Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-67
Regulation title	Advance Healthcare Directive Registry
Action title	Amend Regulation as a result of a Periodic Review
Date this document prepared	April 29, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

The State Board of Health (board) proposes to amend 12VAC5-67 Advance Healthcare Directive Registry by removing restrictive language which would prevent physicians who have patients who are incapable of communication from searching the Registry to determine whether their patient has submitted an advance directive to the Registry.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

No acronyms are used in this Agency Background Document. No technical terms are utilized in this document.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

These amendments to the Advance Healthcare Directive Registry Regulations (12VAC5-67) were approved by the State Health Commissioner, when the Board was not in session, on August 7, 2014.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The board pursuant to §§54.1-2994 through 54.1-2996 of the Code of Virginia, is required to make available a secure online central registry for advance health care directives. Section 54.1-2995 of the Code of Virginia directs the board to promulgate regulations to carry out the provisions of this article.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

To fulfill the statutory mandate to review regulations and to protect the citizens of the Commonwealth, the Virginia Department of Health conducted a periodic review of 12VAC5-67 "Advance Healthcare Directive Registry" pursuant to Executive Order (EO) 12 (2010). As a result of the Periodic Review, it was noted the regulations had existing language which prevents physicians who have patients who are incapable of communication from searching the Registry to determine whether their patient has submitted an advance directive to the Registry. This restriction is not required by the Code. This regulatory action will protect the health and welfare of Virginians by ensuring that the medical wishes of individuals who have submitted an Advance Health Care Directive to the Registry are honored if they are incapacitated and unable to manage their own care.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and

(ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

These amendments update the regulations to reflect current practice and changes to the Code created by SB575 (2014). The Department does not expect that this regulatory action will be controversial because the action simply brings the regulatory language into conformity with statutory language and current practice.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

12VAC5-67-20 - Criteria for submission of an advance directive to the registry. - Add language which allows authorized representatives to submit documents to the Registry.

12VAC5-67-30- Access to the registry.- Removal of restrictive language which would prevent physicians who have patients who are incapable of communication from searching the Registry to determine whether their patient has submitted an advance directive to the Registry. Insertion of clarifying language stating physicians have the authority to query the Registry for directive information of patients incapable of communication.

Issues

Please identify the issues associated with the proposed regulatory action, including:
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 indicate.

The primary advantage of the regulatory action is greater clarity of the regulations and allowing physicians with non-communicative patients the ability to search the registry to determine if their patient has submitted an advance directive to the Registry. There are no disadvantages to the agency, the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements in this proposal that exceed federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality will be particularly affected by the proposed regulation.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The alternative regulatory methods are not applicable.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	Physicians and patients who have submitted an advance directive to the registry.
Agency's best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	There are approximately 34,000 licensed physicians in the Commonwealth of Virginia and 2,505 individuals who have submitted to the registry.
Benefits expected as a result of this regulatory proposal.	Physicians will have greater access to the Registry in appropriate situations.
Projected cost to the state to implement and enforce this regulatory proposal.	None
Projected cost to localities to implement and enforce this regulatory proposal.	None
All projected costs of this regulatory proposal	None

for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	

Alternatives

Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no other viable alternatives other than the proposed amendments to obtain the objectives of the board.

Periodic review and small business impact review report of findings

If this fast-track regulation is not the result of a periodic review and/or small business impact review report of the regulation, please delete this entire section.

If this fast-track regulation is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

If this fast-track regulation is also a small business impact review report of the regulation, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (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 is required.

No comments were received from the public during the recent periodic review. There is a continued need for the regulation as it is mandated by law. The Department has not received any complaints or comments concerning the regulation from the public. The regulation is clearly written and easily understandable and the Department is confident based on this most recent review that the regulation does not overlap, duplicate or conflict with federal state law or regulation.

Family impact

Please assess the 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 board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s) or regulations that are being repealed and replaced, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
20		A. Documents that may be submitted to the registry include: 1. A health care power of attorney. 2. An advance directive created pursuant to Article 8 (§ 54.1-2981 et seq.) of Chapter 29 of Title 54.1 of the Code of Virginia or a subsequent act of the General Assembly. 3. A declaration of an anatomical gift made pursuant to the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq. of the Code of Virginia). B. The document shall be submitted for filing only by the person who executed the document. C. The person submitting documents to the registry shall be responsible for payment of any fee required by the contracted vendor, public-private partnership, or any other entity through	A. Documents that may be submitted to the registry include: 1. A health care power of attorney. 2. An advance directive created pursuant to Article 8 (§ 54.1-2981 et seq.) of Chapter 29 of Title 54.1 of the Code of Virginia or a subsequent act of the General Assembly. 3. A declaration of an anatomical gift made pursuant to the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq. of the Code of Virginia). B. The document shall be submitted for filing only by the person who executed the document or his legal representative or designee. C. The person submitting documents to the registry shall be responsible for payment of any fee required by the contracted vendor, public-private partnership, or any other entity through which the department has made the registry available to citizens of the Commonwealth. Fees associated with the registry shall not exceed the direct costs associated with the development and maintenance of the registry and with the education of the public about the availability of the registry. Intent: Allows authorized representatives to

		which the department has made the registry available to citizens of the Commonwealth. Fees associated with the registry shall not exceed the direct costs associated with the development and maintenance of the registry and with the education of the public about the availability of the registry.	submit documents to the Registry, reflecting changes to the Code made by SB575 (2014). Reflects current practice. Greater clarity.
30		The person registering documents may specify a legal representative or other persons to have access to such documents. It shall be the responsibility of the person registering to provide all such persons with the information necessary to access the registry. In accordance with patient authorization, health care professionals may have access to the registry.	The person registering documents may specify a legal representative or other persons to have access to such documents. It shall be the responsibility of the person registering to provide ~~all~~ such persons with the information necessary to access the registry. Licensed health care providers shall have access to the registry for the purpose of a query for advance directive information on patients who are comatose, incapacitated or otherwise mentally or physically incapable of communication. ~~In accordance with patient authorization, health care professionals may have access to the registry.~~ Intent: Removal of restrictive language which would prevent physicians who have patients who are incapable of communication from searching the Registry to determine whether their patient has submitted an advance directive to the Registry. Insertion of clarifying language stating physicians have the authority to query the Registry for directive information of patients incapable of communication.