



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:	Pharmacy technicians
Date:	4/22/02

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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 necessary in order to comply with Chapter 317 of the 2001 Acts of the Assembly requiring the Board to promulgate regulations for the registration of pharmacy technicians. The statute requires regulations to specify criteria for the training program, examination, and evidence of continued competency; it further specifies that current certification from the Pharmacy Technician Certification Board qualifies a person for registration.

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 registration of pharmacy technicians is found in § 54.1-3321:

§ 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.

(2001, c. 317.)

§ 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.*

(2001, c. 317.)

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.

Chapter 317 of the Acts of the Assembly (HB 1826; Delegate Morgan) mandated 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 for 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 competence and integrity.

While certain aspects of regulating the new occupation are already set in the Code, amendments to 18 VAC 110-20 are necessary to establish the educational and testing criteria for registration of technicians that 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 had 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. Therefore, an applicant for registration is required to be trained in the knowledge and skills necessary to perform the technician tasks permitted by law and to pass an examination establishing minimal competence in that core knowledge.

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, the regulations set a limitation 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 were necessary to specify the number of hours of continuing education and the approved providers. Amendments to fees charged by the Board were 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.

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.

The substantive provisions in the amended regulations primarily involve setting criteria for training, examination and utilization of pharmacy technicians registered by the Board. An applicant for registration must either provide evidence of current certification by the Pharmacy Technician Certification Board (PTCB) or complete a board-approved training program and pass a board-approved examination. To establish an approved training program, an entity must apply to the board and provide evidence that the curriculum will instruct in the applicable laws and regulations and in the tasks restricted to pharmacy technicians. Instructors are required to be licensed pharmacists, pharmacy technicians with one year of experience who are registered in Virginia or certified by PTCB, or other persons approved by the board. Pharmacies may permit a person to perform tasks that are restricted to registered technicians while that person is in a training program for no more than nine months without having that person registered. A pharmacist may monitor no more than two trainees at any one time and supervise no more than four persons, including both technicians and trainees.

Every pharmacy that employs technicians is required to maintain a site-specific training program and manual to teach such functions as proper use of equipment and computers and performing pharmacy calculations consistent with the pharmacy's practice. The examination must test entry-level competence, meet recognized test measurement standards, and be administered by an independent third party.

For renewal of registration, the technician must attest to having five contact hours of continuing education in an approved CE program. Provisions are made for extensions and exemptions of requirements and for maintenance of documentation. Fees are set at \$25 for an application or annual renewal and \$150 for approval of a training program.

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.

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 issues addressed through regulation were the training and examination necessary for registration.

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 factors which have increased workload and stress in pharmacies today including a significant increase in prescription volume, shortages in the pharmacist work pool, shrinking reimbursement for dispensed prescriptions, increased workload in processing prescriptions due to increased steps in processing insurance claims and increased numbers of patients participating in prescription payment plans, increased numbers of drugs in inventory, and greatly increased numbers of drugs in pharmacy inventories. These pressures have exposed many pharmacists to excessive workloads with greater risks for making dispensing errors. In a small percentage of pharmacies, new technology and robotics have been useful in addressing the problem, but in the vast majority of situations, especially retail pharmacies, the pharmacy is using the pharmacy technician to assist the pharmacist with the workload. In response to this need to handle the increasing workload, the Board several years ago increased the ratio of pharmacist to technicians from 1:1 to 1:3, provided the technician held a national credential as assurance of minimal competence. It is estimated that as many as a third to a half of the technicians now hold that credential (PTCB). While this did prove helpful in some settings, there are not enough PTCB certified technicians to meet the demand. The PTCB examination is only administered three times a year, and is a relatively difficult examination.

While there was a recognition of the need to allow pharmacists to supervise more technicians to handle workload, there was also a serious concern about the lack of training for some technicians and the absence of criteria for minimal competence as well as lack of accountability for the technician. Pharmacists were then and remain responsible for checking the final prescription product before it is dispensed, but a number of dispensing errors have been made by technicians and not caught by the checking pharmacist prior to dispensing.

