Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12VAC5-31
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:	May 21, 2001

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The purpose of the intended regulatory action is 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 vital improvements in practice and technology are reflected thus providing Virginians with an enhanced level of emergency medical services.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

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 the Board of Health to "develop a comprehensive, coordinated, emergency medical care system in the Commonwealth . . .." 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.

These intended regulations would establish minimum standards for agency, vehicle and personnel. The regulations include existing standards; as well as additional requirements agencies must meet to maintain licensure. EMS vehicle classifications are 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 requirements for forms, to authorize qualified emergency medical services personnel to follow Durable 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.

These intended regulations 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 to 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.

These regulations allow for the inclusion of additional definitions of 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 these regulations 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.

These regulations streamline the recertification process for EMS personnel by allowing recertification through continuing education. An EMS agency's Operational Medical Director would be allowed to exempt qualified EMS personnel from the required written examination for recertification and authorize sequential testing of practical skills throughout the certification period for EMS Personnel.

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 regulations establish procedures, standards and responsibilities for state-endorsed emergency medical services (EMS) physicians who are associated with EMS agencies, personnel and training programs. There is an established line of medical control and accountability over both EMS practice and training. 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 prescribe enforcement actions for those persons who fail to obtain registration.

These regulations 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 are 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 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)

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

These 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 these regulations is to protect the health, safety and welfare of Virginia's citizens and to ensure that a quality standard for the provision of emergency medical services exists throughout the Commonwealth. These regulations 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 address the many associated changes arising from improved practice and technology and increased public expectations and awareness.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The intent of the regulatory action changes is to clarify and simplify the content of EMS regulations. The changes are intended to improve EMS agency and personnel compliance and incorporate the latest emergency patient care techniques, procedures and medical technology. Existing 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.

These regulations 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 are included to update the administration of EMS education and training programs. For example, the minimum prerequisites to enroll in an EMS certification course would be defined by regulation.

Furthermore, this 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 and Emergency Medical Technician - Enhanced certification levels, not currently recognized in Virginia, would be adopted as Virginia EMS certification levels. This action would enhance the level of Advanced Life Support in the Virginia EMS system to care for critical patients.

These regulations 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 are established.

This regulatory action addresses 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 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.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

Issues to the public include:

Fluidity of the statewide EMS system would be enhanced. Emergency Medical Services for children would be enhanced by increased requirements for pediatric equipment and supplies on ambulances. Safety issues concerning EMS personnel and EMS vehicle equipment and marking requirements are identified and addressed specifically. Automated External Defibrillation Registry is created.

Issues to the Department of Health:

Variance approval is delegated to the Office of EMS. Terms are defined using Code of Virginia definitions. Reporting requirements for EMS Agency and personnel would allow for a more consistent communication flow. Clarification of the licensure application and enforcement processes is provided.

Issues to the regulated community and locality:

Designated Emergency Response Agencies are identified. Telecommunication issues are complex due to the challenges of implementing new technology and needs for interoperability. Staffing requirements for EMS vehicles present a challenge for rural agencies as the availability of volunteer hours competes with other demands of modern living. A Response Interval Standard and Mobilization Interval Standard are created as performance measures. Local EMS Resource is identified and defined. Supplemented Transports are defined and regulated. Primary Service Areas of EMS agencies are identified and defined. Program Site Accreditation for EMS education and training is identified and defined. Public Safety Answering Point is defined. Quality Management Programs are identified and defined on a statewide basis. Response Obligation to Locality is created that requires Designated Emergency Response Agencies to assist within their locality. Special Conditions are defined. Specialized Air Medical Training is created. Inter-Facility Wheelchair Transport Service is defined and regulated. Virginia EMS Compliance Manual is created and specified. EMS Agency availability (24 hour basis) is required for non-Designated Emergency Response Agencies. Participation in regional trauma triage plans is required.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

A. The projected cost to the state to implement and enforce the proposed regulations:

There are no anticipated implementation costs associated with these regulations. Enforcement cost is estimated to be $ 592,376.00.

1. Fund Source: Fund Code 0213.

2. Budget Activity: Program Code 4020100.

3. Delineation of Costs: All on going. These proposed regulations do not require any one-time costs.

B. There are no identified costs to localities associated with these regulations.

C. Entities affected by these regulations include EMS Agencies currently licensed; private transportation companies transporting emergent and non-emergent wheelchair bound persons; localities/governments providing emergency medical services response.

