Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-31
Regulation title	Virginia Emergency Medical Services Regulations
Action title	Amend 12VAC5-31-1140 by eliminating language requiring the signature of a medical practitioner on the patient care report when EMS personnel administer drugs, perform invasive procedures or assist patients with their medications.
Date this document prepared	November 22, 2013

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

This revision eliminates the requirement to have a medical practitioner sign a patient care report (electronic or otherwise) attesting to the delivery of a drug or the performance of an invasive procedure because EMS providers are certified and authorized to administer drugs pursuant to the regulations of the Board of Health and an oral or written order or standing protocol of their Operational Medical Director. This also conforms to the Board of Pharmacy regulatory change in 18VAC110-20-500 indicating the same amendments.

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.

The Commissioner of Health approved the final regulations, Virginia Emergency Medical Services 12VAC5-31-1140, on behalf of the Board of Health on November 22, 2013

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.

During the 2013 session of the Virginia General Assembly, several bills (HB 1499 and SB 773) were introduced and subsequently passed that amended §54.1-3408 of the *Code of Virginia* permitting certified EMS personnel acting within their scope of practice to administer drugs and devices pursuant to an oral or written order or standing protocol.

Before the Office of EMS could remove language in the EMS Regulations that requires EMS personnel to obtain the signature of the medical practitioner who assumes responsibility for the patient, the Board of Pharmacy had to first remove language pertaining to medical practitioner signature in their existing regulations that appears in 12VAC110-20-500. The Board of Pharmacy met on June 18, 2013 and adopted changes in regulation that became effective September 25, 2013.

Section 32.1-111.4 of the Code of Virginia provides the statutory authority for these regulations:

§ 32.1-111.4. Regulations; emergency medical services personnel and vehicles; response times; enforcement provisions; civil penalties.

A. The State Board of Health shall prescribe by regulation:

1. Requirements for record keeping, supplies, operating procedures and other agency operations;

2. Requirements for the sanitation and maintenance of emergency medical services vehicles and their medical supplies and equipment;

3. Procedures, including the requirements for forms, to authorize qualified emergency medical services personnel to follow Do Not Resuscitate Orders pursuant to § 54.1-2987.1;

4. Requirements for the composition, administration, duties and responsibilities of the State Emergency Medical Services Advisory Board;

5. Requirements, developed in consultation with the Emergency Medical Services Advisory Board, governing the training, certification, and recertification of emergency medical services personnel;

6. Requirements for written notification to the State Emergency Medical Services Advisory Board, the State Office of Emergency Medical Services, and the Financial Assistance and Review Committee of the Board's action, and the reasons therefore, on requests and recommendations of the Advisory Board, the State Office of Emergency Medical Services or the Committee, no later than five workdays after reaching its decision, specifying whether the Board has approved, denied, or not acted on such requests and recommendations;

7. Authorization procedures, developed in consultation with the Emergency Medical Services Advisory Board, which allow the possession and administration of epinephrine or a medically accepted equivalent for emergency cases of anaphylactic shock by certain levels of certified emergency medical services personnel as authorized by § 54.1-3408 and authorization procedures that allow the possession and administration of oxygen with the authority of the local medical director and a licensed emergency medical services agency;

8. A uniform definition of "response time" and requirements, developed in consultation with the Emergency Medical Services Advisory Board, for each agency to measure response times starting from the time a call for emergency medical care is received until (i) the time an appropriate emergency medical response unit is responding and (ii) the appropriate emergency medical response unit arrives on the scene, and requirements for agencies to collect and report such data to the Director of the Office of Emergency Medical Services who shall compile such information and make it available to the public, upon request; and

9. Enforcement provisions, including, but not limited to, civil penalties that the Commissioner may assess against any agency or other entity found to be in violation of any of the provisions of this article or any regulation promulgated under this article. All amounts paid as civil penalties for violations of this article or regulations promulgated pursuant thereto shall be paid into the state treasury and shall be deposited in the emergency medical services special fund established pursuant to § 46.2-694, to be used only for emergency medical services purposes.

B. The Board shall classify agencies and emergency medical services vehicles by type of service rendered and shall specify the medical equipment, the supplies, the vehicle specifications and the personnel required for each classification.

C. In formulating its regulations, the Board shall consider the current Minimal Equipment List for Ambulances adopted by the Committee on Trauma of the American College of Surgeons.

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.

Each licensed Emergency Medical Services (EMS) agency is required to have an Operational Medical Director (OMD) that meets specific criteria outlined in the EMS Regulations. Certified EMS providers work under the direction and authorization of the OMD to include performing medical procedures and drug administration. Requiring a medical practitioner to sign patient care reports (electronic or otherwise) documenting drug administration or procedures -- that they may not be familiar with - is onerous to the emergency department practioner and unnecessary. Approved patient care guidelines (protocols) already exist authorizing the EMS provider to perform the drug administration or medical procedure under the authorization of the OMD. There is documentation (medication administration record) that is part of the

patient care report showing what was administered or performed and signed by the EMS provider. This action removes extra, unwanted demands on an already burdened medical practitioner in an emergency department, while maintaining a process that can be documented and establishes accountability, and protects the health, safety and welfare of patients.

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?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

This action eliminates unnecessary requirements and additional burdensome documentation for the medical practioner'. Key stakeholder groups and members of the EMS system support this change and no opposition is anticipated or has been voiced for this regulatory change.

