Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12 VAC 5-90
Regulation Title:	Regulations for Disease Reporting and Control
Action Title:	Cancer Reporting
Date:	May 11, 2001

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

An amendment to the cancer reporting section of the Regulations for Disease Reporting and Control is proposed. The amendment explains the process for the notification of patients reported to the statewide registry. It was previously promulgated as an emergency regulation.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Section 32.1-71.01 of the Code of Virginia mandates the Board of Health to promulgate regulations regarding patient notification.

The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the regulation and that it comports with applicable state law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amendment is to incorporate the provisions of the emergency regulation. The amendment will provide information about the process that the Virginia Cancer Registry will use to notify cancer patients that they have been reported to the state registry.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The amendment explains the procedure for the notification of patients reported to the statewide registry. The regulatory action is required to fully implement the emergency regulations regarding the notification of cancer patients about their inclusion in the statewide cancer registry.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

The primary advantage of the regulation is that it will explain the process by which cancer patients will be notified that they have been reported to the state cancer registry. The advantage of notification is that everyone included in the registry will be aware of the registry and their inclusion in it. The potential disadvantage to the public is that persons receiving the information could have concerns about the registry and how the data are used and protected. The advantage to the agency is that the existence of the state cancer registry will be more well known. The primary disadvantage is that resources have to be diverted from other registry business to carry out the notifications, and the funding supplied is not sufficient to cover the expenses. The patient notification provisions have already been promulgated through emergency regulations.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

General funds have been provided that will cover approximately one-half of the cost of the mandated patient notification process; the agency intends to absorb the remaining cost.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The amendment states in Section 12 VAC 5-90-190 the procedure for the notification of patients reported to the statewide registry. That is, beginning with cancers diagnosed on January 1, 2001, a notification will be sent to persons reported to the state registry within 30 days of the registry receiving a completed case record. The notification will include the purpose, objectives, reporting requirements, confidentiality policies and procedures, and a copy of the Privacy Protection Act. Patient notification is mandated by the Code of Virginia.

Alternatives

Please describe the specific 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.

No alternatives are available. This regulation is required by law

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

No comments were received.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The agency believes the language of the regulation will be understandable.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The regulation will be reviewed three years after the date it becomes effective.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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 regulation will not impact the family. It only provides information about how the mandatory notification of individuals that they are in the state cancer registry will occur.