



Virginia
Regulatory
Town Hall

Proposed Regulation Agency Background Document

Agency Name:	Department of Health Professions
VAC Chapter Number:	18 VAC 76-30-10 et seq.
Regulation Title:	Regulations Governing Public Participation Guidelines
Action Title:	New regulations
Date:	10/12/02

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of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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

Regulations are promulgated to provide guidelines for public participation in the regulatory process of the department and are intended to enable electronic communication, notification and comment in the development of regulations. Regulations provide for notification lists, documents required to be sent to those on the lists, requirements for petitioning the department to begin rulemaking, notices and hearings required for each stage of the process, and the appointment and duration of advisory committees formed to address a specific regulatory issue.

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 statutory authority for this regulation is the Administrative Process Act. The APA specifically mandates the adoption of public participation guidelines pursuant to the provisions of the Act. Regulations so adopted do not exceed the mandate of the Act but do provide additional clarity to the public for their participation in the regulatory process.

§ 2.2-4007. (Effective October 1, 2002) Notice of intended regulatory action; public participation; informational proceedings; effect of noncompliance.

A. Any person may petition an agency to request the agency to develop a new regulation or amend an existing regulation. The petition shall state (i) the substance and purpose of the rulemaking that is requested, including reference to any applicable Virginia Administrative Code sections, and (ii) reference to the legal authority of the agency to take the action requested. Within fourteen days of receiving a petition, the agency shall send a notice identifying the petitioner, the nature of the petitioner's request and the agency's plan for disposition of the petition to the Registrar for publication in the Virginia Register of Regulations in accordance with the provisions of subsection B of § 2.2-4031. On the date of publication in the Virginia Register of Regulations, the agency shall commence a twenty-one-day period for acceptance of written public comment on the petition. The agency shall issue a written decision to grant or deny the petitioner's request within ninety days following the close of the comment period. However, if the rulemaking authority is vested in an entity that has not met within that ninety day period, the entity shall issue a written decision no later than fourteen days after it next meets. The written decision issued by the agency shall include a statement of its reasons and shall be submitted to the Registrar for publication in the Virginia Register of Regulations. Agency decisions to initiate or not initiate rulemaking in response to petitions shall not be subject to judicial review.

B. In the case of all regulations, except those regulations exempted by §§ 2.2-4002, 2.2-4006 or § 2.2-4011, an agency shall provide the Registrar of Regulations with a Notice of Intended Regulatory Action that describes the subject matter and intent of the planned regulation. At least thirty days shall be provided for public comment after publication of the Notice of Intended Regulatory Action. An agency shall not file proposed regulations with the Registrar until the public comment period on the Notice of Intended Regulatory Action has closed.

C. Agencies shall state in the Notice of Intended Regulatory Action whether they plan to hold a public hearing on the proposed regulation after it is published. Agencies shall hold such public hearings if required by basic law. If the agency states an intent to hold a public hearing on the proposed regulation in the Notice of Intended Regulatory Action, then it shall hold the public hearing. If the agency states in its Notice of Intended Regulatory Action that it does not plan to hold a hearing on the proposed regulation, then no public hearing is required unless, prior to completion of the comment period specified in the Notice of Intended Regulatory Action (i) the Governor directs the agency to hold a public hearing or (ii) the agency receives requests for a public hearing from at least twenty-five persons.

D. Public participation guidelines for soliciting the input of interested parties in the formation and development of its regulations shall be developed, adopted and utilized by each agency pursuant to the provisions of this chapter. The guidelines shall set out any methods for the identification and notification of interested parties, and any specific means of seeking input from interested persons or groups that the agency intends to use in addition to the Notice of Intended Regulatory Action. The guidelines shall set out a general policy for the use of standing or ad hoc advisory panels and consultation with groups and individuals registering interest in working with the agency. Such policy shall address the circumstances in which the agency considers the panels or consultation appropriate and intends to make use of the panels or consultation.

E. In formulating any regulation, including but not limited to those in public assistance and social services programs, the agency pursuant to its public participation guidelines shall afford interested persons an opportunity to submit data, views, and arguments, either orally or in writing, to the agency or its specially designated subordinate. However, the agency may begin drafting the proposed regulation prior to or during any opportunities it provides to the public to submit comments.

