Virginia Regulatory Town Hall

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Periodic Review
Date this document prepared	3/23/08

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The agency is amending regulations 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.

Some of the issues being addressed by amendments to regulations include: 1) Practical experience leading up to licensure by allowing interns to count hours within the school curriculum and by clearly delineating expiration dates for internships; 2) Oversight of continuing education approval by setting expiration dates for courses; 3) Guidance for free clinics to allow greater access to areas where drugs are kept; 4) Oversight of pharmacy technician training by setting a time limit on work by a person engaged in a program and an expiration for programs approved by the Board; and 5) Elimination of board approval of robotic systems by incorporating criteria for such systems in regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to 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:
…
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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …

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/cgi-bin/legp504.exe?000+cod+TOC5401000

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

Regulations of the Board of Pharmacy are complex and broad in scope and applicability to a variety of practice settings. Periodically, it is necessary to review and revise to clarify existing requirements, add new language to address problems that have arisen, delete outmoded regulation, or revise requirements to allow for newer technologies. In revising requirements adapted to the current practice of pharmacy, the Board has acted to preserve or construct appropriate safeguards to help ensure safety in practice and in the efficacy and integrity of the drugs being dispensed.

In its promulgation of amended regulations as described in the substance section of this document, the Board has incorporated interpretative language now found in several guidance documents and included some provisions that have been tested in pilot programs that are currently approved. While guidance statements advise practitioners on policy matters, they are not enforceable and cannot be relied upon for compliance. Therefore, incorporation of guidance into regulation will make policies more explicitly clear for licensees. Likewise, less restricted

policies in pilot programs that have shown to be effective and efficient without any increased risk of medication error have been incorporated in regulations.

The Board identified issues with 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The following sections of the regulations have been addressed in the promulgation of amended regulations:

18VAC110-20-10. Definitions.
Several definitions were added to clarify existing or amended regulations. For example, the definition of a correctional facility was added to clarify the term and be more inclusion of all types of facilities. Some terms were defined, such as "chart order," for more flexibility, and others, such as "NABP" were defined to enable use of the acronym in regulation.

18VAC110-20-20. Fees.
Since there is an expectation that pharmacy technician programs are modified frequently to reflect changes in medications and pharmacy practice, the Board is adding a fee of $75 for renewal of program approval every two years; there are associated fees for late renewal and reinstatement.

18VAC110-20-30. Requirements for practical experience.
Current requirements of the Board were made consistent with new ACPE standards for preceptors and experiential training, so amendments to section 30 conform to national standards for pharmaceutical preceptors and practical experience in order to facilitate reciprocity.
Subsection C requires practical experience can be gained only after completion of the first professional year, but it is unclear when first professional year ends as some schools now operate year-round rather than in semesters. The Board has set completion of certain core curricula as criteria for practical experience and set time limitations on the credit that can be given.

18VAC110-20-40. Procedure for gaining practical experience.
Currently, pharmacy intern permits are issued for the period of pharmacy schooling. The Board will consider an extension of that time frame for good cause and with a specified expiration date and a limitation of the years of an internship.
The number of interns that may be supervised may be problematic when the internship programs at different pharmacy schools overlap. The Board eliminated the restriction on supervision of one pharmacy intern during the same time period to alleviate a barrier to obtaining a preceptor,

but retained the principle that the primary assignment of an intern to a preceptor must be one-to-one.

18VAC110-20-60. Content of the examination and grades required; limitation on admittance to examination.
The current regulation does not require an applicant to wait a certain time period to take the jurisprudence exam if he has failed it multiple times. There is concern with the security of test items for computerized testing, so the Board has set a 30-day requirement for retesting. Provisions of guidance document 110-39, relating to Americans with Disabilities accommodations for taking the NAPLEX and law examination have been incorporated into section 60.

18VAC110-20-70. Requirements for foreign-trained applicants.
The regulations are amended to clarify that an applicant must pass the Foreign Pharmacy Graduate Equivalency Examination before becoming an intern. If an applicant cannot pass the FPGEE, the years spent in an internship may be wasted and the public may not be well protected.

18VAC110-20-80. Renewal and reinstatement of license.
The Board added a provision to allow electronic notification when there is a change of address and also added a time frame of 14 days for notification, rather than "immediately."

18VAC110-20-90. Requirements for continuing education.
In subsection A, the date listed is unnecessary and is deleted. Subsection D is amended to require maintenance of CE documentation for three years, if the Board chooses to audit for the previous two renewal cycles.

18VAC110-20-100. Approval of continuing education programs.
Amendments will require a Board-approved program to have an expiration date; ACPE has an expiration of three years for a written program and one year for a live program. If a live program is to be given more than once, all dates must be on the original application or provided in advance of the program. In addition, the requirement for maintenance of records should be increased from three years to five years for auditing purposes; ACPE requires approved programs to maintain documentation for five years.

18VAC110-20-101. Application for registration as a pharmacy technician.
An amendment will clarify that an individual enrolled in a Board-approved pharmacy technician training program may work for a maximum of 9 months prior to Board registration (would include language from 18VAC110-20-111 (C).

18VAC110-20-102. Criteria for approval for training programs.
There are amendments to further specify a process and requirement for submitting changes to programs and to require programs to self-evaluate the currency of a training program and renew with the Board every two years.

18VAC110-20-103. Examination.

Provisions of guidance document 110-39, relating to Americans with Disabilities accommodations for taking the pharmacy technician examination were incorporated into section 103.

18VAC110-20-104. Address of record.
The current provision allows thirty days for notification of a change of address; the Board added a more restrictive requirement (14 days) but not as restrictive as the current requirement for pharmacists, which is to notify "immediately." There should be consistency in the rules. The Board also will allow for electronic communication and will require the technician to maintain a copy of current registration at his principal place of practice.

18VAC110-20-106. Requirements for continued competency.
Subsection B should appropriately reference 18VAC110-20-100, which sets out requirements for Board approval of continuing education providers. The requirement to maintain documentation of CE has been changed from 2 years to 3 years to ensure CE certificates are available for Board audits.

18VAC110-20-110. Pharmacy permits generally.
Amendments will delete the requirement for the outgoing PIC to take a final inventory but will allow him to do so unless the owner objects and submits written notice to the Board.
An amendment is added to ensure that a permit can not be issued to operate a pharmacy from a private residence or dwelling and that more than one permit may not be issued to operate other types of permits out of the same Rx department space; e.g. a pharmacy could not also get a second pharmacy permit, or a manufacturer's permit to operate both businesses out of the same physical space. There may be an exception for special or limited-use pharmacy permits.

