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:	Regulatory Review
Date:	6/13/03

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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.

Regulations for the practice of pharmacy provide licensure requirements for pharmacists, and permitting requirements for pharmacies, humane societies, manufacturers, wholesale distributors, warehousers, medical equipment suppliers, and other entities who handle controlled substances and devices. Provisions also establish requirements for renewal or reinstatement of a license and fees to support the regulatory and disciplinary activities of the board. An identified problem with requiring all back renewal fees for pharmacist reinstating a license has been corrected and a flat reinstatement fee established to cover board costs of reinstatement. There are no new requirements for licensure as a pharmacist, registration of a pharmacy technician, or pharmacy permits proposed. The Board has modified regulations to clarify current law and regulation, alleviate problematic rules, and set more reasonable standards for reinstatement of a pharmacist license if the pharmacist has been out of practice for at least five years.

Regulations set standards for practice by pharmacists and for the operation of a pharmacy, including requirements for the physical layout of a pharmacy, sanitation, security, and storage or

disposal of drugs and devices. Regulations set forth specific requirements for nuclear pharmacies, and for pharmacies in hospitals or long-term care. Standards for record-keeping and inventories, dispensing and transmission of prescriptions, refills, labeling and packaging of drugs are established in regulation. There are also standards for compounding sterile pharmaceutical products, unit dose dispensing, robotic pharmacy systems, and for the issuance of a controlled substance registration to an authorized person or entity. As technology has advanced the practice of pharmacy, regulations are being modified to address outdated requirements and encourage economies and efficiencies in practice. To this end, the Board attempted to regulate more flexibility, often allowing an individual pharmacy to develop its own procedures provided the goal is accomplished, and provided the procedures are written in a policy and procedure manual available for inspection. In adoption of proposed regulations, the Board considered every request from practitioners and entities involved in varying aspects of pharmacy practice and implemented those that could reasonably be adopted within the scope of federal and state law.

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 authority to issue licenses and permits to pharmacists and pharmacies and to control the sale and dispensing of prescription drugs is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.

http://leg1.state.va.us/000/lst/h3107564.HTM

http://leg1.state.va.us/000/lst/h3108148.HTM

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.

The agency is recommending that the regulation be amended in order to address the numerous questions and recommendations that arose from the periodic review conducted by board members and advisors from all aspects of pharmacy practice. In some cases, there is a need for clarification of a rule; in others there is a need to amend the regulation to allow the practice of pharmacy to be more responsive to patient needs and changing times. The rationale for the changes in each section is fully discussed in the section on Detail of Changes.

The Board has amended regulations that restrict practice or inhibit modernization and utilization of newer technology, provided the change is within the parameters of law and federal rules and provided it is good policy that protects the health, safety and welfare of the public.

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.

PART I. GENERAL PROVISIONS.

Under the section on definitions, the Board has included commonly used acronyms and has amended the term "pharmacist-in-charge" to "PIC" throughout the regulation, which is now defined. The term "on duty" is defined according to the definition that is now board policy in a guidance document.

There are no changes in the amount of the current fees being charged; the amendments are intended to group fees into listings for ease of compliance. However, there are changes in

policies intended to reduce the financial burden on a person who is late in renewing a license or who has a lapsed license and is seeking reinstatement. One new fee for a reinspection is established.

PART II. LICENSURE REQUIREMENTS FOR PHARMACISTS

Changes to licensure requirements for practical experience were adopted for clarification and consistency with the law. This section was also amended to address a problem of some applicants for licensure from other states, where the licensing board relies on the pharmacy school to certify hours of practical experience; the Board modified the regulation to accept such certification. To alleviate a problem experienced by some applicants for licensure by endorsement, the Board has amended its regulation to accept verification of practical experience hours worked as a pharmacist in another state within the United States in lieu of intern hours in order to meet the practical experience requirement.

An amendment to subsection D clarifies the meaning of a requirement for six months of practical experience as a pharmacy intern as a minimum of 1,000 hours of practical experience for clarity to the applicants. Amendments to the requirements for foreign trained applicants were necessary to make it clear to graduates of foreign colleges of pharmacy that it is necessary for them to meet all requirements for foreign graduates prior to sitting for the NAPLEX and law examination.

Rules for reinstatement are less burdensome, since an applicant would no longer required to pay all back renewal fees. Likewise, amendments will facilitate the reactivation or reinstatement of an inactive or lapsed license by capping the number of required CE hours at five years, not to exceed a total of 60 hours. To address concerns about pharmacists whose licenses have been suspended, lapsed or inactive for more than five years, the Board will also require passage of the board-approved law examination and documentation of either active practice in another state or practical experience of at least 160 hours within the past six months as a pharmacy intern.

PART III. REQUIREMENTS FOR PHARMACY TECHNICIAN REGISTRATION.

Amendments to modify board policy on renewal and reinstatement will allow licensees more time to submit a late renewal and will alleviate the financial burden for some applicants for reinstatement.

PART IV. PHARMACIES.

The Board has adopted a less restrictive rule for serving as the pharmacist-in-charge to allow a pharmacist to serve as PIC at two pharmacies rather than just one. The Board has also adopted a specific rule that a PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC and set rules for notification to the Board.

An amendment will require the policy and procedure manual to include the schedules of drugs to be maintained if a pharmacy applies for a special or limited use permit; that information could affect the advisability of issuing such a permit.

Requirements for notice of a pharmacy closing or change of ownership and for a change in the hours are clarified to ensure that the board and public are properly notified as soon as possible and to identify the person responsible for providing notice.

Amendment will clarify that if a pharmacy makes changes to a previously-approved security system, it must be re-approved to ensure that the new security system is adequate to protect against theft or loss. The Board has also has established a reinspection fee of $150. An amended rule will allow the pharmacy to open and begin operation once approval is given by the inspector or board staff.

There are several amendments clarifying the square footage required for a pharmacy and eliminating unnecessary requirements on minimum standards, equipment and resources.

Amendments to the section on access to the prescription department in the absence of a pharmacist are added to allow a pharmacy technician, with permission of a pharmacist employed at that pharmacy, to disable the alarm and enter the pharmacy accompanied by management to retrieve prescriptions which had already been filled and checked by a pharmacist. That entry would have to be fully documented, and the access code changed by the PIC after such an event.

Amendments are adopted to ensure that there are written procedures detailing security of the dispensed prescriptions if a prescription is delivered at a time when the pharmacist is not present and to allow the pharmacy to keep the cabinet, drawer, or safe containing Schedule II drugs unlocked during hours that the prescription department is open and a pharmacist is on duty.

PART V. NUCLEAR PHARMACIES

Amended language requires nuclear pharmacies to have adequate space and equipment, commensurate with the scope of services in compliance with standards and requirements of the Nuclear Regulatory Commission (NRC) and the Virginia Department of Health. A new subsection set forth rules for the dispensing of radiopharmaceuticals to include requirements for the content and transmission of the order.

PART VI. DRUG INVENTORY AND RECORDS

An amendment will specify which records must be maintained at the same location as the stock of drugs to which the records pertain to include executed order forms, prescriptions, and inventories of Schedule II through V drugs. The Board will allow off-site storage of other records, such as invoices, if so allowed by the DEA.

The Board has made a provision to allow an electronic image of a prescription to be maintained in an electronic database in lieu of a hard copy file for Schedule VI prescriptions. An amendment would also permit a pharmacy to use an automated record as the prescription rather than a hard copy or electronic image if the pharmacy system's automated data processing system fields are automatically populated by an electronic transmission.

PART VII. PRESCRIPTION ORDER AND DISPENSING STANDARDS

Amendments are intended to clarify the requirements for transmission of prescriptions by facsimile device (fax) and will allow forwarding a faxed chart order from a long term care facility or from a hospice. Amendments to the section on electronic transmission of Schedule II-V prescriptions specify that such transmission must comply with any security or other requirements of federal law and with all security requirements of state law related to privacy of protected health information. Another amendment will relieve the burden of having to maintain a hard copy of an electronically transmitted prescription, if the record is maintained in accordance with requirements on automated data processing.