For this reason, the General Assembly amended the Code to require registration of technicians and mandated the Board to establish educational, training and examination qualifications. The amended rules have set minimal criteria for training in an approved program and for passage of an examination in order to make registration accessible to most persons currently working in the pharmacy. There are several advantages to the public. By requiring registration, the Board will have the ability to hold the technician accountable for his actions and will be able to take action against the registration if warranted which will keep a technician who is impaired, incompetent, or otherwise not authorized to perform technician tasks from leaving one pharmacy and becoming employed by another. There will be consistent standards for training and testing providing greater assurance to the public that the persons working in the prescription department are knowledgeable in their tasks. Because of the pharmacist shortage and low reimbursements, hiring additional pharmacists is usually not an option for pharmacies with excessive workload. Pharmacies will benefit from being able to have one pharmacist supervise up to four technicians, thus increasing the capacity to provide quality pharmacy services without hiring additional pharmacists.

As with any restrictions in the ability to perform certain tasks, those restrictions may create temporary shortages in the workforce. A disadvantage to pharmacies may be higher wages demanded by registered technicians although most pharmacies already offer incentive programs with higher wages to a technician who obtains PTCB certification, because performance and retention improves. Pharmacies may have employees who are currently performing technician tasks who are not able to qualify for registration or who choose not to meet criteria for registration. These employees will not be able to continue to perform technician duties, but may be retained to perform clerical tasks. Pharmacies may have some expenses associated with costs of training personnel to meet criteria for registration, or in recruiting persons who already meet requirements.

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 training programs and of applicants for registration is covered by application fees. The renewal fee of \$25 is intended to offset an increase in the disciplinary workload of the agency, related to complaints, investigations, and cases docketed against technicians. Without any history for such complaints, the Board is unable to fully determine the potential impact. It is not anticipated that any additional FTE will be needed to administer this program. There may be a temporary need for a part-time employee to assist with the initial registration process when the program is first implemented, but once the existing pool of technicians is registered, existing staff should be able to handle the increase in workload. The Board already has a staff person who is a former pharmacy technician who will oversee the registration program.

Agencies of the Commonwealth that offer pharmacy services may take advantage of the opportunity to increase the ratio of technicians working for each pharmacist.

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

The Board is making every effort to assure that the criteria for registration meets the intent of the legislation for improving competency and accountability of personnel involved in accurately dispensing prescriptions without creating undue hardships on the regulated community. The regulated community has been invited to participate in every step of the regulation development process. The Board has and will continue to solicit input from interested parties throughout the process.

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 \$5,000) for mailings to the Public Participation Guidelines mailing lists, advisory committee meetings, 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 individuals who currently perform the duties of a pharmacy technician, the pharmacists who provide supervision and the pharmacies that employ technicians.

Estimate of number of entities to be affected:

There are 5,485 pharmacists with active licenses – some of whom work in non-clinical settings and would not be supervising technicians. The National Association of Chain Drug Stores reports that there are 3,068 pharmacists employed in community pharmacies in Virginia, and the national ratio appears to be 1.5 technicians to each pharmacist. Currently, there are approximately 1,525 pharmacies licensed in the Commonwealth; it is estimated the average pharmacy would have at least three registered technicians, so the total number of technicians is estimated to be between 4,500 to 5,500. The Pharmacy Technician Certification Board (PTCB) reported in January 2002 that there were 2,952 certified technicians with Virginia addresses. Since PTCB certification automatically qualifies someone for registration in Virginia, the number seeking that credential is expected to increase. Therefore, there may be an estimated 2,000 to 2,500 persons who would need to take a training program and examination approved by the Board to qualify for registration.

Projected costs to the affected entities:

For those already certified by PTCB, the only additional cost for registration in Virginia will be \$25 for filing an application. To obtain PTCB certification, a person may either study independently or take classes designed to provide the core knowledge in areas tested for certification. An applicant for PTCB certification must pass the competency-based examination at a cost of \$105; to continue to hold that credential (CPhT), a technician must complete 20 hours of continuing education every two years with one hour in pharmacy law and pay a recertification fee of \$25.

For those who do not have PTCB certification and will be required to enroll or participate in a training program, there may or may not be cost involved. The major retail chain stores already offer formalized training to their employees at no cost, so most persons seeking registration will have that available to them through one of the in-house programs. Many hospital pharmacies already employ PTCB-certified technicians, so there will be no additional cost to the employees or the employers, other than the cost to the employer of having the training program approved by the Board. For those who will seek an educational program through a pharmacy school or community college, there will be a cost for training. For example, J. Sargeant Reynolds offers 19 hours of course work for pharmacy techs at a cost of \$42 per hour. Since there are no requirements for a prescribed number of educational hours, it may not be necessary to take all 19 hours, but if a student chose to do so, the total cost would be \$798. The cost of an examination will depend on the contract developed for independent administration, but it is expected to be below the cost of the PTCB exam (\$105).