F. In the case of all regulations, except those regulations exempted by §§ 2.2-4002, 2.2-4006, or § 2.2-4011, the proposed regulation and general notice of opportunity for oral or written submittals as to that regulation shall be published in the Virginia Register of Regulations in accordance with the provisions of subsection B of § 2.2-4031. In addition, the agency may, in its discretion, (i) publish the notice in any newspaper and (ii) publicize the notice through press releases and such other media as will best serve the purpose and subject involved. The Register and any newspaper publication shall be made at least sixty days in advance of the last date prescribed in the notice for such submittals. All notices, written submittals, and transcripts, summaries or notations of oral presentations, as well as any agency action thereon, shall be matters of public record in the custody of the agency.

G. If an agency wishes to change a proposed regulation before adopting it as a final regulation, it may choose to publish a revised proposed regulation provided the latter is subject to a public comment period of at least thirty additional days and the agency complies in all other respects with this section.

H. Before delivering any proposed regulation under consideration to the Registrar as required in subsection I, the agency shall deliver a copy of that regulation to the Department of Planning and Budget. In addition to determining the public benefit, the Department of Planning and Budget in coordination with the agency, shall, within forty-five days, prepare an economic impact analysis of the proposed regulation. The economic impact analysis shall include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply; the identity of any localities and types of businesses or other entities particularly affected by the regulation; the projected number of persons and employment positions to be affected; the impact of the regulation on the use and value of private property; and the projected costs to affected businesses, localities or entities to implement or comply with the regulations, including the estimated fiscal impact on such localities and sources of potential funds to implement and comply with such regulation. Agencies shall provide the Department with such estimated fiscal impacts on localities and sources of potential funds. The Department may request the assistance of any other agency in preparing the analysis. The Department shall deliver a copy of the analysis to the agency drafting the regulation, which shall comment thereon as provided in subsection I, and a copy to the Registrar for publication with the proposed regulation. No regulation shall be promulgated for consideration pursuant to subsection I until the impact analysis has been received by the Registrar. For purposes of this section, the term "locality, business, or entity particularly affected" means any locality, business, or entity that bears any identified disproportionate material impact that would not be experienced by other localities, businesses, or entities. The analysis shall represent the Department's best estimate for the purposes of public review and comment on the proposed regulation. The accuracy of the estimate shall in no way affect the validity of the regulation, nor shall any failure to comply with or otherwise follow the procedures set forth in this subsection create any cause of action or provide standing for any person under Article 5 (§ 2.2-4025 et seq.) of this chapter or otherwise to challenge the actions of the Department hereunder or the action of the agency in adopting the proposed regulation.

I. Before promulgating any regulation under consideration, the agency shall deliver a copy of that regulation to the Registrar together with a summary of the regulation and a separate and concise statement of (i) the basis of the regulation, defined as the statutory authority for promulgating the regulation, including an identification of the section number and a brief statement relating the content of the statutory authority to the specific regulation proposed; (ii) the purpose of the regulation, defined as the rationale or justification for the new provisions of the regulation, from the standpoint of the public's health, safety or welfare; (iii) the substance of the regulation, defined as the identification and explanation of the key provisions of the regulation that make changes to the current status of the law; (iv) the issues of the regulation, defined as the primary advantages and disadvantages for the public, and as applicable for the agency or the state, of implementing the new regulatory provisions; and (v) the agency's response to the economic impact analysis submitted by the Department of Planning and Budget pursuant to subsection H. Any economic impact estimate included in the agency's response shall represent the agency's best estimate for the purposes of public review and comment, but the accuracy of the estimate shall in no way affect the validity of the regulation. Staff as designated by the Code Commission shall review proposed regulation submission packages to ensure the requirements of this subsection are met prior to publication of the proposed regulation in the Register. The summary; the statement of the basis, purpose, substance, and issues; the economic impact analysis; and the agency's response shall be published in the Virginia Register of Regulations, together with the notice of opportunity for oral or written submittals on the proposed regulation.

J. When an agency formulating regulations in public assistance and social services programs cannot comply with the public comment requirements of subsection F due to time limitations imposed by state or federal laws or regulations for the adoption of such regulation, the Secretary of Health and Human Resources may shorten the time requirements of subsection F. If, in the Secretary's sole discretion, such time limitations reasonably preclude any advance published notice, he may waive the requirements of subsection F. However, the agency shall, as soon as practicable after the adoption of the regulation in a manner consistent with the requirements of subsection F, publish notice of the promulgation of the regulation and afford an opportunity for public comment. The precise factual basis for the Secretary's determination shall be stated in the published notice.