18VAC110-20-111. Pharmacy technicians.
The Board has added a requirement for a pharmacy to maintain the start date and completion date for each pharmacy technician in training; there is a nine month limitation on performing pharmacy technician related duties when in training, but inspectors are not readily able to check whether the individual is in compliance.

18VAC110-20-120. Special or limited-use pharmacy permits.
Guidance document 110-22 provides guidelines for granting waivers relating to restricted access to a free clinic pharmacy under a special-use permit; the Board has placed the criteria in regulation.

18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.
An amendment is needed to require a closing pharmacy to transfer prescription files somewhere where a patient can access.

18VAC110-20-140. New pharmacies, acquisitions and changs to existing pharmacies.
Language is added to specify that once a pharmacy permit is issued, drugs cannot be stocked earlier than 2 weeks prior to the opening date, and that a pharmacist must be present on a daily bases to ensure safety and integrity of the drugs. If the pharmacy is not ready to open within 2 weeks, the permit holder must notify the Board.

18VAC110-20-180. Security system.
The regulation requires all alarms to be monitored in accordance with accepted industry standards and be capable of sending a signal to the monitoring entity.
The Board will require an alarm that was "grandfathered" to be upgraded if there is a break-in and loss of drugs. If a pharmacy that is open 24 hours a day changes its hours, it must have an alarm system installed before it closes.

18VAC110-20-190. Prescription department enclosures; access to prescription department.
Subsection A is amended to eliminate the specific requirement for a door to the prescription enclosure and provided that the enclosure must be locked and alarmed when the pharmacist is not on duty and that it must be capable of being locked whenever the pharmacist is out of the prescription department.
Subsection B is clarified with updated terminology. Language is added to allow interns, technicians and other persons authorized by the pharmacist to possess a means of entry only when a pharmacist is on duty.

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.
There is a clarification of the storage and security of will-call drugs, and the Board has added medical devices similar to drug paraphernalia that cannot be displayed outside the Rx department. It has also clarified that adulterated or misbranded drugs must be separated from other stock used for dispensing.

18VAC110-20-210. Disposal of drugs by pharmacies.
The Board has added "other board-approved methods" to disposal by incineration, in case other methods become DEA or EPA approved.

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.
The Board has required a perpetual inventory for Schedule II drugs to include a monthly count-back to reconcile count at least every 30 days. Electronic monitoring is acceptable provided alerts of discrepancies are reviewed at least monthly.
The Board has clarified that storage of records for Schedule II through V drugs must be at the same address as the pharmacy within the building where drugs are located, but amendments provide for an electronic database or storage offsite for Schedule VI drugs provided they are retrievable within 48 hours of request. The records are required to be maintained for not less than two years from the date of transaction.

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.
The Board has eliminated the ratios of pharmacist to technician trainee and pharmacy technicians; the pharmacist may determine the number that he can safety and competently supervise at any one time.
In subsection E, the Board added a requirement to retain knowingly forged prescriptions for at least 30 days in the event it is needed for an investigation.

18VAC110-20-275. Delivery of dispensed prescriptions.

A rule is necessary to require that the contract and policy and procedure manual for alternate delivery sites be maintained at both pharmacy and the alternate site.
A controlled substance registration can only be issued for alternate delivery sites if there are patient safety reasons not to deliver directly to the consumer and if compliance are not being compromised for convenience. The language "if required by law" will be removed in subsections B and C

18VAC110-20-280. Transmission of a prescription order by facsimile machine.
The rule is clarified to mean that a hospice can be home hospice, and the term "nursing home" should be changed to long term care facility. Amendments will also provide that a nurse may fax a verbal order as a prescriber's agent even though the order is not being faxed from prescriber's practice location.

18VAC110-20-286. Chart orders for outpatients
New language was added to set out conditions from guidance document 110-35 that would allow retail pharmacies to use chart orders.

18VAC110-20-320. Refilling of Schedule III through VI prescriptions.
Subsection D is amended to allow for early refill due to good cause or absence (vacation).
That subsection is also amended to clarify that the intent is refering to the timing of refills and not about the ability to change Rx based on the strength of drug in stock.

18VAC110-20-340. Packaging standards for dispensed prescriptions.
The Board has included provisions of Guidance Document 110-12 and Guidance Document 110-23 on packaging.

18VAC110-20-350. Special packaging.
Amendments eliminate language redundant with the statute and update the language consistent with electronic records.

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.
An amendment will require pharmacist's initials to filling record for automated counting devices or dispensers to verify process as stated in subsection A.
Amendments to add language from Guidance Document 110-16 related to returning drugs to stock that are dispensed to a patient but not picked up from the pahrmacy.

18VAC110-20-391. Prescription blanks.
Language from a Board guidance document related to what can be on the face of a prescription blank provided by a pharmacy to a provider is included in regulation. It prohibits non-essential information from being put on the face of the prescription blank.

18VAC110-20-395. Purchase of drugs.
An amendment is necessary to allow for a non-licensed warehouse to sell to pharmacy through intra-company sales.

18VAC110-20-425. Robotic pharmacy systems.

The Board has eliminated the requirement for an application and approval of a robotic pharmacy system and included the requirements for such a system in regulation. Among the rules set out are packaging standards for drugs stored in robotics and consistency with USP standards.

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.
An amendment is for clarity only.

18VAC110-20-450. After-hours access to the pharmacy.
The rules for after-hours access to pharmacy are now in conflict with JCHAO standards, so the Board has revised this section to permit a nurse to have access to drugs maintained by the pharmacy outside the pharmacy. There are also provisions for security of such drugs.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.
Amendments were added to: 1) require a pharmacist to check drugs before leaving the pharmacy to be stocked on the floor; 2) require maintenance of manual or electronic delivery records for at least 2 years; and 3) require records to be maintained for Schedule VI, as well as II-V, but allow the records to be kept off-site.

18VAC110-20-490. Automated devices for dispensing and administration of drugs.
The Board tracked the language in 555 (5) related to requiring a pharmacist to check delivery orders before they leave the pharmacy. It requires maintenace of records of filling for Schedule VI and auditing records of Schedule VI, but allows pharmacies to keep these records electronically or off-site. There is a clarification of what a "sample of administration" and a requirement to retain all records required by this section for 24 months.

