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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq. 18VAC110-15-10 et seq. 18VAC110-50-10 et seq. 18VAC110-21-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers, Warehousers, and Third-Party Logistics Providers Regulations Governing Delegation of Informal Fact-Finding Proceedings to an Agency Subordinate Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	Periodic review
Date this document prepared	4/3/19

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Board has determined that provisions in Chapter 20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, Chapter 21, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, section 15, *Criteria for delegation of informal fact-finding proceedings to*

an agency subordinate, will be moved into a separate chapter, Chapter 16, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Amendments are being promulgated for Chapters 20 and 50 to address current issues with practice, to clarify certain requirements, and to incorporate provisions currently found in guidance documents. The proposed amendments will to update and streamline requirements where possible.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

USP-NF = United States Pharmacopeia-National Formulary

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On March 26, 2019, the Board of Pharmacy amended 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy and 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers, Warehousers, and Third-Party Logistics Providers. It also adopted 18VAC110-21-10 et seq., Regulations Governing Pharmacists and Pharmacy Technicians and 18VAC110-16, Regulations for Delegation to an Agency Subordinate.

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no changes; this action is the result of a periodic review of Chapters 20 and 50.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards, including the Board of Pharmacy, the responsibility to promulgate regulations and establish renewal schedules:

> *§ 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 and Chapter 25 of this title…*

The specific authority to control prescription drugs in the Commonwealth 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 regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

Regulation of the practice of pharmacy is both complex and essential to public health and safety. The Board takes seriously its statutory responsibility to ensure the safety, integrity and efficacy of prescription drugs in the Commonwealth. At the same time, the practice of pharmacy is constantly changing as new technologies become available. To incorporate efficiency and cost-effectiveness, rules for pharmacy practice must be changed while balancing the assurances that controlled substances are dispensed in a manner that protects from medication error and diversion that is harmful to the patient and the community.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

As part of the periodic review, the Board has determined that provisions in Chapter 20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, Chapter 21, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, section 15, *Criteria for delegation of informal fact-finding proceedings to an agency subordinate,* will be moved into a separate chapter, Chapter 15, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Issues

Please identify the issues associated with the regulatory change, 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 there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) The primary advantage to the public may be stronger provisions defining unprofessional conduct, such as "performing any act likely to deceive, defraud, or harm the public. While the Board may currently be able to establish grounds for disciplinary action, additional specificity strengthens the ability of the Board to take action if there is harm to the public. There are no disadvantages to the public.
2) With exception of clearer rules for licensees, there are no advantages or disadvantages to the agency; and
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to administer effectively the regulatory system.*" Additionally, § 54.1-3307 of the Code of Virginia requires:
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered…
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
The proposed regulations are the foreseeable result of the statute requiring the Board to protect the health and safety of patients in the Commonwealth and do not represent a restraint on competition.

Requirements More Restrictive than Federal

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no requirements more restrictive than federal.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected – no other state agencies are particularly affected.

Localities Particularly Affected – No localities are particularly affected.

Other Entities Particularly Affected – No other entities are particularly affected.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

Proposed amendments to regulations were published in the Virginia Register of Regulations on December 24, 2018. Public comment was requested for a 60-day period ending February 22, 2019. A Public Hearing before the Board of Pharmacy was held on January 9, 2019. There was no comment at the hearing.

There were 189 comments posted on Townhall. The following were comments for which no response is necessary.

Several people were confused by the overstrikes of requirements that resulted from the division of Chapter 20 into two chapters, so it appeared that certain regulations, such as those relating to registration of pharmacy technicians, were being eliminated.

One person questioned how often an inventory of Schedule III-V drugs is required and whether the Board intends to go back to administering its own examination for pharmacy technicians.

One person supported the changes to: 1) allow a back-up pharmacy for issuing a seven-day supply of a drug to a long-term care facility; and 2) allow the pharmacist the discretion of whether to return a forged prescription to the customer.

An undergraduate student questioned the 15-hour continuing education requirement at the same time she is trying to complete his degree. (CE hours are not required for students, only for licensees)

One person commented that the limitation on the number of times a facility can change a PIC seems to be based on a fee limitation rather than a number of times cap that may or may not appropriately fix the solution. (There is no limitation on the number of times a facility can change a PIC)

Several people concurred with the division into two chapters, so the requirements for pharmacists, interns, and technicians are more clearer set out separately.