Costs for compliance with continuing education requirements will also vary depending on the source. It is likely that many large retail pharmacies will make in-service training available to technicians at no charge, much as is currently provided in many hospitals. There are more than enough hours of continuing education available on the internet at no cost. There are other self study courses in various trade magazines where the charge is typically \$5 or \$10 for the certificate of completion. Often live continuing education by an ACPE approved provider is sponsored and offered at no cost to the participants. If a technician acquires continuing

education hours through a conference, there would be some costs associated with registration and expenses.

The pay scale for technicians depends on many factors, including PTCB certification, previous experience, employment setting and years in practice. The average pay for a technicians ranges from \$6.50 to \$13.00 an hour, depending on experience and certification; but there are a number of certified technicians who earn over \$15 an hour. Those persons who undergo the training and examination to become registered technicians in Virginia will likely command higher hours rates, while those employees who do not will be performing non-technician, clerical duties and will likely be maintained at the lower end of the pay scale.

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.

The following fees are established for pharmacy technicians: \$25 for initial application or annual renewal of registration; \$10 for a late fee paid within 60 days of expiration of registration; \$25 for a delinquent fee to reinstate registration; \$125 for reinstatement after revocation or suspension; and \$150 for approval of a training program.

18 VAC 110-20-101. Application for registration as a pharmacy technician.

This section sets forth the requirement for submission of an application fee and an application along with evidence of satisfactory completion of a training program and passage of a board-approved examination. In lieu of the training program and examination, an applicant may present evidence of certification by the Pharmacy Technician Certification Board (PTCB).

18 VAC 110-20-102. Criteria for approval of training programs.

To become an approved program, an entity is required to submit an application on a form approved by the board and a fee. The curriculum must provide instruction in applicable laws and regulations and prepare an applicant to perform the technician tasks specified. Instructors in an approved program must be a licensed pharmacist, a registered technician with at least one year of experience or a PTCB-certified technician. The length of the program must be sufficient to prepare an applicant to sit for the examination and to demonstrate entry-level competence. Program records must be retained for at least two years from date of an applicant's completion or the termination of the program at a site from which they are readily retrievable.

18 VAC 110-20-103. Examination.

Proposed regulations authorize the board to approve one or more examinations to test entry-level competence. An approved examination must be administered by an independent third-party and must meet recognized standards of the Joint Technical Standards for Education and Psychological Testing. The Board may contract with a testing agency for test development and administration. The passing score of the examination must be determined by the Board.

18 VAC 110-20-104. Address of record.

In this section, the technician is required to inform the Board of a change of address within 30 days. Notices required by law or regulation mailed to the address of record are deemed to be legally given.

18 VAC 110-20-105. Renewal and reinstatement of registration.

Pharmacy technicians must renew annually on or before December 31st; registration may be renewed by meeting the renewal requirements and paying the late fee for 60 days after the expiration date. After the 60 days, registration may be reinstated by the executive director provided all requirements have been met and fees have been paid. After 5 years, the registration may not be reinstated, and requirements for initial registration in section 101 must be met.

18 VAC 110-20-106. Requirements for continued competency.

To annually renew a registration, a pharmacy technician must have 5 contact hours of approved continuing education that meet the criteria in current regulations. Provisions are made for extensions or exemptions from the requirement. Regulations also require maintenance of documentation

18 VAC 110-20-111. Pharmacy technicians.

- ?? Each pharmacy that employs or uses technicians must have a site-specific training program for training technicians who work in that pharmacy. The program must include training in specific computer programs, proper use of other equipment being utilized, and pharmacy calculations specific to the practice.
- ?? Documentation of successful completion of the site-specific training program must be maintained during the duration of a technician's employment and for two years following termination at a location that is either on-site or readily retrievable.
- ?? Persons who are engaged in a training program may be allowed to perform acts restricted to pharmacy technicians for no more than nine months without that person becoming registered. The pharmacy is required to maintain on-site and available for inspectors evidence of the persons enrollment in an approved training program.

18 VAC 110-20-270. Dispensing of prescriptions; certification of completed prescription; supervision of pharmacy technicians.

Section 270 is amended to eliminate the acts restricted to a pharmacist, as they are now set forth in § 54.1-3320 (A) of the Code. In addition to those restricted acts, regulations stipulate that the

compounding of extemporaneous preparations must be performed under the personal supervision of a pharmacist. In accordance with the Code, the pharmacist is not allowed to monitor at any one time more than four persons performing tasks restricted to a technician (which would include both technicians and trainees).

