Virginia Regulatory Town Hall

Periodic Review and Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Board of Pharmacy
VAC Chapter Number:	18 VAC 110-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Pharmacy
Action Title:	Periodic review
Date:	8/19/02

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

Regulations are promulgated to provide licensure requirements for pharmacists, and permitting requirements for pharmacies, humane societies, manufacturers, wholesale distributors, warehousers and medical equipment suppliers 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.

Standards for practice by pharmacists and for the operation of a pharmacy are established, including requirements for the physical makeup, 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.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The statutory authority for this regulation is found in § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the Code of Virginia.

Section 54.1-2400 establishes the general powers and duties of health regulatory boards including the responsibility to establish qualifications for licensure, to set fees and schedules for renewal, to establish requirements for an inactive license and to promulgate regulations, in accordance with the Administrative Process Act, which are reasonable and necessary to effectively administer the regulatory system.

§ 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.*

Chapters 33 and 34 of Title 54.1 sets forth statutory provisions for the licensure and practice of pharmacists and for the permitting, licensing or registration of pharmacies and other entities handling controlled substances or devices. The applicable Code sections may be accessed at:

http://www.dhp.state.va.us/pharmacy/pharmacy_laws_regs.htm#law

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

An announcement of the board's review of its regulations governing the licensure of pharmacists and pharmacies 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 March 26, 2001 to April 25, 2001. 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, 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. 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. Those recommendations are identified by sections in the regulation under the Substance portion of this report.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The goals for this regulation are as follows:

1) Achieve high ratings on Customer Service Satisfaction Survey for application process and renewal of licensure.

The Board has reviewed the responses of recent licensees and registered facilities on the Customer Service Satisfaction Surveys and determined that the application process and renewal of licensure was effective in that instructions for making application are clear and easy to understand and complete. Of those that responded, 94.3% of pharmacists, 95.6% of pharmacy interns and 98.4% of pharmacies agreed or strongly agreed that the instructions were easy to understand. Asked if the application was processed promptly, 91.5% of pharmacists, 98.5% of pharmacy interns and 93.3% of pharmacies agreed or strongly agreed. Asked if the forms were easy to complete, 96.1% of pharmacists, 97.1% of pharmacy interns and 96.6% of pharmacies agreed or strongly agreed. Therefore, only clarifications in regulations are being considered in the application process.

2) Reduce the number of deficiencies noted on facility inspections.

In 1999, the plan for inspection of pharmacies was revised by the Department to require routine inspections every two years with the intent of reducing deficiencies and improving the safety of

prescription drugs. Therefore, when the new plan was implemented in 2000, there were a number of pharmacies that had not been inspected for several years and deficiencies had not been previously detected. The average number of deficiencies per inspection for that year was 4.34. As the Board intended, the plan for regular inspections has improved compliance and reduced deficiencies, as evidenced by the average per inspection for 2002. Pharmacies being inspected this year are the same ones that were inspected in 2000, and the rate of deficiency per inspection has decreased from 4.34 to 2.95. That is an indication that record-keeping has improved, that security systems are better protecting the drugs and that there is general adherence to the rules for safety and efficacy of prescriptions.

At the same time, the Board is examining ways it can amend rules that inhibit the use of new technology and may create deficiency reports. For example, current language allows a pharmacist to record dispensing data either manually on the prescription itself or in a data processing system. With a change in statute, the Board has adopted a proposed regulation to allow for alternative systems for recording dispensing information.

The summary data of inspections and deficiencies is as follows:

YEAR	INSPECTIONS	DEFICIENCIES	AVERAGE/INSPECTION
1999	680	2028	2.98
2000	1002	4351	4.34
2001	892	2874	3.22
2002 (YTD)	516	1545	2.95

3) Review regulations for unnecessary barriers to new technology or reduction in pharmacist workloads which might improve error rates and consumer safety.

As newer technology is coming to market at the same time increasing numbers of prescriptions are being written, the Board is constantly faced with the challenge of protecting the safety and integrity of prescription drugs consistent with the statutory mandate in Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*. Since the *Code* often dictates the content of a prescription, the method of record-keeping and the process for dispensing, the Board's regulatory response to changing practice and efforts to reduce medication errors must typically follow a change in statute. In some cases, the desired change in practice or implementation of technological advances raises issues of patient and drug safety. To ensure that a proposal does not compromise the safety and integrity of prescription drugs, the Board has supported the use of pilot projects where new methodology can be implemented in a controlled environment.

