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Periodic Review and Small Business Impact Review Report of Findings

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-66
VAC Chapter title(s)	Regulations Governing Durable Do Not Resuscitate Orders
Date this document prepared	July 20, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the ***Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code***.

Acronyms and Definitions

Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.

All acronyms utilized in this document are included in the "Definitions" section of the regulations **(**12VAC5-66-10).

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Section 32.1-12 of the Code of Virginia authorizes the Board to "make, adopt, promulgate and enforce such regulations…as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner or the Department."

Section 32.1-111.4 of the Code of Virginia requires the Board to "prescribe by regulation…[p]rocedures…to authorize qualified emergency medical services personnel to follow Do Not Resuscitate Orders pursuant to § 54.1-2897.1"

Section 32.1-111.5 of the Code of Virginia requires the Board to "prescribe by regulation…qualifications necessary for authorization to follow Do Not Resuscitate Orders pursuant to § 54.1-2897.1"

Alternatives to Regulation

Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.

Sections 32.1-111.4 and 32.1-111.5 require the Board to promulgate regulations related to the personnel authorized to follow Do Not Resuscitate Orders. There are no viable alternatives to comply with the mandates in the Code.

Public Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Be sure to include all comments

submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

Commenter	Comment	Agency response
R. Brent Rawlings – Virginia Hospital & Healthcare Association	**Regulations Governing Durable Do Not Resuscitate Orders** The Department of Health should consider amending the Regulations Governing Durable Do Not Resuscitate Orders (12 VAC 5-66) to clarify how the regulations apply to situations where there is a "required reconsideration" of a DNR during surgery or procedures. Over the past twenty years, consensus has emerged from several professional societies on how best to respond to patients with active DNR orders who might benefit from surgery and related interventions. Additional background on required reconsiderations and professional society positions is provided below. **Background:** Many patients at the end of life often would benefit from some surgery or other procedures to improve their quality of life. While it is not unreasonable to presume that most patients would want all possible resuscitative efforts if they were to suffer a cardiac or pulmonary arrest during a surgery or procedure, this cannot be presumed for patients who have a DNR order in place. Such patients, who have a documented acceptance of allowing natural death, may prefer to forego resuscitative efforts even in the context of a surgery or procedure where the cause of arrest is potentially reversible. **Professional Society Positions:** ASA, ACS, AAP and others all endorse what is referred to as **"required reconsideration."** In brief, required reconsideration is the expectation that prior to undergoing a surgery or procedure where cardiac or pulmonary arrest is possible, the treating team will discuss with the patient or his/her surrogate what risks are associated with the procedure as well as what resuscitative measures the patient/surrogate consider most appropriate given the patient's treatment goals and values.	The submitted comments request VDH to consider amending DDNR regulations for the purpose of a "required reconsideration" of the DDNR status for a patient undergoing a surgical or invasive procedure. As specifically stated by the supporting professional organizations; **American Medical Association-** *"Confirm whether the patient wants the DNAR order to remain in effect when obtaining consent for surgical or other interventions…"* **American Academy of Pediatrics**: - *"required reconsideration" and should be incorporated into the process of informed consent for surgery and anesthesia…"* **American Association of Nurse Anesthetist** – *"reconsideration of the advance directive is an important part of the informed consent process…"* Regulatory changes regarding the informed consent process fall under the scope of practice of a particular healthcare provider, which is not under the regulatory purview of the State Board of Health. Such change would be more appropriately considered by the professional boards within the Department of Health Professions, such as the Board of