Several people commented in support of the changes proposed as being pro-active in addressing outdated procedures and rules. Several particularly noted support for long-term care patients, making it easier for them to get necessary medications.

A number of commenters simply acknowledged that they had read the proposed amendments; this was in response to an alert that was sent from the Board to licensees informing them of the amended regulations posted on Townhall with the opportunity to comment during the 60-day comment period.

Commenter	Comment	Agency response
133 commenters on Townhall	In opposition to a requirement of five hours of "live" continuing education for each renewal year. Commenters noted the additional time and expense involved in obtaining live or real-time interactive CE and the problem with availability, particularly in more rural areas of the state. Several people commented that they could support fewer hours than five each renewal cycle.	Board members reiterated their support for "live" CE in which practitioners have an opportunity to ask questions and interact with peers and instructors. Live CE does not require attendance at a meeting or conference but can be real-time interactive. The Board reduced the live hours from five to three in response to comment.
17 commenters on Townhall	In support of live CE, noting the positive impact of interaction with one's peers.	The Board concurs.
Sheri Franscisco Sovah Health Danville	One person objected to specific wording mentioning RobotRX and recommended more vague wording to allow other automation devices.	The Board does not believe there is specific wording for one system of robotics. There have been a number of robotic systems approved as pilots, so the Board will review the specifics of the pilots to determine whether changes to regulations are warranted.
Kaiser Permanente	In section 140, which proposes to authorize the Board to rescind a pharmacy permit if the pharmacy is not operational within 90 days, extend the time to 120 days to allow more time for extenuating circumstances.	The issue of rescinding a pharmacy permit is being addressed in Fast-track Action 5080.
	In section 425, eliminate the requirement for a "root cause analysis" if a robot picks an incorrect medication in a robotic pharmacy system but require an investigation and the outcome of the corrective action plan to be summarized and documented.	The Board concurs with the recommended change and amended section 425 accordingly.
National Association of Boards of Pharmacy (NABP)	In section 10, amend the definition of a faxed prescription to allow an electronic image.	The Board considered the requested amendment but decided there was need for further review and consideration before making a change.
	Delete definition of "personal supervision" to allow audio-visual technology supervision of compounding in retail pharmacies.	The deletion of the definition was not addressed in the NOIRA; the Board does make an allowance for personal supervision of compounding when a pharmacist is present and monitoring the clean room.
	In section 25, delete the ability of the Board to take disciplinary action based on a restriction on a license or permit in another U. S. jurisdiction.	The Code requires suspension of a license if it is suspended in another jurisdiction, but the Board believes there are situations in which it should similarly restrict a license in Virginia based on action in another state.
	In section 110, delete the proposed requirement for a minimum of two years of experience as a licensed pharmacist before someone could be named as pharmacist-in-charge (PIC)	The need for a PIC to have some experience as a licensed pharmacist has been a long-standing issue with the Board. It has seen cases in which a person was put in position to be a PIC who did not have the knowledge and experience to manage all

	responsible for the pharmacy's compliance with law and regulation.	aspects of compliance with laws and regulation for the practice of a pharmacy. Therefore, the Board did not revise the regulation.
	In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist. Possibly allow the "prescription department manager" or "consultant pharmacist" to determine the number of technicians.	A change in the pharmacist to pharmacy technician ratio would be a major policy change, and it was not addressed in the NOIRA.
	In section 270, allow a failed electronic prescription of a Schedule VI utilize an electronic signature on a faxed prescription.	The Board concurred with the comment and amended section 270 accordingly.
	In section 270, allow for a "two-step" verification process for an on-hold prescription.	The Board amended section 270 to clarify that "a pharmacist" can verify the data entry rather than requiring it to be done by the "pharmacist on-duty".
	In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.	Section 360 was not amended in the proposed action, so the Board did not consider the comment.
	In new chapter 21, section 10, strike the definition of PTCB and insert new definition for certification meaning any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies.	The comment will be considered in the context of a legislative proposal that was discussed by the Board and will be considered at its June Board meeting.
Remedi Senior Care	In section 10, clarify the definition of "initials."	The Board reviewed the definition and did not believe any clarification was necessary.
	In section 110, delete the proposed requirement for a minimum of two years of experience as a licensed pharmacist before someone could be named as pharmacist-in-charge (PIC) responsible for the pharmacy's compliance with law and regulation.	Same response as above.
	In section 530, amend the requirement for the pharmacy providing services to the long-term care facility to have a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with dispensing, and the responsibilities of each pharmacy.	The Board amended section 530 to delete the requirement for a written contract and simplify the process of allowing another pharmacy to provide a long-term care facility with a medication.
	In section 25 on unprofessional conduct, change the "shall" to "may" in listing the practices that are considered to be unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia.	The current language uses the word "shall." Section 25 specifies the meaning of "unprofessional conduct" in the context of the Code (54.1-3316) which authorizes the Board to take disciplinary action if a person or entity "has engaged in unprofessional conduct specified in regulations promulgated by the Board." The acts set out in section 25 are unprofessional conduct;

