



Virginia
Regulatory
Town Hall

**Final Regulation
Agency Background Document**

Agency Name:	Department of Health
VAC Chapter Number:	12VAC5-65
Regulation Title:	Regulations Governing Do Not Resuscitate Orders
Action Title:	Adopt Regulations to Make Emergency DDNR Regulations Permanent
Date:	January 25, 2002

Please refer 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* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The regulation establishes a Durable Do Not Resuscitate (DDNR) Order that follows the patient throughout the entire health care setting. This creates 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.

Patients in consultation with physicians determine advanced 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 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.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

12 VAC 5-66-20. Authority for regulation - "Duly executed orders".

To assure the public and medical community that DDNR Orders in existence prior to the effective date of these regulations remain valid, the statement "and all Durable Do Not Resuscitate Orders will" remain "valid" was inserted.

12 VAC 5-66-40. The Durable DNR Form

For clarification and to be consistent with the statute, a sentence was amended to read "..unless that person knows the patient would object to such revocation."

12 VAC 5-66-80.C.6. DDNR Implementation Procedure

For accuracy and consistency, "administration of cardiac medications" was inserted.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency; including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

The State Health Commissioner, vested with the authority of the State Board of Health pursuant to 32.1-20 of the Code of Virginia, adopted this amendment as final regulation on January 20, 2002. The Virginia Department of Health is hereby amending the Regulations Governing Durable Do Not Resuscitate Orders that appears in 12 VAC 5-65.

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, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

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

Section 54.1-2991 of the Code of Virginia contains mandatory language authorizing the State Board of Health to promulgate emergency regulations. Specifically, the Code states “That the Board of Health shall promulgate regulations to implement the provisions of this act related to Durable Do Not Resuscitate Orders to be effective within 280 days of its enactment.”

Section 54.1-2987.1. 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 final 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.

The purpose of these regulations is to provide required oversight of the use of the Durable DNR Order. The goal of these regulations is to provide a consistent manner throughout the health care system for physicians and qualified health care personnel to use and honor DNR's. These new regulations are required as the previous Code section authorizing EMS Do Not Resuscitate Orders have been repealed and replaced with 54.1-2897.1. The emergency regulations for the Durable Do Not Resuscitate Orders expired on January 3, 2001.

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 of the regulatory action's detail.

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.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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. It allows the citizen to make the choice instead of qualified health care providers. 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.

The advantage to the Commonwealth is a universally recognized manner in which Do Not Resuscitate Orders are issued and followed by qualified health care personnel.

There are no identified disadvantages to this regulation to the public or the Commonwealth..

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Public comment was received from the Virginia Hospital and Healthcare Association and Virginia Health Care Association. The comments received supported both Associations and addressed the same sections. The comments specifically addressed the following sections:

12 VAC 5-66-10. Definitions - "Durable DNR Order"

For accuracy and consistency, "administration of cardiac medications" should be inserted. The definition in the proposed regulation is identical to that found in the Code. The agency determined that consistency could be attained by inserting the statement "administration of cardiac medications" into 12 VAC 5-66-80.C.6.

12 VAC 5-66-20. Authority for regulation - "Duly executed orders".

To assure the public and medical community that DDNR Orders in existence prior to the adoption of these regulations remain valid, the statement "and all Durable Do Not Resuscitate Orders" will remain valid.

12 VAC 5-66-40. The Durable DNR Form

Comments were received indicating that an internal numbering system be used by the agency for tracking purposes or the use of numbers be eliminated. The agency determined that the use of a number, assigned by the issuing physician, would best allow the individual physician to track his patient. The numbering of the form is not intended to be used by the state agency to track the use of the forms and the inclusion of the numbering provision remains intact as a tool for use by the issuing physician.

Comments indicated that the "Content of the Form" section may be confusing to some. However, the form is printed and distributed by the state agency and this section simply states what is required to be printed on the form.

Comments also suggested that a clear copy of a DDNR Order be acceptable for use instead of an original. The agency has determined that an original or other authorized alternate forms of DDNR identification must be demonstrated to persons authorized to honor DDNR Orders. The health, safety and welfare of the citizens mandates that all reasonable measures be taken to properly identify a person in making this critical decision.

For clarification and to be consistent with the statute, a sentence was amended to read "..the person authorized to consent on the patient's behalf unless that person knows the patient would object to such revocation."

12 VAC 5-66-50

Positive comments were received concerning alternate forms of DDNR identification. However, the comments indicated that the regulation should be amended to allow hospitals or nursing homes to purchase these alternate forms for patients. The agency had determined that nothing in the provision prevents hospitals and nursing homes from providing funds for the purchase of these authorized alternative forms of DDNRs.

12 VAC 5-66-60. Other Durable DNR Orders.

Comments were received that the regulations seems to create an "unofficial" Durable DNR Order. The agency examined this issue and added suggested wording identifying that EMS personnel specifically can honor a DNR Order that contains the same required information that is found on the DDNR Order.

12 VAC 5-66-70

"Effective" date was changed to "Issuance" date.

12 VAC 5-66-80

Comments were received that suggested that all references to "other DNR Orders" be removed from the regulations. The agency examined this suggestion and determined that EMS personnel are routinely expected to deal with "other DNR Orders". To prevent confusion in an emergency situation in the field and to clarify for EMS providers which DNR Orders can be honored, the agency determined that these references should remain in place.

It was noted that a physician, physically present on the scene of an emergency, is not given the authority by the statute to revoke a DDNR Order. However, on an emergency scene, a physician is the highest medical authority and if a physician assumes patient care responsibility from EMS personnel in the field, the EMS personnel must concede patient care over to the physician.

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 crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

There are no substantive changes being proposed from the emergency regulations that were in place.

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.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the 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 serve to assist families implementing decisions made by its members in regards to life-extending treatment and care.