Virginia
Regulatory
Town Hall

Emergency Regulation
Agency Background Document

Agency Name:	Board of Pharmacy, Department of Health Professions
VAC Chapter Number:	18 VAC 110-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Pharmacy
Action Title:	Pilot programs in pharmacy
Date:	6/15/00

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

Emergency Preamble

Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an "emergency situation" means: (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. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

Please include a brief summary of the emergency action. There is no need to state each provision or amendment.

Amendments to regulation are required in order to comply with an enactment clause in Chapter 876 of the 2000 Acts of the Assembly requiring the Board to promulgate regulations within 280 days of enactment for innovative programs (pilot projects) in pharmacy for which some waiver of law or regulation would be necessary.

Basis

Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

The legal authority to promulgate the emergency regulation is in second enactment clause of Chapter 876 of the 2000 Acts of the Assembly, which states: "That the Board shall promulgate regulations, in consultation with the Board of Medicine, to implement the provisions of this act to be effective within 280 days of its enactment."

The Office of the Attorney General has certified that the "emergency situation" which exists is specified in § 9-6.14:4.1 (C)(5)(ii) of the Code of Virginia as one in which the agency is required by statutory law to have a regulation in effect within 280 days from the enactment of the law.

Substance

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

Section 20 is being amended to comply with a statutory mandate for the Board to provide regulations for the implementation of pilot projects or innovative programs in pharmacy which are not specifically authorized by the Code of Virginia or Board regulations. The law requires any person who proposes to use an innovative process or procedure related to the dispensing of drugs or devices that would not be in compliance with law or regulation to apply to the Board of Pharmacy for approval. The law does not permit the Board to expand the current scope of practice for pharmacists nor shall a pilot project be allowed to interfere with dispensing of drugs in accordance with instructions from prescribers.

Further, § 54.1-3307.2 of the Code specifies the content of the application to include safety issues, potential benefit to the public, promotion of technical or scientific advances, compliance with prescriber instructions, potential for diversion, impact on costs, means of monitoring and providing quality assurance, and the reporting of outcomes to the Board. The process for review

and approval is through an informal conference committee which has the authority to make a case decision on each individual application and to set certain terms and conditions for approval of a pilot project. Approval is for a finite period of time, with requirements for review of outcomes and any additional information necessary to determine renewal of approval. The applicant has the right to appeal the decision of a committee before the Board of a panel of the Board in accordance with the Administrative Process Act. The law requires that the application be submitted on a form provided by the Board to be accompanied by a fee to be determined.

§ 54.1-3307.2. Approval of innovative programs.
A. Any person who proposes to use a process or procedure related to the dispensing of drugs or devices or to the practice of pharmacy not specifically authorized by Chapter 33 (§ 54.1-3300 et seq.) of this title or by a regulation of the Board of Pharmacy may apply to the Board for approval to use such process or procedure. The application under this section may only include new processes or procedures, within the current scope of the practice of pharmacy, that relate to the form or format of prescriptions, the manner of transmitting prescriptions or prescription information, the manner of required recordkeeping, the use of unlicensed ancillary personnel in the dispensing process, and the use of new technologies in the dispensing process. The authority granted the Board under this section shall not authorize expansion of the current scope of practice for pharmacists and shall not interfere with the requirement that pharmacists only dispense drugs in accordance with instructions from a prescriber, as defined in § 54.1-3401.
B. The application to the Board shall address safety to the public regarding the new process or procedure, any potential benefit to the public, promotion of scientific or technical advances in the practice of pharmacy, compliance with prescriber's instructions for any drug dispensed, any impact the new process may have on the potential for diversion of drugs, maintenance in the integrity of and public confidence in the profession of pharmacy and of the drugs dispensed, impact on cost to the public and within the health care industry, means of monitoring the new process or procedure for any negative outcomes or other problems, and the reporting of such outcomes to the Board.
C. An informal conference committee, composed of not less than two members of the Board and in accordance with § 9-6.14:11, shall receive and review the application and any investigative report requested by the committee. The committee shall have the authority to grant or deny approval of the request. The committee may grant approval of the request unconditionally or may impose conditions on the approval as follows:
1. The committee may grant approval for a finite period of time, after which time the applicant must provide additional information as requested by the committee in order to continue the approval;
2. The committee may require that ongoing reports concerning performance and problems be submitted; or
3. The committee may impose such other conditions as it deems necessary to provide assurance of public health and safety and accountability for controlled substances.
D. If an applicant does not agree with the decision of the committee, the applicant may request a hearing before the Board or a panel of the Board, in accordance with § 9-6.14:12.
E. Application under this section shall be on a form provided by the Board and shall be accompanied by a fee determined by the Board.