To authorize the approval of pilot projects, § 54.1-3307.2 of the Code of Virginia was added in 2000; emergency regulations became effective in 2001and final regulations in 2002. The Code is specific about the content of the application for approval of a pilot project to include safety issues, potential benefit to the public, promotion of technical or scientific advances, compliance with prescriber instructions, potential for diversion, impact on costs, means of monitoring and providing quality assurance, and the reporting of outcomes to the Board. Through the informal conference process, the Board has the opportunity to review a proposed project, determine which provisions of law or regulation would need to be waived, evaluate its merits and safeguards, and set certain conditions for implementation and outcome in an order which would be signed by the

Board and the applicant. Requirements of law and regulation for approval of a pilot program or project are necessary and sufficient to address concerns about patient safety and the risks of drug diversion. To date, three pilot projects have been approved; and two more applications are pending a hearing before a committee.

Another example of the Board's response to technology and removing barriers to changes in pharmacy practice is the rule governing approval of a robotic system. Beginning in January 2001, pharmacies that wanted to use robotics to fill prescriptions in a hospital or long term care facility may seek approval of such a system by an informal conference committee of the Board based on an inspection of the system and on a quality assurance plan adopted by the pharmacy. Application and inspection fees were established to offset the costs of initial approval or review of a modified system. Amendments to regulations were adopted pursuant to a petition for rule-making that requested a Board waiver of its requirement for a final check by the pharmacist if a drug is being dispensing by a robotic pharmacy system which assures accuracy of the final dispensing point through bar scanning technology. To date, six robotic systems have been approved.

The Board has also suggested updates to several statutes affecting the practice of pharmacy to conform to current practice. Laws passed in the 2002 Session of the General Assembly will: 1) expand the use of "chart orders" which may contain more than one prescription order to hospice patients and patients receiving home infusion, 2) allow pharmacies to use a combination of computer and manual records when necessary to maintain accurate records of dispensing, and 3) allow for delivery of prescriptions to locations other than directly to the patient pursuant to regulations of the Board. The Board has adopted emergency regulations to implement new provisions and intended to replace them with permanent regulations.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

Throughout the periodic review, there have been numerous alternatives suggested for individual regulations but no alternative to adoption of regulations for the practice of pharmacy. To offer further clarification or explanation for pharmacy rules, the Board has adopted 31 Guidance Documents, but they are interpretative rather than enforceable and therefore do not provide a viable alternative to regulation. In fact, several of the advisory groups made specific suggestions for inclusion in the regulation of language currently found in a guidance document. For example, the subcommittee on free clinics has requested that language in Guidance Document 110-22 on access to the pharmacy in a free clinic be included in the rules, so pharmacists are clear about the ability of non-pharmacists to access the pharmacy under certain circumstances.

In addition, several of the comments or requests for rule changes from the subcommittees cannot 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 have also been adopted by the Board.

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.

Finally, in the development of amended regulations, the Board will study the overall structure of regulations governing the practice of pharmacy. There may be a need to reorganize or combine certain sections with similar rules, so the regulated entities have greater clarity. The Board will also consider the possibility of repealing the current regulations and promulgating several sets of regulations aimed at varying practice settings. As the practice of pharmacy has become more complex, the number of rules has grown to over 700; it can be cumbersome to the regulated entities to find a particular rule that applies to a situation in their practice. While that would necessitate some duplication of rules that apply to all pharmacists or pharmacies, the resulting regulation would be more concentrated and may be beneficial in terms of clarity and compliance. So, for example, all of the rules governing the practice of hospital pharmacy would be stated in one set of regulations, while the rules for the licensure, practice and renewal of a pharmacist license would be in another. The Board will look at model regulations of the National Boards of Pharmacy (NABP) and rules from other states in making a determination on the structure and format to propose.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

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 Board intends to amend 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 detail any changes that would be implemented.

18 VAC 110-20-30. Requirements for practical experience.
The subcommittee on initial licensing questioned how the 300 hours of experience in compounding/dispensing is verified. Rather than amend the regulation, the Board may be able to modify the form to request more specific information.

18 VAC 110-20-40. Procedure for gaining practical experience.
Some states do not use clerkships to gain practical experience in pharmacy but rely instead on the pharmacy school to certify the hours of experience. Currently, the rule in Virginia is that practical experience gained within any state must be registered with and certified by the board of that state in order to be accepted or certified by this board. The Board will consider whether a change to allow the schools to certify experience would continue to ensure that students have had practice in all essential aspects of pharmacy.