K. If one or more changes with substantial impact are made to a proposed regulation from the time that it is published as a proposed regulation to the time it is published as a final regulation, any person may petition the agency within thirty days from the publication of the final regulation to request an opportunity for oral and written submittals on the changes to the regulation. If the agency receives requests from at least twenty-five persons for an opportunity to submit oral and written comments on the changes to the regulation, the agency shall (i) suspend the regulatory process for thirty days to solicit additional public comment and (ii) file notice of the additional thirty-day public comment period with the Registrar of Regulations, unless the agency determines that the changes made are minor or inconsequential in their impact. The comment period, if any, shall begin on the date of publication of the notice in the Register. Agency denial of petitions for a comment period on changes to the regulation shall be subject to judicial review.

L. In no event shall the failure to comply with the requirements of subsection F be deemed mere harmless error for the purposes of § 2.2-4027.

M. This section shall not apply to the issuance by the State Air Pollution Control Department of variances to its regulations.

Rulemaking authority for the Director of the Department of Health Professions is found in Chapters 25, 25.1 and 25.2 of Title 54.1 of the Code of Virginia.

<http://leg1.state.va.us/000/lst/h3505993.HTM>

<http://leg1.state.va.us/000/lst/h3506002.HTM>

<http://leg1.state.va.us/000/lst/h3505600.HTM>

The Office of the Attorney General has certified by letter that the Department has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal 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.

In accordance with provisions of the Administrative Process Act, the Department is developing regulations for public participation in the development and promulgation of regulations. Regulations require notices to be sent to the public for any meeting at which a regulatory action is to be considered, for an intended regulatory action, for comment on a proposed regulation, and for adoption of a final regulation. Opportunities for written and oral comment are provided at each stage of the regulatory process, including holding a public hearing on any regulatory action. Regulations have allowed for individuals and organizations to petition the Department for rulemaking on an issue of interest and have also provided for the appointment of advisory committees on issues related to rule-making. Regulations are also proposed as necessary to provide for electronic submissions by the agency and the affected parties.

The guidelines are identical to those set by all 14 boards within the Department with the exception of the regulation for responding to a petition for rulemaking. In accordance with amendments to the APA by the 2002 General Assembly, the time limit for an agency response to a petition is set at 90 days following a 21-day comment period. During a recent periodic review of regulations, it was determined that public participation guidelines adopted by all boards are reasonable, clearly stated and adequate to protect the public interest in the development and promulgation of regulations. These regulations are intended to ensure participation in the process of developing and promulgating regulations for the health professions, which are essential for public health, safety and welfare.

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 Department has adopted a new set of regulations for public participation guidelines in the process of rule-making. Regulations set requirements for notification lists and documents to be sent during the promulgation of regulations. There are provisions for petitions for rule-making,

notices, public hearings and periodic review of all regulations. Rules establish the appointment of ad hoc advisory committees and set a limitation on service for those committees.

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.

For the most part, regulations providing public participation guidelines are requirements on the Department in compliance with the Administrative Process Act. The primary issue identified during the promulgation of these regulations was the need to incorporate electronic forms of regulatory submission, notification and communication that are currently available or may become available in the near future. Therefore, language that would permit notification and comment by facsimile, email or other electronic means was incorporated in the proposal. Regulations will also ensure that an electronic mailing list may be maintained on a state website in addition to the traditional list for mailings by the Department.

While requirements for public participation in the regulatory process should be electronically inclusive, the Department continues to be obligated to notify by regular mail if an entity chooses that form of notification. The regulation must continue to provide for notification and comment in that fashion.

Advantages and Disadvantages

There are no disadvantages of the proposed regulations to members of the public, who may chose to remain on the regular mailing list, be notified of regulatory actions electronically or both. Public comment on Notices of Intended Regulatory Action or proposed regulations is currently permitted and being received by facsimile or email, so these regulations will ensure that type of transmission is acceptable.

There are no disadvantages to the Department which is currently posting meeting notices affecting regulations and all regulatory submissions on the Townhall. If electronic notification and comment becomes more prevalent, there may be a modest reduction in the Department's cost of mailings.

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.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Department must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some costs (less than \$1000) for mailings to the Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations to regulated entities.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be persons or organizations that request notices of any meeting at which a regulatory action is being taken by the Department or required notices during the promulgation of regulations.

Estimate of number of entities to be affected:

There are currently 3 entities listed on the mailing list created by the Department of Health Professions to receive comment on the NOIRA for establishment of regulations for a prescription monitoring program. Depending on the issue, PPG mailing lists from the individual boards are also utilized by the Department. For example, the NOIRA on prescription monitoring was also sent to PPG notification list for the Boards of Medicine, Dentistry and Pharmacy.