Since the law is specific about the information and data to be submitted with an application, and the approval process is a case decision on the merits and content of each application, the Board determined that only the fee(s) needed to be set in regulation along with the proposed application form. Fees set by regulation are modest and consistent with other fees charged to entities regulated under the Board.

Through the informal conference process, the Board will have the opportunity to review a proposed project, determine which provisions of law or regulation would need to be waived, evaluate its merits and safeguards, and set certain conditions for implementation and outcome in an order which would be signed by the Board and the applicant. Requirements of law and regulation for approval of a pilot program or project are necessary and sufficient to address concerns about patient safety and the risks of drug diversion.

Alternatives

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

There were no alternatives to adoption of a regulation as it was mandated by Chapter 876 of the 2000 Acts of the Assembly. The two issues considered in the development of regulations were: the necessity for incorporating any application requirements in regulation and the amount of fee necessary to adequately cover the expenses of the Board in making a case decision on a pilot project. (See discussion above.)

To determine an application fee that would be sufficient but not excessive, the Board calculated the cost of an average informal conference and set the fee accordingly. In addition, the applicant may be required to pay for an inspection at a cost of $150 for location in which the pilot is to be implemented as identified on the application. If necessary, the board or the committee may require the hiring of a technical consultant to provide expertise with the cost to be born by the applicant. A fee of $25 is set for a change in the name of the pharmacist responsible for the pilot program.

During the development and review of the proposed emergency regulation, an issue was raised about the necessity of a $200 fee for an annual review and monitoring of reports and outcome data. It was noted that the statute does not require the submission and review of ongoing reports on pilot projects and does not preclude the Board from granting unconditional approval of a new process.

Since the statute requires, as a part of the application for a pilot project, the "*means for monitoring the new process or procedure for any negative outcomes or other problems, and the reporting of such outcomes to the Board*," the Board determined that the original order should provide a schedule for any submission of reports and outcome data and should set the period of approval for the pilot. Based on the extensiveness of the required review and monitoring, the committee would determine and the order would state the necessary fee, not to exceed $200 per

approval period. If a pilot is not complex and has a low risk of prescription error or other failings, the interim review may occur by staff at no additional cost to the pharmacy. If the pilot is categorized as risky and outcome data is complex, the order may require continued monitoring by the informal conference committee or may necessitate additional inspections or expert testimony.

The Board believes that it has an affirmative obligation, as set forth in the statute, to monitor the outcomes for pilot projects to ensure public safety. That monitoring will be ongoing throughout the time the pilot continues to be approved, until such time as the Board has amended its regulations based on the proven results of the pilot or it has been discontinued. Additionally, § 54.1-3307 mandates the Board to maintain "*the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered*."

Proposed emergency regulations were reviewed with the full Board of Medicine on June 8, 2000, in compliance with a requirement for consultation during the development of regulations. The only concern expressed was about the potential for costs associated with the hiring of consultants for technical expertise. In response to that concern, the Board added a provision in the regulation to require the applicant to pay those costs if deemed necessary to make a decision on the application. If, during the duration of the emergency regulation, it becomes apparent that the application fee is insufficient to cover the expenses incurred in the review and approval process, the Board may reconsider the fee in determining replacement regulations.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The Board has determined that there is no potential impact on the family or on family stability as a result of this regulation.