-690 G and is expanded to cover Schedules II – VI. Current allowances under B only provide for Schedule VI. New subsection C is added to establish the hub-and-spoke model that may be used by EMS agencies obtaining CSRs under these new provisions. C allows EMS entities that have obtained CSRs and DEA registrations to deliver and transfer drugs to designated locations of the CSR holder. (Designated location is

			one of the new definitions added to 20-10.) New subsection D states that, for sites that are not designated locations of the entity providing the drugs, nothing shall preclude a hospital, EMS agency, regional EMS council, or designated location of an entity from transferring or distributing drugs in Schedule VI during a shortage of drugs or in an emergency. New subsection E carves out deliveries or transfers of drugs in Schedules II – V between all related entities during a shortage of drugs, public health emergency, or mass casualty event. New subsection F clarifies that a hospital pharmacy may provide drugs to a hospital-owned EMS agency operating as an extension of the hospital pharmacy's DEA regulation in compliance with federal law. New subsection G provides requirements for a pharmacy to supply drug kits to EMS agency vehicles for restocking when the EMS agency responsible for the vehicles has a CSR and DEA registration pursuant to these regulations. These requirements are intended to ensure proper recordkeeping and notification to authorized entities while allowing an EMS agency vehicle to obtain restocked drugs as needed to ensure public access to medications during an emergency event. New subsection H provides requirements for storage and sealing of drugs stored on EMS vehicles or other EMS vehicles, including fixed wing aircraft and licensed rotary aircraft. The requirements separate Schedule VI drugs, which are required to be stored in a manner to deter theft/loss but not required to be sealed, with controlled substances in Schedules II – V, which have specific requirements for storage listed in H 1 and H 2. H 3 provides an alternative security option to sealing a kit containing Schedules II – V. New subsection I sets forth requirements for EMS entities holding a CSR to

			implement procedures to review expiration dates of drugs to ensure no expired drugs are administered. This provision is included for the safety of the public. New subsection H requires EMS entities holding a CSR to report drug theft or unusual loss to the Board in accordance with Virginia Code § 54.1-3404. This is a standard requirement for CSR holders. New subsection K requires EMS entities holding a CSR to audit security of drug storage locations and perform a random audit of Schedule II – V drugs and required recordkeeping of each designated location every six months. Documentation of these audits is required to be kept for two years from performance of the audit. Requiring the EMS entities to perform these audits limits the need for the Board to send inspectors to every designated location under EMS entity hub-and-spoke CSRs. This will use Board resources more efficiently, may help in keeping costs down over time, and may assist with ensuring compliance and mitigation of diversion.
20-690		Contains requirements regarding persons or entities that may or must obtain CSRs	"EMS councils" are included in the list of entities that may be registered by the Board under subsection B. New subsection G is added to state that the Board may issue a CSR to an EMS agency or regional EMS council to receive controlled substances in Schedules II – V from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy. The entity receiving the CSR must identify to the Board any designated locations to which the entity may deliver controlled substances. Under the new language, the entity is required to obtain a DEA registration prior to delivery of Schedules II - V. The entity is also required to provide the Board with the name and physical location of each designated location and attest that each designated location complies with storage and security requirements of 20-710. Changes to designated locations must be submitted to the Board in advance of delivering controlled

			substances to those locations, and those locations must be approved sites under federal law. These requirements related to designated locations are necessary for the Board to implement the hub and spoke model for EMS entities to ensure security of drug stock and protection of the public. New subsection H clarifies that an EMS entity only receiving Schedule VI drugs or temporarily storing a secured drug kit within the EMS building if the vehicle cannot store the drug kit because of maintenance or inability to maintain appropriate temperature must obtain a CSR or operate as a designated location of a registered EMS agency headquarters.
20-710		Contains requirements for storage and security for controlled substances registrants	New subsection E is added which permits an EMS entity to store controlled substances in an automated dispensing device located at a secured site at the registered location or designated location of the EMS entity that meets certain requirements: (i) that the ADD is installed and operated by the EMS entity; (ii) that the ADD is not used to directly dispense controlled substances to an ultimate user; and (iii) that the ADD is in compliance with state law requirements. These requirements are intended to allow registered EMS entities the flexibility to use ADDs while ensuring protection of the public. Subsection F 6 (previously E 6) replaces “emergency medical services agencies” with “registered EMS agencies or regional EMS councils or designated locations of registered EMS agency headquarters or regional EMS councils” to reflect the hub and spoke model set forth in these amendments as a whole. “Intravenous fluids with no added drug” is deleted and “Schedule VI drugs or temporarily securing a secured drug kit which may contain Schedule II through Schedule VI drugs when the EMS agency vehicle cannot maintain appropriate drug storage temperature or is out of service” is added to reflect the changes in these amendments as a whole in the exemption of a location from needing to comply with alarm system requirements for other controlled