		whether a licensee or permit holder is guilty of those acts is a case decision based on the evidence presented.
CVSHealth	In section 10, amend the definition of personal supervision to allow a pharmacist to not be physically present in the pharmacy but to supervise through the use of "real-time, two-way technology communication" between the pharmacist and the technician.	Deletion of a requirement for personal supervision is a policy consideration that was not included in the NOIRA, so the requested amendment was not made.
	In section 110, delete the requirement that a pharmacist have two years of experience before serving as the pharmacist-in-charge.	Same response to same comment above.
	In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist.	The issue is a policy change that was not addressed in the NOIRA.
	In section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy." Allow for trailers or other moveable facilities in a declared emergency.	Deletion of the square footage requirement for a pharmacy was not addressed in the NOIRA. The Board already has regulatory and statutory authority to allow trailers or other temporary facilities in a declared emergency.
	In section 240, allow for chart orders in correctional facilities.	The current language in the regulation relating to use of chart orders is identical to provisions of § 54.1-3408.01 of the Code of Virginia. The Board believes a change in the Code is necessary if there is an amendment to regulation.
	In section 270, except for electronic prescriptions, only require written prescriptions for "controlled substances" to have a signature. In section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug. In section 270, amend the rule to not require data entry verification and prospective drug utilization review by a pharmacist who is dispensing an on-hold prescription at a future date.	Amendments to section 270 that would eliminate the requirement for a written signature for Schedule VI drugs and would allow a pharmacist to alter or adapt a prescription address issues that were not included in the NOIRA and would likely necessitate a change in the Code of Virginia. There was an amendment to clarify the role of a pharmacist in verification of the data entry.
	In section 355, amend to allow for using returns of dispensed drugs to be restocked for reuse in an automated counting device.	The requested amendment was not addressed in the NOIRA and therefore not considered in final adoption of regulations.
	In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.	Section 360 was not amended in the action, so the Board did not consider an amendment in response to comment.

	In section 420, change the provision of a seven-day supply of a drug in unit dose systems in hospitals or long-term care facilities to allow for dispensing of a 14-day supply.	Section 420 was not amended in the action, so the Board did not consider an amendment in response to comment.
	In section 530, allow pharmacies with shared ownership to provide services with long-term care facilities without written contracts.	Amendments to section 530 will allow for such services.

Detail of Changes Made Since the Previous Stage

*Please list all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

Current chapter-section number	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
Chapter 20 Section 270	Consistent with the Code requirements for a prescription, the regulation states that written prescriptions must include the prescriptions manual signature – with the exception of electronic prescriptions	In subsection B, there is a new allowance for cases in which the electronic prescription has failed and must be routed to a FAX machine. In those cases involving a Schedule VI prescription, an electronic signature would be acceptable.	A faxed prescription is considered a written prescription and requires a manual signature. The amendment is in response to a specific request to allow a failed electronic prescription to come to the pharmacy's fax machine with an electronic signature. The allowance is only for Schedule VI prescriptions for consistency with federal rules.
Chapter 20 Section 270	There are requirements for an on-hold prescription and the responsibilities of the pharmacists	In subsection E, the current rule says "the pharmacist on-duty shall verify the accuracy of the data entry at that time." The revised regulation says "a pharmacist shall verify…"	The amendment will allow any pharmacist, rather than just the one present and on-duty to check for verification of the data entry.
Chapter 20 Section 425	Amendments added requirements for a "root cause" analysis of sources of discrepancies or errors in a robotic system	The term "root cause" analysis was eliminated in two places in section 425 and replaced with a requirement for identifying and correcting the source of an error in compliance with the pharmacy's policy and procedures.	The amendment was requested by commenters; the Board adopted the recommended language for handling an error in the selection of an incorrect medication.
Chapter 20 Section 530	Amendments to pharmacy responsibilities to long-term care facilities included the	The amendment eliminates the requirement for a written contract. Each pharmacy has responsibility for its share	The section was amended in response to comments.

