

PROPOSED REGULATIONS OF THE VIRGINIA BOARD OF PHARMACY

18 VAC 110-10-10 et seq.

PUBLIC PARTICIPATION GUIDELINES

Part I. Statement of Purpose.

18 VAC 110-10-10. Purpose.

The purpose of this chapter is to provide guidelines for the involvement of the public in the development and promulgation of regulations of the Board of Pharmacy. The guidelines do not apply to regulations exempted or excluded from the provisions of the Administrative Process Act (§ 9-6.14:4.1.1 of the Code of Virginia). These rules seek to expand participation by providing for electronic exchange with the public and thereby increasing participation, reducing costs, and improving the speed of communication.

18 VAC 110-10-20. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"*Administrative Process Act*" means Chapter 1.1:1 (§ 9-6.14:1 et seq.) of Title 9 of the Code of Virginia.

"*Board*" means the Board of Pharmacy.

"*Notification lists*" means lists used by the board to notify persons pursuant to these rules. Such lists may include electronic mailing lists maintained through a state website or regular mailing lists maintained by the board.

"*Person*" means an individual, a corporation, a partnership, an association, a governmental body, a municipal corporation, or any other legal entity.

Part II. ~~Mailing List~~ Notification Lists.

18 VAC 110-10-30. Composition of the mailing list lists.

A. The board shall maintain ~~a list~~ lists of persons ~~or entities~~ who have requested to be notified of the formation and promulgation of regulations.

B. Any person ~~or entity~~ may request to be placed on ~~the mailing~~ a notification list by indicating so electronically or in writing to the board. The board may add to ~~the~~ a list any person ~~or entity~~ it believes will serve the purpose of enhancing participation in the regulatory process.

C. The board may maintain additional ~~mailing~~ lists for persons ~~or entities~~ who have requested to be informed of specific regulatory issues, proposals, or actions.

D. The board shall periodically request those persons on the ~~mailing list~~ notification lists to indicate their desire to either continue to receive documents by regular mail, be notified electronically or be deleted from the ~~list~~ lists. Persons who elect to be included on an electronic mailing list may also request that all notices and mailings be sent in hard copy. When either regular or electronic mail is returned as undeliverable or there has been no response to the request from the board, ~~individuals or organizations~~ such persons shall be deleted from the list.

18 VAC 110-10-40. Documents to be sent to persons ~~or entities~~ on the ~~mailing list~~ lists.

Persons ~~or entities~~ on the ~~mailing list~~ notification lists, as described in 18 VAC 110-20-30, shall be mailed or have electronically transmitted the following documents related to the promulgation of regulations:

1. A ~~Notice of Intended Regulatory Action~~ notice of intended regulatory action.
2. A ~~Notice of Comment Period~~ notice of the comment period on a proposed regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.
3. A ~~copy of any final regulation adopted by the board~~ notification of the adoption of a final regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.
4. A notice soliciting comment on a final regulation when the regulatory process has been extended.

**Part III.
Public Participation Procedures.**

18 VAC 110-10-50. Petition for rulemaking.

A. As provided in § 9-6.14:7.1 of the Code of Virginia, any person may petition the board to develop a new regulation or amend an existing regulation.

B. A petition shall include but need not be limited to the following:

1. The petitioner's name, mailing address, telephone number, and, if applicable, the organization represented in the petition.
2. The number and title of the regulation to be addressed.
3. A description of the regulatory problem or need to be addressed.
4. A recommended addition, deletion, or amendment to the regulation.

C. The board shall receive, consider and respond to a petition within 180 days.

D. Nothing herein shall prohibit the board from receiving information from the public and proceeding on its own motion for rulemaking.

18 VAC 110-10-60. Notice of Intended Regulatory Action.

A. The ~~Notice of Intended Regulatory Action~~ notice of intended regulatory action (NOIRA) shall state the purpose of the action and a brief statement of the need or problem the proposed action will address.

B. The NOIRA shall indicate whether the board intends to hold a public hearing on the proposed regulation after it is published. If the board does not intend to hold a public hearing, it shall state the reason in the NOIRA.

C. ~~The NOIRA shall state that a public hearing will be scheduled, if, during the 30-day comment period, the board receives requests for a hearing from at least 25 persons.~~ If prior to the close of the 30-day comment period on the NOIRA, the board receives a request for a public hearing on the proposed regulation from at least 25 persons, such a hearing shall be scheduled.

18 VAC 110-10-70. Notice of Comment Period.

A. The ~~Notice of Comment Period~~ notice of comment period (NOCP) shall indicate that copies of the proposed regulation are available electronically or from the board and may be requested in writing from the contact person specified in the NOCP.

B. The NOCP shall indicate that copies of the statement of substance, issues, basis, purpose, and estimated impact of the proposed regulation may also be requested in writing.

C. The NOCP shall make provision for ~~either oral or written submittals~~ comments on pertaining to the proposed regulation ~~or on the impact on regulated entities and the public and on the cost of~~

compliance with the proposed regulation by regular mail, internet, facsimile or electronic means. With the exception of comment received at a scheduled public hearing, oral comment may not be accepted.

18 VAC 110-10-80. Notice of Meeting.

A. At any meeting of the board or advisory committee, at which the formation or adoption of regulation is anticipated, the subject shall be described in ~~the Notice of Meeting~~ a notice of meeting, which has been posted electronically on the Internet and transmitted to the Registrar for inclusion in The Virginia Register.

B. If the board anticipates action on a regulation for which an exemption to the Administrative Process Act is claimed under § 9-6.14:4.1. of the Code of Virginia, the ~~Notice of Meeting~~ notice of meeting shall indicate that a copy of the proposed regulation is available on a state website or upon request to the board at least two days prior to the meeting and that a copy of the regulation shall be made available to the public attending such meeting.

18 VAC 110-10-90. Public hearings on regulations.

The board shall conduct a public hearing during the 60-day comment period following the publication of a proposed regulation or amendment to an existing regulation, unless, at a noticed meeting, the board determines that a hearing is not required.

18 VAC 110-10-100. Biennial Periodic review of regulations.

A. ~~At least once each biennium~~ Unless otherwise directed by Executive Order, the board shall conduct an informational proceeding at least every two years to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance.

B. Such proceeding may be conducted separately or in conjunction with other informational proceedings or hearings.

C. Notice of the proceeding shall be transmitted to the Registrar for inclusion in The Virginia Register and shall be sent to the mailing list identified in 18 VAC 110-10-30.

**Part IV.
Advisory Committees.**

18 VAC 110-10-110. Appointment of committees.

A. The board may appoint an ad hoc advisory committee whose responsibility shall be to assist in the review and development of regulations for the board.

B. The board may appoint an ad hoc advisory committee to provide professional specialization or technical assistance when the board determines that such expertise is necessary to address a specific regulatory issue or need or when groups of individuals register an interest in working with the agency.

18 VAC 110-10-120. Limitation of service.

A. An advisory committee which has been appointed by the board may be dissolved by the board when:

1. There is no response to the Notice of Intended Regulatory Action, or
2. The board determines that the promulgation of the regulation is either exempt or excluded from the requirements of the Administrative Process Act (§ 9-6.14:4.1 of the Code of Virginia).

B. An advisory committee shall remain in existence no longer than 12 months from its initial appointment.

1. If the board determines that the specific regulatory need continues to exist beyond that time, it shall set a specific term for the committee of not more than six additional months.
2. At the end of that extended term, the board shall evaluate the continued need and may continue the committee for additional six month terms.