18VAC110-20-500. Licensed emergency medical services agencies program.
Amendments will: 1) require a pharmacist to check before sealing the drug kit used by EMS agencies; and 2) allow for intravenous solutions to be stored outside the drug box.

18VAC110-20-535. Repackaging of already dispensed prescriptions.
This is a new section that incorporates a Board guidance document into regulation. This section will allow a provider pharmacy for a LTCF to repackage a patient's medications that have been dispensed by another pharmacy into unit-dose or compliance packaging to conform to the system used in the LTCF under certain conditions.

18VAC110-20-536. Prescription drugs sent outside the facility.
This new section, which incorporates language from a Board guidance document into regulation, allows a long term care facility to send a patient's medication out on pass with the patient, provided the medication is appropriately packaged and labeled for outpatient use.

18VAC110-20-540. Emergency drug kit and 18VAC110-20-550. Stat-drug box.
These section was amended by incorporating language from guidance document 110-11 to clarify that emergency drug kits and stat-drug boxes may only be provided to those facilities that have licensed individuals to access the drugs, so assisted living facilities that use med aides to administer could have a stat-drug box, if they have a nurse on duty for accessing the box.

18VAC110-20-555. Use of automated dispensing devices.
Amendments allow the device in nursing homes to be use to house drugs that would be in the emergency kit and be accessed prior to receiving electronic authorization from the pharmacy reviewer. They also require that the device be able to produce a record of each distribution from the device. This is consistent with hospital language for these devices.

18VAC110-20-570. Drugs in infirmaries/first aid rooms.
Subsection D was deleted as it pertains to administration of over-the-counter drugs, which are not regulated by the Board of Pharmacy.

18VAC110-20-580. Humane societies and animal shelters.
An amendment specifies that the record of training for persons at a humane society or animal shelter should be maintained at the facility and retained for two years. It is also clarified that only euthanasia drugs can be stored or administered at permitted facility.

18VAC110-20-590. Drugs in correctional institutions.
Amendments allow for the use of other types of forms to accompany returned drugs to the pharmacy; it is currently restricted to drug administration record and facilities to stock certain prescription drugs, including vaccines, with a controlled substances registration.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.
Amendments conform requirements for inspection to other pharmacy types and clearly specify who can be a responsible party for a controlled substance registration (CSR).

18VAC110-20-700. Requirements for supervision for controlled substances registrants.
The Board has amended to:

- Require the responsible party to inform the board of a change within 14 days and submit a new application naming the responsible party for the CSR.
- Allow pharmacy techs to have access to the controlled substances to perform certain tasks.
- Clarify who may qualify as supervising practitioner to include all practitioners with prescriptive authority.

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.
Changes were made to the requirements for the security system to mirror the language for pharmacies.

Issues

Please identify the issues associated with the proposed regulatory action, including:
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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

There are no particular advantages or disadvantages to the public or the Commonwealth. Amendments that clarify the requirements for regulants may reduce non-compliance. Amendments that facilitate the use of technology, such as those for robotic pharmacy systems, may improve access and accuracy in the dispensing process.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements more restrictive than applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected by the proposed regulation.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Elaine J. Yeatts, Senior Policy Analyst, Virginia Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233; Email: elaine.yeatts@dhp.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	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. There would be a one-time expense of approximately $3,000 for promulgation of the amended rule, including meetings of the Regulation Committee at which this regulation has been developed. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There are no on-going expenditures for the agency related to amendments to regulations.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The businesses affected would be: 1647 pharmacies permitted in Virginia 513 non-resident pharmacies The individuals affected would be: 9491 pharmacists 8750 pharmacy technicians 1415 pharmacy interns The entities affected would be: 613 controlled substance registration 34 humane societies
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	It is unknown how many of the permitted pharmacies are small businesses, but the number would be a small minority. Most pharmacies are now owned by large, national corporate chains.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	• There are approximately 80 approved pharmacy technician programs. They would incur a biennial cost of $75 for renewal of Board approval. • Costs for maintaining CE documentation for 3 years rather than 2 years would be miniscule.

	Cost-savings would include: • Allowing students to use school hours of experience; eliminating the additional 300 hours • Elimination of $150 fee and cost of an informal conference for approval of a robotic pharmacy system • Elimination of ratio of techs and interns per pharmacist reducing costs for pharmacies • Allowing maintenance of certain records and invoices off-site or by electronic means • Elimination of specific requirements for pharmacy enclosures allowing chains to use industry template for new pharmacies

Alternatives

Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

In order to conduct a thorough review of pharmacy regulations, the Board assigned the task to an Ad Hoc Committee on Regulatory Review to recommend changes for clarity and consistency with changes in pharmacy education and practice. Board members comprising the committee were joined by representatives of chain drug stores, pharmacy schools, the Virginia Pharmacists Association, hospital pharmacies, correctional institutions, EMS agencies, pharmaceutical manufactures, and a consumer organization – all of whom were invited to participate in the discussion of each regulation and to provide suggested changes.

In its announcement of periodic review, the Board requested comment on whether there is a need for amendments for consistency with changes in pharmacy practice and patient care. In order to address issues that have been raised and to clarify current regulations, the Board issued a Notice of Intended Regulatory Action to accomplish the purpose of its periodic review of regulations and has responded to comments received on the NOIRA.

