

Virginia Board of Pharmacy

CHAPTER 10

PUBLIC PARTICIPATION GUIDELINES

Part I

General Provisions

18VAC110-10-10. Purpose.

The purpose of this chapter is to provide guidelines for the involvement of the public in the ~~development and promulgation~~ initial formation and development, amendment or repeal 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 2.2-4000~~ et seq. 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.

18VAC110-10-20. 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 40~~ 40 (~~§9-6.14:1 2.2-4000~~ et seq.) of Title ~~9 2.2~~ 9 2.2 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~~ the Virginia Regulatory Town Hall 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.

"Regulation" means any statement of general application, having the force of law, affecting the rights or conduct of any person, adopted by the board in accordance with the authority conferred on it by applicable laws.

Part II

Notification Lists

18VAC110-10-30. Composition of notification lists.

A. The board shall maintain lists of persons who have requested to be notified of the initial formation and promulgation, development, amendment or repeal of regulations.

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

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

D. The board shall periodically request those persons on the notification lists to indicate their desire to either continue to receive documents by regular mail, be notified electronically or be deleted from the 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, such persons shall be deleted from the list.

18VAC110-10-40. Documents to be sent to persons on the notification lists.

A. Persons on the notification lists, as described in 18VAC110-10-30, shall be mailed or have electronically transmitted the following documents related to the promulgation of regulations:

1. A notice of intended regulatory action.

2. A 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 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 ~~3~~. A notice soliciting comment on a final regulation when the regulatory process has been extended.

B. Notification of the adoption of a final regulation and copies of the regulation shall be posted on the board's website prior to the 30-day adoption period.

C. 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.

Part III

Public Participation Procedures

18VAC110-10-50. Petition for rulemaking.

A. As provided in ~~§9-6.14:7.1~~ 2.2-4007 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, and shall have the sole authority to dispose of the petition.

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

18VAC110-10-60. Notice of Intended Regulatory Action.

A. The board shall issue a notice of intended regulatory action (NOIRA) whenever it considers the adoption, amendment or repeal of a regulation. ~~The notice of intended regulatory action (NOIRA)~~ 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. 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 or if the Governor directs the board to hold a public hearing, such a hearing shall be scheduled.

18VAC110-10-70. Notice of Comment Period.

A. Prior to the 60-day comment period, the board shall issue a notice of comment period (NOCP) whenever it propose to initiate, amend or repeal a regulation or amend an existing regulation under a fast-track process. ~~The notice of comment period (NOCP)~~ 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 comments pertaining to 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~~ shall not be accepted.

18VAC110-10-80. Notice of meeting.

A. At any meeting of the board or advisory committee at which the formation, amendment, repeal, or adoption of a regulation is anticipated, the subject shall be described in a notice of meeting, which has been posted electronically on the ~~Internet~~ Virginia Regulatory Town Hall and transmitted to the Registrar of Regulations 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~~ 2.2-4002 or §2.2-4011 of the Code of Virginia, the notice of meeting shall indicate that a copy of the proposed regulation ~~is available on a state website or upon request to~~ may be requested from the board at least two days prior to the meeting. A copy of the regulation shall be made available to the public attending such meeting.

18VAC110-10-90. 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.

18VAC110-10-100. Periodic review of regulations.

A. ~~Unless otherwise directed by executive order,~~ The board shall conduct ~~an informational proceeding~~ a periodic review of its regulations at least every two years consistent with an executive order issued by the Governor and with § 2.2-4007.1 of the Code of Virginia to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance.

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

C. Notice of the proceeding shall be transmitted to the Registrar of Regulations for inclusion in the Virginia Register and shall be sent to the ~~mailing list~~ notification lists identified in 18VAC110-10-30.

Part IV

Advisory Ad Hoc Committees

18VAC110-10-110. 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.

18VAC110-10-120. Limitation of service.

A. An ~~advisory~~ ad hoc 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~~ ad hoc committee shall remain in existence no longer than ~~12~~ 18 months from its initial appointment unless ~~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.~~ The board may authorize the ad hoc committee to continue for an additional specified period of time to complete the task for which it was appointed.

~~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.~~