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.

This action deletes paragraph B from 12 VAC5-31-1140 as follows:

~~A.~~ EMS personnel and EMS agencies shall provide the receiving medical facility or transporting EMS agency with a copy of the prehospital patient care report for each patient treated before the transporting personnel leave the facility. Should EMS personnel be unable to provide the full prehospital patient care report prior to leaving the facility, EMS personnel shall provide an abbreviated documented report with the critical EMS findings and actions at the time of patient transfer and the full prehospital patient care report shall be provided to the accepting facility within 12 hours.

~~B. The signature of the prescriber, as defined in § 54.1-3401 of the Code of Virginia who assumes responsibility for the patient shall be included on the prehospital patient care report for an incident when a drug is administered, or self-administration is assisted (excluding oxygen), or an invasive procedure is performed. EMS personnel shall not infer that the prescriber's signature denotes approval, authorization or verification of compliance with protocol, standing orders or medical control orders. The receiving prescriber signature requirement above does not apply to drugs that are maintained by EMS personnel during transport of patients between healthcare facilities, provided adequate documentation of ongoing drugs are transferred with the patient by the sending facility.~~

~~If a patient is not transported to the hospital or if the attending prescriber at the hospital refuses to sign the prehospital patient care report, the PPCR shall be signed by the agency's operational medical director within seven days of the administration and a signed copy delivered to the hospital pharmacy that was responsible for any drug kit exchange.~~

This amendment would allow the EMS provider to document the administration of a drug or procedure as part of the "protocols" as established by their contracted OEMS-approved Operational Medical Director The drug administration documentation is supported by the Board of Pharmacy regulations 18VAC110-20-500. This amendment will reduce the amount of time an agency needs to be out of service to gain signatures prior to the exchanging of drug kits within facilities and returning the units back to service.

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.

Amending the identified regulation will permit a quicker "in-service" time for the EMS unit to prepare for the next request for service. The time spent seeking a medical practioner signature for medication administration or a specific procedure only delays the in-service time for a response unit. Delays in returning EMS units to service can be particularly troubling in high volume systems or in a rural agency with limited resources trying to meet EMS call demands. There are no disadvantages to the public or the Commonwealth.

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 that exceed applicable 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.

This proposed amendment affects all localities in the Commonwealth of Virginia.

Regulatory flexibility analysis

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.

This recommended change allows greater regulatory flexibility by creating a less stringent compliance and reporting process.

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.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	No anticipated additional costs.
Projected cost of the *new regulations or changes to existing regulations* on localities.	No anticipated additional costs.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Hospital and pharmacies providing drug kits will be affected, but it is in line with the amended Board of Pharmacy Regulations allowing such a practice.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	This affects the licensed EMS agencies in Virginia, 685 as of September 30, 2013.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential	No anticipated additional costs.

purposes that are a consequence of the proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	Reduces out of service time for EMS agencies at hospitals to better serve their jurisdictions and patients.

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.

There are no viable alternatives identified that would be less intrusive or least burdensome.

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 institution of the family or family stability.

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.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

1140		A. EMS personnel and EMS agencies shall provide the receiving medical facility or transporting EMS agency with a copy of the prehospital patient care report for each patient treated before the transporting personnel leave the facility. Should EMS personnel be unable to provide the full prehospital patient care report prior to leaving the facility, EMS personnel shall provide an abbreviated documented report with the critical EMS findings and actions at the time of patient transfer and the full prehospital patient care report shall be provided to the accepting facility within 12 hours. B. The signature of the prescriber, as defined in § 54.1-3401 of the Code of Virginia who assumes responsibility for the patient shall be included on the prehospital patient care report for an incident when a drug is administered, or self-administration is assisted (excluding oxygen), or an invasive procedure is performed. EMS personnel shall not infer that the prescriber's signature denotes approval, authorization or verification of compliance with protocol, standing orders or medical control orders. The receiving prescriber signature requirement above does not apply to drugs that are maintained by EMS personnel during transport of patients between healthcare facilities,	~~B. The signature of the prescriber, as defined in § 54.1-3401 of the Code of Virginia who assumes responsibility for the patient shall be included on the prehospital patient care report for an incident when a drug is administered, or self-administration is assisted (excluding oxygen), or an invasive procedure is performed. EMS personnel shall not infer that the prescriber's signature denotes approval, authorization or verification of compliance with protocol, standing orders or medical control orders. The receiving prescriber signature requirement above does not apply to drugs that are maintained by EMS personnel during transport of patients between healthcare facilities, provided adequate documentation of ongoing drugs are transferred with the patient by the sending facility.~~ ~~If a patient is not transported to the hospital or if the attending prescriber at the hospital refuses to sign the prehospital patient care report, the PPCR shall be signed by the agency's operational medical director within seven days of the administration and a signed copy delivered to the hospital pharmacy that was responsible for any drug kit exchange.~~ Rationale: This would allow the EMS provider to document the administration of a drug or procedure as part of the "protocols" as established by their contracted OEMS approved Operational Medical Director The drug administration documentation is supported by the Board of Pharmacy regulations 18VAC110-20-500. This reduces the amount of time an agency needs to be out of service to gain signatures prior to the exchanging of drug kits within facilities and returning the units back to service.

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