In its adoption of proposed regulations, the Board authorized the division of Chapter 20 to establish one set of rules for pharmacists and pharmacy technicians and another for pharmacies. Since the amendments proposed in this action are fairly extensive, it was decided to retain all sections in one chapter in order to make the changes clear to the regulated public. After completion of this action, the agency will separate the sections, so the underlined and overstruck language will only reflect the technical division rather than actual amendments.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
National Association of Chain Drug Stores	Section 110 • Concern that 3-week timeframe specified for approval of a pharmacy permit is not sufficient time; asks for at least six weeks or issuance of a temporary permit. • Opposed to a requirement for the PIC to mark a permit VOID on the date of termination. • Supports allowing the outgoing PIC to take an inventory for his own protection.	The Board has not specified a time frame for issuance of the permit but has added a requirement for the applicant to attest to compliance with all laws. The Board did not require the PIC to mark the permit VOID. The Board deleted the requirement for the outgoing PIC to take an inventory but makes it permissive for him to do so.
"	Section 111 • Concern about any requirement for technicians to display his registration in a conspicuous place – would be difficult with limited space. • Supports limitation on time in training for technicians; supports 2 years	Section 111 does not require posting of registration but does require pharmacies to maintain evidence if someone working as a technician is enrolled in a training program. The time limitation for a trainee to perform tasks restricted to technicians is currently set at 9 months, which is sufficient time for someone training part-time to become registered.
"	Section 130 Requests clarification of requirement for closing pharmacy to transfer prescription to where a patient can have access.	The rule has been clarified to mean the transfer shall be to another pharmacy where a patient may have access for the purpose of obtaining refills.
"	Section 180 Opposes a mandate for "hard-wiring" or wireless (battery) technology for alarm systems – should be based on accepted industry standards.	The Board's requirement for the alarm system is that it meet "industry standards."
"	Section 190 Supports allowing pharmacies to use drop-down gates or a door with a lock, but should allow the PIC discretion to determine security measures.	The specific requirements for entrances were removed and replaced with a rule that specifies the enclosure shall be capable of being locked in a secure manner at any time the pharmacist is not present in the prescription department.
"	Section 200 • Supports use of will-call devices but suggests a workgroup and study of the issue. • Does not support restrictions on display of medical devices similar to drug	There were no amendments to allow will-call devices at this time. The Board requires that <u>controlled</u> medical devices not be placed in an

	paraphernalia.	area removed from the prescription department with free access to the public; they are controlled and require a prescription to obtain.
"	Section 210 Asks that the Board not propose rules for proper drug disposal methods.	The Board did not impose specific rules on disposal.
"	Section 240 • Concern expressed about a perpetual inventory requirement for Schedule II drugs – asked to exclude hydrocodone products. • A requirement to maintain invoices of Schedule VI drugs would be a storage problem in the pharmacy.	The Board did require a perpetual inventory of Schedule II drugs, but did not include hydrocodone. Invoices of Schedule VI drugs must be maintained for purposes of inspections but may be kept electronically or offsite.
"	Section 270 Supports changes or elimination of the technician and trainee ratios.	The Board did eliminate the ratios.
"	Section 320 Concern that amendment might prevent pharmacists from making a substitution where the prescriber had inadvertently written an incorrect dosage, etc.	The amendment is 320 will allow for an early refill if there is a valid reason. There is no amendment that would prevent reasonable substitution.
"	Section 330 Any requirement for labeling or counseling guides in alternative languages would be problematic for many pharmacies. Other options, such as translation services, should be guidance. Also recommends that rules for medication guides not be added until FDA has issued guidance on them	The Board proposed no amendments in 330.
"	Section 355 • Any amendments to use of automated dispensing devices should include consideration of systems that will likely be used in the future. • Asks for clarification of Board's intent in regard to requiring pharmacist's initials on filling record. • Concern about requiring the manufacturer's expiration date on filling record for automated dispensing devices – most mix lots in a dispensing cell. In the event of recall, the entire cell is discarded.	The Board's intent on requiring the pharmacist's initials is to verify the accuracy of the process being followed. The Board's amendment replaces the word "second" lot with a "subsequent" lot to allow mixed lots, but the regulation on an expiration date for drugs in the bin has not been amended.

Family impact

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

There is no impact of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

- In all sections where appropriate, the term "controlled substances" is replaced with the term "prescription drugs". Both terms are defined in §54.1-3401.
- In all sections where appropriate, record-keeping requirements are made more uniform and to allow for off-site or electronic storage if retrievable within 48 hours and if such storage is allowed under federal law and regulation. Currently DEA does not always allow such storage for Schedule II-V records.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	n/a	Sets out definitions of terms and words used in regulations	Definitions are added for clarification purposes for "alternate delivery site" and "chart order", because the terms are used in several places in the regulations, but were not previously defined. Definitions are added for "correctional facility", "NABP", "FPGEC certificate", "forgery", "perpetual inventory", and "pharmacy technician trainee" because the terms are new terms used in the proposed revisions to the regulations.
20	n/a	Establishes fees charged to licensees and applicants	Language was removed from subsections C and I that related to a one-time fee reduction for renewal fees in 2005 and 2006 and a 2006 controlled substances application fee reduction that is now expired. The fee for a robotic pharmacy system approval is removed as the requirement for approval is removed in the proposed revisions Renewal fees, late fees, and reinstatement fees are established for approval of pharmacy technician training programs due to a revision of regulations

			related to the expiration of such programs every two years.
30 & 40	n/a	Establishes requirements and procedures for gaining practical experience for licensure in pharmacy	• Because of changes in the curriculum for U.S. colleges of pharmacy and new standards of the accrediting organization for such colleges (ACPE), requirements for practical experience are revised. The new standards in place in 2007 require students to obtain at least 1700 hours practical experience as part of the college curriculum. For this reason, the Board, which has previously required 1500 hours with 300 of the hours being gained outside the school program is proposing to allow all 1500 hours to be gained within the school program. The current requirement for 300 hours outside the school curriculum was removed. • The current regulations require 1000 hours for graduates of colleges of pharmacy prior to 1/1/2003 and graduates after 1/1/2003 1500 hours. This split was put in place when the Board first moved to 1500 hours so that students currently enrolled in colleges of pharmacy that may not have obtained enough hours would not be penalized. However, because all U.S. students now have enough hours, the Board is proposing to remove the 1000 hour allowance for graduates prior to 2003. The Board considers that someone who graduated prior to 2003, but has not yet been licensed in the U.S. probably needs at least 1500 hours of practical experience in order to ensure minimum competency, particularly foreign graduates who have graduated that long ago. Pharmacists reciprocating from another state who may not have had that many pre-licensure hours, may use hours worked as a pharmacist in the other state toward the requirement. Removing the 1000-hour exception will make requirements equal for any new applicant. • Sections 30 and 40 were reorganized for clarity and better flow, so much of the struck through language is just moved to another section. • The Board currently does not allow a person to gain more than 50 hours practical experience in one week and this requirement was retained, but in the revisions the Board also established a minimum number of hours on average (20 hours per week averaged over a month) which are required for credit. The Board does not consider that a pharmacy intern receives full benefit of pharmacy experience for anything over 50 hours

