

Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Department of Health (State Board of)
VAC Chapter Number:	12 VAC 5-31
Regulation Title:	Virginia Emergency Medical Services Regulations
Action Title:	Comprehensive Revision and Consolidation of regulations addressing emergency medical services in Virginia, i.e., Adoption of Chapter 31 and Repeal of Chapter 30
Date:	July 21, 2000

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

Purpose

Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.

The overarching purpose of the intended regulatory action is three-fold: to consolidate the Commonwealth's regulations regarding emergency medical services in a logical and "user-friendly" manner, to remove unnecessary requirements, and to update regulatory provisions so that they reflect crucial changes in technology that will provide Virginians will an enhanced level of emergency medical services.

These intended regulations contain criteria, standards and requirements for emergency medical services (EMS) agencies, personnel, vehicles, training programs, medical direction and early defibrillation services. The intent of the regulations is to protect the health, safety and welfare of Virginia citizens and to ensure that a quality standard for the provision of emergency medical services exists throughout the Commonwealth. The intended regulations will consolidate many guidelines and procedures that have historically been separated. It has been 10 years since the Rules and Regulations governing EMS were revised and adopted by the Board of Health. The

provision of EMS is dynamic and these regulations are intended to address the many associated changes arising from technology and public expectations.

Basis

Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.

The following is a comprehensive summary of Virginia law that authorizes the State Board of Health to adopt regulations addressing the provision of emergency medical services in Virginia:

Section 32.1-111.3 of the Code of Virginia directs that the Board of Health "shall develop a comprehensive, coordinated, emergency medical care system in the Comonwealth "

Section 32.1-111.4 of the Code of Virginia vests authority for the regulation of emergency medical services in the State Board of Health. The law specifically requires that the Board regulate such services by establishing minimum standards for agencies and for emergency services vehicles by type of service rendered and specify the medical equipment, supplies, vehicle specifications and the personnel required for each classification. The law further requires the use of licensure, certification and inspection for compliance.

The intended regulatory action would establish minimum standards for agency, vehicle and personnel. The regulations would include most existing standards and additional requirements for agencies to assist identification of licensed EMS agency's ability to maintain minimum licensure requirements. EMS vehicle classifications would be consolidated with the intent of simplifying the permitting process and standardizing the equipment and personnel requirements.

(See http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-111.4)

Section 32.1-111.4 of the Code, essentially, directs the State Board of Health to prescribe by regulation: Requirements for record keeping, supplies, operating procedures and other [EMS] agency operations; requirements for the sanitation and maintenance of emergency medical services vehicles and their medical supplies and equipment; procedures, including the

Town Hall Agency Background Document

requirements for forms, to authorize qualified emergency medical services personnel to follow Do Not Resuscitate Orders pursuant to § 54.1-2987.1; requirements for the composition, administration, duties and responsibilities of the State Emergency Medical Services Advisory Board; requirements, developed in consultation with the Emergency Medical Services Advisory Board, governing the certification and recertification of emergency medical services personnel.

The intended regulatory action would require licensed EMS agencies to establish protocols and operating procedures for record keeping. New certification levels would be established at the Advanced Life Support level to conform with national education and practice standards.

(See http://leg1.state.va.us/cgibin/legp504.exe?000+cod+32.1-111.4)

The Board, in order to provide consistent interpretation and enforcement of the EMS regulations, has determined that clear definitions of words and terms are required to assist EMS agencies and personnel in their understanding of regulations pertaining to the statewide EMS system. The Board also recognizes the need for a specified process to review and grant variance and exemption requests submitted by local EMS agencies and personnel who are unable to meet established minimum statewide system standards.

The intended regulatory action would allow for the inclusion of additional definitions of medical terms to address new procedures and equipment developed since the 1990 regulations were promulgated. The need for standardization of EMS vocabulary across the Commonwealth is clear and this intended action would address this need.

(http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-111.9)

§ 32.1-111.5 of the Code directs the Board of Health to prescribe by regulation the qualifications required for certification and recertification of emergency medical attendants. It also requires that such regulations shall include authorization for continuing education and skills testing, authorization for exemptions of testing, and options for sequential skills testing for recertification.

This intended regulatory action would streamline the recertification process for EMS personnel by allowing recertification through continuing education. An EMS agency's

3

Town Hall Agency Background Document

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Form: TH-01
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Operational Medical Director would be allowed to exempt qualified EMS personnel from the required written examination for recertification and authorize sequential testeing of needed practical skills throughout certification.

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-111.5

The primary role of the EMS physician is to ensure quality patient care and training. Because of rapidly changing technology and advances in EMS procedures and techniques, all aspects of the organization and provision of basic and advanced life support emergency medical services (EMS) require the active involvement and participation of physicians. These intended regulations will establish procedures, standards and responsibilities for state-endorsed emergency medical services (EMS) physicians who are associated with EMS agencies, personnel and training programs. The intent is to establish a clear line of medical control and accountability over both EMS practice and training. The need for medical oversight of EMS agencies, personnel and training is intrinsic to the delegated medical practice that authorizes emergency medical services in the Commonwealth. The law requires physician authorization in order for a certified EMS technician to practice or administer medications.

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+54.1-3408

§ 32.1-111.14:1 of the Code requires that all persons possessing an automated external defibrillator (AED) must register with the Board before placing such equipment in use. The Code also directs the Board of Health to establish requirements for AED registration to include training standards for operators, maintenance of the devices, medical direction for registered users. Additionally, these regulations will prescribe disciplinary actions for those persons who are required to do so but who fail to obtain registration.

