Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12VAC5-65
Regulation Title:	Regulations Governing Durable Do Not Resuscitate Orders
Action Title:	Adopt Regulations to Make Emergency DDNR Regulations Permanent
Date:	March 8, 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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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 proposed regulation establishes a Durable Do Not Resuscitate (DDNR) Order that follows the patient throughout the entire health care setting. The amendments will create a document that will depend less on the situation in which declarants find themselves and will be more likely to be honored. Once issued by a physician for his patient, the DDNR Order would apply wherever that patient may be – home, emergency vehicle, adult care residence, nursing home or hospital. EMS Do Not Resuscitate Orders (DNRs) provided for in the existing EMS DNR regulations apply only in the out of hospital setting.

Patients in consultation with physicians determine the content of advance directives concerning terminal illness and/or life sustaining measures. With a Durable Do Not Resuscitate Order, the

affected patient is allowed to have some measure of control over his or her illness and/or injury through determination not to employ life-sustaining measures. These regulations will establish a process that enables qualified health care providers to respond more appropriately to the expressed desires and needs of certain patients. The regulations will also provide an appropriate framework to guide the operation of this important program.

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 General Assembly has determined that regulations to govern Durable Do Not Resuscitate Orders are essential to protect the health, safety or welfare of citizens.

Specifically, the second enactment clause of SB 1174 (Act of Assembly c. 814, 1999) states "[t]hat the Board of Health shall promulgate regulations to implement the provisions of this act related to Durable Do Not Resuscitate Orders" as emergency regulations. Such emergency regulations were adopted as required. The proposed regulations are intended to replace the emergency regulations, which became effective January 3, 2000.

Section 54.1-2987 C of the Code specifies that qualified emergency medical services personnel and licensed health care practitioners in any facility, program or organization operated or licensed by the Board of Health or by the Department of Mental Health, Mental Retardation and Substance Abuse Services or operated, licensed or owned by another state agency are authorized to follow Durable Do Not Resuscitate Orders that are issued in accordance with statute and regulations promulgated by the Board of Health and available to them in a form approved by the Board.

Legal counsel in the Office of the Attorney General has certified that the agency has the authority to promulgate these regulations.

The applicable law may be viewed on the General Assembly Legislative Information System website at:

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+54.1-2987.1

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 replace prior Emergency Medical Services DNR and emergency regulations. These proposed regulations do not contain specific expiration date requirements for the DDNR Orders. Prior to the emergency regulations, EMS DNR Orders were valid for only one year and were required to be renewed by a physician and patient annually. The eliniation of a revocation date enables citizens of the Commonwealth to work with their physicians to establish a DDNR Order without fear of expiration.

These proposed regulations clarify that minors are eligible for DDNR Orders. EMS DNR Orders were not valid for minors and could not be honored in emergency situations in the field. By allowing the parents or guardians of minors to institute DDNR Orders, the emergency medical personnel responding in or out of the hospital to assist the minor can intiate or wthhold appropriate treatments.

These proposed regulations enable citizens to intiate DDNR Orders with their physicians without being terminally ill. Past regulations required that the patient be diagnosed as terminal. These proposed regulations enable patients to make their decisions, in consultation with their physicians, well in advance of critical illness or pressing illness.

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.

Section 54.1-2987 C of the Code specifies that qualified emergency medical services personnel and licensed health care practitioners in any facility, program or organization operated or licensed by the Board of Health or by the Department of Mental Health, Mental Retardation and Substance Abuse Services or operated, licensed or owned by another state agency are authorized to follow Durable Do Not Resuscitate Orders that are issued in accordance with statute and regulations promulgated by the Board of Health.

The proposed regulations establish a Durable Do Not Resuscitate (DDNR) Order that follows the patient throughout the entire health care setting. Once issued by a physician for his patient, the DDNR Order would apply wherever that patient may be – home, emergency vehicle, adult care residence, nursing home or hospital.

Part I (section 12VAC5-65-10) of the proposed regulations contains definitions of key words and terms used throughout the body of the proposed regulations. The proposed regulations allow Durable DNR orders to be issued by "a physician for his patient with whom he has a bona fide physician /patient relationship as defined in the guidelines of the Board of Medicine."
The definition of "qualified health care personnel" is included in the proposed regulations. Those personnel, which are authorized to honor DDNR Orders, are defined as licensed health care

personnel, and include qualified emergency medical services personnel. The definition excludes certified health care personnel.

Part II (sections 20 through 60) contains provisions relating to the authority, purpose, administration, application and effective date of the proposed regulations. These sections are identical in the proposed regulations and the prior EMS DNR regulations.

Part III (sections 70 through 90) has provisions that address the content and distribution of the DDNR Order Form, revocation of a DDNR Order and allowance of alternate forms of DDNR Order identification. The DDNR Order Form is included as part of the proposed regulations. The proposed regulations state that altered DDNR Orders cannot be honored by health care personnel. There are also provisions that clarify that the regulations do not limit the issuance of or authorization of practitioners to follow Do Not Resuscitate Orders other than DDNR Orders for patients who are currently admitted to a hospital or other health care facility.

The proposed regulations contain a provision stating that the DDNR Order shall be completed by a physician on a patient with whom he has a bona fide established physician/patient relationship. The proposed regulations state that the DDNR Order shall remain valid until revoked. The proposed regulations specify that a DDNR Order is valid in any facility, program or organization operated or licensed by the State Board of Health, or by the Department of Mental Health, Mental Retardation and Substance Abuse Services or operated, licensed or owned by another state agency. The proposed regulations contain a DDNR Order Form and allow the use of authorized alternative forms of Durable DNR Order identification approved by the State Board of Health.