			a week, or anything much under 20 hours per week. The Board has had problems with particularly foreign graduates who are in the U.S. working a primary job elsewhere, e.g. research, but will want to work 5 hours a week in a pharmacy, or work one weekend a month. The Board does not consider that this provides for meaningful practical experience. • In order to gain practical experience, a person must first register with the Board for a pharmacy intern registration. The proposed regulations clarify the requirements for eligibility for registration as a pharmacy intern for the purpose of gaining practical experience and put the eligibility requirements in one place. This will provide Board staff with clear guidance for assigning an expiration date to pharmacy intern registrations. This will also address problems the Board has had in the past with pharmacy school students who obtain a registration and then are removed or voluntarily remove themselves from school temporarily or permanently but do not surrender the registration by making the registration invalid if this happens. It will also make it clear that the intern registration is only valid for the period of time needed to gain the required practical experience.
50	n/a	Sets the minimum educational requirements	The allowance for graduation from a three-year course of study for those persons who graduated prior to 1936 was removed, because the Board now considered this obsolete. Any person who graduated prior to 1936 would most likely be over 92 years old. The Board has not had any reciprocity requests for this type of degree for a number of years.
60	n/a	Sets the content of the examination and grades required & a limitation on admittance to examination	• The changes reorder the regulation for clarity with the requirements for the competence examination being together before the law examination. • The change establishes a 30-day waiting period to retake the law exam after failing it. This is necessary to protect the integrity of the computerized examination. The law exam is a computer based examination that applicants may schedule to take at their convenience year-round. Allowing a candidate to retake an examination too quickly leads to greater ability to compromise the examination by allowing the candidate to more easily memorize questions. A one-month wait time is the shortest period of time test developers recommend before allowing a re-take.

			There have been several instances of compromised examinations nationally with pharmacy examinations. Approximately five years ago the foreign pharmacy equivalency examination was compromised by students memorizing items (test questions) and posting them on a website. That examination had to be completely re-written and is now a paper and pencil examination given only twice a year, which is very inconvenient for applicants. Last August, NAPLEX, the national competency examination used by all 50 states and DC, as well as the Georgia pharmacy law examination, had to be suspended because of a security breach in which students taking a particular review course were memorizing items and providing them to the person teaching that course for his database. Over half the items being used on the various computerized test forms were made available for this review course which was widely available. As a result of the suspension, the examination was not available for pharmacist applicants to take for approximately two months while the test forms were being refurbished with new questions. This affected a number of persons waiting to take NAPLEX for the first time or person who were retaking it because of failing. Fortunately, in this case the computerized examination was able to be reinstated relatively quickly because there were enough unused items in the bank that could be shifted onto forms. If there is another breach, NAPLEX will most likely have to move back to paper and pencil format as well. NAPLEX currently has a 3-month waiting period for re-takes after failing. Paper and pencil examinations can only be given several times a year which greatly inconveniences persons waiting to be licensed and costs them pharmacist salary while waiting. Before the Board went to computerized testing, the law examination was given only twice a year along with the paper and pencil NAPLEX. • Language of a current guidance document related to testing accommodations under the ADA was included in regulation.
70	n/a	Sets requirements for foreign-trained applicants.	This section was re-worded to clarify and simplify the requirements for foreign graduates. There had been some confusion as to the sequence of testing and practical experience and the re-written section clarifies this in conformity with the statute.
80	n/a	Sets requirements for	New language allows electronic notification of

		renewal and reinstatement	address of record changes and provides for 14 days for such notification.
90	n/a	Sets requirements for continuing education	• The statute citation was corrected. • An amendment requires pharmacists to maintain CE records for three years instead of two because the Board usually audits for the past two renewal cycles. At the time of the audit, the CE records for the first renewal cycle audited may be over two years old.
100	n/a	Sets criteria for approval of continuing education programs	• New language requires an assignment of and expiration date for approved CE programs not to exceed two years. Nationally-recognized CE pharmacy programs are not approved for more that two years. Most of the live programs approved are given on a one-time basis, but stay on the Board's active database because they don't expire. After two years, the content of the program will most likely have changed and even if the sponsor wants to give the program again, it will need to be updated for new content, probably new speakers, etc. With self-study programs, after two years, the material may be obsolete and need to be reviewed and updated. • New language allows a sponsor to give a live approved program more than once during the approved time frame, by so notifying the Board of the dates and locations of the program.
101	n/a	Sets requirements for applying for registration as a pharmacy technician	Language that allows a person to work in a training capacity as a pharmacy technician for no more than nine months was copied from 111 to this section. The Board's original intention with the current language was that a person could be engaged in on-the-job training for up to nine months before having to meet requirements and be registered. The problem with the current placement is that this person could work at one pharmacy for up to nine months, then go to another pharmacy and work up to nine months, and continue to do this without being registered. By repeating it in this section, the nine-month limitation is also on the person performing technician tasks, as well as on the pharmacy that employs the technician.
102	n/a	Sets criteria for approval of training program	• New language requires that each program have a "program director". This has been required in the past via the application form, but not specified in the regulation. • Current regulations require instructors to either be pharmacists or pharmacy techs with current unrestricted licenses. New language allows for the director and the instructors to possibly be on probation or have some restriction, and still be

			affiliated with a program as long as they are not suspended or revoked. The Board had some pharmacists who were on probation want to teach in a training program, who were otherwise very qualified. • New language clarifies that programs are required to provide some type of certificate of successful completion to the participant or to the Board upon request. • New language requires programs to report major changes in personnel, address, name, program content, etc within 14 days. • New language requires program approvals to expire after two years, with ability to renew every two years. Currently, any approved program stays in the board's active database of approved programs and is listed on the web. There have been issues with programs that go out of business, programs that change personnel without notifying the Board, and programs teaching out-of-date information. The renewal requirement will include a self-evaluation for the program to ensure that personnel and curriculum meet current requirements. This language is modeled after regulations relating to certain training programs approved by the Board of Nursing.
103	n/a	Sets criteria for examination for pharmacy techs	New language for pharmacy techs references the new language related to ADA accommodations for pharmacists.
104	n/a	Sets requirements for addresses & maintenance of certification	• New language, that conforms to requirements for pharmacists, allows for submitting address of record changes electronically within 14 days of such change. • New language requires a pharmacy technician to maintain his registration certificate at his principal place of business, or if none, at his address of residence. The NOIRA had contemplated requiring posting of the registration, but comment from NACDS stated that wall space is limited in some pharmacies and posting would be a hardship.
106	n/a	Sets requirements for continuing education for techs	A section reference is corrected. New language requires records to be kept for three years, for the same reasons as pharmacists in 90.
110	n/a	Sets general requirements for pharmacy permits	• Changes in C and new D remove the requirement for an outgoing PIC to take an inventory, but do give him the right to do so unless the owner provides notice showing good cause why he should not be allowed to do so. The current

