Virginia Regulatory Town Hall

Notice of Intended Regulatory Action
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:	Registration of technicians
Date:	5/1/2001

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

Purpose

Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.

Chapter 317 of the Acts of the Assembly (HB 1826; Delegate Morgan) mandates that the Board of Pharmacy adopt final regulations for the registration of pharmacy technicians by July 1, 2003. As required by § 54.1-3321 of the Code of Virginia, regulations must establish the criteria of training and examination necessary for registration and requirements for evidence of continued competency as a condition of renewal. Consistent with the mandate in § 54.1-2400, the Board must also establish fees to support the regulatory and disciplinary activities related to registration of pharmacy technicians and any other qualifications necessary to ensure competency and integrity.

Basis

Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary and the authority to levy and collect fees that are sufficient to cover all expenses for the administration of a regulatory program.

§ 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 317 of the 2001 Acts of the Assembly provided the statutory authority for this regulation through the following amendments:

§ 54.1-3300. (Effective until July 1, 2004) Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a location where patients receive services and a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which the practice of pharmacy is conducted; drugs, medicines or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine

store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging and dispensing of drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) of this title unless the context requires a different meaning.

§ 54.1-3320. Acts restricted to pharmacists.

A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:

1. The review of a prescription, in conformance with this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;

2. The receipt of an oral prescription from a practitioner or his authorized agent;

3. The conduct of a prospective drug review as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;

4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;

5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy, resolution of any drug therapy problem, or the substitution of any drug prescribed;

6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;

7. The supervision of pharmacy interns and pharmacy technicians; and

8. Any other activity required by regulation to be performed by a pharmacist.

B. A pharmacy intern may engage in the acts to be performed only by a pharmacist as set forth in subsection A for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

C. Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more than four pharmacy technicians at one time.

Article 4.
Registration of Pharmacy Technicians.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

B. To be registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.

C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

§ 54.1-3322. Denial, revocation, and suspension of registration as a pharmacy technician.

The Board may revoke, suspend or refuse to issue or renew any registration of a pharmacy technician upon determining that the applicant or the registered pharmacy technician:

1. Has been negligent as a pharmacy technician;

2. Has engaged in or attempted to engage in any fraud or deceit as a pharmacy technician;

3. Has engaged in acts that may only be performed by a pharmacist;

4. Has become incompetent to perform the duties of a pharmacy technician because of a mental or physical condition;

5. Uses drugs or alcohol to the extent that he is rendered unsafe to perform the duties of a pharmacy technician;

6. Has violated or cooperated with others in violating any provision of law relating to the practice of pharmacy or of any regulation of the Board;

7. Has been convicted of any felony or any crime involving moral turpitude, or has been convicted of violating any federal drug law or any drug law of Virginia or any other state or jurisdiction; or

8. Has been prohibited from performing the duties of a pharmacy technician by any other state, or has been prohibited by a health regulatory board of any state or by any federal agency from practicing, or assisting in the practice of, any health care profession.

Substance

Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. 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 citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.

Amendments to 18 VAC 110-20-10 et seq. will be necessary to implement provisions of HB 1826 for the establishment of criteria for the registration of pharmacy technicians, but certain aspects of regulating the new occupation are already set in the Code. For example, the legislation explicitly sets out those acts restricted to a pharmacist and those duties that may be performed by a technician, so the scope of practice for technicians is clearly prescribed. Supervision of technicians is specifically defined in § 54.1-3300 as requiring the direction and control of a pharmacist who is physically present in the facility when the technician is performing duties and is available for oral communication. Likewise the ratio of technicians to supervising pharmacist is established in the law (§ 54.1-3320) at no more than four technicians to one pharmacist at one time. Provisions for unprofessional conduct by technicians have been added in the Code (§ 54.1-3322), so it will not be necessary to address the grounds for disciplinary action in regulation.

Regulations establishing the educational and testing criteria for registration of technicians must be promulgated as well as any other qualifications the Board determines are essential to ensure that technicians are competent to work with the preparation of prescription drugs. While the pharmacist remains responsible for the work of technicians under his supervision, the Board has an obligation to develop criteria for technician registration that are sufficient to provide for the health, safety and welfare of the public dependent on the accuracy and integrity of prescription drugs.

While the Code permits persons enrolled in a pharmacy technician training program to engage in the acts restricted to a registered technician for the purpose of gaining practical experience, there may need to be some limitation set in regulation on the length of time a person may work within a training program. The Code also requires that regulations address continued competency for renewal of registration, so amendments will be necessary to specify such requirements. Amendments to fees charged by the Board will be promulgated to provide an application fee, renewal fee and other miscellaneous fees as necessary to cover the anticipated administrative and disciplinary functions related to registration and practice of pharmacy technicians.

During 2000, members of the Board worked in conjunction with representatives of various pharmacy groups on the possible regulation of pharmacy technicians. Most of the issues related to registration v. licensure, the ratio of pharmacist to technicians, the duties and responsibilities of technicians, and the criteria for registration were debated and resolved prior to the introduction of legislation in 2001. Therefore, the major issue to be addressed through regulation will be the training and examination necessary for registration.

Alternatives

Please describe, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet the essential purpose of the action.

As stated above, House Bill 1826 provided a specific mandate for registration of pharmacy technicians and explicitly establishes their scope of practice, the number of technicians who may be supervised by a pharmacist at one time, and the causes for unprofessional conduct and disciplinary action by the Board. The Code further requires completion of a training program and examination as qualification for registration, but the type of training and testing will be determined by the Board as set forth in regulation.

National certification is available through the Pharmacy Technician Certification Board and is recognized in the law as evidence of competency to be registered by the Board. Beyond PTCB certification, the Board is likely to adopt regulations requiring an organized training program that is site-specific but which meets the criteria for training set by the Board. So, for example, an individual pharmacy, a retail chain or a hospital system could establish a training program based on the type of pharmacy being practiced. The National Association of Boards of Pharmacy recommends site-specific training for pharmacy technicians. In its regulations, the Board intends to establish the basic criteria and knowledge base that a training program must cover in order to be an approved program. The Board does not intend to review and approve the curriculum and

operation of every training program offered in the Commonwealth. The Board of Nursing has established in regulations the components that must be included in a medication administration training program; the Board of Pharmacy intends to promulgate similar regulations for pharmacy technician training programs.

In addition, the law requires an examination that meets the criteria of the Board, so regulations must establish the requirements for testing as evidence of satisfactory completion of training and competency to practice. Requirements for evidence of continued competency as a condition of renewal of registration will also have to be determined and set in regulation. The Board will utilize information from the 27 other states that register or license technicians to set fees and requirements that are reasonable but sufficient for public protection.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent 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 proposed regulatory action would not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, or strengthen or erode the marital commitment. The impact on disposable family income is unknown at this time. While there will be a modest fee for registration of technicians, it is possible that technicians who have met the standards set for such registration will be in demand and able to command a slightly higher salary in a pharmacy.