Virginia Regulatory Town Hall

townhall.virginia.gov

Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Exchange of kits with controlled substances by EMS agencies
Date this document prepared	6/10/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

Amendments to section 500 of Regulations Governing the Practice of Pharmacy are proposed to establish consistent standards for the security, safety and records of drugs dispensed by a hospital pharmacy to an EMS provider for administration to patients in emergency situations. Amendments include specificity about the content of the records for the kit containing drugs and devices and about which practitioners may reconcile contents to the administration record or witness destruction of drugs. An amendment will authorize the PIC of a hospital pharmacy to allow the exchange of the kit in the emergency department in order to relieve the EMS crew from having to take the kit to the hospital pharmacy for exchange.

The most substantive change is authorization for a one-to-one exchange of Schedule VI drugs or devices. Rather than replacement of the entire kit, the amended regulation will allow EMS providers to replace those drugs or devices directly from drug stock in the emergency department or from an automated drug dispensing device. In order to obtain and possess drugs not dispensed by the pharmacy, the EMS agency will need to obtain a controlled substance registration which may be issued for a single agency or for multiple agencies within a jurisdiction.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

EMS = Emergency medical services
CSR = Controlled substance registration
PIC = Pharmacist-in-charge

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On June 4, 2014, the Board of Pharmacy amended sections 10 and 500 of 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards, including the Board of Pharmacy, the responsibility to promulgate regulations and establish renewal schedules:

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 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 and Chapter 25 of this title…

The specific authority to control prescription drugs in the Commonwealth is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulatory action is to facilitate the work of emergency medical services while protecting the integrity and security of drugs administered to patients. Amended regulations will expedite the process of dispensing and exchanging drug kits essential to the work of EMS providers, which will result in less disruption for health care providers at the hospital who are focused on patient care and less down time at the hospital for EMS providers who need to be available to answer emergency calls in the community.

While the Board has worked on expediting and facilitating the drug kit process, it has also focused on more specificity about records and security. All schedules of drugs are available to EMS providers, in accordance with the protocol of their medical directors. Hence, there is opportunity for diversion or adulteration that could threaten the health and safety of a community. Regulations relating to drugs dispensed to an EMS agency are promulgated by the Board, rather than by the Department of Health which oversees EMS agencies. Therefore, it is important for the Board to adopt rules that are consistent and clear for the wide variety of EMS providers across the state.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The amendments have been developed in consultation with EMS providers and hospital pharmacists who are involved EMS agencies. Drafts were circulated and discussed over a series of meetings, so the Board believes consensus has been achieved and the proposed rules will not be controversial. Therefore, the Board has adopted the proposed changes by a fast-track action.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

Amendments to regulations for drugs carried by emergency medical service agencies are found in 18VAC110-20-500, which is amended as follows:

- Several amendments clarify that the kits carried by EMS agencies usually include "devices" in addition to "drugs."

- Amendments to #2 specify how a kit is to be sealed by the hospital pharmacy to ensure detection if the seal is broken. Many kits now utilize a mechanism for sealing that can only be resealed or relocked by the pharmacy once the kit is opened.
- An amendment in #3 clarifies that the written protocol for administration of drugs or devices, which has been signed by the medication director for EMS, has to be maintained by the pharmacy participating in a kit exchange.
- An amendment in #4 will allow the reconciliation of the record of drugs administered with the contents of an opened kit to be performed by a pharmacy technician or nurse in lieu of the pharmacist.
- Amendments to #5 will clarify what records have to be maintained for one year. The proposed regulation will specify the content of the records for filling and verifying the contents of the kit and also the record for exchange of the kit.
- A new provision is included as #6 to set out the requirement for destruction of partially used drugs and which two persons are allowed to witness the destruction.
- An amendment in #8 adds "irrigation solutions" to intravenous solutions as controlled substances that may be stored separately from the kit.
- A new #9 is added to clarify that any drug or device that shows evidence of tampering or damage must be removed from the kit and replaced.
- A new #10 is added to allow the hospital pharmacy to authorize the exchange of the kit in the emergency department of the hospital. If the kit contains Schedules II-V drugs, the exchange has to be handled by a licensed nurse, prescriber or pharmacist.
- A new subsection B is added in response from requests from EMS agencies which have been allowed by Board interpretation to perform a one-to-one exchange of Schedule VI drugs or devices. It will allow the one-to-one exchange provided the agency (or the jurisdiction) has obtained a controlled substance registration to authorize possession of the drugs not dispensed by a pharmacy. Schedule II-V drugs must be kept separate and sealed and are not eligible for a one-to-one exchange.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