18 VAC 110-20-60. Content of the examination and grades required; limitation on admittance to examination.
Current regulations require an applicant who has failed the examination three times to complete an additional six months of practical experience as a pharmacy intern. An amendment may be necessary to clarify the number of hours equivalent to six months and the process for gaining the additional experience.

18 VAC 110-20-70. Requirements for foreign trained applicants.
The Board will consider adoption of model language from the National Association of Boards of Pharmacy on licensure of foreign trained applicants.

18 VAC 110-20-80. Renewal of license.
There has been discussion of the advantages and disadvantages of an annual versus biennial renewal. The Board concluded that it should study the issues while pharmacists and pharmacies have a chance to absorb the increased annual fee. To recommend a biennial renewal would automatically double the renewal fee, which might be more burdensome on licensees.

18 VAC 110-20-90. Requirements for continuing education.
Several issues were raised including the need to allow more flexibility in acquiring hours, the possibility of requiring live hours, and the possible need to require specific hours in drug laws. There is also consideration of including in regulation all or part of the guidance document on sanctions for failure to comply with continuing education requirements.

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 Board has interpreted the statute to mean that a pharmacist could only be the PIC for one pharmacy location. There is some interest in expanding that interpretation to permit the pharmacist to serve as PIC for more than one pharmacy, but it is uncertain as to whether the Board could amend its regulation without a change in the Code.

Current regulations require a revised permit application to be filed within 14 days when a new PIC is named; after the 14-day deadline, the pharmacy is not to operate. The Board would like to consider extending the number of days required for naming a new PIC or provide for some type of notification and waiver request for extenuating circumstances.

18 VAC 110-20-130. Pharmacy closings, going out of business, and change of ownership.
The Board considered some situations in which a change of ownership has occurred and the two pharmacies have experienced difficulty in meshing the two data systems to allow patient information is transferred to the new owner without disruption in pharmaceutical services. The Board determined that the requirement for transfer of data is essential for public safety and did not recommend a change. The previous owner or seller is held responsible for assuring the transfer of records; amendments may be necessary to specify that it is his responsibility to provide adequate resources or training to ensure continuity of services.

18 VAC 110-20-135. Change of hours in an existing pharmacy.
The rules may need to be amended to designate who is responsible for notification to the Board of a change in hours, whether the responsibility should fall to the pharmacist-in-charge or the owner.

18 VAC 110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.
It may be necessary to conform the regulations in subsection B to HIPAA requirements on confidentiality of patient records, because currently 18 VAC 110-20-380 permits prescription records to be available to anyone other than authorized persons at the permitted pharmacy acquiring the records if patients are notified in writing. However, it may be better to repeal or amend section 380 as it is most likely inconsistent with HIPPA and is inconsistent with § 32.1-127.1:03.

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 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.

There are also questions about the requirement for a new inspection if the footprint of the pharmacy remains the same but the walls are expanded. Amendments may be necessary to

clarify that any changes that would affect the coverage of the alarm system requires a re-inspection to ensure drugs are protected.

18 VAC 110-20-150. Physical standards for all pharmacies.
The prescription department of a pharmacy is required to have a minimum of 240 square feet. Questions have arisen about whether the footage may include a separate area used for counseling, so the Board needs to clarify that requirement.

The Board will consider whether this section should be amended to allow the use of trailers or other moveable facilities in situations where there has been a natural disaster, a fire or other catastrophic event. Legislation proposed by the Board would permit the waiver of this or any other requirement in times of officially declared emergencies or disasters. If enacted, it would likely make regulatory action to address the issue unnecessary. Additionally, the Board may already waive regulations through a special use permit and has used this tool in past emergency situations.

A question has been raised about the necessity of a requirement for a sink with hot and cold running water in the immediate compounding and dispensing area. The Board will consider its elimination. The Board will also consider the need for requiring that a refrigerator be maintained within the prescription department versus at some other location accessible to the pharmacist.

The hospital subcommittee raised a question about whether the size requirement for hospital pharmacies should be different from the 240 sq. ft. requirement and proportionate to the number of beds, but that change was not recommended but the hospital pharmacy should be contiguous to the hospital floors. There is also a need for clarification on satellite pharmacies as to whether the space in those pharmacies could be added together to make up the required space.

