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Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq. 18VAC110-50-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Periodic review
Date this document prepared	9/12/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. 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 Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated.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 considered 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

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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 new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is 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 16, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

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 there are no disadvantages to the public or the Commonwealth, please indicate.

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 identify and describe any requirement of the proposal which is 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 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.

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 of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/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 via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

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**	a) 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 for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	All persons and entities regulated under the Board of Pharmacy are potentially affected by changes to existing regulations.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	At the end of 2017, there were 36,441 persons or entities that have been issued a license, registration, or permit by the Board. (*See current chart of entities regulated by the Board below-Q3-FY15 to Q2-FY18*) There is no estimate of the number of small businesses; the majority of pharmacies are part of large national chains. Since regulations in the new Chapter 21 for pharmacists and pharmacy technicians are largely identical to current regulations, the changes are unlikely to have any effect on them.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and**	There are no additional costs.

b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	The benefits of this action are more clarity and specificity in regulation.

Business CSR	1,037	1,096	1,116	1,136	1,042	1,125	1,151	1,173	1,109	1,158	1,196	1,263
CE Courses	13	12	12	11	11	9	9	9	9	9	9	9
Humane Society	0	0	0	0	0	0	0	0	0	0	0	0
Limited Use Pharmacy Technician	21	21	22	22	19	20	21	22	18	18	19	18
Medical Equipment Supplier	603	637	645	659	595	618	622	631	251	261	258	267
Non-resident Manufacturer	-	-	-	-	-	-	-	-	-	-	-	18
Non-resident Medical Equipment Supplier	-	-	-	-	-	-	-	-	303	320	335	347
Non-resident Outsourcing Facility	-	-	-	-	-	10	12	13	14	22	26	27
Non-resident Pharmacy	637	639	659	679	686	690	691	692	693	714	732	736
Non-resident Wholesale Distributor	768	802	825	834	733	759	767	782	712	744	749	747
Non-restricted Manufacturer	23	24	26	30	30	31	32	34	30	30	29	30
Outsourcing Facility	-	-	-	-	-	1	1	0	0	0	0	0
Permitted Physician	3	3	3	4	3	3	3	4	1	1	1	2
Pharmacist	13,058	13,394	13,746	13,902	13,539	13,813	14,210	14,379	14,054	14,258	14,714	14,221
Pharmacist-Volunteer Registration	0	4	0	0	0	0	0	0	0	0	0	0
Pharmacy	1,827	1,825	1,834	1,840	1,843	1,854	1,852	1,844	1,842	1,849	1,857	1,864
Pharmacy Intern	2,048	2,070	2,013	2,154	1,973	2,058	2,072	2,094	1,852	1,929	1,848	1,813
Pharmacy Technician	12,935	13,686	14,155	14,644	13,056	13,719	14,373	14,826	13,242	13,913	14,552	12,636
Pharmacy Technician Training Program	113	116	118	122	116	120	128	128	128	138	140	142
Physician Selling Controlled Substances	627	671	707	704	629	666	719	741	638	674	727	611
Physician Selling Drugs Location	269	226	233	221	215	222	205	211	163	168	175	128
Pilot Programs	7	10	10	10	18	18	20	20	9	9	10	9
Repackaging Training Program	1	1	1	1	1	0	0	2	2	2	2	2
Restricted Manufacturer	71	71	71	71	69	69	69	70	66	66	66	68
Warehouser	47	48	48	49	45	47	49	50	47	45	47	47
Wholesale Distributor	118	120	121	125	118	120	119	119	106	113	116	118
	34,226	35,476	36,365	37,218	34,741	35,972	37,125	37,844	35,289	36,441	37,608	34,789

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.

Since publication of the Notice of Intended Regulatory Action in the summer of 2016, the Regulation Committee of the Board reviewed regulations section by section to consider inclusion of guidance on the board's interpretation of its regulations and other requests for amendments. The Committee met on 11/29/16, 2/28/17, and 5/10/17. After each meeting, the amendments recommended were adopted by the Board over a period of three board meetings – 12/12/16, 3/21/17, and 6/27/17. The Board sought to amend regulations for greater clarity and consistency with newer technology and practices in pharmacy.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There is no alternative method other than amending regulations for the practice of pharmacy to achieve the goal of public safety for the drug supply.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

The Board has reviewed and amended its regulations for clarity, consistency, and current application to pharmacy practice; it has determined that they are necessary for protection of public health and safety.

1) There is a continued need for the regulation as it is mandated in § 54.1-3307 of the Code of Virginia.
2) The Board receives comments from interested parties and petitions for rulemaking on a regular basis. Some of the petitions relate to a modification that would allow an entity to facilitate their services. Whenever possible, the Board has been responsive to those requests. Several of the petitions resulted in no regulatory action being initiated at that time, but the issue was referred to the Regulation Committee for further study and recommended action.
3) Regulations for the Board of Pharmacy are relatively complex because the dispensing of drugs has the potential for patient harm, and the opportunity for diversion is apparent. Wherever possible, the Board has amended its regulation for more clarity.
4) Virginia regulations for pharmacies must be consistent with federal law and regulation but do not overlap or duplicate.
5) Chapter 20, Regulations Governing the Practice of Pharmacy has been amended 46 times in the last ten years; there are five regulatory actions in process at this time. Regulations are frequently evaluated and amended as technological changes and other factors affect the practice of pharmacy.

Public comment

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

Commenter	Comment	Agency response
Dale StClair	Opposes a change noted in the NOIRA that would require a chart order in long term care facilities to	The regulation as amended would require a chart order that is being used as a prescription for out-patient dispensing to

	include a quantity or duration of treatment.	comply with requirements for a prescription. (see 240 C) It does not affect chart orders filled by the provider pharmacy for the facility.
Travain Sutphin	Same as above	Same as above
Steve Ford VHCA	Same as above	Same as above
Otto Wachsmann	Expressed concern about: 1) the proposal to prohibit the use of dormitory style refrigerators; 2) changes in the physical barrier requirements; and 3) requirement for security system to be hard-wired.	The Board did not choose to make changes to the refrigeration requirements or the physical barriers. The amendment to the security system will not require additional inspections; the current requirement states that a security device must be based on accepted alarm industry standards – which require some ability for the alarm to work if cell coverage is disrupted. The Board regards the amendments to subsection A to be clarifying in nature.
Bill Irvin	1) Same comment as above regarding section 240; and 2) Requested that the Board not eliminate the ability to fax a prescription from a long term care facility to a pharmacy	1) Same response as above 2) The Board did not eliminate the provision allowing for a faxed prescription.

Family impact

Please assess the impact of this 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 on the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

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	Since Chapter 20 no longer applies to

		and terms used in the Chapter	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	Proposed new chapter-section	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

number	number, if applicable		
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	The requirements in Section 110 are identical to those currently found in

		reinstatement	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.