



Virginia
Regulatory
Town Hall

Proposed Regulation Agency Background Document

Agency Name:	Department of Health (State Board of)
VAC Chapter Number:	12 VAC 5-218
Regulation Title:	Rules and Regulations Governing Outpatient Health Data Reporting
Action Title:	Adopt Regulations to Administer Outpatient Patient Level Data System
Date:	September 9, 2002

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of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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

The regulation is necessary as Virginia statutory law (as amended by HB 2763, Act of Assembly c. 341, 2001) requires that the regulation be effective within 280 days or less from its enactment. Emergency regulations were previously adopted and will expire unless made permanent. The regulation is not otherwise exempt under the provisions of §9-6.14:4.1(C) (4).

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.

The Code of Virginia §§32.1-276.3, 32.1-276.6, 32.1-276.8 and 32.1-276.9 directs the State Board of Health to implement an outpatient patient level data system in association with the nonprofit, tax-exempt organization established in accordance with Code of Virginia §32.1-276.2 et seq.).

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 outpatient patient level data system collects information on at least five surgical procedures when performed on an outpatient basis in ambulatory surgical centers, hospitals and by physicians performing office-based surgery. The information is collected utilizing existing nationally adopted billing forms including but not limited to the data elements on the UB-92 and HCFA 1500 forms. The nonprofit, tax-exempt organization established in accordance with Code of Virginia §32.1-276.2 et seq. collects, edits and verifies the data submitted. The information will be used to assist businesses and consumers in making informed health care decisions, and will also be available to health care providers, planners, and policymakers. The law includes a study of the impact and cost-benefit of this data collection system and the information's value to the public.

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.

No changes are proposed to the existing Emergency regulations are recommended for inclusion in the final regulations.

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 advantages to consumers are access to information about outpatient surgical health providers, their location, and certain performance information. Other advantages to the Commonwealth include the use of the collected data for health policy, health research, and quality improvement activities by health care providers. There have been no identified disadvantages to the public.

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.

The nonprofit, tax-exempt organization (as described in Code of Virginia §32.1-276.2 et seq.) has funded costs associated with initial development, collection, and processing of the outpatient data during the first year. The nonprofit will continue funding for the second year at an amount of \$36,000 to process and edit data. After the first twelve months of data submission, provider fees may be collected from providers who submit data that is not considered processed and verified following editing and calculation of minimum accuracy rates. A pilot study of the costs and benefits of the data collection program is expected to be conducted after data collection is considered to be complete and accurate - within the next two to three years. It is expected that funding will ultimately include core contributions from General Appropriations as with the inpatient patient level data system. Total fiscal impact from all sources is estimated to be between \$36,000 to \$50,000 per year using the nonprofits' existing data infrastructure to reduce costs.

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.

No changes to the Emergency Regulations in effect are proposed to the final regulations.

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.

There are no relevant alternatives to the proposed regulatory action required by Virginia statutory law.

Public Comment

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

The Department of Health has not received any public comment on the regulations.

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 Department of Health, upon examination of the regulation, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

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 agency has determined that it will initiate a review and re-evaluation of the regulation no later than three years after the proposed regulation is to be effective. The purpose of the review and re-evaluation is to determine if the regulation should be continued, amended, or terminated.

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.

This regulatory action has no impact on the authority or rights of parents in the education, nurturing and supervision of their children.

This regulatory action has no impact on the economic self-sufficiency, self-pride or the assumption of responsibility for oneself, one's spouse, one's children or one's elderly parents.

This regulatory action has no impact on marital commitment.

This regulatory action may impact a family's disposable family income in a positive manner by providing additional information regarding outpatient surgical procedures, thus facilitating the family's ability to select cost-effective health care alternatives from the choices available.