18 VAC 110-20-160. Sanitary conditions.
There is a question about the meaning of the term “entire area” in the requirement for it to be maintained in a clean and sanitary manner and in good repair and order; some have wondered what that means and whether that includes the stock room or other such areas. The Board may choose to clarify and further specify the requirement or leave it discretionary to be judged on a case-by-case basis.

Subsection B may be combined with subsection A or deleted since subsection A seems to cover all areas of the prescription department.

18 VAC 110-20-170. Required minimum equipment.
The Board will consider amendments to clarify that a pharmacy may use electronic resources related to the type of pharmacy practice in place of the paper copies of pharmacy laws, regulations, guidelines and other resources.

18 VAC 110-20-180. Security system.
The Board will consider amending the rule requiring that only the pharmacists working at the pharmacy should have access to the alarm system for the prescription department. There may a

need for some alternative in situations where the pharmacist becomes ill, and it is necessary for someone else to enter the prescription department to retrieve a prescription. For security reasons, the Board would need to adopt some policy for notification or guidance about the circumstances in which someone else could have access. The subsection in section 180 may be combined with subsection B 2 in 18 VAC 110-20-190, dealing with provision of a key or access code by the pharmacist to another person and may be amended to provide for other forms of security locking such as a punch pad.

18 VAC 110-20-190. Prescription department enclosures.
The Board has 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 may also be unnecessarily prescriptive and burdensome.

The requirement for a locking device to prevent unauthorized entry in the absence of the pharmacist may need clarification. Varied interpretations have been given, and there is question as to whether this requirement is necessary. With newer technology, some of the terminology used for security rules may be outdated and too rigid.

The Board will consider inclusion in regulation of the "guidelines for waivers for free clinics related to access to the pharmacy," which is currently adopted as a guidance document. Representatives of free clinics in Virginia have requested an amendment to permit entry to the pharmacy by two persons if, after a diligent attempt to do so, the PIC cannot be located to give permission for the designated individuals to enter. A written record of such entry would have to be maintained and the PIC notified within 12 hours.

18 VAC 110-20-200. Storage of drugs, devices and controlled paraphernalia.
There may be a need to clarify the requirement for a prescription awaiting delivery to be placed in a "secure place" outside of the prescription department with access limited to pharmacists and clerical assistants.

The restriction on controlled paraphernalia being placed on "open display" has varied interpretations and may be eliminated as unnecessary. The Board needs to address and clarify issues related to syringes, contrast media and other schedule VI medical devices and drugs such as IV solutions that must be maintained in locations other than the pharmacy. Security requirements for these types of controlled substances may need to be clarified.

18 VAC 110-20-220. General requirements for pharmacies providing radiopharmaceutical services.
The Board will consider deleting the requirement that radioactive drugs be separated from non-radioactive drugs. It may also need to clarify certain requirements in the policy and procedures manual. It may also consider amendments to permit qualified practitioners (such as nuclear technologists) or persons other than pharmacists to have access to the licensed area in emergency situations.

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

Current regulations permit the maintenance of records in a database at a site away from the pharmacy but do not allow that for paper records. The Board will consider whether paper records are essential or whether it might be possible to permit records to be scanned into a database, provided it can preserve and provide an exact image of a prescription for inspection. If paper records are maintained, the Board will consider permitting those records to be maintained off-site provided they can kept in Virginia and can be retrieved within a set time period (probably within 48 or 72 hours).

Other issues related to a combination system of manual and automated records and the use of chart orders for home infusion and hospice patients have already been addressed in adoption of emergency regulations resulting from changes in the Code in 2002. The Board may recommend combining requirements in sections 240 and 250 to achieve the desired result of a system that has accountability for order entry and for drug distribution regardless of the methodology used.

18 VAC 110-20-250. Automated data processing records of prescriptions.
"The hard copy" of a prescription is required but may be clarified to include a format other than a paper copy. This section may appropriately be combined with section 240 on manner of maintaining records.

18 VAC 110-20-270. Dispensing of prescriptions; acts restricted to pharmacists; certification of completed prescriptions.
The Board will consider a recommendation for language consistent with the American Pharmacists Association guidelines for duties/training of nuclear pharmacy technicians to allow certified nuclear pharmacy technicians to be able to take verbal orders for diagnostic tests, but not therapeutic doses. This section is also being amended for consistency with the new law on registration of pharmacy technicians.

