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|  | ***Commonwealth of Virginia*** |  |
|  | **Public Participation Guidelines**  **Virginia Board of Pharmacy**  **Title of Regulations: 18 VAC 110-11-10 et seq.**  **Statutory Authority: §§ 54.1-2400 and 2.2-4007**  **of the *Code of Virginia***  **Revised Date: December 15, 2016**  9960 Mayland Drive, Suite 300 (804) 367-4456 (TEL)  Henrico, VA 23233-1463 (804) 527-4472 (FAX)  email: pharmbd@dhp.virginia.gov | |

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# Part I Purpose and Definitions

## 18VAC110-11-10. Purpose.

The purpose of this chapter is to promote public involvement in the development, amendment or repeal of the regulations of the Board of Pharmacy. This chapter does not apply to regulations, guidelines, or other documents exempted or excluded from the provisions of the Administrative Process Act (§2.2-4000 et seq. of the Code of Virginia).

## 18VAC110-11-20. 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 40 (§2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

"Agency" means the Board of Pharmacy, which is the unit of state government empowered by the agency's basic law to make regulations or decide cases. Actions specified in this chapter may be fulfilled by state employees as delegated by the agency.

"Basic law" means provisions in the Code of Virginia that delineate the basic authority and responsibilities of an agency.

"Commonwealth Calendar" means the electronic calendar for official government meetings open to the public as required by §2.2-3707 C of the Freedom of Information Act.

''Negotiated rulemaking panel'' or ''NRP'' means an ad hoc advisory panel of interested parties established by an agency to consider issues that are controversial with the assistance of a facilitator or mediator, for the purpose of reaching a consensus in the development of a proposed regulatory action.

"Notification list" means a list used to notify persons pursuant to this chapter. Such a list may include an electronic list maintained through the Virginia Regulatory Town Hall or other list maintained by the agency.

"Open meeting" means any scheduled gathering of a unit of state government empowered by an agency's basic law to make regulations or decide cases, which is related to promulgating, amending or repealing a regulation.

"Person" means any individual, corporation, partnership, association, cooperative, limited liability company, trust, joint venture, government, political subdivision, or any other legal or commercial entity and any successor, representative, agent, agency, or instrumentality thereof.

"Public hearing" means a scheduled time at which members or staff of the agency will meet for the purpose of receiving public comment on a regulatory action.

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

"Regulatory action" means the promulgation, amendment, or repeal of a regulation by the agency.

"Regulatory advisory panel" or "RAP" means a standing or ad hoc advisory panel of interested parties established by the agency for the purpose of assisting in regulatory actions.

"Town Hall" means the Virginia Regulatory Town Hall, the website operated by the Virginia Department of Planning and Budget at www.townhall.virginia.gov, which has online public comment forums and displays information about regulatory meetings and regulatory actions under consideration in Virginia and sends this information to registered public users.

"Virginia Register" means the Virginia Register of Regulations, the publication that provides official legal notice of new, amended and repealed regulations of state agencies, which is published under the provisions of Article 6 (§2.2-4031 et seq.) of the Administrative Process Act.

# Part II Notification of Interested Persons

## 18VAC110-11-30. Notification list.

A. The agency shall maintain a list of persons who have requested to be notified of regulatory actions being pursued by the agency.

B. Any person may request to be placed on a notification list by registering as a public user on the Town Hall or by making a request to the agency. Any person who requests to be placed on a notification list shall elect to be notified either by electronic means or through a postal carrier.

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

D. When electronic mail is returned as undeliverable on multiple occasions at least 24 hours apart, that person may be deleted from the list. A single undeliverable message is insufficient cause to delete the person from the list.

E. When mail delivered by a postal carrier is returned as undeliverable on multiple occasions, that person may be deleted from the list.

F. The agency may periodically request those persons on the notification list to indicate their desire to either continue to be notified electronically, receive documents through a postal carrier, or be deleted from the list.

## 18VAC110-11-40. Information to be sent to persons on the notification list.

A. To persons electing to receive electronic notification or notification through a postal carrier as described in 18VAC110-11-30, the agency shall send the following information:

1. A notice of intended regulatory action (NOIRA).

2. A notice of the comment period on a proposed, a reproposed, or a fast-track regulation and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any supporting documents.

