Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions	
Virginia Administrative Code (VAC) citation	18 VAC 110-20	
Regulation title	Regulations Governing the Practice of Pharmacy	
Action title	Delegation of Informal Fact-finding to an Agency Subordinate	
Document preparation date	3/1/05	

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.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Proposed regulations were adopted by the Board of Pharmacy to comply with amendments to § 54.1-2400 (10) and the third enactment clause in HB 577 by the 2004 General Assembly. Subdivision 10 establishes authority for health regulatory boards to appoint special conference committees and to delegate an informal fact-finding proceeding to an appropriately qualified agency subordinate. The enactment clause adds a mandate for the adoption of regulations, "*Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.*" The proposed regulations will replace emergency regulations that have been in effect since July 15, 2004.

Section 15 is added to Part I, General Provisions, in order to establish in regulation the criteria for delegation, including the decision to delegate at the time of a probable cause determination, the types of cases that cannot be delegated, and the individuals who may be designated as agency subordinates.

Statement of final agency 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 1, 2005, the Board of Pharmacy adopted final amendments to 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy, in order to establish standards for delegation of certain types of informal fact-finding to an agency subordinate.

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 numbers, 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 provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system and to delegate informal fact-finding to an agency subordinate:

§ 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. …

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than two members of the Board and one member of the relevant advisory board, to act in accordance with § 2.2-4019 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final 30 days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the 30-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 2.2-4020, and the action of the committee shall be vacated. This subdivision shall not be construed to limit the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001, the authority to conduct informal fact-finding proceedings in accordance with § 2.2-4019, upon receipt of information that a practitioner may be subject to a disciplinary action. Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

One of the most important functions of the Department of Health Professions is the investigation and adjudication of disciplinary cases to ensure that the public is adequately protected if a health care professional violates a law or regulation. The law enacted by the 2004 General Assembly and adoption of these proposed rules give another tool to health regulatory boards seeking to bring closure to cases in a timely manner by allowing cases to be delegated to an agency subordinate, who could be a single board member trained and qualified to conduct a fact-finding proceeding.

In § 2.2-4019 of the Administrative Process Act (APA), provisions for an informal fact finding proceeding establish the rights of parties to a disciplinary care including the right to "appear in person or by counsel or other qualified representative before the agency *or its subordinates*, or before a hearing officer for the informal presentation of factual data, argument, or proof in connection with any case." A "subordinate" is defined in the APA as "(i) one or more but less than a quorum of the members of a board constituting an agency, (ii) one or more of its staff members or employees, or (iii) any other person or persons designated by the agency to act in its behalf." The proposed regulations specify that health regulatory boards can conduct fact-finding proceedings by delegation to a subordinate, the types of cases that are not appropriate for delegation and the criteria for a subordinate.

The board will retain the authority to determine whether to delegate any proceedings, the type of disciplinary case that could be delegated and who would serve as its subordinate. While certain standard of care cases may continue to be heard by board members appointed to a special conference committee, other disciplinary matters could be delegated to a person qualified by knowledge and background to determine the facts in the case. Delegation to an agency subordinate will be available to address cases that may arise from audits for continuing education compliance, or inspection-related violations. Proposed regulations state the types of cases that may not be heard by a subordinate but leave the final decision of delegation to a committee of the Board. The ability of a board to delegate certain cases through a proceeding conducted by a subordinate will alleviate the disciplinary burden for board members, ensure resolution in a timelier manner and reserve board member time for hearing more serious matters.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Section 15 is added to Part I, General Provisions, in order to establish in regulation the criteria for delegation, including the decision to delegate at the time of a probable cause determination, the types of cases that cannot be delegated except as may be approved by a committee of the board, and the individuals who may be designated as agency subordinates.

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 there are no disadvantages to the public or the Commonwealth, please indicate.

1) The only advantage to the public may be a speedier resolution of disciplinary cases, but the cases that would likely be heard by a subordinate of the Board of Pharmacy would probably not involve standard of care for patients or cases of drug diversion. It is likely that the Board will delegate cases that involve such violations as failure to obtain continuing education. Therefore, there may not be any real advantage or disadvantage to the public.

2) There are no disadvantages to the agency or the Commonwealth. If adjudication of certain types of cases could be handled with the use of a subordinate rather than a committee of the Board, there may be some advantages in resolution of cases and a modest reduction in costs for informal fact-finding. Scheduling a single board member to sit as an agency subordinate will be easier than scheduling for two or more members, so it may be possible for cases to be heard more quickly. On the other hand, recommendations of the subordinate will have to be ratified by the Board, so resolution of the case may be somewhat delayed until the next scheduled meeting at which a quorum of the Board can be present.

3) There is no other pertinent matter of interest related to this action.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes made to the text of the proposed regulation since publication of the proposed stage.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Proposed regulations for delegation to an agency subordinate were published on December 13, 2004 with a 60-day comment period ending February 11, 2005. A public hearing on the proposed regulation was held on January 20, 2005. There were no written or oral comments.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

The proposed regulations replace emergency regulations currently in effect. There have been no changes since the publication of the emergency regulations.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
n/a	15	n/a	Subsection A references the statutory authority for delegation of informal fact-finding to an agency subordinate and establishes that such delegation may occur upon a determination that probable cause exists that a practitioner may be subject to a disciplinary action. Subsection B sets out the types of cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, to include those that involve: 1. Intentional or negligent conduct that causes or is likely to cause injury to a patient; 2. Drug diversion; 3. Impairment with an inability to practice with skill and safety; 4. Indiscriminate dispensing; 5. Medication error in administration or dispensing. While the Board has set out the types of cases that may not be delegated, it has allowed for maximum flexibility by stipulating that a committee of the Board can approve delegation for any case, based on the particular facts and circumstances involved. Subsection C sets out the criteria for the individual who may serve as an agency subordinate to include board members (both current and former), professional staff and others deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals. The Board

			has provided for flexibility in the choice of an agency subordinate but also specified that the Board will authorize agency subordinates. Therefore, the authority for subordinates rests with the Board as an extension of its authority in disciplinary matters. The proposed regulation also provides that the executive director will maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated, and that the board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

Family impact

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

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