Form: TH- 03

Virginia Regulatory Town Hall

Final 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
Date:	2/4/02

Please refer 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* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

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 final amended regulations replace emergency regulations, which became effective on January 10, 2001.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes to proposed regulations have been made in the adoption of final amendments.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On February 4, 2002 , the Board of Pharmacy adopted final amendments to 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy, in order to implement a fee and process for the approval of pilot programs in pharmacy.

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, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final 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.

Chapter 33 establishes the Board of Pharmacy and authorizes the Board to license and regulate pharmacies engaged in filling and dispensing prescription medications.

The Board of Pharmacy is mandated by **§ 54.1-3307.2** to establish a fee and application process for approval of innovative or pilot programs.

§ 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 § 2.2-4019, 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 § 2.2-4020.
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 Assistant Attorney General who provides counsel to the Board has certified that the Board has the authority to promulgate the amended regulations and that they do not conflict with existing state 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 final 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.

Amendments are adopted to ensure the protection for the health, safety and welfare of patients of hospitals or long term care facilities who depend on the protection and integrity of prescription drugs consistent with the Board's statutory mandate in Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*.

§ 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 has 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 of the regulatory action's detail.

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 pharmacy programs that 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 final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 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.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

A public hearing was held before the Board of Pharmacy at the Department of Health Professions in Richmond on November 8, 2001. No comment was presented at that time nor was any written or electronically submitted comment received.

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 crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the 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.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the 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.

The Board has reviewed the adopted regulations and concluded that the amendments have no effect on strengthening the authority and rights of parents, on economic self-sufficiency, on the marital commitment or on disposable family income.