Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12 VAC 5 – 67
Regulation title	Advance Health Care Directive Registry
Action title	A new regulation to implement a secure online central registry for citizens to submit advance health care directives
Date this document prepared	June 26, 2008

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Preamble

The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

1) Please explain why this is an "emergency situation" as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

This regulation is being developed due to an emergency situation, specifically, due to the third enactment clause of House Bill 805 (Acts of Assembly c. 301, 2008) and the third enactment clause of Senate Bill 290 (Acts of Assembly c. 696, 2008) – which are identical bills – which calls for the State Board of Health

to "promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment."

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.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe 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 describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

For changes to existing regulations, use this chart:

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

The regulation will be entirely new to Virginia regulatory law.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

In light of the requirements that emergency 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.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives, and 3) potential impacts of the regulation. The agency will additionally solicit private industry input.
Anyone wishing to submit written comments for the public comment file may do by mail, email or fax to Kim Barnes at 109 Governor Street, Suite 724, Richmond, Virginia with fax at 804-864-7670 or email at kim.barnes@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public meeting will not be held pursuant to an authorization to proceed without holding a public meeting.

Participatory approach

Please indicate the extent to which an ad hoc advisory group will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

Due to the relatively clear mandate in the statutory law and the absence of any broad discretion in implementing the law through regulations, the State Board of Health and the Department of Health believe that it is appropriate to use the participatory approach to develop a proposal if it receives at least 25 written requests to use the participatory approach prior to the end of the public comment period. Persons requesting the agency use the participatory approach and interested in assisting in the development of a proposal should notify the department contact person by the end of the comment period and provide their name, address, phone number, email address and their organization (if any). Notification of the composition of the advisory committee will be sent to all applicants.

Family impact

Assess the potential 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.