			requirement for taking an outgoing inventory was for protection of the outgoing PIC, so that diversions subsequent to his leaving, but before the incoming PIC's inventory could not be attributed to him. However, this "protection" has resulted in many citations during inspections of not having these inventories that are difficult to prove in that the former PIC will say that he took the inventory and left it at the pharmacy, and does not know what happened to it because he is no longer there to make sure it is maintained. The Board considered that the taking of the outgoing PIC inventory should be allowed but not required. It did recognize that there would be situations in which an owner did not want to allow it, e.g. termination due to violence, etc. • New G clarifies in regulation long-standing Board interpretation that only one pharmacy permit would be issued to a designated prescription department space. The Board has been asked in the past to issue two pharmacy permits to a single operation, or a pharmacy permit and a wholesale distributor license to a single operation. The Board does not consider this to be in the best interest of maintaining accountability and security of controlled substances. Usually the request has related to a single pharmacy's desire to represent themselves to be a "closed shop pharmacy" to a wholesale distributor for the purpose of obtaining preferential pricing, when in fact, the operation is a retail operation that does some long-term care facility business as well. The fact that a distributor requires two separate licenses is some indication that it expects the two operations to be separate, and that preferentially priced drugs for nursing home patients, for example, will not be intermingled and inadvertently or deliberately dispensed to retail patients. There are federal laws prohibiting this type of diversion. • New H prohibits operating a pharmacy from a private residence. There is already a prohibition from operating other types of facilities licensed by the Board of Pharmacy from a private residence, but currently not pharmacies. This had never been an issue until about two years ago when a person applied to operate a pharmacy from her garage in a residential subdivision. Local laws and ordinances did not prohibit this as long as she didn't use delivery trucks over a certain weight limit, and the Board had nothing

			to prohibit it, so was forced to issue the permit, although it considers the operation of a pharmacy and maintenance of a stock of controlled substances in one's private dwelling, not conducive to maintaining security and accountability of the drugs. There is only one pharmacy in Virginia currently operating from a private dwelling, and this one will be "grandfathered" by the provision.
111	n/a	Sets requirements for use of pharmacy technicians	Clarifies that pharmacies have to maintain the start date for technicians in training to assist in identifying technicians who have exceeded the 9-month rule.
120	n/a	Sets requirements for special or limited-use permits	Language was taken from the current guidance document allowing non-pharmacist access to free-clinic pharmacies under certain strict conditions for certain limited reasons, such as securing a drug order. This has been necessary because many free-clinic pharmacies are only open a few hours a week, and may not be at times that drugs are delivered or maintenance work needs to be done, etc.
130	n/a	Sets rules for closing a pharmacy or a change of ownership	New language specifies that a pharmacy that closes must transfer prescription records with active refills to another pharmacy for access by the patient. Until recently this has not been a problem because prescription files are usually a salable asset. There have been a couple of situations in which a pharmacy was forced to close by a landlord against his will, and the pharmacy owner refused to transfer the records.
140	n/a	Sets rules for new pharmacies, acquisitions or changes to existing pharmacies	New language in E incorporates a Board guidance document into regulation relating to the amount of time a drug stock can sit in a new pharmacy prior to the pharmacy opening for business and under what conditions. This is to address a recent problem with pharmacies applying for a permit weeks and sometimes months in advance of opening in order to get other needed licenses such as DEA registration and third-party contracts. In some cases a pharmacy opened, stocked some prescription drugs that sat for over a year, and the pharmacy never opened. This amounts to an abandoned stock of prescriptions drugs with no oversight. Under the new rule, the Board will allow a permit to be issued well in advance of opening for paperwork purposes, but not allow drugs to be stocked until within two weeks of the designated opening date, and requires a pharmacist be present daily once the drugs are stocked.
180	n/a	Sets the rules for security systems	• Changes reorganize and clarify requirements for the alarm system on pharmacies. • A change was made for 24-hour pharmacies that were approved without an alarm system, but for

			some reason have to close. Currently, a pharmacy is allowed 72 hours for the pharmacy to install a security system. New language requires this be done prior to closing. The Board considered that it was not safe for a stock of prescription drugs to be without a security system when closed for business at any time.
190	n/a	Sets rules for prescription department enclosures and access to the department	• This section was rewritten and reorganized to remove any specific requirement for structural enclosures, such as counter height, gap between the door and floor, etc. Instead new language requires that the enclosure be sufficient to protect the drug stock from diversion whether or not a pharmacist is on duty, leaving the details up to the pharmacy, provided upon inspection, security can be demonstrated. • Language reference "keys" is updated to include other means of access. • New language makes the pharmacist on duty responsible for the security of the pharmacy during the time he is on duty.
200	n/a	Sets requirements for storage of drugs, etc.	• The regulation was amended to clarify who could have access to already filled prescriptions after hours, to include any individual designated by the pharmacist. Current language refers to "designated clerical assistants" when in reality, if necessary to leave filled prescriptions, it is usually with a member of management. • Language was added to clarify that Schedule VI medical devices do not have to be in the pharmacy, but may be stored in restricted areas similar to controlled paraphernalia. • Language was added to include a requirement for otherwise adulterated or misbranded drugs be maintained in the pharmacy like expired drugs, but separated from working stock.
210	n/a	Sets rules for disposal of drugs	An amendment added "or other board-approved method" to the incineration as a means of destroying unwanted drugs. New methods are being developed to address this problem and the Board wanted the ability to approve them if sound.
240	n/a	Establishes rules for maintaining records, etc.	• There is a new requirement for pharmacies to maintain a perpetual inventory of Schedule II controlled substances for quicker detection of diversion of these substances. This has been a problem in the past in which tens of thousands of dosage units of these drugs were diverted without detection for a year or more in some cases. This requirement is for at least monthly monitoring of