PART VIII. LABELING AND PACKAGING STANDARDS FOR PRESCRIPTIONS

Requirements for use of the generic name of the drug on the prescription label are eliminated for drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer. The rule on requesting nonspecial packaging has been amended to adopt the less restrictive federal rule. Rather than specifying guidance for determination of an expiration date to be used on a drug that is being repackaged, the Board has amended the regulation to require the pharmacist to determine the appropriate date in accordance with USP guidelines. Requirements for drug products in automated dispensing devices have been amended to ensure that the older drug product is used first and that drugs cannot remain mixed in the lot past their expiration date.

PART IX. STANDARDS FOR PRESCRIPTION TRANSACTIONS.

The rules for transfer of a copy of a prescription have been amended to provide for transfer between two pharmacies of a prescription whether it has been filled or not. Rules have also been amended to allow for electronic transfer without a pharmacist from the provider pharmacy having to "release" the prescription. Other amendments restate the rules in a clearer format.

Rules on issuing a copy of a prescription that cannot be refilled are repealed, since current pharmacy practice is to provide the patient with a printout of prescriptions rather than a copy of the actual prescription. Likewise, rules on confidentiality of patient information are repealed because it is superceded by state and federal law on patient privacy and is therefore unnecessary and may be in conflict.

Rules for physicians who hold a permit from the Board to dispense drugs to the public when pharmacy services are not reasonably available in their geographic area have been updated to specify those sections of the regulations with which the permitted physician must comply and to state that a physician may apply for a special or limited use permit.

PART X. COMPOUNDING STERILE PHARMACEUTICAL PRODUCTS

This section is amended to clarify that a policy and procedure for the compounding, dispensing and delivery of sterile products should be consistent with USP-NF standards and guidance and to clarify the requirement for certification of laminar flow hoods or other environmental control devices.

PART XI. UNIT DOSE DISPENSING SYSTEMS.

The amendment to the section on transmission of a verbal order to a nurse or pharmacist at the hospital is intended to allow such transmission when such a practitioner is not an employee of the hospital, since some health care workers are employed by agencies and work under contract with a hospital.

PART XII. PHARMACY SERVICES TO HOSPITALS.

Rather than requiring a monthly review of drug therapy for any patient in the hospital for one month or greater, the amended regulation requires the pharmacist to maintain a policy and procedure manual for providing reviews of drug therapy to include at a minimum any irregularities in drug therapy, drug interactions, drug administration, or transcription errors.

Amendments will allow receipts of floor stock drugs and the records that are used to document administration of Schedule II through V drugs to be maintained by the hospital pharmacy in offsite storage provided they are retrievable and can be made available for inspection or audit within 48 hours of a request by the board or an authorized agent. The Board also will allow hospital pharmacies to fulfill the requirement for separation of schedule II records for administration by listing schedule II drugs in a separate section on a page that contains other schedules of drugs. Further, amendments will require that an automated device used to dispense drugs in a hospital be able to produce a report for each discrepancy in the count of a drug on hand in the device and that each report be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered. The discrepancy must either be resolved or reported to the board as a theft in accordance with statute.

At the request of the hospital subcommittee, the Board has specified that certain controlled substances such syringes, contrast media and other schedule VI medical devices and drugs such as IV solutions could be maintained in locations other than the pharmacy and ordering and distribution delegated to non-pharmacy personnel. Security and storage requirements for these types of controlled substances need to be set forth in the hospital policy and procedure manual and must be checked monthly by the pharmacist-in-charge.

The current rule on dispensing by hospital pharmacies to persons other than their own patients has been repealed.

PART XIII. PHARMACY SERVICES TO LONG TERM CARE FACILITIES.

Amendments on the transfer of drugs for destruction or return and the requirements for an emergency drug kit or a stat drug box are clarified.

Amendments will allow for an expansion of the use of automated dispensing devices in long term care facilities to include provisions to ensure the security of the drugs, control by the pharmacy, removal only upon a valid prescription from a prescriber, and loading of the device by

a pharmacist or technician specifically trained in its use. An amendment for limited use of floor stock clarifies the "persons licensed to administer" means nurses or physician assistants.

PART XIV. OTHER INSTITUTIONS AND FACILITIES

Amendments to this section will in correctional facilities: 1) allow the use of the patient name rather than the prescription number on the record; 2) allow for unused or discontinued drugs to be returned to the provider pharmacy or to a secondary pharmacy within 30 days; 3) allow drugs to be forwarded by a pharmacist from the correctional facility to a returns company; and 4) add that drugs may be stocked at a medical clinic or surgery center that is part of the facility and is staffed by one or more physicians providing the clinic applies for and receives a controlled substance registration.

PART XV. EXEMPTED STIMULANT OR DEPRESSANT DRUGS AND CHEMICAL PREPARATIONS

There were no amendments adopted.

PART XVI. MANUFACTURERS, WHOLESALE DISTRIBUTORS, WAREHOUSERS, AND MEDICAL EQUIPMENT SUPPLIERS

An amendment will permit the original order to be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier.

PART XVII. CONTROLLED SUBSTANCES REGISTRATION FOR OTHER PERSONS OR ENTITIES.

Amendments require that nursing homes without in-house pharmacies that use automated drug dispensing systems have a controlled substances registration (CSR) in order to maintain a stock of drugs. Therefore, nursing homes are added to the list of entities authorized or required to obtain a CSR. There is also a clarification that a pharmacist must supervise the controlled substances in a nursing home without an in-house pharmacy. Finally, an amendment would clarify that an alarm system is not required for researchers or animal control officers.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

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

The Code of Virginia requires the Board of Pharmacy to regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding or disposal of drugs and devices. Among the criteria to be considered in its regulations, the Board is charged with maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered and with safeguarding against the diversion of drugs and devices (§ 54.1-3307). Therefore, while the regulatory amendments proposed are intended to remove unnecessary barriers to the licensure of pharmacists and to the efficient, cost-effective practice of pharmacy, the Board's primary obligation is to ensure that the safety and efficacy of prescription drugs are not compromised. Amendments that facilitate licensure or economically benefit a pharmacy have been adopted with safeguards to ensure minimal competency and drug security and effectiveness. The following are examples of changes that will benefit both licensed pharmacies and the public they serve by improving the availability of pharmacy services, encouraging efficiencies and the use of electronic storage, and assisting in the adoption of cost-saving automation:

- Changes in the requirements for reinstatement may serve as an incentive to former licensees who now practice in other states to return to practice in Virginia. Eliminating the requirement for all back renewal fees to be paid and capping the hours of required continuing education may facilitate licensure for a few applicants. In addition, the acceptance of hours of active practice in another state in lieu of practical experience in an internship may facilitate initial licensure for a few applicants. The public is benefited if the number of licensed pharmacists can be increased, which could result in cost-savings and improved oversight of pharmacy services.
- Each pharmacy is required by law to have a pharmacist-in-charge (PIC), but the Board is aware of the difficulty many experience in finding pharmacists who are willing to assume responsibility for serving as the PIC. To alleviate this problem and ensure that pharmacies were not left without a pharmacist in charge, the Board amended its regulation to permit one pharmacist to be "fully engaged" in the practice of pharmacy and serve as PIC at two locations. The Board believes the one pharmacist can adequately oversee two pharmacies without jeopardizing public health and safety. Likewise, the amendment to specify the maximum length of absence of a PIC from the pharmacy will ensure that the pharmacy is not left without a PIC indefinitely or that the PIC who is absent for an extended period remains responsible for a stock of drugs over which he has no control.
- Amended rules for the inspection and permitting of new pharmacies will ensure that the approval process is as efficient and timely as possible to allow a facility to begin serving the public.
- Several changes in regulation are designed to facilitate the modernization and efficiency of pharmacies with the intent of encouraging utilization of new technology and adoption of cost-saving measures. By allowing off-site or electronic storage of certain records, both retail and hospital pharmacies will better be able to contain costs. Physical space can better be utilized for the storage and preparation of prescriptions, so long as certain records are readily accessible or obtainable.
- Efficacies in pharmacy practice, such as - the ability to transfer a prescription from one pharmacist to another, authorization to forward a faxed chart order as a prescription, elimination of certain labeling requirements for prescription in hospitals, repeal of the requirement to give a patient a hard copy of each prescription upon request, and the

electronic notation of a request for nonspecial packaging - will benefit both the pharmacies and the consumers they serve by eliminating unnecessary requirements in getting prescription drugs dispensed to the patient.