	need for a pharmacy to have a written contract with another pharmacy that dispenses an immediate supply of drugs without transferring a prescription.	of the dispensing function as prescribed in law and regulation.	
Chapter 21 Section 120	The proposed amendment designated five of the 15 hours required for continuing education to be live or real-time interactive	The Board has revised the proposed requirement to reduce the live hours from five to three.	The amendment was made in response to comment. The Board affirmed its belief that some hours should be in a format that allows interaction with one's peers.

The Board has referred all comments on proposed regulations that were beyond the scope of the NOIRA or on sections not amended in the proposed action to the Regulation Committee for further review and discussion.

Detail of All Changes Proposed in this Regulatory Action

*Please list all changes proposed in this action and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

Chapter 20

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	n/a	Sets out definitions for words and terms used in the Chapter	Since Chapter 20 no longer applies to pharmacists and pharmacy technicians, terms applicable to educational credentials and CE are deleted. The term "initial or initials" are defined to be inclusive of other unique personal identifiers. The definition of "robotic pharmacy system" is amended to clarify that such a system may be used in the performance of "compounding" in addition to other uses. The definition of "electronic prescription" is amended to be consistent with the definition used in HB2165 and SB1230
15	n/a	Sets out criteria for delegation to an agency subordinate	Repealed in Chapter 20 and replaced by 18VAC110-15-10.
20	n/a	Sets out fees associated with licensure	All fees related to regulation of pharmacists and pharmacy technicians

			are deleted and now found in Chapter 21. Fees for humane society permits are deleted since the fee is no longer charged. Humane societies (now animal shelters) used to get a permit and a controlled substance registration (CSR). Now only the CSR is required.
21	n/a	Sets requirements for submission of a public address by individuals regulated by the board	Deleted in Chapter 20; replaced in Chapter 21.
25	n/a	Sets out practices that may constitute unprofessional conduct	Those that pertain exclusively to actions by a pharmacist or pharmacy technicians are deleted. Additional practices are included based on situations encountered in disciplinary cases and/or included in other chapters enacted by other health regulatory boards.
Part II	n/a	Sections 30 – 100 pertain to licensure of pharmacists	Deleted in Chapter 20; replaced in Chapter 21
Part III	n/a	Sections 101 – 106 pertain to registration of pharmacy technicians	Deleted in Chapter 20, replaced in Chapter 21
110	n/a	Sets out the general requirements for a pharmacy permit	Subsection D is amended to require a pharmacist to have a minimum of 2 years of experience before becoming a PIC (pharmacist-in-charge). The Board has authority to grant an exception. *There are numerous responsibilities of a PIC for the inventory and security of the pharmacy (see Guidance Document 110-27). The Board is concerned that inexperienced pharmacists do not have the broad knowledge of pharmacy operations sufficient to serve as PIC. The change is intended to protect the public but also the pharmacists who might be assigned the job of PIC by an employer before he/she was ready to assume such a responsibility.*
n/a	112	Sets out the requirement for supervision of pharmacy technicians within a pharmacy.	The requirement in subsections A and B of Section 112 are currently found in subsections A and B of section 270. They did not seem to belong in the Part on Prescription Orders And Dispensing Standards so were moved to Part III on Pharmacies
140	n/a	Sets out the requirements for new pharmacies, acquisitions and changes to existing pharmacies	Subsection C is added to clarify that a closing inventory by a PIC is not required, but that on the date a pharmacist first engages in business under new ownership, a complete and

