



Fast Track Regulation Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-10-10 et seq.
Regulation title	Public Participation Guidelines
Action title	Periodic review; clarifications
Document preparation date	3/29/07

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The Board has acted to update and clarify its guidelines for public participation in the development and promulgation of initial, amended or repealed regulations, such as inclusion of electronic notification and the Virginia Regulatory Townhall as an option for comment, clarification of certain terms used in the regulation and an extension of the time limitation on ad hoc committees.

Statement of agency final action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On March 29, 2007, the Board of Pharmacy took action to amend 18VA110-10-10 et seq., Public Participation Guidelines, through the fast-track regulatory process.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

The specific statutory mandate for guidelines for public participation in the regulatory process is found in the subsection D of § 2.2- 4007:

§ 2.2-4007. Notice of intended regulatory action; public participation; informational proceedings; effect of noncompliance.

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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The Board has updated and clarified its guidelines for public participation in the development and promulgation of initial, amended or repealed regulations, such as inclusion of electronic notification and the Virginia Regulatory Townhall as an option for comment. Changes are recommended by a committee of board and/or department staff, which reviewed each regulation for effectiveness, consistency and clarity. The intent is for amendments to be clarifying rather than substantive. Full participation by the public and regulated entities in the regulatory process is necessary to ensure that regulations fulfill the purpose of protecting the health and safety of the public in a manner that is not overly burdensome to those being regulated.

Rationale for using fast track process

Please explain why the fast track process is being used to promulgate this regulation.

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from (1) 10 or more persons, (2) any member of the applicable standing committee of either house of the General Assembly or (3) any member of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The fast-track process is being used to promulgate the amendments because there is general agreement with the changes proposed. The action is not controversial, as it is reflected by the fact that there was no public comment on a Notice of Intended Regulatory Action filed by other boards within the Department of Health Professions. Both the Department of Planning and Budget and the Governor’s office have recommended that these amendments be promulgated by a fast-track action.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the “Detail of changes” section.)

The regulation has been reviewed for consistency with law, clarity and ease of compliance. There are no substantive amendments.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

There are no disadvantages to the public of these amendments. Clarification of regulation, additional opportunity for comment, and an extension of service for an ad hoc committee appointed to advise the board on the development of a regulation are all intended to give interested parties more access to the process.

There are no advantages or disadvantages to the agency or the Commonwealth.

There are no other pertinent matters of interest.

Economic impact

<p>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</p>	<p>The agency will incur some one-time costs (less than \$1,000) for mailings and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings or distribute notices by email. There are no ongoing expenditures related to this amendment. As a special fund agency, the Board 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.</p>
<p>Projected cost of the regulation on localities</p>	<p>None</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>The individuals who may be affected would be persons interested in the regulatory work of the board.</p>
<p>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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>The agency has no estimate of the number of entities that will be affected. Interest in any given regulatory process varies, so the number of entities that may respond will also vary.</p>
<p>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</p>	<p>There would be no additional costs to the affected entities.</p>

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.

During its review of the board's public participation guidelines (PPG), staff of the board and the department examined PPG regulations of a number of other state boards and agencies. The purpose was to determine whether there was alternative language that could be adopted that would state the regulations more clearly or whether there were other provisions that would make regulations more effective. Several of the amendments recommended by the review committee were adopted from other such regulations.

The committee also reviewed sections of the Administrative Process Act and the current Executive Order on the promulgation of regulations to ensure that the guidelines were consistent with those requirements.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no potential impact of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes.

Amendments in section 10 on the purpose for the regulations.

An amendment is adopted to specify that the development and promulgation includes the initial formation and development, amendment or repeal of regulations. Cites for the provisions of the Administrative Process Act (APA) of the Code of Virginia throughout the regulations will be updated to reflect the recodification that took place since this chapter was last amended.

Amendments to section 20 on definitions.

The definition for "notification lists" will be amended to refer specifically to the Virginia Regulatory Town Hall and to ensure that notification includes electronic means as well as mailing paper copies.

A new definition for "regulation," consistent with the definition of the APA will be added for clarity since the public often confuses law and regulation.

Amendments to section 40 on documents to be sent to persons on the notification lists.

A requirement that persons on the notification list be sent a notification of the adoption of a final regulation and instructions as to how to obtain a copy of the regulation will be deleted and replaced with a requirement that the board must post notification of the adoption of a final

regulation and copies of the regulation on the board's website prior to the 30-day adoption period.

The board will also include a rule found in the PPG regulations of many other boards or agencies that provides that the failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation otherwise adopted in accordance with this chapter.

Amendments to section 50 on a petition for rulemaking.

An amendment will provide that the board has the sole authority to dispose of the petition to ensure that petition requests would be brought to the board and not reviewed and dismissed by staff or some other entity.

Amendments to section 60 on a notice of intended regulatory action.

The following are added: 1) an introductory sentence to explain the purpose of a notice of intended regulatory action, and 2) the APA requirement for a public hearing if the Governor so directs.

Amendments to section 70 on a notice of comment period.

An introductory sentence to explain the purpose of a notice of comment will be added.

Amendments in section 80 on the notice of meeting.

Amendments are adopted to clarify and update the language of the regulation.

Amendments to section 100 on a periodic review of regulations.

Amendments will be proposed to clarify that the periodic review of regulations should be consistent with the Executive Order of the Governor in accordance with the APA. Other terms will be amended for consistency in the regulation.

Amendments in section 120 on limitation of service.

The board proposes to extend the duration of an ad hoc committee from 12 to 18 months because the development of regulatory language with such a committee often includes discussion of issues prior to adoption and publication of a NOIRA and consideration of comment on the NOIRA and the proposed regulation. Rather than setting in regulation a time of six months for any extension of the committee, the board would be authorized to continue the committee for an additional period of time to complete the specific advisory task for which it appointed.