- Automated dispensing devices are now used extensively in hospitals as an efficient means of giving those who administer to patients ready access the drugs prescribed. With certain safeguards, that efficiency will now be available to long term care facilities. While there is a cost associated with leasing the machines, those that wish to utilize these devices will experience a savings since it is less costly than having unit-dose carts manually filled by technicians.

In addition to benefiting from efficiencies in the practice of pharmacy, the public will specifically benefit from the amended regulations in other ways, such as:

- Currently, there are no provisions for ensuring ability to resume practice for a pharmacist who has been out of practice for more than five years; the Board has added a requirement to take the law exam and to verify either active practice in another state or hours in an internship in Virginia. While continuing education is necessary to ensure a pharmacist's knowledge base remains current with the changes in prescription drugs, that is not a substitute for active practice if a pharmacist has allowed his license to lapse for an extended period of time.
- Clarification of responsibility for notifying the public and the board in situations where a pharmacy is closing or changing its hours will ensure that the public is adequately prepared for such an event and not left without the ability to obtain their prescriptions.
- New regulations to permit access into the pharmacy by a pharmacy technician and a member of store management in the absence of a pharmacist will greatly facilitate access to prescriptions that have already been filled and verified by the pharmacist as ready for delivery. Safeguards stipulated for such entry should ensure against diversion or any inappropriate or unlawful activity in the absence of the pharmacist.
- Amended provisions for the use of automated dispensing devices will improve access and utilization but will also ensure that drugs with older expiration dates are not left indefinitely mixed with drugs that have newer expiration dates. These requirements are intended to ensure the safety and efficacy of prescription drugs dispensed in this manner.

There are no disadvantages to the public; it should benefit from increased efficiencies, use of technology, improved access, and efforts to ensure minimal competency of pharmacists to practice.

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

The primary advantages to the agency (Board of Pharmacy) are: 1) clarification of rules that have generated questions to Board staff from applicants and licensees; and 2) a reduction in cost for annually providing hard copy of updated laws and regulations to all licensees. In 2002, the estimated cost for mailing the law packet was $10,000. To reduce the cost, each pharmacy was provided a CD instead. Amended regulations will eliminate the requirement to have a copy in each pharmacy, since the information is readily available electronically or may be obtained by requesting a copy from the Board office.

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

There are no additional matters of interest.

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 $2,500) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

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

The entities that are likely to be affected by these regulations would be licensed pharmacists and permitted pharmacies.

Estimate of number of entities to be affected:

There are currently 7655 pharmacists with active licenses and 888 with inactive licenses. There are 1507 permitted pharmacies.

Projected costs to the affected entities:

- Changes in the renewal and reinstatement requirement will benefit pharmacists whose license is lapsed for more than 60 days. Currently, that person would be required to reinstate the license by submission of an application, payment of all back renewal fees and a delinquent fee of $70. That could become excessive for a pharmacist who has been practicing in another state and wishes to return to practice in Virginia. The amended regulation would permit someone to renew within one year following license expiration by payment of a late fee of $30. Thereafter, reinstatement could be granted with payment of a fee of $210. The number of applicants for reinstatement that would be affected is unknown; approximately 20 pharmacists seek reinstatement each year, and a few of those may now be able to renew with payment of the renewal and late fees rather than going through a reinstatement process.

- If a pharmacist who has allowed his Virginia license to lapse for more than five years is unable to document active practice in another jurisdiction, he would be required to serve a 160-hour internship. There would be a reduction in his earning potential during that period, because a staff pharmacist earns approximately $40/hour while a pharmacy technician or intern earns approximately $12/hour. In addition, he would be required to pass the board-approved law examination at a cost of $200. Requiring internship hours (combined with continuing education and passage of the law examination) for a pharmacist who has not been actively practicing for more than five years is the least burdensome method for assuring minimal competency to resume practice. Capping the amount of CE required for relicensure at 5 years may reduce the cost for a few applicants; costs for continuing education courses can range from $10 to an on-line course to several hundred dollars for a live seminar.

- There are approximately 8 to 10 pharmacists per year that fail the initial inspection or are substantially unprepared for inspection at the first visit. Presently, the regulations require that the permit application be denied and resubmitted at a cost of $270. Amended regulations will allow the pharmacy to schedule a reinspection at a cost of $150 and avoid the cost and processing of resubmitting the application.

- Amending regulations to permit one pharmacist to act as PIC of two pharmacies will facilitate the ability to find persons willing to serve in that capacity. It is not expected to result in a cost-saving, since it is likely that the additional responsibility would be compensated on top of the basic salary paid to a pharmacist.

- Eliminating certain required equipment and resources may result in a cost savings to some pharmacies that will not longer have to purchase a set of weights and balances or an electronic scale at an approximate cost that ranges from $700 to $1200. Amending the requirements for the pharmacy to maintain a copy of pharmacy laws and regulations will result in a cost saving to the Board and hence to licensees. The most recent estimate for copying and mailing to all pharmacies was approximately $10,000. Those and other pharmacy resources are readily available and retrievable through the Internet at no cost.

- The ability to store certain records in off-site storage could provide a significant benefit to pharmacies that are now required to utilize valuable in-house space for such use. To the extent a pharmacy is able to take advantage of the amended regulation, off-site storage will certainly be less costly space and may permit the pharmacy to expand its operation or utilize

storage space for other purposes. For nuclear pharmacies, there may be some savings by amending requirements for a certain amount of separate square footage for various aspects of the practice.

- An amendment to allow a pharmacy to maintain a scanned or electronic image rather than a hard copy is permissive. If a pharmacy chooses to adopt that technology, it will incur the cost of scanning equipment but that will be greatly offset by the savings that result from not having to file and store thousands of hard copy prescriptions. Valuable physical space would be replaced by electronic storage at a cost saving to the pharmacy. An amendment that will allow a notation on a patient's electronic record of a request for nonspecial packaging will also relieve the retail pharmacies of the cost of securing and maintaining hard copies of a signed release from the patient.

- Amendments to permit transfer of prescription from pharmacy to pharmacy will allow transfer prior to filling the prescription, so that facilities such as the Medco pharmacy that does a large mail order business can shift workloads to other pharmacies and provide less costly services to its customers.

- Permissive language will allow nursing homes to maintain floor stock drugs in an automated dispensing device. Though there is a cost for leasing or purchasing such a machine, it is less costly and more efficient than a system in which pharmacy technicians are used to fill a unit dose cart for patient-specific administration. A controlled substance registration with the Board would be required for an entity that maintains a stock of drugs at a cost of $100 per year.

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.

PART I. GENERAL PROVISIONS.

18 VAC 110-20-10. Definitions.

To facilitate an understanding of the regulation, the Board has included commonly used acronyms, such as PIC for pharmacist-in-charge, DEA for Drug Enforcement Administration and FDA for the United States Food and Drug Administration. Throughout the regulation, the term "pharmacist-in-charge" has been amended to PIC, which is now defined. The term "on duty" is defined in regulation as it is currently through board policy in a guidance document.

18 VAC 110-20-20. Fees.

There are no changes in the amount of the current fees being charged; the amendments are intended to group fees into listings for ease of compliance. However, there are changes in

policies intended to reduce the financial burden on a person who is late in renewing a license or who has a lapsed license and is seeking reinstatement. Currently, a licensee who fails to renew within 60 days of expiration may renew by payment of the renewal fee and late fee. After the 60 days, the license or permit had to be reinstated with a new application, payment of all back renewal fees and a delinquent fee. Revised regulations allow someone one year from the expiration date to renew a late license, registration or permit. In proposed regulations, the reinstatement fee is set at an amount to cover the review of a reinstatement application and a late fee. All back renewal fees are no longer required.

A new reinspection fee is established with the conditions and need for such a fee explained in section 140.

PART II. LICENSURE REQUIREMENTS FOR PHARMACISTS

18 VAC 110-20-30. Requirements for practical experience.

To facilitate the review of applications, the date for the stated requirement of 1,000 hours of practical experience was revised from enrollment prior to 1999 to graduation prior to 2003. Graduation dates are easier to identify on documentation submitted with an application. There is no change in the requirement.