D. The estimated number of affected entities: 800 agencies and approximately 40,000 EMS personnel.

E. The projected cost of the regulation to affected agencies: Many EMS agencies exceed the current requirements and already meet the proposed new requirements. Approximately $1,000 per permitted vehicle to purchase additional required equipment is needed to meet these regulations excluding the cost of an Automated External Defibrillator that is approximately $3,000. Cost for agencies eligible for matching funds through the Rescue Squad Assistance Fund will be substantially less.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

Part I Definitions and General Requirements.

Part I contains many new and revised definitions of EMS related terms. Examples of new terms defined in these proposed regulations are: Air Medical Specialist, Chief Executive Officer, Chief Operations Officer, EMS Physician, Designated Emergency Response Agency, Primary Service Area, Program Site Accreditation, Public Safety Answering Point and Quality Management Program. Revised and expanded terms include: Medical Control, Medical Directions, Major Medical Emergency, Test Site Coordinator, Triage, Vehicle Operating Weight, Wheelchair and Wheelchair Interfacility Transport Service.

Changes in the variance process would delegate from the State Health Commissioner to the Office of EMS the authority to grant variances. Requirements for review of variance requests by the governing body of a locality would be standardized. Falsification of variance information would become grounds for denial or termination of a variance. The Office of EMS would be delegated enforcement authority by the Commissioner.

Part II. EMS Agency, EMS Vehicles and EMS Personnel.

Article 1 EMS Agency

Establishes regulations regarding EMS Agency licensure and requirements.

Section 2015 specifies The Virginia EMS Compliance Manual as a comprehensive guide to related policies for use by EMS Agencies and the Office of EMS.

2035 Creates a Designated Emergency Response Agency that is defined and identified as a primary emergency response agency by a locality.

2040 Requires EMS Agency response availability twenty-four hour availability without the use of mutual aid.

2045 Mandates EMS Agency participation in a regional trauma triage plan.

2055 EMS Agency licensure classifications have been changed.

2060 Ownership of an EMS Agency must be clearly identified.

2090 Termination of EMS Agency licensure requires notification of the Office of EMS and others in advance of termination. It also requires signage to be removed from the business location and medication kits be returned to the appropriate pharmacy.

2105 An EMS Agency that does not use an EMS Vehicle must maintain a minimum level of equipment. Also requires an agency to maintain 75 triage tags for use in a major medical emergency.

2110 Medication storage requires the temperature of stored medications on EMS vehicles be monitored and medications removed when temperature extremes are reached.

2120 Requires a criminal history background check be conducted by an EMS agency on all new members no more than sixty days prior to the individual's affiliation with the agency.

2125 EMS Vehicle Records must include a report of any reportable motor vehicle collision.

2130 Patient Care Record forms must specifically identify personnel meeting staffing requirements and include the signature and identification number of all EMS personnel on the EMS Vehicle. During local emergencies, a triage tag may be used to document patient care.

2140 An EMS Agency Status Report must be submitted when requested by the Office of EMS or upon change in specified officer positions.

2145 A copy of the regulations must be available at all EMS agency locations.

2150 Operational Medical Director requirements are established specifying responsibilities of both the agency and OMD. Conflict resolution and a change in medical director are included as are requirements for malpractice insurance.

2155 Establishes Quality Management Reporting requirements for EMS Agencies and Operational Medical Directors to monitor assess and improve the quality and appropriateness of patient care.

2160 Requires that Designated Emergency Response Agency standards be established by the local EMS response plan, specifically addressing response capability, a Unit Mobilization Interval Standard and a Responding Interval Standard. The plan is developed in consultation with the locality and the Operational Medical Director.

2165 Establishes a requirement for a minimum of eight EMS personnel who are qualified to function as an Attendant-In-Charge.

2170 Designated Emergency Response Agency Mutual Aid establishes a response obligation to locality and mutual aid agreements with adjacent Designated Emergency Response Agencies that share a common border and are in another locality.

Article 2 Emergency Medical Services Vehicle Permit.

2200 Requires that an EMS Vehicle must be equipped in compliance with the regulations at all times unless exempted.

Article 3 Emergency Medical Services Vehicles Classifications and Requirements

2300 Requires that the Gross Vehicle Operating weight of a ground ambulance be no more than the manufacturer's gross vehicle weight minus 700 pounds. Smoking is prohibited in an EMS transport vehicle. Possession of a firearm or weapon on an EMS Vehicle is prohibited with exceptions noted.

