Virginia Regulatory Town Hall

Proposed 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 projects
Date:	5/8/01

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Amendments to regulation are required in order to comply with Chapter 876 of the 2000 Acts of the Assembly requiring the Board to promulgate regulations for approval of innovative programs (pilot projects) in pharmacy for which some waiver of law or regulation would be necessary. The proposed regulations replace emergency regulations, which became effective on January 10, 2000, and are identical to those regulations.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the

Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

1. *To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*

2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*

3. *To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

4. *To establish schedules for renewals of registration, certification and licensure.*

5. *To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*

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 and Chapter 25 of this title.*

7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*

8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*

9. *To take appropriate disciplinary action for violations of applicable law and regulations.*

10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 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 thirty 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 thirty-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 § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*

12. *To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

The specific statutory mandate for pilot projects in pharmacy is found in § 54.1 3307.2:

§ 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.

The Office of the Attorney General has certified by letter that the Board has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

§ 54.1-3307.2 of the Code of Virginia is specific about the content of the application for approval of a pilot project 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.

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 the fee(s) needed to be set in regulation along with the proposed application and renewal process. 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.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

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.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

1) The primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions:

There are numerous advantages to the public of pilot projects, which will often serve to make pharmacy services more accessible and economical. If the necessary safeguards have been put in place, a particular law or regulation may be waived without undue risk of harm to the patient or of diversion of controlled substances. In addition to the quality control measures and outcome data outlined by an entity in its application, the Board may impose additional conditions or seek additional information prior to granting approval.

Individual businesses may enjoy substantial benefits from a pilot project. For example, the Kaiser Permanente Infusion Pharmacy in Northern Virginia found it very difficult and costly to comply with the requirement that a prescription could only be delivered to the end user/patient. Many of their prescriptions were for infusion products that must be constantly refrigerated, so

delivery to a mailbox or residence with no one at home was too risky. In seeking to conduct a pilot project, Kaiser had to provide a plan for delivery to an alternate pharmacy near the patient's home and agree to monthly audits to ensure that the drugs are getting to the correct patients as well as delivery logs and other measures designed to ensure drug safety and efficacy. Not only will patients benefit by being able to pick up infusion products close to their home, but Kaiser will benefit by a less costly, cumbersome method of delivery and less waste of products that have been compromised and must be destroyed.

2) The primary advantages and disadvantages to the agency or the Commonwealth:

There are no discernable advantages or disadvantages to the agency or the Commonwealth. The fee structure set in regulation is intended to ensure that costs related to review and approval of pilot projects are borne by the applicants. Agencies of the Commonwealth that offer pharmacy services may take advantage of the pilot project process to institute an innovative program.

3) Other pertinent matters of interest to the regulated community, government officials, and the public:

Some pilot projects may potentially have broad implications and applications. If issues of public health and safety are found to be adequately addressed, the pilots may serve as a model for changes in public law and policy. Pilot projects will give the Board flexibility in allowing for the use of innovations and new technologies in the practice of pharmacy. Data gathered in quality assurance reviews of the pilots will give the Board and the General Assembly needed information on which to base future policy decisions.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: 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 or entities for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: 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 copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be pharmacies that wish to initiate an innovative practice for which a waiver of law or regulation would be necessary. An application for board approval may be filed by an individual, a single pharmacy or a corporate entity.

Estimate of number of entities to be affected:

Currently, there are approximately 1,500 pharmacies licensed in the Commonwealth; the number that would apply for approval of a pilot project is unknown. In the first 3 months of the emergency regulations, one application has been filed, heard by the conference committee, and approved.

Projected costs to the affected entities:

The cost for compliance will be $250 for filing an application for board review. If an inspection is required, there is a fee of $150 per location. The fee for continued approval is set by the committee in its order, but may be no more than $200 per approval period.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

18 VAC 110-20-20. Fees.

Amendments are proposed to establish the fees for filing an application ($250); inspection of a pharmacy location ($150, if required); hiring of a consultant (actual costs); and change of the name of the pharmacist responsible for the pilot. In addition, there are provisions for setting an approval period in the committee's order with a schedule for submission of reports and outcome data. The order may also specify an appropriate fee for continued approval not to exceed $200 per approval period.

Alternatives

Please describe the specific 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 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.

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. To date, it would appear that the application fee is sufficient to cover the expenses incurred in the review and approval process.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received until March 1, 2001. During the 30-day comment period, no comments were received from members of the public.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The proposed regulations are identical to emergency regulations currently in effect. The emergency regulations were reviewed and approved by the Department of Planning & Budget, the Secretary of Health and Human Resources and the Office of the Governor. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations are currently under review and will be reviewed again during the 2003-04 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory 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.

In its preliminary analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability and no impct on disposable family income.