			accurate inventory is required. All inventories must be in compliance with Section 110. Subsection G is added to specify that if the pharmacy is not operational within 90 days from issuance of the permit, it is rescinded unless an extension is granted. *Once the Board grants a permit for operation of a pharmacy, there are controlled substances stocked that should not be left in a facility that is not operational. The Board will allow 90 days from the date the permit is issued for last minute preparations to occur.*
150	n/a	Sets out the physical standards for all pharmacies	Subsection F is amended to exempt pharmacies with a limited-use permit that does not stock prescription drugs from the requirement to have a sink with hot and cold running water. *There are some entities that have a pharmacy permit for consulting or medication management purposes only; they do not need to have a sink with hot and cold water.* To protect the integrity and safety of drugs that must be maintained in cold storage, a specific requirement is added in Subsection H for daily recording of the temperature and adjustment necessary to ensure the appropriate range. The temperature record has to be maintained for two years so it is available for board inspectors to review and ensure compliance.
180	n/a	Sets out requirements for a pharmacy security system	Subsection A 2 is amended to require a device for detection of breaking to have at least one hard-wired communication method, so if the power is cut, the device will still be capable of sending an alarm signal. Subsection A 5 is added to require that the alarm system include notification to the PIC or a pharmacist working at the pharmacy in the event of a breach.
200	n/a	Sets out requirements for storage	Subsection B is amended to allow a pharmacy to use a combination of the methods for dispersion of Schedule II drugs. Those drugs may either be dispersed with other schedules or maintained in a securely locked cabinet or safe. The amendment, allowing both methods to be used, is the current guidance found in Guidance Document 110-40.

240	n/a	Sets out the manner of maintaining records, prescriptions, and inventory records	Currently, Guidance Document 110-16 offers the Board's interpretation of requirements for performing inventories. Amendments to section 240 are consistent with guidance on inventories for Schedules I and II drugs and require a physical count to be performed. The perpetual inventory of Schedule II drugs should indicate the physical count of drugs on hand at the time of the inventory and must include a written explanation for any difference between the physical count and the theoretical count. *Schedule II drugs are the most likely to be diverted, so a pharmacy is required to keep a "running" count of dispensing. At the monthly reconciliation of inventory for Schedule II drugs, the physical count and the "running" count should be the same.* *While inventories of Schedules I and II drugs must include a physical count, inventories of Schedules III through V may be performed by estimated the count unless the container contains greater than 1,000 tablets or there has been a theft or unusual loss of drugs. In which case, a physical count is required. The proposed amendment is consistent with federal rules, which allows the count to be estimated if it is less than 1,000 tablets.* *Subsection C 2 on chart orders is amended to specify that an order for out-patient dispensing must meet the minimum requirements for a prescription, found in section 286. Since the order is going to be dispensed by an outside pharmacy, the pharmacist will need the same information as a regular prescription for purposes of record-keeping, etc.*
270	n/a	Sets out the requirements for dispensing and certification of a completed prescription	Subsections A and B, relating to supervision of pharmacy technicians are deleted and moved to General Provisions. A new subsection A is added to specify that a prescription must include the quantity or duration of the order, so the pharmacist can calculate the authorized quantity using directions for use. It also provides that a written prescription must

			include the prescriber's manual signature. *The additional requirements are intended to ensure that the prescription was ordered by the prescriber himself or herself and that the pharmacist has enough information to provide appropriate directions to the patient.* Subsection D is amended to give a pharmacist who is presented with a forged prescription the option of returning it to the customer or keeping it for law enforcement. *Current regulation prohibits the return of a forged prescription but pharmacists sometimes feel threatened by refusing to return it. For their protection, the amended regulation gives them the option depending on the situation.* *Subsection F adds language currently found in Guidance Document 32 on the use of a drop-box for refill prescriptions. The drop-box must be secure and made confidential, and the pharmacist must inform the public that containers left in the drop-box should not have unused drugs.*
280	n/a	Sets out requirements for transmission of a prescription order by facsimile machine	An amendment to subsections B and D clarify that a faxed prescription is considered a written prescription and must contain the prescriber's manual signature.
290	n/a	Sets out requirements for dispensing of Schedule II drugs	Subsection D is added to include language currently found in Guidance Document 110-41 regarding the additions or corrections a pharmacist is allowed to make on a Schedule II prescription, including those that require consultation with the prescriber. It also specifies those changes the pharmacist is never allowed to make.
355	n/a	Sets out requirements for repackaging of drugs and the records and labeling required	Subsection C is added to specify that repackaging must be in compliance with USP-NF standards.
390	n/a	Sets out prohibitions on kickbacks, fee-splitting, etc.	Currently, prohibitions pertain to actions by a pharmacist so provisions of this section were duplicated in Chapter 21. However, a pharmacy is also prohibited from engaging in these acts, and the Board could take disciplinary actions against a pharmacy permit. Therefore, the language in Section 390 is modified to pertain to pharmacies.