2305 Requires equipment and supplies in the patient compartment must be secured or affixed to protect the crew and patient.

2325 Has been updated to reflect new technologies available.

2330 EMS Communications has been updated, in part, to reflect new technologies available.

2335 through 2345 Establishes EMS Vehicle marking requirements that have been amended to enhance safety simplify specifications and allow for the design needs of EMS agencies.

2350 Specifically addresses medication storage related to non-transport EMS Vehicles.

2360 Establishes Advance Life Support equipment packages to allow for fluidity in transfer of staffing and equipment that reflects the "everyday and real life" needs of EMS Agencies.

2375 EMS Vehicle equipment requirements have been updated based on innovations, practice and technology. The equipment listing has been reformatted in chart form for ease of use.

Article 4 EMS Personnel Requirements and Standard of Conduct

2505 Specific criminal and enforcement history is identified as disqualifiers from EMS certification or entry into regulated activities. A conviction for driving under the influence will prevent EMS Personnel from functioning as the Operator of an EMS Vehicle for a period of five years.

2510 EMS Personnel are required to report suspected violations of EMS regulations within fifteen days.

2525 Disclosure of patient information is updated to reflect current standards for protecting patient confidentiality.

2540 EMS Personnel are prohibited from falsifying an application.

2545 - 2550 EMS Personnel are prohibited from making false statements or submissions.

2555 Misappropriation or theft of medications is prohibited.

2565 Prohibits sexual harassment by EMS personnel.

2575 The Virginia EMS Provider Skill and Medication Schedule identifies the range of skills and medications approved for each level of certification.

2580 Places the responsibility for adequate staffing of an ambulance or EMS vehicle on the EMS Agency.

2585 Extraordinary care outside of existing protocols.

2610 Provides a means to resolve provider disagreements over patients' needs.

2620 Clarifies and requires the receiving physician's signature on a patient's call record.

2625 Specifies when an EMS Vehicle can be operated under emergency conditions.

2635 Establishes conditions under which an EMS student may practice under supervision.

2645 Clarifies the authorization required for an Attendant-In-Charge to treat a patient.

2660 Specifies the circumstances under which equipment may be moved between EMS Vehicles.

2680 Establishes requirements for the transport of patients with specialized medical needs.

Part III EMS Education and Certification

Part III Expands and details EMS training, certification examination, instruction and EMS accreditation requirements.

Sections 3010 through 3030 specify curricula and Course Coordinator qualifications for each level of EMS certification.

3040 Establishes a requirement for Program Site Accreditation.

3050 through 3070 Establishes Course Coordinator reporting requirements to the Physician Course Directors and outlines requirements for course approval requests and accountability of Course Coordinators and Instructors.

3080 Establishes procedures for certification examinations as specified in the "Virginia EMS Certification Examination Manual".

3090 through 3150 Stipulates requirements for enrollment and certification eligibility for all levels of EMS Certification.

3160 through 3200 Identifies requirements for EMS certification examination, retests and integrity of certification retests.

3210 Outlines requirements that are specified in the "Virginia EMS Training Program Administration Manual."

3230 through 3280 Establishes certification periods, certification through reciprocity, equivalency, legal recognition and reentry, and voluntary inactivation of certification.

2390 though 3330 Establishes recertification requirements, continuing education conditions.

3340 and 3350 Specifies conditions for ALS Coordinator endorsement and renewal.

Part IV EMS Physician

4000 through 4060 Establishes requirements, qualifications, application and renewal of EMS physician endorsement by the Office of EMS.

4070 Establishes the roles of an EMS Physician and the Office of EMS' authority to set limits.

4080 through 4110 Stipulates the requirements for an agreement to serve as an Operational Medical Director (OMD). In addition, OMD responsibilities and conflict resolution methods are detailed.

4120 through 4140 identifies the responsibilities of a Physician Course Director.

Part V Wheelchair Interfacility Transport Services, Vehicles and Personnel

5000 through 5020 Establishes requirements for licensure, application and issuance.

5030 through 5060 Stipulates requirements for vehicle permitting and specifications.

5070 through 5080 Establishes personnel requirements and standards of conduct.

