Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12 VAC 05-67
Regulation title	Regulation Governing the Advance Health Care Directive Registry
Action title	Regulation to implement a secure online central registry for citizens to submit advance healthcare directives
Date this document prepared	March 17, 2011

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

This regulation is being developed as directed by the third enactment clause of HB 805/SB290 of the 2008 Session which calls for the State Board of Health to "promulgate regulations to carry out the provision of this article". The key provisions of this regulation consist of a description of the documents that may be submitted to the Registry, a provision for reasonable fees to be charged by a vendor with whom the Department of Health may contract for implementing the Registry, and provisions outlining who may gain access to documents in the Registry.

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.

The Commissioner of the Virginia Department of Health approved fast track regulations on behalf of the Board of Health.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

The Code of Virginia, as amended by the legislation cited above, authorizes the promulgation of this regulation in Article 9 of chapter 29 of Title 54.1 (Section 54.1-2994 et seq.), and refers to this law elsewhere in Title 54.1.

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.

The regulation will implement a central online registry accepting the submission by citizens of advance directives, i.e., legally enforceable documents that divulge and explain their intentions regarding the continuation of medical care in the event of their inability to make decisions as the need arises. The goal of the regulation is to administer effectively the registry to allow restricted access to such documents so that citizens' wishes regarding their intentions can be made available to hospitals and other providers of health care services, relatives and others, as needed and authorized. The regulation is essential to protect the welfare of citizens because it will allow a central and secure means for providers of health care services to quickly and accurately identify and understand patients' wishes regarding the provision and continuation of health care services.

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.

This regulation is expected to be noncontroversial. No opposition was brought forth during the deliberations of the enabling statute during the Virginia legislative process.

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.)

This regulation will be entirely new to the Virginia Administrative Code.

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.

There are no disadvantages to the public or 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 applicable 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.

Localities will not be affected.

Regulatory flexibility analysis

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 proposed regulation does not impact small businesses.

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.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	$0.00
Projected cost of the *new regulations or changes to existing regulations* on localities.	$0.00
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The citizens of Virginia
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	No small businesses affected
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	$0.00
Beneficial impact the regulation is designed to produce.	The regulation is designed to produce a secure, centralized repository of advance health care directives for the citizens of Virginia.

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.

In light of the requirements that regulations be adopted, contained in the statutory law cited above, arguably, there is no alternative available to the State Board of Health. Conceptually, an alternative lies in continuation of the status quo, which entails a less reliable means of allowing health care providers to be informed of their patients' wishes regarding the provision and continuation of health care services.

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.

While the regulation is not likely to affect the family in the manners described directly above, the regulation is likely, in a general way, to promote the general interests and tranquility of the family by providing for a secure method of identifying and gaining access to the documented wishes of an ill or injured family member in the traumatic event where a medical emergency coincides with the family member's inability to express his or her wishes.

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 in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale

For new chapters, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC 05-67	Establish criteria for submission of an advance directive; and Define who can have access to information in the registry;	§54.1-2995	Creates the definition of documents that may be submitted to the advance healthcare directive registry, establishes proof of document validity, and establishes persons who may be granted access to such information. There is no fiscal impact to these regulations.

Enter any other statement here

This permanent regulation will replace emergency regulations that expired on April 30, 2010. The only difference between the permanent regulations and the emergency regulations are that the permanent regulations delete the requirement that an advance directive be notarized before being submitted to the registry. That provision was deleted as required by HB267 of the 2010 Session, which specifically removed the requirement that an advance directive be notarized prior to being submitted to the registry.