Subsection E is added for clarity to make applicants aware that the law (§ 54.1-3312) requires all required practical experience to be gained within the United States.

18 VAC 110-20-40. Procedure for gaining practical experience.

- This section was amended to address a problem of some applicants for licensure. Pharmacy education in Virginia organizes the practical experience required for licensure with pharmacy internships registered with the Board. In other states, the licensing board relies on the pharmacy school to certify hours of practical experience, so the Board modified the regulation to accept such certification from the school.

- A requirement for an applicant for examination to file affidavits or certificates of experience with the board no less than 30 days prior to the date of the examination was deleted as unnecessary. When the regulation was enacted the examination was only given three times a year. This requirement ensured that the board would have time to verify the documents in time for the candidate to sit for the examination. Now examinations are given via computer and can be scheduled immediately once the application is approved.

- Some states do not require as many hours of practical experience in an internship or do not maintain complete records, so an applicant for licensure by endorsement in Virginia, who may have already been practicing in another state, might be required to first work in an internship. To alleviate this problem experienced by some applicants, the Board has amended its regulation to accept verification of practical experience hours worked as a pharmacist in another state within the United States in lieu of intern hours in order to meet the practical experience requirement.

18 VAC 110-20-60. Content of the examination and grades required; limitation on admittance to examination.

An amendment to subsection D clarifies the meaning of a requirement for six months of practical experience as a pharmacy intern. There was no standard by which the Board could judge the time as an intern (six months of 4 hours a week could only total approximately 100 hours). The policy of the Board is to require the internship to be six months of full-time work, so the requirement has now been set at 1,000 hours of practical experience for clarity to the applicants.

18 VAC 110-20-70. Requirements for foreign trained applicants.

Amendments to the requirements for foreign trained applicants were necessary to make it clear to graduates of foreign colleges of pharmacy that it is necessary for them to meet all requirements for foreign graduates prior to sitting for the NAPLEX and law examination. The rewording of the section is intended for clarity.

18 VAC 110-20-80. Renewal and reinstatement of license.

- The amendments in section 80 are the same as those described on renewal and reinstatement in section 20 on Fees. A pharmacist who fails to renew his license by the expiration date may renew his license at any time during the first renewal cycle after expiration, rather than the current 60 days, by submission of the renewal fee and late fee.

- Reinstatement would no longer require payment of all back renewal fees, which could serve as a strong deterrent to a pharmacist who has allowed a Virginia license to lapse while working elsewhere and now wants to return to the state and reinstate his license. With the proposed regulation, an applicant for reinstatement would have to pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements.

- Amendments to subsection F are intended to facilitate the reactivation or reinstatement of an inactive or lapsed license. The current regulation was interpreted as meaning that someone had to document compliance with <u>all</u> CE hours for the number of years in which the license has not been active or current. The revised regulation would cap the number of required hours at five years, not to exceed a total of 60 hours of CE.

- To address concerns about pharmacists whose licenses have been suspended, lapsed or inactive for more than five years, the Board proposes to require, in addition to 60 hours of CE, passage of the board-approved law examination and documentation of <u>either</u> active practice in another state or practical experience of at least 160 hours within the past six months as a pharmacy intern.

18 VAC 110-20-90. Requirements for continuing education.

The Board proposes a clarification of the requirement for retention of CE documentation to specify that, in addition to documents for the current renewal year, licensees are required to maintain original documents for the two previous renewal cycles. Pharmacists are no longer required to maintain them at their "principal place of practice" because CE is no longer audited as part of the pharmacy inspection. Random audits are conducted by the agency, and licensees are required to send in documentation upon a request from the Board.

PART III. REQUIREMENTS FOR PHARMACY TECHNICIAN REGISTRATION.

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

Amendments to section 105 modify board policy on renewal and reinstatement as described above.

PART IV. PHARMACIES.

18 VAC 110-20-110. Pharmacy permits generally.

- The Code of Virginia requires the pharmacist-in-charge (PIC) to be "fully engaged" in the practice of pharmacy at that location. The current rule states that a pharmacist may only be PIC of one pharmacy. Based on requests from the regulated entities, and due to the pharmacist shortage, the board carefully considered and proposed a less restrictive rule for to allow a pharmacist to serve as PIC at two pharmacies rather than just one. Due to the pharmacist shortage, it is not always possible to find a good PIC. The board determined that a pharmacist, for example, working full time for a chain pharmacy, could conceivably work an average of 20 hours one week at one pharmacy, and 20 hours the same week at a second pharmacy and still be "fully engaged" at both locations, have full knowledge of pharmacy practice at that site, and easily be able to control the practice at both locations. In this example, the board considered that an alternative in some cases would be to have a part-time pharmacist or "floater" or a pharmacist who had not interest in taking the PIC responsibilities become PIC at one of the two locations, which would be less optimal than having one full-time pharmacist who was motivated to take on the PIC responsibilities cover both locations on a regular basis.

- Pharmacies and pharmacists have often been unclear as to whether a PIC who is absent from the pharmacy for an extended period should resign as PIC. The board has taken action against pharmacies for not obtaining a new PIC when the PIC was absent for an extended period of leave such as 6 to 8 weeks maternity leave. Pharmacists and pharmacies have complained about the lack of a clear standard for how long the PIC can be absent and still be considered to be "fully engaged." Clearly, the PIC should be allowed to be absent for vacations or short illnesses, but an extended absence would leave the pharmacy without a anyone legally in charge of the practice. There is also a risk to the PIC who is not able to be present because he remains responsible to the Board for the inventory and operation of the pharmacy. Therefore, the Board has adopted a specific rule that a PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of upcoming absences for longer than 30 days, he is responsible for notifying the

board, returning the permit, and taking the required inventory. If there is an unanticipated absence by the PIC of 15 days and the PIC is not likely to return within the next 15 days, the owner must immediately notify the board and take steps to obtain a new PIC.

- The current rule requires that when a PIC leaves that position, a new PIC be named within 14 days. Again, primarily because of the pharmacist shortage, some pharmacies have experienced great difficulty in meeting this deadline, particularly in rural areas, and when the owner has to advertise a position, then go through the hiring process. An amendment authorizes the executive director to grant an extension of the 14-day deadline for good cause shown for an additional 14 days. Also there was not clarity as to exactly when the 14 days begin. The board amendments specify that the 14 days begin when with the original date of resignation or termination of the PIC.

18 VAC 110-20-120. Special or limited-use pharmacy permits.

The Board is allowed, for good cause shown, to issue a special or limited-use pharmacy permit that relieves a pharmacy of some aspects of regulation that does not pertain to its particular operation. An amendment will require the policy and procedure manual to include the schedules of drugs to be maintained by the pharmacy because that information could affect the advisability of issuing such a permit.

18 VAC 110-20-121. Innovative program approval.

Regulations for the approval and continuation of an innovative or pilot program that were previously stated in section 20 (Fees) have been restated in this new section. For ease of reading and identifying fees, the fee section was restructured to contain only fees. Most of rules not directly setting a fee were moved to other sections. The rules for pilot programs have not been changed.

18 VAC 110-20-130. Pharmacy closings, going out of business, and change of ownership.

Requirements for prior public notice of a pharmacy closing or change of ownership are set in § 54.1-3434.01 of the Code of Virginia, but there has been some confusion about what is required if the closure is sudden and appropriate notification is not possible. The amended rule will provide that if the pharmacy is not able to meet the notification requirements of § 54.1-3434.01, the owner must ensure that the board and public are properly notified as soon as he knows of the closure and must disclose the emergency circumstances preventing the notification within the required deadlines.

18 VAC 110-20-135. Change of hours in an existing pharmacy.

The amendment to section 135 will identify the owner of a pharmacy as the person responsible for providing notice for a change in the hours of operation in accordance with § 54.1-3434 of the Code of Virginia. There had been a comment received requesting clarification as to whether the owner or the PIC was the responsible party.

18 VAC 110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

An amendment will specify that if a pharmacy makes changes to a previously approved security system, it must file an application with the Board. Alarm systems are approved by an inspector prior to operation of the pharmacy to ensure that they meet requirements. Any change may make the system less effective and out of compliance. The Board's policy under the current rules has been that a change to a security system constitutes a "remodeling" requiring an inspection. However, this has not always been clear to the regulated community and has created some confusion and sometimes additional expense for the regulated, and has resulted in disciplinary action in some cases where an alarm system was changed without approval and there was a subsequent theft with loss of drugs. The amendment will make board policy very clear.