Part IV (sections 100 and 110) contain implementation procedures for DDNR Orders. Specifically, procedures relating to the following are included: issuance of the Order, confirmation of DDNR Order validity status, resuscitative measures to be withheld or withdrawn, provision of comfort care or alleviation of pain, revocation of Orders, documentation in the patient's medical record of care withheld or rendered, and general considerations outlining implementation when there are misunderstandings or questions about the validity of DDNR Orders or other DNR Orders. The provisions in these sections in the proposed regulations are essentially the same as the corresponding provisions in the past EMS DNR regulations. The one substantive difference is that a provision in the proposed regulations, as authorized by the enabling statute, allows the issuance of DDNR Orders for minors; the EMS DNR regulations did not allow issuance of DNRs for minors.

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.

An advantage to citizens with this regulation is the ability of a citizen, in advance of an emergent or immediate need, to decide whether to request life-sustaining measures should be taken. These regulations will give citizens the primary ability to choose how they are to be cared for in certain medical situations. This regulation also advantages the health care system and health care personnel as it allows the desire of the patient to be known in cases where the patient cannot express his opinion.

There are no identified disadvantages to this regulation.

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.

The projected cost to the state to implement and enforce this regulation is $5,000 annually. This includes the cost of printing the forms and staff time dealing with orders of the form. This funding for expenditures is derived from the Office of Emergency Medical Services. All funding is from Special Funds obtained through Two-for-Life funding code 0213 and program codes 4020100 and 4020300.
All citizens of the Commonwealth may choose to be affected by this regulation if they decide to participate.
The agency anticipates approximately 60,000 forms will be distributed annually with 35,000 - 40,000 additional forms being completed for use each year.
The projected cost to for affected individuals or other entities is estimated to be non-existent.

Additionally, the costs savings that will accrue from the avoidance of unwanted or inappropriate resuscitation efforts would likely be significant for the health care system, but are, at present, unquantifiable to any reliable degree.

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.

The substantive provisions of these regulations, which did not exist before the emergency regulations adopted in 1999, have been discussed in the Substance section, above. Some definitions have been amended since the emergency regulations and some clarifying provisions have been added, in response to public comment and as discussed below.

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.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed regulations, the Board has not considered any alternatives to the regulations, nor are any warranted. The Board has, however, carefully drafted the regulations to ensure that they embody the most appropriate, least burdensome and least intrusive framework for effectively administering the Durable Do Not Resuscitate Program.

Public Comment

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

Several concerns were expressed by the public during the public comment period. The requirement that an original DNR form be with patients at all times was viewed by the Virginia Health Care Association, Lake Taylor Hospital and the Virginia Hospital and Healthcare Association as adding a burden to long term facilities. The possibility for loss of the original form could require a facility to readdress the DNR issue with those parties and complete new forms. The agency examined this issue and determined that facilities could execute multiple original documents, maintaining one with the patient at all times and securing the others for use in case of loss.

Secondly there was a concern that the requirement to post the DNR Order on the back of the bedroom door or on a bedside table would not provide sufficient confidentiality in health care facilities. The agency examined this issue and determined that health care facilities maintaining DNR Orders in a patients record satisfy the requirements of the regulation.

Comment was received from Medicorp Health System and the Virginia Hospital and Healthcare Association encouraging the development of alternative forms of identification. The agency continues to examine this issue and anticipates recommending alternative forms to the Board of Health in the near future.

Two other comments concerned a request to reconsider the requirement that a physician be physically present and that qualified health care personnel be allowed to honor other DNR

Orders from health facilities. These sections state that prohibitions do not exist and establish no specific requirements.

The Virginia Hospital and Healthcare Association (VHHA) expressed concern over the definition of "Cardiopulmonary Resuscitation", "Qualified Healthcare Provider" and the need for a definition of "Persistent Vegitative State." The agency clarified the definitions in order to reflect the standard of practice. "Persistent Vegitative State" was determined to be a confusing definition and was removed from the regulation.

A clarifying statement was added to the regulations indicating that all EMS DNR Orders in effect on the date when the emergency regulations went into effect and until the date the new forms where made available are considered Durable DNR Orders at the request of the VHHA.

The VHHA expressed concerns over the requirement of a unique number being assigned to each Durable DNR form by the physician. The agency examined this issue and determined that EMS agencies are required by regulation to reference a unique number on their patient care reporting documentation to indicate that a Durable DNR Order was followed.

The VHHA expressed concern over the authority for other Durable DNR Orders. The Code of Virginia allows other Do Not Resuscitate Orders provided they meet the requirements proposed. The regulations address the specific requirements contained in § 54.1-2987.1.

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 examined all public comment and determined that the regulation is clearly written and understandable by the affected individuals and entities. Several sentences have been revised to more clearly convey the intended meaning and make clearer statements. Statements are included in the regulation clearly indicating that it does not affect or conflict with other associated health care regulations.

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 intends to perform a review of this regulation within three years of the regulation's effective date to determine if it should be continued, ammended or terminated.

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.

This regulation will have no direct, discernable effect on the specific family-related matters identified in the prefatory instructions to this section, but will serve to assist families in implementing decisions made by its members in regards to life-extending treatment and care.

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