18 VAC 110-20-280. Transmission of a prescription order by facsimile machine.
The Board will consider a recommendation to allow orders for radiopharmaceuticals to be transmitted by standard facsimile machine or by utilizing dedicated nuclear medicine software systems. Such orders must originate at an institution or healthcare facility licensed to receive and possess radiopharmaceuticals, and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions. Radiopharmaceutical orders are understood to have originated with an authorized nuclear physician at the ordering facility and a signature is not required.

There is also a recommended change in the language regarding facsimile transmission shall occur only with permission of the patient. Some would like ability for a nurse agent of a physician to "refax" an order. For example a discharge order from a hospital may be faxed to the nursing agency which is picking up care for a patient. The nursing agency would like to be able to further fax that order to a pharmacy. Clarification may be necessary as to whether pharmacy address and phone number is required for faxed prescription.

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

The Board may want to consider combining sections 280 and 285. Clarification may be needed to specify whether an electronic transmission has to be from a practice location similar to the faxed prescription.

18 VAC 110-20-330. Labeling of prescription as to content and quantity.
The Board will consider the need to add a requirement for "beyond-use dating" on each prescription. There has been consumer interest in such a requirement for a number of years, but the Board has been unable to come up with a dating system that gives the consumer an accurate date for each individual drug. Factors such as variations in storage conditions make it difficult to adopt a policy for "beyond-use dating." The United States Pharmacopeia has now adopted guidance on dating, which the Board will consider and may want to incorporate by reference.

If a drug contains a single active ingredient, it must have the generic name on the label; that requirement may need to be clarified for some pharmacists. Also the Board may eliminate some labeling requirements where the drugs are not being self-administered, such as in adult home where directions for dosage are on the medical record.

18 VAC 110-20-350. Special packaging.
The Board will consider modifying the record-keeping requirement for special packaging to permit an electronic record of a request for non-special packaging.

18 VAC 110-20-355. Pharmacy repackaging of drugs; records required; labeling requirements.
Since the pharmacist may not actually oversee or personally supervise the process of repackaging of bulk drugs, the Board will consider modifying the regulation to require the initials of the pharmacist who verified the accuracy of the repackaging rather than the pharmacist who supervised the process.

There may also be amendments needed to the repackaging requirements related to lot numbers, expiration dates and returns for resale related to new computerized dispensing systems, such as Baker cells. There Board will consider adopting the United States Pharmacoepia (USP) guidelines for repackaging; such a change would result in less specific state regulation but would alleviate the need for change whenever USP changes the standard.

18 VAC 110-20-412. Policy and Procedure Manual.
In the rules for compounding, a policy and procedures manual is required. The Board may consider adopting the USP guidelines for sterility, but the P & P manual may allow more flexibility, especially for hospitals.

18 VAC 110-20-414. Labeling requirements.
There is concern that there are different standards for out-of-state pharmacies which may be lower than in-state. Current law requires non-resident pharmacies to comply with requirements of resident 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 likely 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. Quality assurance.
Current regulations require all laminar flow hoods or other environmental control devices to be certified according to accepted standards for operational efficiency by a qualified independent contractor at least every six months; the Board will consider changing the standard to once a year or after relocation.

18 VAC 110-20-416. Records for sterile compounding.
These requirements may need some clarification regarding the difference between compounding for administration vs. bulk compounding in pharmacy. With IV's (Pyxis) piggyback or mini bag plus-Advantage System, the current rules may not be practical; some clarification is needed.

18 VAC 110-20-420. Unit dose dispensing system.
The Board may need to look at definitions and review USP definitions related to unit dose. In order to be considered unit dose, there needs to be the lot number on the individual unit so that in the event of recall the dose can be tracked back. With some systems, the original lot number is lost if recycled, but JCAHO requires lot numbers and procedure for recall. Also there was a request to amend the definition of unit dose system, with respect to directions for use, to allow some systems which do include directions for use to be considered unit dose systems. There may also be a need for clarification of the seven-day system and a "back-up" dose, and a request for clarification for "open ended" orders with no quantity specified and no expiration date on the order.

18 VAC 110-20-440. Responsibilities of the pharmacist-in-charge.
The hospital subcommittee recommended an amendment to drop the requirement for a monthly review of charts by the pharmacist if a patient is treated in the hospital for a period of one month or longer.