The Board has had problems with some pharmacies, particularly with applications for new pharmacies and change-of-locations, where an inspection date is set, but the pharmacy substantially fails to meet the requirements for issuance of a permit, or the applicant knows that the pharmacy is not ready for the inspection on the established date but fails to notify the inspector or the board. The inspector wastes time in traveling to conduct an inspection that essentially cannot be conducted, and then has to return to inspect when the pharmacy is ready. The only option currently available to the Board is to deny the application on the basis that the inspection showed that the pharmacy did not meet requirements for a permit, and require the submission of a new application and fee of $270, with a new waiting period o 14 days to reschedule an inspection. This is a burdensome method to cover the cost associated with the subsequent reinspection which is not covered by the initial application fee, and may result in loss of revenue to the new pharmacy if opening is delayed. To address the problem, the Board has established a reinspection fee of $150 in 18 VAC 110-20-20 to be paid prior to a reinspection being conducted. The fee is the same fee currently charged for an inspection for any other reason such as change of location or remodeling, and is intended to cover only the cost of the inspection.

Current rules require that drugs cannot be stocked within the proposed pharmacy or moved to a new location until approval is granted or the permit is issued by the Executive Director of the board or his designee. The amended rule will allow the pharmacy to open and begin operation once approval is given by the inspector or board staff. This is clarification of what has been board policy under current rules.

18 VAC 110-20-150. Physical standards for all pharmacies.

An amendment will clarify that the 240 square feet required for a prescription department does not include a patient waiting area or the area used for counseling. This clarification was requested by the regulated community.

18 VAC 110-20-160. Sanitary conditions.

The requirement for the prescription department and work counter space and equipment in the dispensing area to be maintained in a clean and orderly manner was eliminated as partially redundant because section A of this section already requires that the entire pharmacy, of which

the prescription department is a part, be maintained in a clean and sanitary manner and good repair and order. Additionally requirement for work counter space being "orderly" was considered to be very subjective, as pharmacists have differing work habits and what may be considered "orderly" to one pharmacist may be considered very confusing by another.

18 VAC 110-20-170. Required minimum equipment or resources.

Section 170 is amended to eliminate unnecessary equipment or resources, so rather than a general dispensing information reference that might contain the entire scope of pharmaceuticals, the pharmacy must maintain a reference consistent with the scope of pharmacy practice at the location of the permitted pharmacy. For example, a nuclear pharmacy would have no need for a general dispensing reference. A set of prescription balances and weights or an electronic scale would only be required if the pharmacy engages in dispensing activities that require the weighing of components. It is not required to have a copy of the current Virginia Drug Control Act and board regulations since that information is readily retrievable on the internet or may be requested from the board.

18 VAC 110-20-180. Security system.

Current rules restrict access to the alarm system for the prescription department area of the pharmacy to the pharmacists working at the pharmacy, but new provisions in section 190 would allow access by other persons under certain conditions, so an amendment is adopted accordingly.

18 VAC 110-20-190. Prescription department enclosures; access to prescription department.

In recognition of locking mechanisms other than the traditional lock with manual key (such as a lock with a key pad that unlocks when a code is punched in), the Board has modified the language in this section. There is also an amendment to update terminology from "clerical assistants" to include the term pharmacy technicians as specifically authorized to be in the pharmacy during the hours the pharmacist is on duty. Clerks are covered by "other persons".

New subsections D and E are added to address a problem identified during regulatory review. Current regulations do not allow anyone to enter the prescription department in the absence of a licensed pharmacist. Pharmacies have occasionally had problems with a patient needing to pick up a prescription that has already been filled, reviewed and certified for accuracy by a pharmacist. Current regulations already allow a pharmacists to place filled prescriptions somewhere outside of the prescription department for "after-hours" pickup by a patient under certain conditions. This problem occurs when a pharmacist is unexpectedly not available during regular business hours, for example, if the pharmacist had to leave unexpectedly due to an emergency, or if the pharmacist scheduled to open the prescription department in the morning is ill and cannot make it to open. There are likely prescriptions which have already been filled and checked but not yet picked up by the patient. For example, a patient calls in a refill request on a given day and it is filled that day, but when he comes to pick it up the next morning during regular pharmacy hours, there is no pharmacist there due to an unexpected event. To alleviate the problem, the Board has established conditions under which a pharmacy technician, with

permission of a pharmacist employed at that pharmacy, could disable the alarm and enter the pharmacy accompanied by management to retrieve the already filled prescriptions. That entry would have to be fully documented, and the access code changed by the PIC after such an event. Now that pharmacy technicians are to be registered with the Board, the Board feels comfortable that they will have jurisdiction over the person entering the pharmacy and that there will be accountability. There is no competency issue since the pharmacy technician will only be retrieving prescriptions already checked by a pharmacist.

18 VAC 110-20-200. Storage of drugs, devices, and controlled paraphernalia.

- An amendment is adopted to ensure that there are written procedures detailing security of the dispensed prescriptions if a prescription is delivered at a time when the pharmacist is not present. Additionally, it is required that a log be made and maintained for a period of one year of all prescriptions that are delivered to a patient when a pharmacist is not present, to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription. This new requirement is in concert with the change to 190 to allow the pharmacy technician to retrieve already filled can checked prescriptions in the absence of the pharmacist.

- Current regulations require that all Schedule II drugs be dispersed with other schedules of drugs or maintained within a securely locked cabinet, drawer, or safe. An amendment will allow the pharmacy to keep the cabinet, drawer, or safe unlocked during hours that the prescription department is open and a pharmacist is on duty. This amendment is to clarify the current policy of the Board and is also consistent with DEA's interpretation of its regulation that the Board rule mirrors.

- An amendment will allow controlled paraphernalia to be placed on open display, provided it is in still in close proximity to the prescription department where patrons do not have free access to such items and where the pharmacist can exercise reasonable supervision and control.

PART V. NUCLEAR PHARMACIES

18 VAC 110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

All amended language was recommended by the sub-committee on nuclear pharmacies that advised the Board during regulatory review. Rather than specifying square footage for radioactive storage and product decay area, amended language requires nuclear pharmacies to have adequate space and equipment, commensurate with the scope of services in compliance with standards and requirements of the Nuclear Regulatory Commission (NRC) and the Virginia Department of Health. The current language in regulation related to the physical space requirements is obsolete. By referencing the NRC and Health Department physical requirements, the regulation can remain current, and will not create any unnecessary burden on these pharmacies.

A new subsection D set forth rules for the dispensing of radiopharmaceuticals to include requirements for the content and transmission of the order.

PART VI. DRUG INVENTORY AND RECORDS

18 VAC 110-20-240. Manner of maintaining records, prescriptions, inventory records.

An amendment allow off-site storage of certain required records, such as invoices, if allowed by DEA and will specify which records must be maintained at the same location as the stock of drugs to which the records pertain to include executed order forms, prescriptions, and inventories of Schedule II through V drugs. The Board has been asked to allow for off-site storage of records by a majority of the regulated community. DEA does not allow for off-site storage of certain records, but will, upon request, allow others to be stored at an off-site location. The Board considers this a reasonable request provided the records are readily retrievable for inspection when requested.

18 VAC 110-20-250. Automated data processing records of prescriptions.

The Board has made a provision in section 250 to allow an electronic image of a prescription to be maintained in an electronic database in lieu of a hard copy file for Schedule VI prescriptions, provided it preserves and provides an exact image of the prescription which is clearly legible and made available within 48 hours. DEA does not currently allow this for Schedule II – V prescriptions, but the Board included permissive language to allow this if the federal rules are amended.

An amendment would also permit a pharmacy to use an automated record as the prescription rather than a hard copy or electronic image if the pharmacy system's automated data processing system fields are automatically populated by an electronic transmission.

Another amendment clarified that a pharmacy could elect to maintain a dispensing log rather than daily printouts. The current rule was intended to allow a pharmacy to choose but the current wording states that "if the system provides a printout, the printout shall be etc." which has led some pharmacies to believe that they did not have the option of keeping the log if their system provided a printout which all systems will do. The amendment will make it clear that the pharmacy can choose the method of recordkeeping it prefers.