Projected costs to the affected entities:

There are no costs for the affected entities to comply with these regulations.

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.

New regulations are recommended in the following sections:

18 VAC 76-30-10. Purpose.

- The purpose is to provide guidelines for the involvement of the public in the development and promulgation of regulation and includes participation in the rule-making process by electronic exchanges.

18 VAC 76-30-20. Definitions.

- Definitions are proposed to facilitate an understanding of the terms used in the regulation. For example, “person” is defined to include individuals, corporations, partnerships, associations, governmental bodies, municipal corporations, and any other legal entity. The inclusiveness of the term enables the agency to use one word to cover all types of entities.

18 VAC 76-30-30. Composition of lists.

- The Department is required to maintain lists of persons who wish to be notified, either by regular mail or electronically about the formation and promulgation of a regulation. There are also provisions for continuation or removal of names from the lists.

18 VAC 76-30-40. Documents to be sent to person on the lists.

- The documents that are required to be sent are set forth in this section.

18 VAC 76-30-50. Petition for rulemaking.

- The content of a petition and process for filing and responding is stated in this section. In accordance with amendments to the APA by the 2002 General Assembly, the time limit for a Department response to a petition is set at 90 days following a 21-day comment period.

18 VAC 76-30-60. Notice of Intended Regulatory Action.

- Requirements for a Notice of Intended Regulatory Action are set as well as a requirement for a public hearing to be held on a proposed regulation if requested by at least 25 persons during the 30-day comment period on the NOIRA.

18 VAC 76-30-70. Notice of Comment Period.

- This section describes the content and purpose of the NOCP. A change from emergency regulations was adopted to clarify that the public may provide comment on proposed regulations electronically, including facsimile or internet. The regulation will also clarify that oral comment, outside of a scheduled public hearing, will not be accepted.

18 VAC 76-30-80. Notice of Meeting.

- Requirements for a notice of meeting are set out in this section, which states that the notice shall also be posted electronically.

18 VAC 76-30-90. Public hearings on regulations.

- This section requires a public hearing be held on any proposed regulation unless the board determines that such a hearing is unnecessary.

18 VAC 76-30-100. Periodic review of regulations.

- Requirements are established for an informational proceeding to occur at least biennially to receive comment on existing regulations and for notice of the proceedings to be published in the Register and sent to those on the mailing list.

18 VAC 76-30-110. Appointment of committees.

- This section provides for the appointment of ad hoc advisory committees to assist the board in the development of regulations in order to provide for inclusion of professional assistance or technical expertise.

18 VAC 76-30-120. Limitation of service.

- This section provides for the dissolution of an advisory committee when its services are no longer necessary. If an advisory committee needs to remain in existence for longer than 12 months, the board may extend its service for another six months.

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.

In the adoption of proposed regulations, the Department's intent was to implement but not duplicate provisions of the Administrative Process Act (§ 9-6.14:1 et seq. of the Code of Virginia). Regulations are identical to those set by all 14 boards within the Department with the exception of the regulation for responding to a petition for rulemaking. In accordance with amendments to the APA by the 2002 General Assembly, the time limit for an agency response to a petition is set at 90 days following a 21-day comment period. During a recent periodic review of regulations, it was determined that public participation guidelines adopted by all boards are reasonable, clearly stated and adequate to protect the public interest in the development and promulgation of regulations. Therefore, the Department chose to adopt the model for public participation guidelines already in effect.

Public Comment

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

An announcement of the Department's intent to develop regulations governing public participation in the regulatory process was posted on the Virginia Regulatory Townhall and sent to the Registrar of Regulations. Public comment was received from August 12, 2002 until September 11, 2002. During the 30-day comment period, no comments were received from members of the public.

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.

Since no public comment was received, the proposed regulations are identical to the PPG regulations for all boards, with the exception of the rule for responding to a petition for rule-making. The PPG regulations for all boards had been carefully reviewed and amended in 2001 to clarify certain and update the requirements.

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.

Public participation guidelines require the Department to review its regulations each biennium or as required by Executive Order. Therefore, the Department intends to review regulations governing public participation in the regulatory process during the 2005-06 fiscal year.

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.

In its analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability, economic self-sufficiency, or the marital commitment. The proposed regulations will not increase or decrease disposable family income.