18 VAC 110-20-450. After-hours access to the pharmacy.
There is a recommendation to change the phrase “supervisory nurse” to “authorized nurse” as the nurse who may have access to the pharmacy in the absence of the pharmacist in order to obtain emergency medication.

18 VAC 110-20-460. Floor stock drugs; proof of delivery; distribution records.
The Board will address the recommendation to allow off-site storage of distribution records provided they are retrievable within a certain period of time (probably 48 hours).

18 VAC 110-20-470. Emergency room.
The Board may address the issue of "starter packs" for indigent patients and also allowing a separate record for the emergency room because the pharmacist-in-charge finds it difficult to be responsible for something not done by pharmacy staff.

18 VAC 110-20-480. Pharmacy services.

There is a request to add "volunteers"to the list of persons who can utilize an in-house hospital pharmacy. Some information provided suggests that they are considered "employees" under Robinson-Patman; and there may be a limit who can get prescription services based on contracting/pricing. This section may need to be reviewed as to whether it should be included in these regulations as it may not have any relation to public protection.

18 VAC 110-20-490. Automated devices for dispensing and administration of drugs.
This section may need some clarification (or perhaps a guidance document) for audits on automated devices in hospitals. Current wording requires all records to be audited every day, and some contend that this is not feasible, although this same auditing is required in a manual system.

18 VAC 110-20-500. Licensed emergency medical service agencies program.
The term “technician” will have to be clarified to distinguish EMS personnel from pharmacy technicians.

18 VAC 110-20-510. Identification for intern or resident prescription form in hospitals.
The current system of allowing residents and interns to use the hospital Drug Enforcement Administration (DEA) number in writing prescriptions does not allow for good tracking of their prescriptions. There are questions as to whether attending physicians may use the number and questions as to whether interns and residents may use it when the residency program is off-site from the hospital.

18 VAC 110-20-530. Pharmacy's responsibilities to long term care facilities.
In long term care, most orders for Schedule VI drugs do not reflect quantity or duration of therapy; pharmacist may calculate this based on protocol, etc. There may be a need for exemption like there is for chart orders, so all prescription information is not required for doctor’s orders for long term care patients. Also there may be a need to amend the 30-day requirement for drug destruction to apply only to those drugs stockpiled at the facility, not for those that can be returned to pharmacy. Those drugs may only be sent to the return location several times a year.

There may be a need to separate assisted living facilities from long term care facilities. Certain requirements may be unnecessarily burdensome, such as the requirement for the physician to review charts for recertification of orders. When an individual living in an assisted living facility is discharged from a hospital, the hospital often refuses to fax the discharge order to the provider pharmacy. Rules may need to permit the facility to fax the order to avoid a delay in patient care. There is also a request to clarify what constitutes a valid prescription for assisted living, e.g. is a chart order sufficient.

18 VAC 110-20-540. Emergency drug kit.
The long term care subcommittee recommended to the Board that an amendment be considered to allow additional drugs in the stat or emergency boxes. There is a need for doses of oral Schedule II medications and for Duragesic patches. Amending these rules may be a problem, because they cannot conflict with DEA rules. Clarification is also needed about whether facilities using medication aides can have stat and emergency boxes; the intention of the

regulation was that only places where nurses were administering could have them, but that needs to be stated in plain language.

18 VAC 110-20-550. Stat-drug box.
The Board may need to require for the form to include the person who removes the drug from the stat box for better tracking.

18 VAC 110-20-555. Use of automated dispensing devices.
The Board has received a request for the use of automated dispensing devices in long term care but is concerned about issues related to security and medication errors. In developing proposed regulations, there will be further discussion and consideration of the issue.

18 VAC 110-20-560. Floor stock.
There was also a request to allow floor stock on long term care units within hospitals. That issue will be reviewed further as well.

18 VAC 110-20-590. Drugs in correctional institutions.
Rather than being required to return drugs directly to the provider pharmacy for drug destructions, there is a request to permit the institution to return drugs to a secondary pharmacy or directly to a destruction company. Other issues that will be considered are the removal of the requirement for the prescription number to be on the administration record and changes to the stat box provisions. Current emergency and stat box provisions do not take care of needs under existing conditions where out of state pharmacies have the contract to provide services to Virginia correctional facilities.

18 VAC 110-20-710. Requirements for storage and security for controlled substances registrants.
There is a need for clarification about when an alarm system is required; it may not be necessary for certain entities such as researchers and animal control officers.

Family Impact Statement

Please provide a preliminary 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 effect on family income.