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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-90 & 12VAC5-100
Regulation title(s)	Regulations for Disease Reporting and Control
Action title	Repeal the Virginia Cancer Registry Sections of the Disease Reporting Regulations and Establish a New Regulatory Chapter for Cancer Reporting
Date this document prepared	May 25, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH) including what diseases must be reported, who must report them and other provisions related to the Virginia Cancer Registry. VDH is proposing the amendment of the regulations to create an separate regulatory chapter for the Virginia Cancer Registry and update those regulations.

The amendments being proposed are necessary to ensure the regulations reflect the organizational structure of VDH, to clarify regulatory language, to ensure regulatory language is clearly written and easily understandable and ensure the regulations are efficient. Finally some minor formatting edits are necessary.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity 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 permits the State Board of Health to make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Section 32.1-70 of the Code of Virginia establishes the Virginia Cancer Registry, requiring each hospital, clinic, independent pathology laboratory and physicians in the Commonwealth of Virginia to make available to the Commissioner information on patients having malignant tumors or cancers.

Purpose

Please describe 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, please explain any potential issues that may need to be addressed as the regulation is developed.

Section 32.1-70 of the Code of Virginia establishes the Virginia Cancer Registry and requires each hospital, clinic, independent pathology laboratory and physician in the Commonwealth of Virginia to make available to the Commissioner information on patients having malignant tumors or cancers. Currently regulatory provisions related to the Virginia Cancer Registry are within the Regulations for Disease Reporting and Control. While the Virginia Cancer Registry is related to disease reporting the Virginia Cancer Registry does not operate within the Office of Epidemiology which administers the Disease Reporting and Control Regulations but rather the Office of Family Health Services. Therefore VDH proposes creating a separate regulatory chapter for the Virginia Cancer Registry to reflect the operating procedures of VDH. VDH also proposes updating the regulations as they have not been amended in over 10 years.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

VDH proposes that the Virginia Cancer Registry regulations be repealed from 12VAC5-90 and established in a new regulatory chapter.

The following substantive amendments are being considered to the existing regulatory language:

Those Required to Report – Clarification of language which qualifies when physicians are required to report. As stated the regulatory language causes confusion and lack of reporting among required reporters. Currently the regulations state that physicians are only required to report if it has been determined that a medical care facility, clinic, or instate pathology laboratory has not reported. VDH shall supply language which clarifies how such a determination can be made.

Report Contents and Procedures- Change formatting for ease of reading. Add language which clarifies that when report information is missing the report shall be rejected. Add language to require electronic reporting. Add language stating that in the event the reporter does not report, the department may enter a consenting facility and obtain the information as permitted by § 32.1-70.2 of the Code 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.

Section 32.1-70 of the Code of Virginia establishes the Virginia Cancer Registry and requires each hospital, clinic, independent pathology laboratory and physicians in the Commonwealth of Virginia to make available to the Commissioner information on patients having malignant tumors or cancers. Section 32.1-12 of the Code of Virginia permits the State Board of Health to make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provision of Title 32.1 of the Code of Virginia. This regulatory action is necessary in order for the regulatory chapter to be in compliance with the general principles of Executive Order 17 (2014), which requires that regulations be clearly written and easily understandable and that regulations shall be designed to achieve their intended objective in the most efficient and cost effective manner. The regulations are mandated by law, and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes determined to be appropriate.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including 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 hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Susan Puglisi, Policy Analyst, Office of Family Health Services, 109 Governor Street 10th Floor, Richmond Virginia 23219, 804-864-7175 and susan.puglisi@vdh.virginia.gov . Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action. A regulatory panel will not be used in the development of this regulatory proposal.