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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-90 & 12VAC5-101
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	October 31, 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.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. If applicable, generally describe the existing regulation.

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. The regulatory chapter includes provisions related to the Virginia Cancer Registry. VDH is proposing amendments to the regulations to create a separate regulatory chapter for the Virginia Cancer Registry and to 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.

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.

VCR- Virginia Cancer Registry

VDH – Virginia Department of Health

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.

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 explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe 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.

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 procedure of VDH. VDH also proposes updating the regulations as they have not been amended in over ten years.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

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 has proposed language which clarifies physicians are required to report.

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.

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 proposed regulatory action to the public is increased reporting of malignant tumors and cancer information, leading to more accurate data and more effective programs to respond to cancer across the Commonwealth. VDH does not foresee any disadvantages to the public, the agency or the Commonwealth associated with the proposed regulatory action.

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.

No locality will be particularly affected by the proposed regulation.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the State Board of Health is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail at: Robin Buskey, 109 Governor Street, Richmond VA, 23219, by phone at: 804-864-7253, and email at robin.buskey@vdh.virginia.gov. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

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**	The projected cost to the state is negligible.
Projected cost of the new regulations or changes to existing regulations on localities.	This regulatory chapter will not cause any cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Hospitals, clinics and independent pathology laboratories reporting cancers and malignant tumors, physicians treating patients with cancers and malignant tumors, and patients suffering from malignant tumors and cancers within the Commonwealth shall be affected by the new regulations.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	• 11,300 independent and group labs, and imaging centers (hospitals or those associated or co-located with other healthcare facilities) • 416 urgent and emergent care facilities – total systems that could report to the Virginia Cancer Registry; http://www.vhha.com/research/virginia-

	urgent-and-emergency-care-locations/ • 3,100 physicians (oncologists, internal medicine, family medicine) • 33,498 cancer patients diagnosed in 2015 (this is incidence for one year and does not reflect the total number of cancer cases in Virginia)
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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) 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.	None
Beneficial impact the regulation is designed to produce.	The regulatory action shall make the regulatory chapter conform with the general principle of Executive Order 17 (2014) and increase the accuracy of the data within the Virginia Cancer Registry thus resulting in more effective programming to respond to cancer across the Commonwealth

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.

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. 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 comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No public comments were received during the public comment period following the publication of the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this 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.

VDH has assessed the impact the proposed amendments will have on the institution of the family and family stability. VDH 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; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. 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 follow the instructions in the text following the three chart templates below.

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-	Proposed new chapter-	Current requirement	Proposed change, intent, rationale, and likely impact of proposed

section number	section number, if applicable		requirements
	12VAC5-101-10		Creation of a definition section for the new regulatory chapter. The section shall include definitions of the terms cancer, clinic, independent pathology laboratory, medical care facility and physician. These definitions have been pulled from the existing Regulations for Disease Reporting and Control and the Code of Virginia. The likely impact of this section will be clarity for members of the public when reading the new regulatory chapter.
12VAC5-90-150	12VAC5-101-20	Article 9 (§ 32.1-70 et seq.) of Title 32.1 of the Code of Virginia authorizes the establishment of a statewide cancer registry.	No change to the existing regulatory language simply moving it into the new regulatory chapter. Likely no impact.
12VAC5-90-160	12VAC5-101-30	Clinically or pathologically diagnosed cancers, as defined in 12VAC5-101-10, and benign brain and central nervous system tumors shall be reported to the Virginia Cancer Registry. Carcinoma in situ of the cervix is not reportable.	No change to the existing regulatory language simply moving it into the new regulatory chapter. Likely no impact.
12VAC5-90-170	12VAC-101-40	Any person in charge of a medical care facility, clinic, or independent pathology laboratory which diagnoses or treats cancer patients is required to report. Physicians are required to report cases of cancer in those instances when it has been determined that a medical care facility, clinic, or instate pathology laboratory has not reported. Any person making such report shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.	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 has proposed language stating more clearly that physicians are required to report. The intent of this language is to encourage reporting and receive more accurate data. Likely impact: Increased reporting of malignant tumor and cancer information. Greater clarity of the regulations.
12VAC5-90-180	12VAC5-101-50	Each report shall include the patient's name, address (including county or independent city of	Changes proposed to format for ease of reading. Adding language which clarifies that when report information is missing the report shall be rejected. Adding

		residence), age, date of birth, sex, date of diagnosis, date of admission or first contact, primary site of cancer, histology (including type, behavior, and grade), basis of diagnosis, social security number, race, ethnicity, marital status, usual occupation, usual industry, sequence number, laterality, stage, treatment, recurrence information (when applicable), name of reporting facility, vital status, cause of death (when applicable), date of last contact, history of tobacco and alcohol use, and history of service in Vietnam and exposure to dioxin-containing compounds, when applicable. Reporting shall be by electronic means where possible. Output file formats shall conform to the most recent version of the North American Association of Central Cancer Registries' standard data file layout. Facilities without electronic reporting means and physicians shall submit the required information on the Virginia Cancer Registry Reporting Form. A copy of the pathology report(s) should accompany each completed reporting form, when available. Medical care facilities and clinics reporting via the reporting form should also submit a copy of the admission form and discharge summary. Reports shall be made within six months of the diagnosis of cancer and submitted to the Virginia Cancer Registry on a monthly basis. Cancer programs conducting annual follow-up on patients shall submit follow-up data monthly in an electronic format approved by the Virginia Cancer Registry.	language to require electronic reporting. Adding 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. The intent of these changes is to increase electronic reporting therefore cutting down on VDH staff performing data entry and also including a provision stating that should a reporter fail to report VDH staff may come collect the information. This right of entry and collection is currently permitted by the Code but has not been utilized by VDH staff due to the lack of regulatory language regarding right of entry. Likely impact: More data entered into the Virginia Cancer Registry and therefore greater accuracy of the registry overall.