The intended regulatory action would establish a statewide registry for AED owners. It would allow for the emergent use of AEDs by registered operators. Minimum training standards, equipment maintenance criteria and medical direction involvement would be established.

The Code specifically exempts a health care facility licensed by the Board of Health or the Board of Mental Health, Mental Retardation and Substance Abuse Services or an adult care residence licensed by the Board of Social Services or any person regulated by a health regulatory board

4

within the Department of Health Professions whose scope of practice encompasses such services,

or an emergency medical services agency regulated by the Board from the requirements for AED registration.

(http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-111.14 C 1)

Substance

Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.

The intent of this proposed regulatory action is to clarify and simplify the content of EMS regulations. They also intend to improve EMS agency and personnel compliance and to incorporate the latest changes in emergency patient care techniques, procedures and medical technology. Exisiting regulations provide for multiple classifications of EMS vehicles which complicate the deployment of resources by EMS agencies. The intent of this regulatory action is to simplify specifications for the design and construction of ambulances by establishing a single standard based upon nationally accepted guidelines. New and revised regulations are essential to provide safe, efficient and quality emergency medical care services to all citizens and visitors of the Commonwealth.

The proposed regulatory action would provide for oversight of EMS training programs through specification of policies and procedures for the qualification and enrollment of students, conduct of courses and administration of EMS certification examinations. Revision and reorganization of previously issued guidance documents would be included to update the administration of EMS education and training programs. For example, the minimum prerequisites to enroll in a course would be defined by regulation instead of by a guidance document.

Furthermore, the proposed regulatory action would conform to revisions of national standard training curricula and implement changes in the nature and scope of out-of-hospital patient care techniques. The Emergency Medical Technician - Intermediate certification level, not currently recognized in Virginia, would be adopted as a Virginia EMS certification level. This action would enhance the level of Advanced Life Support in the Virginia EMS system to care for critical patients.

This regulatory action would delineate the qualifications, responsibilities, and authority of physicians serving as Operational Medical Directors and Physician Course Directors. Clear procedures for the endorsement of EMS physicians, requirements for written agreements

between EMS physicians and EMS agencies, policies for termination of such written agreements and a mechanism for resolution of conflicts between EMS physicians and EMS agencies would be established.

This intended regulatory action would also address the fact that survival from sudden cardiac arrest depends directly on rapid access to defibrillation. Every minute of delay in defibrillation reduces the chances of a person surviving sudden cardiac arrest by seven to ten percent. Currently, only licensed emergency medical services agencies are permitted to administer cardiac defibrillation in the out-of-hospital setting. These regulations expand that authority to entities that register their devices and meet approved training and operational standards. The need to have adequately trained individuals operating these medical devices was identified by agencies such as the American Heart Association and American Red Cross. These regulations intend to assure equipment standardization, quality assurance and uniformity of training throughout the Commonwealth. The General Assembly determined (§ 32.1-111.14:1.) that system oversight is necessary to protect the citizens by specifying the conditions under which automated external defibrillators can be used, operated and maintained and authorizing the Board to promulgate appropriate regulations.

Alternatives

Please describe, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet the essential purpose of the action.

The Board is in the process of developing proposed regulations for public comment to ensure that they embody the most appropriate, least burdensome and least intrusive framework for effectively administering the Virginia EMS system.

The agency anticipates that there will be additional definitions added to the regulations as additional comments are received and EMS regulations are implemented. These regulations are required under § 32.1-111.4 of the Code. Adoption of the intended regulations will establish minimum standards for EMS agencies, vehicles, and personnel that reflect currently-accepted and effective approaches. Procedures for agency licensure, personnel certification and enforcement of the regulations will be updated. Each of these elements are essential components to an EMS system in order to guarantee minimum statewide standards of care exist in the Commonwealth. § 32.1-111.5 of the Code directs the State Board of Health to prescribe such regulations.

The proposed regulatory action intends to consolidate multiple guidance documents that previously established procedures and guidelines for the oversight of EMS training programs. Consolidation of these multiple documents into a single chapter of the Virginia Administrative Code will facilitate use of the regulations by the public.

Town Hall Agency Background Document

There are no known alternatives that would better protect the public health and safety of Virginians. Adoption of revised regulations will ensure EMS physicians have authority over patient care, authority to limit immediately the patient care activities of those who deviate from established standards or do not meet training standards, and the responsibility or authority to develop and implement medical policies and procedures. Procedures for endorsement of EMS physicians are an essential component of an emergency medical services system and guarantees a minimum statewide standard of care.

The intended regulations for early defibrillation services are required under § 32.1-111.14:1 of the Code of Virginia.

Family Impact Statement

Please provide a preliminary analysis of the potential 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.

The proposed regulations will greatly benefit Virginia's families by ensuring a higher level of emergency medical services state-wide. Developing a comprehensive, coordinated statewide emergency medical services system is essential to reducing death and disability resulting from sudden or serious injury and illness in the Commonwealth. Standardized methods for inspection, licensing, permitting, certification and medical direction for emergency medical services agencies, vehicles and personnel and the use of automated external defibrillators by a targeted segment of the population is essential to maintain reliable access and a constant state of readiness throughout Virginia.