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Regulatory
Town Hall

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Notice of Intended Regulatory Action (NOIRA) 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	9/27/06

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Board's intent is to update and clarify its guidelines for public participation in the development and promulgation of initial, amended or repealed regulations. 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.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe 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.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

The regulation has been reviewed for consistency with law, clarity and ease of compliance with the following amendments recommended:

Amendments in section 10 on the purpose for the regulations.

An amendment is recommended to specific 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 would be deleted and replaced with a requirement that the board 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.

It is recommended that the following be 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.

It is recommended that an introductory sentence to explain the purpose of a notice of comment be added.

Amendments in section 80 on the notice of meeting.

Amendments are intended 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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

During its review of the board’s public participation guidelines, 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 APA and the current Executive Order on the promulgation of regulations to ensure that the guidelines were consistent with those requirements.

Family impact

Assess the potential 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.