



**Virginia
Regulatory
Town Hall**

**Periodic Review and
Notice of Intended Regulatory Action
Agency Background Document**

Agency Name:	Board of Pharmacy
VAC Chapter Number:	18 VAC 110-10-10 et seq.
Regulation Title:	Regulations Governing Public Participation Guidelines
Action Title:	Periodic review
Date:	06/13/00

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

Regulations are promulgated to provide guidelines for public participation in the regulatory process of the board. They set forth provisions for a mailing list to receive documents related to the promulgation of regulations, procedures to be followed in a petition for rulemaking, notices, public hearings and a periodic review of regulations. The regulations further establish provisions for advisory committees in the development of regulations.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The statutory authority for this regulation is the Administrative Process Act. § 9-6.14:7.1 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.

§ 9-6.14:7.1. 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 agency receiving the petition shall consider and respond to the petition within 180 days. Agency decisions to initiate or not initiate rulemaking in response to petitions are not subject to judicial review.*
- B. In the case of all regulations, except those regulations exempted by § 9-6.14:4.1, an agency shall provide the Registrar of Regulations with a Notice of Intended Regulatory Action which 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 that the agency shall hold a public hearing or (ii) the agency receives requests for a public hearing from twenty-five persons or more.*
- 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 which 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 such panels or consultation appropriate and intends to make use of such panels or consultation.*
- E. In formulating any regulation, including but not limited to those in public assistance 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, at its discretion, begin drafting the proposed regulation prior to or during any opportunities it provides to the public to submit input.

F. In the case of all regulations, except those regulations exempted by § 9-6.14:4.1, 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 § 9-6.14:22. 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. Before delivering any proposed regulation under consideration to the Registrar as required in subsection H below, 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 such 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 H, and a copy to the Registrar for publication with the proposed regulation. No regulation shall be promulgated for consideration pursuant to subsection H until such 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 which bears any identified disproportionate material impact which 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 4 (§ 9-6.14:15 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.

H. 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 G. 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.

I. When an agency formulating regulations in public assistance programs cannot comply with the public comment requirements of subsection F of this section 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.

J. For the purpose of this article, public assistance programs shall consist of those specified in § 63.1-87.

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 of this section be deemed mere harmless error for the purposes of § 9-6.14:17.

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

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

An announcement of the board's review of its regulations governing public participation in the regulatory process was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received until April 27, 2000. During the 30-day comment period, no comments were received from members of the public.

An internal workgroup of regulatory coordinators for the agency and executive directors of regulatory boards met to review the current regulations, provisions of the Administrative Process Act, and changes in the process resulting from the initiation of the Townhall. Amendments to regulations were recommended by that group.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The goals for this regulation are as follows:

- 1) Ensure that persons and organizations are noticed when the board is considering regulatory action.
- 2) Ensure that the public has the opportunity to comment on the promulgation of any regulation.

Since the effective date of the current public participation guidelines in 1994, the board has followed the regulations by sending notices 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 have been provided at each stage of the regulatory process, including holding a public hearing on any regulatory amendments affecting the licensure of the professions the board regulates. With the availability of e-mail and fax, comments may now be received electronically. In addition, the board has provided information on the Regulatory Townhall to all persons on the public participation guidelines mailing list with instruction on how to access regulatory submissions and request to join the mailing list.

Regulations have allowed for individuals and organizations to petition the board for rulemaking on an issue of interest and have also provided for the appointment of advisory committees on issues such as continuing competency.

Following a review of every regulation, the board has determined that the current public participation guidelines are reasonable, clearly stated and adequate to protect the public interest in the development and promulgation of regulations. Amendments proposed are necessary for additional clarity and updating of the requirements.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The current regulations governing public participation in the regulatory process were finalized in 1994 following a thorough review of the regulation. Since that time, there have been no comments or requests for amendments to the regulation.

In the adoption of regulations, the board'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).

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The board is recommending amendments to its Public Participation Guidelines regulations in order to improve the clarity of the rule, to incorporate forms of notification through the Virginia Regulatory Townhall and the Commonwealth Calendar, and to improve the procedures for public involvement in the process.

Substance

Please detail any changes that would be implemented.

Amendments to regulations are recommended in the following sections:

Composition of the mailing list.

- The word "entity" is deleted since "person" is defined as including any legal entity.
- Subsection D is amended to clarify that the board should remove persons from the mailing list if they fail to indicate an interest in continuing to receive notifications from the board.

Documents to be sent to person on the mailing list.

- Amendments will identify the notices to be sent and require that the notices include instructions on how to obtain a copy of the regulation and any supporting documentation, either from the board office or from the Virginia Regulatory Townhall.

Notice of Intended Regulatory Action.

- Subsection C is amended to provide greater clarity in the 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.

Notice of Comment Period.

- An amendment clarifies that the public may provide any comment on proposed regulations, including comments received electronically.

Notice of Meeting.

- The notice of meeting described in this section may take a different form than the one provided by the Registrar, so the capitalized name has been changed to lower case.

Review of regulations.

- An amendment is adopted to recognize that Executive Orders may direct a schedule of regulatory review which is different from a review each biennium, but the review is to occur at least every two years.

Limitation of service.

- Amendments are adopted to eliminate the limitation on service by an advisory committee, since the board may find it advantageous to keep such a committee in service beyond the 12 months currently provided in regulation.

Family Impact Statement

Please provide a preliminary 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 preliminary analysis of the proposed regulatory action, the agency has determined that there is not potential impact on the institution of the family and family stability.