Another amendment establishes the requirement that any requested dispensing data be provided within 48 hours of the request. This is consistent with other provisions of current rule where this timeline for furnishing required data is specified.

PART VII. PRESCRIPTION ORDER AND DISPENSING STANDARDS

18 VAC 110-20-280. Transmission of a prescription order by facsimile machine.

Prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX); amendments are intended to clarify the current requirements and

remove some requirements that had little benefit, made compliance difficult, and regulated entities requested the Board remove. Clarification was made in A1 that rather than the patient giving permission to fax the prescription, the prescription may only be faxed to the pharmacy of the patient's choice. The current wording about the prescriber's signature or an agent signing in lieu of the prescriber in A 2 and 3 was very confusing. These sections have been rewritten to better conform to the requirements of statute for written and oral prescriptions, but the requirements have not changed. A change in A4 will allow a prescription to be faxed from a long term care facility or a hospice. This has been a frequent request from the regulated community. A change to A5 removes the requirement that the faxed prescriptions include documentation that "it has been faxed" and the "name of the pharmacy to which it is being faxed". In order to comply, this information would have to be placed on the prescription by the prescriber or his agent prior to faxing. The vast majority of prescriptions reviewed by inspectors did not include this information prior to faxing and because the requirement was in Board of Pharmacy regulations, the Board has no good way to force prescribers to comply. The requirement was established with the initial fax regulations to prevent diversion by faxing a prescription, then taking the original to get it filled also (writing "faxed" or "to be faxed" on the original should prevent the original from being filled), or by faxing to more than one pharmacy (writing the name of the pharmacy on the prescription prior to faxing should prevent it from being faxed to a second pharmacy). There has been no evidence that diversion has occurred by either of these methods. Because of the difficulty of gaining compliance, and because of no documented need, the Board removed these requirements.

18 VAC 110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.

Subsection A is amended to specify that any electronic transmission of Schedule II-V prescriptions must comply with any security or other requirements of federal law and with all security requirements of state law related to privacy of protected health information._DEA has proposed new rules on the security of electronic transmissions, so the amended regulation in section 285 would clearly state that Virginia pharmacists are subject to those requirements.

An amendment to subsection C would relieve the burden of having to maintain a hard copy of an electronically transmitted prescription, if the record is maintained in accordance with proposed requirements in section 250 on automated data processing.

PART VIII. LABELING AND PACKAGING STANDARDS FOR PRESCRIPTIONS

18 VAC 110-20-330. Labeling of prescription as to content and quantity.

Labeling requirements provide that the generic name of the drug be included on the label or if a generic drug is dispensed when a prescription is written for a brand name drug, the label must contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed. An amendment to this section will eliminate that burdensome and unnecessary requirement for drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer. That information on the label is only necessary when drugs are being self-administered by a patient.

18 VAC 110-20-350. Special packaging.

If nonspecial packaging is requested (non-child resistance), federal law only requires a notation on a record that such a request was made by the patient or the patient's agent. State statute only requires that a request be made in order to dispense in non-child-resistant packaging. Current regulations require a signed release, which is more restrictive, so the rule has been amended to eliminate the requirement for a signed release. This was requested by a number of pharmacies as being overly burdensome.

18 VAC 110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

- Rather than specifying guidance for determination of an expiration date to be used on a drug that is being repackaged, the Board has amended the regulation to require the pharmacist to determine the appropriate date in accordance with USP guidelines. USP guidelines for determining an expiration date change more frequently than Board regulations, so the Board determined that a more flexible regulation is needed to conform to current standard.

- The amendments to subsection C are intended to restate current requirements in a clearer format. Rather than using six months as the expiration date, the pharmacy is allowed to determine a date consistent with USP guidelines. Each bin must be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.

- If lots with different expiration dates are mixed in the same bin, there is a need to be certain that the older drug product is used first and that drugs cannot remain mixed in the lot past their expiration date. To address this problem, the Board has added a provision on using the earlier expiration date and clearing each bin in the automated dispensing device at least once every 60 days with a record made of the run dry dates.

PART IX. STANDARDS FOR PRESCRIPTION TRANSACTIONS.

18 VAC 110-20-360. Issuing a copy of a prescription that can be filled or refilled.

The rules for transfer of a copy of a prescription have been amended to provide for transfer between two pharmacies of a prescription whether it has been filled or not. Rules have also been amended to allow for electronic transfer without a pharmacist from the provider pharmacy having to "release" the prescription. Other amendments restate the rules in a clearer format.

18 VAC 110-20-370. Issuing a copy of a prescription that cannot be refilled. (Repealed.)

The provisions of section 370 are out-dated and not applicable to current pharmacy practice. If a request is made for a copy, a patient is usually given a printout of prescriptions rather than a copy of the actual prescription.

18 VAC 110-20-380. Confidentiality of patient information. (Repealed.)

Rules on confidentiality of patient information are repealed because it is superceded by state and federal law on patient privacy and is therefore unnecessary and may be in conflict.

18 VAC 110-20-410. Permitted physician licensed by the Board.

Section 410 applies to physicians who hold a permit from the Board to dispense drugs to the public when pharmacy services are not reasonably available in their geographic area. It has been updated to specify those sections of the regulations with which the permitted physician must comply and to state that a physician may apply for a special or limited use permit in accordance with 18 VAC 110-20-120, if it is not necessary to meet certain requirements because of the limited or restricted nature of his pharmacy practice.

PART X. COMPOUNDING STERILE PHARMACEUTICAL PRODUCTS

18 VAC 110-20-412. Policy and procedure manual.

This section is amended to clarify that a policy and procedure for the compounding, dispensing and delivery of sterile products should be consistent with USP-NF standards and guidance.

18 VAC 110-20-415. Quality assurance.

The requirement that all laminar flow hoods or other environmental control devices be certified every six months is modified to clarify that initial certification is also required and then recertification thereafter if equipment has been relocated. The board considered a request to extend the six months requirement to one year, but USP guidelines call for reinspection every six months.

PART XI. UNIT DOSE DISPENSING SYSTEMS.

18 VAC 110-20-420. Unit dose dispensing system.

The amendment to the section on transmission of a verbal order to a nurse or pharmacist at the hospital is intended to allow such transmission when such a practitioner is not an employee of the hospital, since some health care workers are employed by agencies and work under contract with a hospital.

PART XII. PHARMACY SERVICES TO HOSPITALS.

18 VAC 110-20-440. Responsibilities of the pharmacist-in-charge.

- Rather than requiring a monthly review of drug therapy for any patient in the hospital for one month or greater, the amended regulation requires the pharmacist to maintain a policy and procedure manual for providing reviews of drug therapy to include at a minimum any

irregularities in drug therapy, drug interactions, drug administration, or transcription errors. Consistent reviews are essential to the correction and preventive of drug errors in hospitals.

- At the request of the hospital subcommittee, the Board has specified that certain controlled substances such syringes, contrast media and other schedule VI medical devices and drugs such as IV solutions could be maintained in locations other than the pharmacy and ordering and distribution delegated to non-pharmacy personnel. Security and storage requirements for these types of controlled substances need to be set forth in the hospital policy and procedure manual and must be checked monthly by the pharmacist-in-charge.

18 VAC 110-20-450. After-hours access to the pharmacy.

Access to the pharmacy to obtain emergency medication by a nurse authorized by the PIC is necessary since a “supervisory” nurse is not always the best nurse to be the designated "night-entry" nurse. The board has received a number of requests for this modification.

18 VAC 110-20-460. Floor stock drugs; proof of delivery; distribution records.

Amendments will allow receipts of floor stock drugs and the records that are used to document administration of Schedule II through V drugs to be maintained by the hospital pharmacy in offsite storage provided they are retrievable and can be made available for inspection or audit within 48 hours of a request by the board or an authorized agent. That provision will alleviate the need to retain the receipts at the hospital, where storage is often a problem. This was a recommendation of the hospital subcommittee during regulatory review.

The Board also adopted another recommendation to allow hospital pharmacies to fulfill the requirement for separation of schedule II records for administration by listing schedule II drugs in a separate section on a page that contains other schedules of drugs.