			this record to detect missing amounts of drug more quickly. All hospital pharmacies and most chain pharmacies already maintain these records, but may not really review them for discrepancies routinely. This is not expected to create any additional workload for most pharmacies. • Struck-through language in A4 was thought to be confusing and not necessary as inventory requirements are already elsewhere in statute or regulation. • New language in 5 allows scanned or electronic images of records of Schedule VI drugs. • Clarifies that records must be maintained for two years. This is not a new requirement, but considered that it should be repeated here.
270	n/a	Sets requirements for dispensing of prescriptions, certification of completed prescriptions and supervision of techs	• New language removes the established ratios of pharmacists to pharmacy technicians and leaves it to the pharmacist on duty to determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely supervise at one time. 18 other states have no ratio, and report no safety issues. • New language clarifies that records showing that the pharmacist verified the accuracy of a dispensed prescription must be maintained for two years unless otherwise specified. This has always been understood and was never a problem except in the case of some hospitals that were having pharmacists initial the label of compounded IV solutions when they checked them. Then the used solution bags were discarded after use, and there was no other record showing which pharmacist had checked the product. This has been problematic in determining the responsible party in dispensing error cases. • New language requires that prescriptions that are determined to be forgeries are not returned to the person presenting it, and are retained at least 30 days by the pharmacy in the event they are needed by law enforcement or for some other legitimate purpose.
275	n/a	Sets requirements for delivery of dispensed prescriptions	• New language in D clarifies that required contracts, agreements, and policy and procedure manuals be kept by both the pharmacy and the alternate delivery site. • New language in E clarifies that the Board will only issue a CSR for an alternate delivery site without a pharmacist or prescriber present at all times when open, if there is a legitimate health

			and safety reason to do so. For example, community services boards are alternate delivery sites for mental health patients in the community who may not have reliable addresses or who need close monitoring of their medication use. The Board has had issues with pharmacies, particularly non-resident pharmacies wanting this ability for their own convenience or to save money in mailing or delivery costs. The Board has security, integrity, and accountability concerns about multiple patient's prescriptions being delivered to a single site where they will accumulate, that is not controlled by a pharmacist or someone with prescriptive authority (and therefore authority to possess drugs), and feels that this should only be allowed when the alternative of delivery directly to the patient is more risky for some reason.
280	n/a	Sets requirements for transmission of a prescription order by fax	• New language allows a long term care facility to fax an oral or written prescription to a pharmacy provided the original is obtained by the pharmacy within 7 days. This has been a problem in assisted living facilities where residents may go out to a physician office visit and come back to the facility with a written prescription. Previously the facility could not fax the prescription to the pharmacy because it was not faxed from the prescriber's practice location, and getting the hard copy to the pharmacy before dispensing may cause a delay in therapy. • Changes were made to change the term "nursing home" to "long term care facility" consistent with the statute. Language was added to clarify that hospice includes home hospice.
n/a	286	Sets requirements for chart orders for outpatients	This new section incorporates a Board guidance document into regulation. Many patients are now being discharged from hospitals with their discharge orders being written on a chart order. This regulation allows a community pharmacy to dispense pursuant to these chart orders provided all necessary information is included and the pharmacist has knowledge that the chart order is intended to be the discharge orders.
320	n/a	Sets requirements for refilling Schedule III through VI drugs	New language in D clarifies that this paragraph relates to the timing of dispensing refills, and authorizes early refills provided the pharmacist documents a valid reason necessitating the early refill, such as the patient is going on an extended vacation.

340	n/a	Sets standards for packaging drugs	New language specifies some of the USP-NF requirements for labeling of compliance packaging for easy reference for the regulated. The requirements are already in place in current language, but the repackager would need to refer to the USP-NF reference.
350	n/a	Sets standards for special and non-special packaging	Amendments eliminate language redundant with the statute and update the language consistent with electronic records.
355	n/a	Sets requirements for repackaging of drugs	• New language clarifies that certain record requirements of A also apply to C when automated counting machines are used to include length of time to keep the record, and that date of filling and pharmacist checking are to be recorded. • New language in D incorporates a Board guidance document related to returning drugs to stock that are dispensed to a patient but never picked up from the pharmacy.
n/a	391	Sets standards for prescription blanks	This new section puts a Board guidance document into regulation related to what can be on the face of a prescription blank provided by a pharmacy to a provider. It prohibits non-essential information from being put on the face.
395	n/a	Sets rules for purchase of drugs	Warehouser is added to the persons from whom a pharmacy may purchase drugs. Many chain drug store distribution centers are licensed as warehousers if they only engage in intracompany sales.
410	n/a	Sets requirements for permitted physicians	The term "pharmacy" was added to this section as it was inadvertently left out of the previous revision.
425	n/a	Sets requirements for robotic pharmacy systems	New language removes the requirement for Board approval of these systems, and incorporates the terms of the Board orders under which all the systems currently approved are operating. The Board considers that it has enough experience with these systems after several years of approvals and monitoring to be able to put requirements in regulations and not have to make each entity wanting to use one of these devices apply, go through an informal conference, and operate under an order.
440	n/a	Sets out the responsibilities of a pharmacist-in-charge	Language delineating the things to be included in a drug review was eliminated and a reference made to the statute that addresses drug reviews. This was a request from hospital pharmacists who did not think the list was comprehensive and recommended its deletion.
450	n/a	Sets the requirements for after-hours access to a pharmacy	• New language removes the ability of an authorized nurse to access the entire pharmacy, but allows the pharmacy to establish a stock of drugs elsewhere that may be accessed when the

			pharmacy is closed. This was also a request from hospital pharmacist, as Joint Commission (JACHO) no longer approves of the after-hours entry into the pharmacy by nursing staff. • New language also specifies that if this after-hours pharmacy stock is in an area of the hospital that is not continuously staffed, such as a nursing unit or ER, it needs to be alarmed.
460	n/a	Sets requirements for floor stock drugs	• New language clarifies that a pharmacist must check for accuracy the drugs being delivered as floor-stock prior to them leaving the pharmacy and that a record of such check be kept. • New language allows for maintenance of records off-site, or electronically provided they can be available in 48 hours and provided this is consistent with federal law.
490	n/a	Sets requirements for automated devices	• Subsection A was amended to match the new requirement for pharmacist check for floor stock in 460. • Hospital pharmacists have complained that this section is too confusing as to the requirements for audits and record-keeping. Clarifying language was added to 5 to clearly describe the expectation for the monthly audit. • Language was removed from several places in this section that related to records, and put into a new #10 which addresses record-keeping. Again, off-site or electronic records are allowed provided they are retrievable within 48 hours, and such storage is consistent with federal law.
500	n/a	Sets requirements for licensed EMS agencies	• Language was added to clarify the requirement for a pharmacist to check the drug kit after filling and make a record of this check. This is consistent with other requirements for dispensing floor-stock and other kits. • Because it is not possible to "preclude any possibility" of theft, language was changed to sealed to deter and aid detection. • New language was added to allow the storage of IV solutions, which are prescription drugs, outside the sealed kit.
520	n/a	Sets rules for drugs in long-term care facilities	The term "drugs" was changed to "prescription drugs" to allow non-prescription drugs to be floor-stocked.
530	n/a	Establishes the pharmacy's responsibilities	Minor clarifications were made to state that unwanted drugs could be properly disposed of, and not destroyed.
n/a	535	Sets standards for repackaging dispensed prescriptions	• This is a new section incorporates a Board guidance document into regulation. It will allow a provider pharmacy for a LTCF to repackage a