1) The primary advantage to the public is the focus on patient care in hospitals and the availability of emergency services by removing any unnecessary barriers and expediting the dispensing and exchanging of drug kits for EMS agencies. There are no disadvantages.
2) While there are no direct advantages or disadvantages to the agency or the Commonwealth, more specific rules for drug kits will facilitate compliance and consistency, which is advantageous to VDH and the Board in their oversight responsibilities.
3) There are no other pertinent matters of interest.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements in this proposal more restrictive than federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no regulatory methods that will accomplish the objectives of applicable law.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	The entities likely to be affected would be EMS agencies and the hospital pharmacies responsible for the EMS kits containing controlled drugs and devices.
Agency's best estimate of the number of (1) entities that will be affected, including (2) small	As of May 1, 2014, there 673 licensed EMS agencies in Virginia. Many of those agencies

businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	would interact with multiple hospitals.
Benefits expected as a result of this regulatory proposal.	The primary benefit is the ability for an EMS agency to perform a one-to-one exchange of Schedule VI drugs or devices without the necessity of reconciling the entire drug kit. This improves efficiency with the exchange process, allows EMS to more quickly address subsequent 911 calls, and lessens the burden on pharmacy staff responsible for reconciling drug kits.. The secondary benefit is greater clarity about the requirements for security and efficacy of drugs in the kit and the responsibilities of parties involved in the contents of a kit.
Projected cost to the state to implement and enforce this regulatory proposal.	There are no costs to the state.
Projected cost to localities to implement and enforce this regulatory proposal.	If EMS agencies in a locality want the ability to perform one-to-one exchanges of Schedule VI drugs, they will need to obtain a controlled substance registration (CSR). Federal and state laws do not authorize the possession of controlled substance without a license or registration issued by the state. If the agency is performing the exchange without the involvement of the pharmacy, it assumes the responsibility and authority for possession of the controlled substance. The cost of a CSR is $90 but it may be issued to a single agency or to multiple agencies within a single jurisdiction. For example, Prince William County reportedly has 258 emergency boxes or kits currently in use by EMS agencies. The County would be able to obtain a single CSR for all of its agencies carrying kits. Most EMS agencies wanting to perform 1:1 exchange already possess a CSR based on past board interpretations.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	See above. All other regulations for security and recordkeeping are consistent with current requirements for hospital pharmacies.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

Alternatives that were less intrusive and costly were recommended by hospital pharmacists and EMS providers and considered over a period of several months and several meetings.

Amendments to 18VAC110-20-500 were adopted as an exempt regulatory action at the full board meeting on June 18, 2013 to conform the requirement for administration of drugs by emergency medical services personnel to the changes in § 54.1-3408, adopted in Chapter 191 of the 2013 Acts of the Assembly. At that time, the Regulation Committee determined additional amendments were needed because the regulations in section 500 were inconsistent with current practices and lacked sufficient specificity.

Verbal comment was received and heard for approximately two hours by the committee. Michael D. Berg, Manager, Regulation and Compliance with the Virginia Department of Health Office of Emergency Medical Services provided information and answered questions from committee members. Comments offered by staff considered during the discussion included: sealing and securing the drug kit, inventory and reporting loss of drugs, verification of drug box contents, records, destruction of drugs, exchange of drug by the emergency department, and one-for-one drug exchange. A draft of regulatory changes was adopted by the full Board at its meeting on September 18, 2013.

At its March 26, 2014 meeting, the Board learned that there were several comments from Virginia EMS agencies requesting that the Board reconsider the previously adopted draft of fast-track regulatory action to amend Regulation 18 VAC 110-20-500. Public comment was received by a pharmacist with INOVA Fairfax Hospital and the Executive Director for the Northern Virginia EMS Council. Joey King with the Northern Virginia EMS Council provided his insight on the needs of EMS agencies throughout Virginia and looks forward to working with the Board to achieve 1:1 exchange of Schedule VI drugs.

At a meeting of the Regulation Committee on May 12, 2014, Battalion Chief Jennie Collins with Prince William County Department of Fire & Rescue provided a handout of slides indicating there are 258 emergency boxes currently in use in Prince William County. Currently the county exchanges Schedule VI drugs on a 1:1 basis as informally condoned by the Board for the past several years. She stated if the Board prohibits 1:1 exchange of Schedule VI drugs and requires box for box exchange, the county will need 645 boxes to meet demand. Concerns expressed by Chief Collins for a box to box exchange include: increase in pharmacy and EMS workload based on need to inventory contents of every box upon exchange; increase need for hospital storage of boxes awaiting exchange; increase demand of drug inventory amidst drug shortages; increase in time associated with exchanging boxes which will delay EMS ability to respond to 911 calls. Chief Collins requested Board allow a 1:1 exchange of Schedule VI drugs and that Schedules II-V drugs are exchanged box for box. The Executive Director of the Northern Virginia Emergency Medical Services Council emphasized the importance of EMS personnel spending as little time as necessary at the hospital when transporting patients, because the demand on EMS increases substantially when ambulances are out of service. Several other persons supported the concept of a one-to-one exchange for Schedule VI drugs and devices.