			substances registrants. This exemption was requested by the EMS stakeholders. New subsection G is added to list the locations at which a registered EMS agency headquarters or regional EMS council may store controlled substances. This list is provided for clarity to the CSR holders and limited to the locations provided for protection of the public by ensuring storage locations meet certain basic requirements. New subsection H is added to provide requirements for storage of drugs at appropriate temperatures. This requirement is necessary for protection of the public, as drugs have very specific storage requirements to ensure integrity of the drug stock.
20-720		Contains requirements for recordkeeping for CSR holders	The introductory provision is amended to include the reporting of any drug theft or unusual loss to the information the person listed as the responsible party on the CSR is responsible for maintaining records on. This provision is added to clearly reference the requirements under § 54.1-3404. Subsection 2 is amended to include the phrase “except as provided in subsection 9.” This is to require record maintenance in accordance with subsection 2 except for instances where an EMS agency or EMS regional council chooses to maintain records in accordance with subsection 9 as addressed below. New subsection 6 is added to include a requirement for the responsible party to maintain records describing the condition and extent of the responsible party’s authorization to dispense controlled substances for each EMS provider employed by or practicing at an EMS agency holding a controlled substances registration. Examples of such documents are provided, and the requirement is stated that the documents must be maintained in a readily retrievable manner and available for inspection and copying by agents of the Board. These recordkeeping requirements are put in place to ensure the Board can access information regarding the authorization to dispense

			controlled substances of the responsible party for an EMS entity, and that documentation is readily accessible for Board inspections. New subsection 7 is added to require records to be maintained by the responsible party of an EMS agency of all controlled substances received, administered, or otherwise disposed of. Records must also be maintained of deliveries of controlled substances between locations of an EMS agency or regional EMS council pursuant to the CSR. This documentation requirement is to ensure the safety of drug stock used by EMS entities with CSRs and ensuring the safety of the public. New subsection 8 is added to require documentation be maintained which verifies the completion of audits for each designated location pursuant to 591 K. This is added to ensure documentation is available for Board inspection regarding required audits. New subsection 9 is added to require EMS entities to maintain records and documentation, whether electronically or otherwise, for two years from the date of the execution of the record. This is again to ensure that the Board is able to inspect required documents. As noted above, EMS agencies or regional EMS councils may maintain records pursuant to subsection 2 or this subsection 9.
	20-721	Provides additional recordkeeping requirements specific to EMS agencies	Subsection A requires EMS entities and their designated locations to maintain written standing protocols signed by the operational medical director for the EMS agency. Oral orders must be reduced to writing and signed by the medical practitioner. Subsection B requires maintenance of records for each dose of drugs in Schedules II – VI administered and destruction of partially administered drugs in the course of providing emergency medical services. B also requires that destruction of partially administered controlled substances (Schedules II – V) must be done by two persons. One person must be the EMS provider. The second person can be a

			pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation must be maintained by the EMS agency or designated location for a period of two years from the date of destruction of the drug. An exception is made for emergency drug kits provided by a pharmacy under section 591. These destruction and recordkeeping requirements ensure that there will always be two individuals with specific credentials to witness destruction of a drug and that records are maintained which Board inspectors may review. These requirements ensure safety of the drug stock and the public. Subsection C lists required records to be maintained for each acquisition of drugs in Schedules II – VI from another registrant of the Board or distribution of drugs in Schedules II – VI to another registrant of the Board. This required listing of recorded information is necessary to ensure Board inspectors have access to information regarding movement of controlled substances to and from registered EMS locations. Access to that information and verification of movement of drug stock is necessary to the Board's mission of protection of the public. Subsection D describes situations in which a designated location of an EMS agency that receives Schedules II – V drugs must notify the registered location within 72 hours of receipt of drug. Those circumstances include receipt of drugs from a hospital while restocking following an emergency response, or the designated location receives drugs transferred from another designated location of the same agency. This requirement ensures that the EMS agency's registered location has record of drugs obtained from methods other than delivery or distribution from the registered location. New subsection E provides requirements for repackaging or prepackaging over-the-counter medication to the extent permitted under federal law. These requirements include specific recordkeeping, labeling, and compliance

			with USP-NF standards. These requirements will allow EMS agencies to repackage or prepackage over-the-counter drugs while ensuring the protection of the public. EMS stakeholders requested this addition to the regulations to account for current cost-saving practices used by some EMS agencies.