18 VAC 110-20-480. Pharmacy services. (Repealed.)

The current rules on dispensing by hospital pharmacies to persons other than their own patients were written primarily as information to pharmacies to provide an interpretation of federal law and regulations prohibiting unfair competition by hospital pharmacies dispensing to the general public with retail pharmacies that do not have the same purchasing contracts. The board determined that this regulation did not have a basis in public protection and as such should be repealed.

18 VAC 110-20-490. Automated devices for dispensing and administration of drugs.

The board has been asked to consider amendments to section 5 of this regulation related to the required audits to clarify requirements. Proposed amendments will require that an automated device used to dispense drugs in a hospital be able to produce a report for each discrepancy in the count of a drug on hand in the device and that each report be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered. The discrepancy must either be resolved or reported to the board as a theft in accordance with statute. The requirement that all records be audited was removed in recognition that 100% review of the discrepancy report,

100% check that all drugs removed from the pharmacy were actually loaded into the device, random checks to ensure that valid orders exist, and checks of at least one day's administration records from each device for each month will be sufficient to detect most diversion and at least at the level required for manual floor stock systems.

18 VAC 110-20-500. Licensed emergency medical service agencies program.

There is a clarification in terminology to specify that a technician referred to in this section is an emergency medical technician, rather than a pharmacy technician.

An amendment is adopted to clarify that the institutional DEA identification number used by a resident is only used as a part of the residency program. The resident may be prescribing as a part of his responsibilities in a clinic associated with a hospital but his duties would not be "within the hospital" as is currently required.

PART XIII. PHARMACY SERVICES TO LONG TERM CARE FACILITIES.

18 VAC 110-20-530. Pharmacy's responsibilities to long term care facilities.

The amendments clarify that if discontinued drugs are transferred to the pharmacy serving a long term care facility, the pharmacy can store those drugs beyond the 30 days while waiting to be shipped to a returns company or destroyed. Current rules require destruction of unused drugs within 30 days, but a revision in regulation will allow the long term care facilities to return them to the pharmacy which can maintain them until the scheduled return or destruction.

18 VAC 110-20-540. Emergency drug kit.

The amendment is intended to clarify that an emergency kit may be prepared for a facility in which only licensed nurses or physician assistants are administering drugs.

The pharmacy preparing the emergency drug kit is required to keep a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced. Amended regulations will allow a kit to have, in lieu of a seal, a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy. To ensure proper tracking for the drugs contained in the kit, the amended rule also requires the kit to have a form to be filled out upon opening the kit and removing contents on which someone can write the name of the person opening the kit, the date, time and name and quantity of item(s) removed.

18 VAC 110-20-550. Stat-drug box.

Similar amendments are proposed for the stat-drug box as for the emergency kit.

18 VAC 110-20-555. Use of automated dispensing devices.

Current regulations permit long term care facilities to maintain automated dispensing devices in place of stat drug boxes or emergency drug kits provided certain conditions have been met. The

long term care subcommittee recommended an expansion of the use of automated dispensing devices, which the Board has accepted. Amendments to this section establish the conditions that must be met for the use of automated drug dispensing systems to include provisions to ensure the security of the drugs, control by the pharmacy, removal only upon a valid prescription from a prescriber and after review of the order by a pharmacist, and loading of the device by a pharmacist or technician specifically trained in its use. All required records must be maintained and the PIC of the provider pharmacy must conduct a monthly audit of the distribution and administration of the drugs and must maintain a written policy and procedure manual to set out the process for ensuring accuracy and accountability of the automated dispensing devices. Any discrepancy report must be resolved within 72 hours or reported immediately to the board if it is a determined that there has been a theft or unusual loss of drugs.

PART XIV. OTHER INSTITUTIONS AND FACILITIES

18 VAC 110-20-590. Drugs in correctional institutions.

Amendments to this section were recommended by the subcommittee on pharmacy services to correctional institutions and include: 1) allowing the use of the patient name rather than the prescription number on the record; 2) allowing for unused or discontinued drugs to be returned to the provider pharmacy or to a secondary pharmacy within 30 days; 3) allowing drugs to be forwarded by a pharmacist from the correctional facility to a returns company; and 4) adding that drugs may be stocked at a medical clinic or surgery center that is part of the facility and is staffed by one or more physicians providing the clinic applies for and receives a controlled substance registration.

PART XV. EXEMPTED STIMULANT OR DEPRESSANT DRUGS AND CHEMICAL PREPARATIONS

There were no amendments adopted.

PART XVI. MANUFACTURERS, WHOLESALE DISTRIBUTORS, WAREHOUSERS, AND MEDICAL EQUIPMENT SUPPLIERS

18 VAC 110-20-680. Medical equipment suppliers

An amendment to subsection C will permit the original order to be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier.

PART XVII. CONTROLLED SUBSTANCES REGISTRATION FOR OTHER PERSONS OR ENTITIES.

18 VAC 110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

Nursing homes without in-house pharmacies that use automated drug dispensing systems are required in the amended language of section 555 to have a controlled substances registration (CSR) in order to maintain a stock of drugs. Therefore, nursing homes are added to the list of entities authorized or required to obtain a CSR.

18 VAC 110-20-700. Requirements for supervision for controlled substances registrants.

The amendment in subsection A is a clarification that a pharmacist must supervise the controlled substances in a nursing home without an in-house pharmacy.

18 VAC 110-20-710. Requirements for storage and security for controlled substances registrants.

An amendment would clarify that an alarm system is not required for researchers or animal control officers.

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.

Since the practice of pharmacy is so varied, and 18 VAC 110-20-10 et seq. is a complex set of regulations affecting the practice is settings ranging from humane societies to major hospital systems, the Board spent approximately two years in conducting a thorough review of every regulation to determine whether it was adequate to protect the distribution of prescription drugs to patients or if there were less burdensome alternatives. The review was organized into ad hoc subcommittees that consisted of one or more board members and appointees who had expertise in a particular aspect of the regulation of pharmacy. The subcommittees consisted of: Initial Licensing, Compounding, Corrections, Controlled Substances Registration, Home Infusion, Long Term Care, Nuclear Pharmacy, Free Clinics, Hospital Practice and Retail Practice. Each of the subcommittees prepared a report with comments or recommendations for changes to the regulation; staff of the Board also made recommendations for changes to address problems or questions that they identified. The recommendations were organized into a chart by section number and recommending subcommittee; all were considered and discussed by the Regulation Committee which then recommended amendments to the Board.

Several of the comments or requests for rule changes from the subcommittees could not be addressed by amending the regulation. In the practice of pharmacy, many of the rules for record-keeping, dispensing, drug, destruction, refills, etc. are determined by federal rules from the Drug Enforcement Administration and/or the Drug Control Act in the Code of Virginia. In several instances, changes in the regulation must be preceded by changes in the law or federal rules. In the reports of the subcommittees, there were requests for changes to allow chart orders for home infusion and hospice patients, to allow the practice of pharmacy to occur in settings other than a pharmacy, to permit alternative record-keeping systems in pharmacies, and to allow delivery of drugs to sites other than the residence of the patient. All necessitated changes in the Drug Control Act and were addressed by legislation adopted in the 2002 General Assembly.

Emergency regulations to implement the law were adopted by the Board and replaced with permanent regulations effective July 16, 2003.

Other changes requested would necessitate a change in the federal DEA rules. For example, one comment received in writing was a request to allow home infusion pharmacies to be able to partially fill prescriptions for "non-terminally" ill patients in the same manner as terminally ill patients. This will require a change by DEA before state law and regulation could be effectively changed.