The Committee voted unanimously to recommend to the full board that it amend the proposed draft of Regulation 18VAC110-20-500. Its recommendations were adopted by the full Board at its meeting on June 4, 2014.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	Sets out definitions for words and terms used in regulations	Adds a definition for EMS, which means emergency medical services and is used in section 500.
500	Sets out the requirements for preparation, security and exchange of a kit containing prescription drugs and devices used by licensed EMS agencies	Subsection A: • Several amendments clarify that the kits carried by EMS agencies usually include "devices" such as syringes, in addition to "drugs." • Amendments to #2 specify how a kit is to be sealed by the hospital pharmacy to ensure detection if the seal is broken. Many kits now utilize a mechanism for sealing that can only be resealed or relocked by the pharmacy once the kit is opened. *Drugs and devices in EMS kits are the responsibility of the PIC of the hospital pharmacy just as the controlled substances in the hospital itself. Therefore, there must be accountability for the drugs released to the EMS agency so the pharmacist can reconcile the drugs against a record of administration to detect diversion. The methodology for sealing and resealing kits is consistent with the system currently used by hospital pharmacies in Virginia.* • An amendment in #3 clarifies that the written protocol for administration of drugs or devices, which has been signed by the medical director for EMS, has to be maintained by the pharmacy participating in a kit exchange. *The protocol for administration is necessary in order to ensure that the drugs that have been used by the EMS providers are included in the protocol for administration.*

		• An amendment in #4 will allow the reconciliation of the record of drugs administered with the contents of an opened kit to be performed by a pharmacy technician or nurse in lieu of the pharmacist. *If authorized by the hospital pharmacy, the kit may be exchanged in the emergency room, so a rule that allows the nurse in the ER to reconcile the contents with the record will facilitate the exchange and enable the EMS crew to be available for emergency calls sooner. If the kit is exchanged at the pharmacy, the technician will be able to reconcile and avoid taking the pharmacist away from patient care. The Code requires reporting of any theft or unusual loss of scheduled drugs to the Board. Discrepancy records must be maintained for two years to aid in any subsequent investigation.* • Amendments to #5 will clarify what records have to be maintained for one year. *Currently, the rule simply requires that an accurate record be maintained for one year, but does not specify the content of the records for filling and verifying the contents of the kit and then the record for exchange of the kit. Records are maintained to protect the drug supply and the persons at the hospital and the EMS personnel who are responsible for the contents of the kits.* • A new provision is included as #6 to set out the requirement for destruction of partially used drugs. *In the regulation originally adopted by the Board, it was required for destruction to be witnessed by the EMS provider and a pharmacist, nurse or prescriber. One board member felt it was unreasonable to expect patient care providers in the hospital to take time to witness destruction of drugs, so the regulation was changed to include a pharmacy technician or a second EMS provider.* • An amendment in #8 adds "irrigation solutions" to intravenous solutions as controlled substances that may be stored separately from the kit. • A new #9 is added to clarify that any drug or device that shows evidence of tampering or damage must be removed from the kit and replaced. • A new #10 is added to allow the hospital pharmacy to authorize the exchange of the kit in the emergency department of the hospital. If the kit contains Schedules II-V drugs, the exchange has to be handled by a licensed nurse, prescriber or pharmacist. • A new subsection B is added in response from requests from EMS agencies which have been allowed by Board interpretation to perform a one-to-one exchange of Schedule VI drugs or devices. *Typically, the exchange is typically made in the Emergency Department and may be made through an automated drug dispensing device. Schedule II – V drugs cannot be exchanged on a one-to-one basis but must be kept separated from the Schedule VI drugs and in a sealed container. The advantage of the one-to-one exchange is immediate restocking of medications that allows a quick turnaround and return by the EMS agency to answer calls. In order to take possession of drugs that are not dispensed through the pharmacy, it will be necessary for the EMS agencies to have a*

		controlled substance registration. The CSR may be issued to a single agency or to multiple agencies within a single jurisdiction. The CSR does not authorize storage of the drugs at the facility but does allow storage on the EMS trucks or ambulances ready for administration to patients. There must be a record of the one-to-one exchange in accordance with the hospital PIC.