	The final determination of whether/which resuscitative measures will be allowed should be the result of a mutually agreed upon plan between the team and the patient/surrogate, and should be clearly documented in the medical record, along with any corresponding decision as to when (if applicable) to reinstate the DNR. **American Society of Anesthesiologists (ASA):** "Policies automatically suspending DNR orders or other directives that limit treatment prior to procedures involving anesthetic care may not sufficiently address a patient's rights to self-determination in a responsible and ethical manner. Such policies, if they exist, should be reviewed and revised..."[i] **American College of Surgeons (ACS):** "Policies that lead…to disregarding or automatically cancelling [DNR] orders do not sufficiently support a patient's right to self-determination."[ii] **American Medical Association (AMA**): Physicians should "[r]evisit and revise decisions about resuscitation—with appropriate documentation in the medical record—as the patient's clinical circumstances change. Confirm whether the patient wants the DNAR order to remain in effect when obtaining consent for surgical or other interventions that carry a known risk for cardiopulmonary arrest and adhere to those wishes." [iii] **Association of periOperative Registered Nurses (AORN):** "Automatically suspending a do-not-resuscitate or allow-natural-death order during surgery undermines a patient's right to self-determination."[iv] **American Academy of Pediatrics (AAP):** "Because surgeons and anesthesiologists are rarely involved in the original DNR decision, they cannot be certain that the implications of the DNR status in the perioperative setting were discussed with the patient's parent (or other surrogate). Therefore, the parent or surrogate, the surgeon, and the anesthesiologist should reevaluate the DNR order for a child who requires an operative procedure. This reevaluation process has been called "required reconsideration" and should be incorporated	Medicine. (Reference 18VAC85-20-350). Lastly, a patient or patient's designated representative has the regulatory ability to revoke their DDNR status for any reason as described in 12VAC5-66-80 (E). Therefore, VDH does not support making the recommended changes to Chapter 66 - Regulations Governing Durable Do Not Resuscitate Orders.

	into the process of informed consent for surgery and anesthesia." [v] **American Society of PeriAnesthesia Nurses (ASPAN):** "Assuming the patient's wishes or applying an institutional policy or medical decision that automatically suspends any patient's DNR, DNAR, DNI or AND directive during the perioperative period denies the patient's right to self-determination and to autonomous, informed choices."[vi] **American Association of Nurse Anesthetists (AANA):** "For a patient undergoing anesthesia, reconsideration of the advance directive is an important part of the informed consent process." [vii] **American Nurses Association (ANA):** "Patients undergoing surgery pose special considerations. Regarding suspension of DNR status during surgery, strong arguments have been made that seriously or terminally ill patients who consent to surgery do so because they desire functional or palliative effects…In that case, automatic suspension or automatic continuation of a DNR order cannot be justified..." [viii]	

Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

The regulations are necessary for the protection of public health, safety, and welfare and intend to achieve that objective in the most efficient and cost-effective manner by providing clarity to healthcare providers regarding an individual's end of life healthcare decisions. The regulations are, for the most part, clearly written and easy to understand for healthcare providers, patients, and their families.

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

Following a periodic review, the Board of Health will amend the regulations to ensure that the language reflects the most up-to-date information available and is consistent with the *Form, Style and Procedure Manual for Publication of Virginia Regulations.*

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

There is a continued need for the regulations, as the Code of Virginia, in §§ 32.1-111.4, 32.1-111.5, and 54.1-2987.1, requires and relies on them. Additionally, the regulation is necessary for providing clear direction regarding how to honor patients' end of life healthcare wishes within Virginia. A public comment was received regarding "required reconsideration" of a valid DDNR as part of the informed consent process for certain operative procedures. Comments discussed the need for clarification on the regulations as it applies to situations where there is a "required reconsideration" of a DNR during surgery or procedures. For example, although there is a DNR order – there are circumstances in which a patient may benefit from some surgery or other procedures to improve their quality of life. Consequently, during such procedure, resuscitative procedures would not be performed in the event of cardiac or respiratory arrest for patients with a DNR order.

The regulation is not complex and does not overlap, duplicate, or conflict with federal or state law or regulation. The last comprehensive review and amendment to the regulations occurred in 2016, since which time there has been no significant change to the technology, economic conditions, or other factors in the areas affected by the regulations. Most hospitals, physician offices, and nursing facilities are not considered small businesses. Additionally, the regulations do not require actions that should result in additional expenditure of resources. As such, the regulations do not create any adverse impact on small businesses in Virginia.