425	n/a	Sets out requirements for use of robotic pharmacy systems	In review of this section and recommendations from systems that use robotic systems, the Board amended to delete counts and procedures that were not necessary to ensure proper functioning and accuracy. Instead, regulations require performance of a root cause analysis if the robot makes an error and correct of the source of the discrepancy. Subsection B is a clarification that intravenous admixture robotics may be used to compound and do not require a separate approval from the board.
490	n/a	Sets out requirements for automated devices for dispensing & administering drugs	Subsection B is amended to clarify that the policy and procedure manual must include provisions for granting and terminating user access. *It is vital that the only appropriately qualified users have access to automated devices that dispense drugs to prevent diversion for personal use or for sale.* *Subsection C 2 is amended to provide that the PIC is responsible for "ensuring" reconciliation of any discrepancy or properly reporting of the loss of drugs. The amendment will allow the PIC to delegate that to another pharmacist rather than being personally responsible for the reconciliation of reporting.* *Subsection D will allow records of automated dispensing devices to be maintained electronically.* *Subsection E is amended to clarify that a discrepancy report is required for all Schedule II through V drugs and any drug of concern; without the specification of schedules, the regulation could be interpreted to include Schedule VI drugs. The regulation is further amended to provide that a discrepancy report must be "initiated" or resolved with 72 hours. Sometimes, it isn't possible to resolve the discrepancy within 72 hours, but the report should at least be initiated.* *Subsection F 3 is amended to clarify that the monthly audit of a device should review the dispensing and administration records of Schedule II through V drugs.*
530	n/a	Sets out the pharmacists responsibilities for drugs in long-term care facilities	The amendment in new subsection B was requested by a pharmacist through a petition for rulemaking. The Board

			agreed with the request but determined that the change could be included in the periodic review. Subsection B allows a provider pharmacy for a long term care facility to share a prescription with a back-up pharmacy to dispense no more than a seven–day supply without transferring the prescription. It will facilitate coverage when the provider pharmacy experiences a temporary shortage in a medication that is needed at the facility.
550	n/a	Provides requirements for use of a stat-drug box in long-term care	The amendment in Subsection A will clarify that the stat-drug box may include a substitution of liquid for solid dosage unit for each drug schedule. New subsection B is added to allow a long-term care facility to have more than one stat-drug box with varying contents.
580	n/a	Sets out requirements for drugs in humane societies and animal shelters	Amendments conform terminology to language in the Code of Virginia, which no longer refers to "animal shelters."
630	n/a	Sets out conditions for issuance of a permit as a medical equipment supplier	This section is amended to clarify that the MES must designate the hours of operation when it is open to the public and to require notification to the Board and to the public if those hours change. *These requirements are similar to those for pharmacies. Medical equipment suppliers are sometimes open for limited hours; the Board needs to know the hours of operation and when the facility is open to know when an inspection can occur.*
680	n/a	Sets out rules for medical equipment suppliers	A new subsection E is added to allow the transfer of a valid order from one MES to another for dispensing. Rules establish how the transfer may occur and the recordkeeping required to ensure all necessary information is conveyed and records maintained.

Chapter 50 Regulations Governing Wholesale Distributor, Manufacturers, Third-Party Logistics Providers, and Warehousers

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
40	n/a	Sets out requirements for safeguards against diversion of drugs	Subsection B is amended to add the same requirement as that for pharmacies in section 18VAC110-20-180. Subsection B 2 is amended to require a device for detection of breaking to have at least one hard-wired communication method and wireless motion sensors, so

			if the power is cut, the device will still be capable of sending an alarm signal. Subsection B 3 is added to require that the alarm system include notification to the monitoring device if the communication line is not operational.
60	n/a	Sets out requirements for issuance of special or limited-use licenses	To allow the issuance of a limited-use license to manufacturers, that category is added in this section. An amendment further specifies that the issuance of such a license is subject to continued compliance with conditions set by the board. For example, if a facility does not stock controlled drugs and devices, it may not be necessary to have the extensive security system required for other such facilities.
80	n/a	Sets out minimum qualifications, eligibility for licensure of wholesale distributors and third-party logistics providers	Subsection C is amended to change the reference from the specific name "Central Criminal Records Exchange" to the generic term "federal criminal history record check."

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-section number	Proposed new chapter-section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
110-20-15	110-15-10	Sets out the criteria for delegation to an informal fact-finding proceeding to an agency subordinate.	The new section in Chapter 15 is identical to the current section in Chapter 20. Since Chapter 20 will only regulate pharmacies, a new chapter is necessary to make the criteria for an agency subordinate applicable to all persons and entities regulated by the Board.