In addition to the changes that were adopted (as detailed above), the subcommittees and/or the Board discussed possible changes that were not adopted. Those include the following:

18 VAC 110-20-30
The board had received a request to clarify how the required 300 hours of practical experience in compounding/dispensing is verified. Rather than amend the regulation, the board will amend the application form to request more specific information.
18 VAC 110-20-70
There was comment that the scores on the Test of Spoken English were too low, and there was concern about the communication skills of some foreign-trained pharmacists. Scores on TSE and the Test of English as a Foreign Language are tied to certification by the National Association of Boards of Pharmacy, so the Board did not address in regulation.
18 VAC 110-20-80
In response to comments made during regulatory review, the Board discussed the possibility of allowing biennial renewal of licenses. Since fees were recently increased to address a growing deficit, the Board deferred consideration until the impact of increases can be absorbed and it can be determined whether pharmacists and pharmacies would be willing to pay double the amount every other year.
18 VAC 110-20-90
Several issues were raised during regulatory review, including the possibility of allowing more flexibility in acquiring hours, the possibility of requiring live hours, and the possible need to require specific hours in drug laws. With concerns related to evolving issues in pharmacy practice, the Board considered a more flexible regulation to require up to 2 hours of the 15-hour CE requirement to address “hot topics” such as bio-terrorism or appropriate prescribing of oxycontin. The intent was for the board to designate a required subject area of CE, give ample notification to pharmacists, and provide specific information about the availability of the required CE. While the purpose of the specified two hours on a topic of current importance was acknowledged as contributing to public health and safety, there were concerns expressed about the Board establishing a “rule” for specific hours without going through the rule-making process. To alleviate concerns about its legality, the Board elected to propose legislation that would establish an exemption in the APA for specifying special subject requirements for continuing education for pharmacists and authorization for two of the 15 hours to be so designated.
There was also consideration of including in regulation all or part of the guidance document on sanctions for failure to comply with continuing education requirements, but that would restrict the Board’s ability to respond to individual situations or to offer confidential consent agreements in lieu of disciplinary action so no such changes were made to the regulation.
18 VAC 110-20-140

Regulations require a 14-day notice to the Board so an inspection can be scheduled prior to issuance of a pharmacy permit. The Drug Enforcement Administration relies on the state to assure requirements for security of drugs have been met; that could not be done without an inspection. There was a suggestion during the review process that the Board amend its regulations or processes to provide a pharmacy permit applicant with the permit number prior to the opening inspection and prior to the actual issuance of the permit in order that the applicant could use that number to speed up the process of obtaining a DEA registration. DEA will not issue a registration until after the Board provides them with the permit number. This usually results in some delay in a pharmacy being able to order Schedule II-V controlled substances and therefore a delay in a new pharmacy being able to provide complete prescription dispensing services upon opening. However, the purpose of the Board providing DEA with the pharmacy permit number is to assure DEA that the Board has inspected the pharmacy and that the pharmacy meets the security requirements for the Board and is therefore eligible to be issued a DEA registration. Providing the pharmacy applicant with a pending number would circumvent the safeguards DEA has in place which prevents the issuance of a DEA registration before the state makes a determination that an applicant facility is eligible to be permitted and issues that permit. The Board did not adopt such a change but did amend regulations to speed up the process by allowing approval to be given by the inspector or board staff so drugs can be stocked prior to the permit is physically issued.

18 VAC 110-20-150

A request was made to allow the use of trailers or other moveable facilities in emergency situations. No change to regulation was made since the Board may already waive some regulations through a special use permit, and legislation was adopted by the 2003 General Assembly to allow for waivers of this and other requirements in time of an officially declared emergency. The Board also considered but did not remove the requirements for hot and cold running water or for a refrigerator in the immediate dispensing area. There was consideration given to allowing all satellite pharmacies in a hospital to be added together to make up the 240 square feet required for a permitted pharmacy, but the Board did not adopt such a change.

18 VAC 11-20-190

The Board considered various alternatives to clarify the requirement that an enclosure to the prescription department be of sufficient height to prevent anyone from reaching over to gain access to drugs. To specify a height or style of enclosure may provide more certainty for inspectors and licensees, but it would also be unnecessarily prescriptive and burdensome.

18 VAC 110-20-220

Requests were received to allow nuclear technologists to have access to the licensed area in emergency situations and to take verbal orders for diagnostic tests. Committee decided not to change the access requirement and that allowing technologists to take verbal orders would require a change in pharmacy technician law.

18 VAC 110-20-330

The board considered adding a requirement for ‘beyond-use dating’ on each prescription. The board felt that there are still too many variables to be able to mandate a specific beyond-use dating policy.

18 VAC 110-20-414

Concern was expressed that there are different standards for out-of-state pharmacies which may be lower than in-state. One example may be where the stability of the product is only 24 hours, yet it is prepared in another state and shipped for longer than the stability time. Another example

may be an intrathecal compounded delivered to a physician office directly. Addressing the problem of inconsistent standards would require a change in the law, which currently allows a non-resident pharmacy to adhere to the rules of its state of residency.

18 VAC 110-20-415

The hospital subcommittee had suggested increasing the recertification requirement for the laminar flow hood from 6 months to 1 year, but the Board determined that new USP guidelines require certification initially, at least every 6 months and upon relocation.

18 VAC 110-20-416

The Board considered some clarification of rules for compounding for administration vs. bulk compounding in a pharmacy but determined that legislation passed by the 2003 General Assembly on pharmacy compounding addressed the issue and additional rule-making was not necessary.

18 VAC 110-20-420

A request was made to change the definition of unit dose to include systems which do include directions for use to be considered unit dose systems. The board determined that the present definition is sufficient and did not want to broaden the definition.

18 VAC 110-20-470

The Board addressed the issue of dispensing "starter packs" for indigent patients in emergency rooms and concluded that a change in statute would be required to accomplish that. Currently, the law requires a physician who dispensing drugs to either hold a license from the Board to do so, dispense in a bona fide medical emergency or dispense when pharmacy services are not reasonably available. A 2002 change in the law will allow a physician to store and dispense donated drugs if he hold a controlled substance registration. The Board also considered allowing a separate drug record for the emergency room because the pharmacist-in-charge finds it difficult to be responsible for something not done by pharmacy staff. The Board did not amend its regulations because the PIC remains responsible for all drugs anywhere in the hospital and a separate record would not alleviate him of that obligation.

18 VAC 110-20-480

A request was made to add volunteers to the employees who may receive prescriptions from a hospital pharmacy. After discussion of the issues, the board repealed this section of regulation since this regulation is based on a court decision involving a federal law. Subsequent court cases may change aspects of the findings. Therefore, since it has no basis in state law, it should not be in regulation.

18 VAC 110-20-530

There was interest in provided an exemption for chart orders in long term care facilities to all required prescription information would not be necessary. The Board did not modify the regulation because the law requires that the prescription or order provide enough direction to let the pharmacist know the limitation on the drugs – either by quantity or by duration.

There was also interest in distinguishing assisted living facilities from nursing homes in regulation, but the definition of a long term care facility, which was taken from federal rules, includes both types. The current regulations do make it clear which rules apply specifically to nursing homes.

18 VAC 110-20-540

A request was made to allow additional drugs in the emergency box such as oral Schedule II medications or Duragesic patches. Amending these rules would conflict with DEA rules and were not changed.

Public Comment

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

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

An announcement of the board's intent to revise its regulations as a result of its periodic review was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the Public Participation Guidelines mailing list for the board. Public comment was received from October 7, 2002 to November 6, 2002. During the 30-day comment period, there was no comment from the public. There was, however, considerable comment from interested parties during the course of open meetings on the various aspects of pharmacy practice.

To conduct the periodic review and develop proposed regulations, ten advisory subcommittees were appointed with representation from the board and pharmacists who practice in or have specialized knowledge of those areas. Among the ten advisory groups - hospital, retail, home infusion, long term care, corrections, controlled substance registration, free clinics, compounding, initial licensing, and nuclear – there were 44 persons invited to participate and share their recommendations for regulatory reform. Others attended as interested parties. Staff and board members also participated in each of the advisory groups, including pharmacy inspectors who have first-hand knowledge of any problems that pharmacies may have with compliance. Each of the advisory groups identified the issues related to regulation associated with that area of pharmacy practice and prepared a report to the board with its recommendations.

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.

Regulations governing the practice of pharmacy have been thoroughly reviewed by staff of the agency, members of the Board, and various interested parties who participated in the discussions and review of regulations by ten subcommittees representing all aspects of practice. The affected individuals and entities were represented in the reports from subcommittees. Rules that had generated questions from applicants or others were amended following recommendations from staff. The Assistant Attorney General who provides counsel to the Board was involved in 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. These regulations will be reviewed again during the 2007-08 fiscal year.

Family Impact Statement

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

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