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 regulations as it was mandated by Chapter 317 of the 2001 Acts of the Assembly. The Code provides 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 was determined by the Board as set forth in regulation.

To develop regulations for the registration of technicians, the Board used a variety of resources and advisors; for example, it looked at the model act and rules from the National Boards of Pharmacy (NABP). It also utilized information from the 27 other states that register or license technicians to set qualifications, educational standards, testing requirements, supervision of practice, continuing education, and fees that are reasonable but sufficient for public protection. The National Association of Chain Drug Stores also provided model regulations for pharmacy technicians.

Qualifications for registration:

The Board debated the need for a minimum age and educational level requirement for technician registration. Health care professional regulation often requires the applicant to be 18 years of age and have at least a high school education or a GED certificate. While it is expected that the vast majority of persons will meet those requirements, representatives of retail pharmacies argued that it would exclude some high school students who work as technicians and become interested in the profession through that involvement. Therefore, the only requirements stipulated are satisfactory completion of an approved training program and a passing score on a board-approved examination.

Fees for technicians:

Members of the Board and representatives of pharmacy groups strongly advocated for application and renewal fees to be minimal. There was some concern that the fee would have a detrimental effect on persons becoming registered, so the initial proposal for an application fee of \$45 was reduced to \$25, which must cover the application review and at least six months of registration before renewal is due. Twenty-nine states currently regulate technicians and three more are in the process. Renewal fees range from \$0 to \$100 annually with the average being \$26.50 a year; in Virginia, the proposed renewal fee is \$25.

Criteria for approved training program

First, 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 considered regulations requiring an organized training program that provides basic knowledge and skills but is also site-specific and 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 (NABP) recommends site-specific training for pharmacy technicians.

Again, the Regulation Committee was presented with a variety of resources to determine current availability of pharmacy technician education. Sample training programs from the large retail pharmacies, such as CVS and Eckerd were provided and reviewed, as well as a description from the “pharmacy technician career studies certificate” offered by J. Sargeant Reynolds Community College with 19 minimum credit hours leading to a certificate as a pharmacy technician. The committee looked at knowledge statements developed by the American Pharmacists Association in its training manual for pharmacy technicians and a training manual published by Morton Publishing. Also reviewed was a recently-updated, model curriculum for pharmacy technician training developed by American Society of Health-System Pharmacists. The Board received a power-point presentation by the National Association of Chain Drug Stores on “The Community Retail Pharmacy Technician Training Program.”

To begin consideration of the appropriate content of a technician-training program, staff used sample pharmacy technician job descriptions for a hospital pharmacy and for a community/retail pharmacy listing the responsibilities of the technician, the knowledge and skills required to function and the qualifications necessary. To develop the suggested curriculum, the committee and the Board reviewed the content from the PTCB examination, listing knowledge statements required to perform activities associated with each function of a pharmacy technician. From those various sources, a draft curriculum for an approved program was developed outlining the specific instruction that was necessary to assure entry-level competence in technician tasks to include the following categories: federal and state laws and regulations, overview of pharmaceutical products, information on specific drug products, information necessary to read a prescription order, proper drug-handling and dispensing techniques, compounding procedures and techniques, and the proper interaction with patients and prescribers.

The original draft with detailed curriculum requirements for an approved training program was widely circulated for comment. While many believed the specificity was instructive to those attempting to set up an approved program and that it would assure more consistency, other expressed concern that training requirements were too task-specific and would be burdensome for the regulated community. Given the varied practice settings and progress of technology, the detailed knowledge and skills may not be necessary for all technicians in all pharmacies and could become quickly outdated. Concern was also expressed that the knowledge required in the suggested curriculum was beyond what was required to perform basic technician functions.

In response to concerns and comments, the Board adopted a rule that requires the training program to provide instruction in applicable laws and regulations and in the tasks that may be performed by a technician to include those listed in § 54.1-3321 of the Code. The pre-registration training requirements were to be more general in nature with pharmacies required to develop "post-registration" site specific training for technicians.