Current chapter-section number	Proposed new chapter-section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
110-20-10	110-21-10	Sets out definitions for words and terms used in the chapter	Definitions for words and terms used in Chapter 21 are identical to those currently found in Chapter 20.
110-20-20	110-21-20	Establishes fees required for initial licensure or registration; for renewal; and other miscellaneous charges	All fees are identical to those currently found in Chapter 20.
110-20-21 and 110-20-104	110-21-30	Sets requirements for maintenance of current address.	Regulations in Chapter 21 are identical to Chapter 20, except there is also are requirement to notify the Board of a name change.

			To maintain current records on regulants, it is necessary for the Board to have the name someone currently uses. Regulants typically do notify the Board of a name change, but it has not been a requirement.
110-20-25	110-21-40	Establishes those practices that may constitute unprofessional conduct within the meaning of § 54.1-3316.	The provisions in the unprofessional conduct section are identical to those currently in Chapter 20, except the Board has proposed several additions. Numbers 11 through 15 are new and recommended to address actions that are clearly unprofessional but may not currently be directly identified in regulation. All of the additional causes for discipline are found in other health professional regulations.
110-20-390	110-21-45	Sets out prohibition on kickbacks, fee-splitting, or interference with suppliers	The prohibitions in Section 45 are identical to those currently found in Chapter 20.
110-20-30	110-21-50	Sets out the requirements for pharmacy practical experience	The requirements in Section 50 are identical to those currently found in Chapter 20.
110-20-40	110-21-60	Sets out the requirements for gaining practical experience	The requirements in Section 60 are identical to those currently found in Chapter 20.
110-20-50	110-21-70	Establishes the curriculum and approved schools of pharmacy	The requirements in Section 70 are identical to those currently found in Chapter 20.
110-20-60	110-21-80	Establishes the content of the examination and limitation to admittance to examination	The requirements in Section 80 are identical to those currently found in Chapter 20.
110-20-70	110-21-90	Establishes the requirements for foreign-trained applicants	The requirements in Section 90 are identical to those currently found in Chapter 20.
110-20-75	110-21-100	Sets out requirements for registration of voluntary practice by out-of-state licensees	The requirements in Section 100 are identical to those currently found in Chapter 20.
110-20-80	110-21-110	Establishes the requirements for renewal and reinstatement	The requirements in Section 110 are identical to those currently found in Chapter 20.
110-20-90	110-21-120	Establishes the requirements for continuing education	The requirements in Section 120 are identical to those currently found in Chapter 20 with the exception of subsection C, which proposes to require that five of the required 15 hours be obtained in courses or programs that are live or interactive. There are two new activities that may be used to fulfill live CE, including one hour for attendance at a board meeting or hearing and one hour for serving as a preceptor for someone gaining practical experience.

			The Board believes pharmacists benefit from some interactive in an educational environment, so a portion of CE hours need to be live or interactive. It would not be necessary for a pharmacist to attend a course in person, but participation in an interactive, real-time course would suffice.
110-20-100	110-21-130	Establishes the requirements for approval of continuing education programs	The requirements in Section 130 are identical to those currently found in Chapter 20.
110-20-101	110-21-140	Sets out requirement for registration as a pharmacy technician	The requirements in Section 140 are identical to those currently found in Chapter 20 with the exception of subsection D. *Currently, the regulation states that a pharmacy technician trainee may perform restricted tasks for nine months before becoming registered. In Guidance Document 110-20, the Board has interpreted the rule to mean "nine consecutive months from the date the pharmacy technician trainee begins performing duties restricted to a pharmacy technician as part of a Board-approved pharmacy technician training program." This allows a trainee more time to begin the program with didactic learning and still have nine months to complete the hands-on practical training.*
110-20-102	110-21-150	Establishes the criteria for approval of pharmacy technician training programs	The requirements in Section 150 are identical to those currently found in Chapter 20.
110-20-103	110-21-160	Establishes the requirements for pharmacy technician examination	The requirements in Section 160 are identical to those currently found in Chapter 20.
110-20-105	110-21-170	Establishes the requirements for renewal and reinstatement	The requirements in Section 170 are identical to those currently found in Chapter 20.
110-20-106	110-21-180	Establishes the requirements for continuing education	The requirements in Section 180 are identical to those currently found in Chapter 20.