Virginia Regulatory Town Hall

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Proposed 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	9/21/04

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

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

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.

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., the 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 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 by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so 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.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no additional costs to the agency for conducting informal fact-finding by a subordinate.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The entities that are likely to be affected by these regulations would be pharmacists, pharmacies and pharmacy technicians regulated by the Board.

Agency's best estimate of the number of such entities that will be affected	The agency has no estimate of the number of entities affected since this is a new regulatory program and the number of cases that may be delegated is unknown.
Projected cost of the regulation for affected individuals, businesses, or other entities	There would be no cost related to these regulations for the affected entities.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

There are no alternatives to the adoption of regulations for implementation of the delegation of informal fact-finding proceedings to an agency subordinate, as it is mandated by Chapter 64 of the 2004 Acts of the Assembly. While adoption of criteria for delegation is mandated by law, the Board is not required to utilize the delegation process and may choose to continue disposition of disciplinary cases through special or informal conference committees of the board, consent orders, or confidential consent agreements.

In an effort to provide some consistency in the scope and content of the regulation, the regulations were developed in consultation with the three attorneys from the Office of the Attorney General who represent the health regulatory boards within the Department of Health Professions. Initially, the regulatory scheme that was recommended included adoption of comprehensive rules for the informal fact-finding proceeding conducted by an agency subordinate, including the pre-conference process, the participants in the informal fact-finding, a schedule for submission of documents, process for conducting the proceeding, creation of a written record of the proceeding, and the review and decision by the board.

Upon further review of the legislation and discussion with staff, it was agreed that regulations should be limited to the specific mandate of the law, namely the criteria for delegation rather than the process to be followed in conducting the proceeding. Therefore, the regulations address the decision to delegate at the point of a probable cause determination that a violation may have occurred, the types of cases that may not be delegated, and the general criteria for the individuals to whom cases may be delegated. The Board of Pharmacy chose to set out those types of cases that will not be delegated, except as may be approved by a committee of the Board. By adopting a list of non-delegable case-types but providing an exception, the Board has more flexibility for delegation, if it is deemed appropriate.

The need for setting out process and procedures will be accomplished by the adoption of a guidance document. For example, the decision to delegate is to be made at the probable cause stage in the continuum of discipline. Boards have delegated the probable cause determination to a committee, the chair or the executive director and may choose to authorize the person or persons who make the probable cause determination the authority to determine whether a case could appropriately be heard by an agency subordinate. In addition, the Board will utilize the Administrative Process Act which sets the legal framework for the conduct of an informal fact-

finding proceeding and the opportunity for the formal taking of evidence upon relevant fact issues in any case.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

The Notice of Intended Regulatory Action was published on August 9, 2004 with comment received until September 8, 2004. There was no public comment received during that period.

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.

Detail of changes

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

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.