3. A notice soliciting comment on a final regulation when the regulatory process has been extended pursuant to §2.2-4007.06 or 2.2-4013 C of the Code of Virginia.

B. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation or regulatory action.

# Part III Public Participation Procedures

## 18VAC110-11-50. Public comment.

A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to (i) submit data, views, and arguments, either orally or in writing, to the agency; and (ii) be accompanied by and represented by counsel or other representative. Such opportunity to comment shall include an online public comment forum on the Town Hall.

1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.

2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.

B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:

1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA).

2. For a minimum of 60 calendar days following the publication of a proposed regulation.

3. For a minimum of 30 calendar days following the publication of a reproposed regulation.

4. For a minimum of 30 calendar days following the publication of a final adopted regulation.

5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

6. For a minimum of 21 calendar days following the publication of a notice of periodic review.

7. Not later than 21 calendar days following the publication of a petition for rulemaking.

C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.

D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with §2.2-4013 C of the Code of Virginia.

E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to §2.2-4012 E of the Code of Virginia.

## 18VAC110-11-60. Petition for rulemaking.

A. As provided in §2.2-4007 of the Code of Virginia, any person may petition the agency to consider a regulatory action.

B. A petition shall include but is not limited to the following information:

1. The petitioner's name and contact information;

2. The substance and purpose of the rulemaking that is requested, including reference to any applicable Virginia Administrative Code sections; and

3. Reference to the legal authority of the agency to take the action requested.

C. The agency shall receive, consider and respond to a petition pursuant to §2.2-4007 and shall have the sole authority to dispose of the petition.

D. The petition shall be posted on the Town Hall and published in the Virginia Register.

E. Nothing in this chapter shall prohibit the agency from receiving information or from proceeding on its own motion for rulemaking.

## 18VAC110-11-70. Appointment of regulatory advisory panel.

A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.

B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.

C. A RAP may be dissolved by the agency if:

1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other time as the agency determines is appropriate; or

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.

## 18VAC110-11-80. Appointment of negotiated rulemaking panel.

A. The agency may appoint a negotiated rulemaking panel (NRP) if a regulatory action is expected to be controversial.

B. A NRP that has been appointed by the agency may be dissolved by the agency when:

1. There is no longer controversy associated with the development of the regulation;

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act; or

3. The agency determines that resolution of a controversy is unlikely.

## 18VAC110-11-90. Meetings.

Notice of any open meeting, including meetings of a RAP or NRP, shall be posted on the Virginia Regulatory Town Hall and Commonwealth Calendar at least seven working days prior to the date of the meeting. The exception to this requirement is any meeting held in accordance with §2.2-3707 D of the Code of Virginia allowing for contemporaneous notice to be provided to participants and the public.

## 18VAC110-11-100. Public hearings on regulations.

A. The agency shall indicate in its notice of intended regulatory action whether it plans to hold a public hearing following the publication of the proposed stage of the regulatory action.

B. The agency may conduct one or more public hearings during the comment period following the publication of a proposed regulatory action.

C. An agency is required to hold a public hearing following the publication of the proposed regulatory action when:

1. The agency's basic law requires the agency to hold a public hearing;

2. The Governor directs the agency to hold a public hearing; or

3. The agency receives requests for a public hearing from at least 25 persons during the public comment period following the publication of the notice of intended regulatory action.

D. Notice of any public hearing shall be posted on the Town Hall and Commonwealth Calendar at least seven working daysprior to the date of the hearing. The agency shall also notify those persons who requested a hearing under subdivision C 3 of this section.

## 18VAC110-11-110. Periodic review of regulations.

A. The agency shall conduct a periodic review of its regulations consistent with:

1. An executive order issued by the Governor pursuant to §2.2-4017 of the Administrative Process Act to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance; and

2. The requirements in §2.2-4007.1 of the Administrative Process Act regarding regulatory flexibility for small businesses.

B. A periodic review may be conducted separately or in conjunction with other regulatory actions.

C. Notice of a periodic review shall be posted on the Town Hall and published in the Virginia Register.