Virginia Regulatory Town Hall

townhall.virginia.gov

Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	6/8/04

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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.*

Preamble

The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

1) Please explain why this is an "emergency situation" as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The adoption of an "emergency" regulation by the Board of Pharmacy is required to comply with amendments to § 54.1-2400 (10) and the third enactment clause in the passage of 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. It further 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 third enactment clause of Chapter 64 of the 2004 Acts of the Assembly, which states "*That the health regulatory boards within the Department of Health Professions shall promulgate regulations to implement the provisions of this act relating to the delegation of fact-finding proceedings to an agency subordinate within 280 days of its enactment*" requires the adoption of the regulation as an emergency in accordance with the Administrative Process Act, § 2.2-4011, which states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. Chapter 64 was enacted on March 10, 2004, the day HB 577 was signed by the Governor.

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

Other than the emergency authority described above, 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., 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 mandates the adoption of regulations for delegation 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 describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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 emergency rules will make another tool available 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 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 emergency 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.

Boards 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 fact-finding 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,

inspections of pharmacies or business-related violations. Emergency regulations would prohibit any case from being heard by a subordinate but would permit a special conference committee of the Board to make the final decision. 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 more timely manner and reserve board member time for hearing more serious matters.

Substance

Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

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 approved 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 authorized agency subordinates. Therefore, the authority for subordinates rests with the Board as an extension of its

			authority in disciplinary matters. The emergency 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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet 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 emergency 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 emergency 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. Each board has determined whether to state the types of cases in the affirmative or negative. The Board of Pharmacy chose to set out those types of cases that will not be delegated with the caveat that cases may or may not be appropriate for delegation with the determination to be made on a case-by-case basis by a committee of the Board. By adopting a list of non-delegable case-types but providing an exception for those approved by a Board committee, the Board has more flexibility for delegation, if it is deemed appropriate.

The need for setting out process and procedures may be accomplished by revising the by-laws of the Board or 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.

Family impact

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

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