Part VI Early Defibrillation Service

6000 through 6080 Establishes requirements for Early Defibrillation Service registration and conditions for application and issuance of a registration.

6090 through 6170 Outlines requirements for an Early Defibrillation Service, personnel and standards of conduct.

Alternatives

Please describe the specific 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.

The Board has developed these 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. There are no known alternatives that would better protect the public health and safety of Virginians. Adoption of these regulations will insure that EMS physicians have authority over patient care, the authority to limit immediately the patient care activities of those who deviate from established standards or do not meet training standards, and the responsibility and 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 guarantee a minimum statewide standard of care.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

The agency received submissions of public comment during the NOIRA period as a result of the publication and distribution of draft versions of the regulations and public forums held across the state. The seven public forums were held in Abingdon, Roanoke, Prince William, Stafford, South Boston, Richmond, and Norfolk. Approximately one hundred people attended the forums and offered comment on new EMS regulations. Substantial sections of the proposed regulations were revised and/or altered as a result of public comment received at the forums or through electronic submission.

Specifically, the agency was requested to significantly change the communication requirements for EMS Vehicles. Original drafts of the regulations proposed that all EMS Vehicles be required to have a fixed radio capable of transmitting and receiving on four specific frequencies. Comments from the Virginia Association of Governmental Emergency Medical Services Administrators (VAGEMSA), the Virginia Association of Volunteer Rescue Squads (VAVRS), a large number of volunteer EMS Agencies and many individual EMS providers submitted comments indicating the prohibited cost and hardship associated with the initial proposal. The agency was able to propose a compromise that maintains the current requirement mandating that EMS Agencies have the capability of receiving and transmitting on one of four specific frequencies.

The original proposed draft regulations also required EMS Vehicles to be sheltered from climate extremes when not in use. The public comments received from Chip Decker (Lifeline

Ambulance), David Smith (REMS), John Sochor (Cobbs Creek) and Paul Young (Phoebus) indicated the financial hardship and storage problems this requirement would impose on the EMS system. The agency removed this requirement from the proposed regulation.

The initial proposal included a requirement for an ambulance to have a child safety seat as part of its minimal equipment. Concern expressed by many EMS Agencies and providers indicated that there is insufficient documentation and study to warrant this requirement in an ambulance. The comments were reviewed and the requirement was removed due to significant public opposition.

Significant public comment was received from volunteer EMS agencies concerning a requirement for an EMT to be with an Advanced Life Support (ALS) provider while performing ALS care. The comments indicated that volunteer agencies are experiencing great difficulty meeting minimum staffing requirements. This specific requirement was promulgated in 1990 and is strongly endorsed by the Medical Direction Committee of the EMS Advisory Board. The need for a second trained EMS provider to assist in the care of a patient in need of advanced care is substantial. The agency, in consultation with EMS physicians and the Medical Direction Committee, determined that the requirement should remain.

The agency did insert a provision that allows an ALS provider to render care without fear of violating regulations when adequate staffing is not available. The EMS agency is assigned the responsibility for adequately staffing its ambulances. The EMS provider cannot be held responsible through regulation for the EMS agency's inability to properly staff its units.

Public comment was received regarding the ability of a fire department to equip its trucks with Automated External Defibrillators (AEDs). The agency originally proposed that fire departments could not equip vehicles with AEDs without first obtaining an EMS Agency license. The agency is now proposing that fire department vehicles be allowed to carry AEDs but only if they are not dispatched for the primary purpose of rendering EMS care. If they are dispatched primarily for EMS response then the fire department must obtain an EMS agency license. VAGEMSA and a significant number of urban departments requested this ability.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The agency has received public comment from VAGEMSA and many individual providers indicating that the proposed regulations are easy to understand and simplify existing requirements for EMS Agency licensure and operation. The scheduling of public forums allowed members of the Virginia EMS system to ask questions and clarify the intent and meaning of the

proposed regulations. In each forum, the consensus reached was that the intended regulations were easily understood and clearly written.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The agency will formally review these regulations every three years with the first review scheduled for 2005. It is anticipated that specific sections will be reviewed more frequently with regulatory changes initiated on an as-needed basis as determined by the EMS Advisory Board, the agency and the Board of Health.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

These regulations will greatly benefit Virginia's families by ensuring a higher level of emergency medical services statewide. 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.