			patient's medications that have been dispensed by another pharmacy into unit-dose or compliance packaging to conform to the system used in the LTCF under certain conditions. • This has been requested by primarily assisted living facilities that may have residents, such as VA residents who can get their medications at no cost from a VA facility, but come in multidose vials. The Board recognized the problems with having a second pharmacy repackage these medications, but felt that the risk of inaccuracies in administering the medications were greater than those associated with repackaging. Some of the problems with such repackaging are that the provider pharmacy does not have the original prescription or order, cannot verify that the original pharmacy dispensed the drug accurately, and is relying on that pharmacy's labeling and product selection. • The regulation does not want to compel a pharmacy to engage in this practice, so the new regulation clearly states that this is not a requirement of a provider pharmacy, as the Board is cognizant that pharmacist may not want to take on this liability.
n/a	536	Establishes rules for prescription drugs sent outside the facility	• This new section also incorporates a Board guidance document into regulation. It allows a long term care facility to send a patient's medication out with the patient on pass, provided the medication is appropriately packaged and labeled for outpatient use. • For patients whose medication is in compliance packaging, this allows the facility to send only those individual containers of medication with the patient provided the patient is given appropriate instructions for use and other required labeling, if all required labeling is not on the individual containers.
540 & 550	n/a	Sets requirements for emergency drug kits and stat boxes	• New language clarifies that these kits may be used in long term care facilities that use mediation aides to administer medications provided the aides do not have access to the kits, and only licensed nurses, pharmacists, or prescribers may access or administer form the kit. • New language in 550 removes the requirement that a signed order, obtained within 72 hours, must cover any drug used from the stat-drug box, and instead just requires that a valid prescription or order of a prescriber must exist prior to the removal of a drug from the stat-drug box. This

			allows verbal order to be used.
555	n/a	Sets requirements for automated dispensing devices	• New language allows the device in nursing homes to be use to house drugs that would be in the emergency kit and be accessed prior to receiving electronic authorization from the pharmacy reviewer. • New language requires that the device be able to product a record of each distribution from the device. This is consistent with hospital language for these devices. • The same audit language was included that was used in the hospital section (490) • Record-keeping requirements were removed from several sections and put in new 13 as in the hospital section (490).
570	n/a	Sets rules for drugs in infirmaries/first aid rooms	Language in D was deleted in that there is no prohibition in law from anyone providing non-prescription drugs.
580	n/a	Sets rules for drugs in humane societies and shelters	• New language makes it clear that drugs in a humane society for euthanasia only be maintained at the permitted address. There is no reason for employees of a humane society to remove drugs from the location, but because this was not clearly stated, there has been some confusion about whether humane society employees could remove the drugs from the permitted location and use them elsewhere. • New language also clarifies that humane societies may only order drugs for euthanasia. Any drugs for treatment of animals at a shelter must be prescribed and dispensed by a veterinarian for the animal(s) being treated. • The two clarifications listed above are not new limitations to humane societies, but were not specifically stated in the Board of Pharmacy regulations. To know these limitations, humane society personnel had to look to the Drug Control Act, this regulation, and the regulations of the State Veterinarian for the scope of authority of humane societies. This clearly places these limitations in one place. • There is a new requirement for certificates of training to be maintained at the facility location. There has always been a requirement that persons administering the euthanasia drugs have the required training, but it has sometimes been difficult for inspectors to ensure that only trained persons are administering if the certificates were not available for inspection. The two-year requirement is consistent with the length of time

			inspectors would be auditing drug administration records.
590	n/a	Sets rules for drugs in correctional facilities	• New language was added to allow for a copy of the medication administration record or alternative record to be returned to the pharmacy with any unused or discontinued drugs. This was requested by the Department of Corrections as the original record is usually retained at the correctional facility. • Clarifying language was added to C at the request of the Department of Corrections due to some confusion as to what could be floor-stocked at medical clinics in correctional facilities.
610, 620, 621, 622	n/a	Sets rules for exempted chemical preparations, prescription products, anabolic steroid products and veterinary products	These sections were amended to clarify that the referenced federal regulations do not actually contain the list of exempted or excluded drug product anymore, but the list is maintained by the DEA administrator.
680	n/a	Establishes requirements for medical equipment suppliers	Amendment conforms record-keeping language to allow off-site and electronic storage.
690	n/a	Sets out rules for persons or entities authorized to obtain controlled substance registration	• Alternate delivery sites are specifically added to the types of entities for which a CSR may be issued to conform this section to 275. • New language was added to conform the inspection requirement for new, change of location, or structural changes to CSR locations to that of pharmacies and other licensed or permitted facilities. • New language clearly designates who can be a responsible party for a CSR. This is to put in regulation what was already required by application form. It is actually a clarification of who had been allowed by the Board to be the responsible party based on who had authority to be in possession of prescriptions drugs in accordance with the Drug Control Act. Additionally, pharmacy technicians were added as persons authorized to be the responsible party for alternate delivery sites, and on a case by case basis other appropriate persons.
700	n/a	Sets requirements for supervision of CSR's.	• Language is clarified and simplified in A from a list of various types of medical practitioners and pharmacists, to "prescribers", which encompasses the list, and pharmacists. • In C, new language allows pharmacy technicians to have access to controlled substances for the purposes of stocking, delivering, and assisting

			with inventories and record-keeping. • New language in E requires that a CSR notify the Board within 14 days of any change of responsible party of supervising practitioner.
710	n/a	Sets requirements for storage and security for CSR's	Changes were made to the requirements for the security system to mirror the language for pharmacies.