Other issues that were resolved after comment on exposure drafts were the qualifications of instructors and the length of the program. Initially, it was thought that only licensed pharmacists should serve as instructors since they are responsible for the supervision of technicians. Others advocated for and the Board adopted a rule that allows technicians to serve as instructors, as well as other persons who may be approved by the Board. Technicians must have at least one year of experience and be registered with the Board or hold current PTCB certification. Other instructors may hold advanced degrees related to pharmacy or pharmacotherapeutics and may be approved on a case-by-case basis. Initially, the committee sought to adopt a minimum number of hours necessary for an approved training program, but determined that the appropriate rule would require the length of the program to be sufficient to prepare a participant to sit for the examination and demonstrate entry-level competence. Since PTCB certification is accepted for technician registration and there are no PTCB requirements for a minimum number of educational hours, the rules of the Board should be similar.

Examination

In addition to training, the law requires an examination that meets the criteria of the Board. The Board determined that rather than listing specific knowledge statements in regulation for approved training programs to include, it would assure that any examination approved by the Board tested the candidate for knowledge necessary for entry level competence. The Board considered that passing a standard examination would somewhat assure the equivalence of training programs. The Board was presented with a sample examination offered by the St. Louis College of Pharmacy and designed to test knowledge derived from the Community Retail Pharmacy Technician Training Manual. The Board also looked at the knowledge statements tested by PTCB. The Board's regulation permits the approval of one or more examinations. To be approved by the Board, the examination must be administered by an independent third party and must meet recognized psychometric standards for reliable and legally defensible testing as provided in regulation. The Board is authorized to contract for development and administration of an examination, but has not yet begun this process.

Renewal requirements

The Code requires the Board to adopt requirements offering some evidence of continued competency as a condition of renewal of registration. The requirement of 5 hours each year is considered minimal and was acceptable to all the pharmacy groups who participated in regulation development. Courses must be approved by the American Council on Pharmacy Education (ACPE), but are available on-line, through pharmacy journals, at regional and statewide meetings and as in-service training. Five hours should be attainable and available to every technician in Virginia and is considered minimal education to maintain competency in the new technologies and drugs that are consistently coming on the market.

Grandfathering of current technicians

All state and national pharmacy organizations concurred with the Board that “grandfathering” of technicians was not acceptable. First, the enabling statute did not authorize the Board to “grandfather” existing practitioners; second, persons currently performing technician functions should be able to complete the training program and pass an examination; and finally, the use of the term “technician” has never been defined so there are persons working in the capacity of and performing the tasks of a pharmacy technician, but there are others who may be called “technicians” who are in fact performing non-technician, clerical duties. Those persons should not be performing technician functions without additional training and an examination testing minimal competence.

Public Comment

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

Chapter 317 of the 2001 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. Knowing that there would be diversity of opinion regarding the utilization and training of technicians, the Board initiated the process of developing regulations by involving all interested parties from the outset. At all meetings of the Regulation Committee and other work sessions, persons representing independent pharmacies, chain drug stores, hospital pharmacies, the Virginia Pharmacist Association, and others were specifically included in the discussions and deliberations. The time line for development of regulations is as follows:

May 1, 2001	Pre-NOIRA adopted by the Board
May 2, 2001	Pre-NOIRA statement submitted for Executive branch review
August 30, 2001	Meeting of the Regulation Committee to begin identification of issues and basic concepts for registration of technicians
September 11, 2001	Permission to publish the NOIRA received; notice sent to persons on PPG mailing list on September 12, 2001
September 19, 2001	Meeting of a sub-committee on technician regulation Solicitation of comment on initial draft
October 8, 2001	Publication of NOIRA – comment ended on November 7th
October 16, 2001	Meeting of Regulation Committee – consideration of comments on draft
November 8, 2001	Public hearing on implementation of legislation concerning the registration of pharmacy technicians
November 30, 2001	Meeting of Regulation Committee to draft regulations
January 25, 2002	Deadline for comments on the draft
February 4, 2002	Board meeting to adopt proposed regulations (Since there were numerous changes to the draft made at the meeting, the final draft, as adopted by the Board, was distributed to all board members and interested parties after the meeting)

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 officially received until November 7, 2001. However, the Board has solicited comment throughout the process by requesting proposals from interested parties, including public comment during each regulatory meeting, and emailing drafts of proposed language as it was in development.

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.

As has been described above, draft regulations have been widely distributed throughout the process of promulgation; therefore, any lack of clarity was noted and addressed as the language was in development. Persons who will have responsibility for compliance with regulation have been involved in crafting the language and setting the qualification. The Assistant Attorney General who provides counsel to the Board has also 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 2004-05 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.

The proposed regulatory action will 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 minimal. 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.