COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

(804) 367-4456 (Tel)
(804) 527-4472(Fax)

Tentative Agenda of Regulation Committee Meeting
Periodic Regulatory Review
March 24, 2016
1PM

TOPIC	PAGES
Call to Order: Ellen Shinaberry, Committee Chairman	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Review Summary of Committee's Recommendations for Periodic Review of *Regulations Governing the Practice of Pharmacy,* chapter 20, and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*, chapter 50	1-6
○ Reference Materials:	
▪ Final Minutes of Regulation Committee Meeting, November 3, 2015	7-12
▪ Draft Minutes of Regulation Committee Meeting, January 5, 2016	13-18
Adjourn	

**The next meeting of the Regulation Committee is scheduled for May 26, 2016.*

DRAFT Substance for Notice of Intended Regulatory Action

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

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 25, 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 Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated.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 to the following sections of Chapter 20 (or the new chapter 25) will be considered in the promulgation of proposed regulations:

PART I. General Provisions.

18VAC110-20-10. Definitions

- Modifying definition for "robotic pharmacy system."

18VAC110-20-20 Fees

- Changing the renewal for pharmacist licenses and pharmacy technician registrations to a date different from December 31st, but retain the facility renewal dates for facilities. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-21 Public address

- Adding requirement for notification to the board if there is a name change and specify documentation that must be submitted. Consider a specific timeframe for notification.

18VAC110-20-25 Unprofessional conduct

- Adding failure to submit corrective action related to inspection deficiency within a specified time frame.
- Adding dispensing any controlled substance with the intent or knowledge that it will be used otherwise than medicinally, for accepted therapeutic purposes, or with the intent to evade any law with respect to the sale or use of such drug.

PART II. Licensure Requirements for Pharmacists.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Specifying a timeframe for validity of law exam score to 3 years, consistent with requirements for record retention.

18VAC110-20-80 Renewal and reinstatement of license

- Clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee rather than the current active renewal fee.
- Revising terms "reactivate" and "reinstate" for correct and consistent usage.

18VAC110-20-90 Requirements for continuing education (CE)

- Accepting additional inter-professional continuing education.
- Changing wording in (B) (2) from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of continuing education.
- Requiring a portion of the 15 required hours to be live or real-time interactive continuing education.

18VAC110-20-100 Approval of continuing education programs

- Deleting ability for board to approve CE programs.

PART III. Requirements For Pharmacy Technician Registration.

18VAC110-20-102 Criteria for approval of training programs

- Including requirement for training program approval number to be printed on certificate awarded by training program.
- Requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.

18VAC110-20-106 Requirements for continued competency

- Changing "certificates" to "documentation" in both sentences of subsection D.

PART IV. Pharmacies.

18VAC110-20-110 Pharmacy permits generally

- Specifying minimum number of hours pharmacist-in-charge (PIC) must practice at the location listed on the pharmacy permit application
- Requiring minimum number of years of experience for pharmacist-in-charge eligibility.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarifying requirements for acquisitions with regard to inspection and inventory
- Requiring an inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarifying requirements for acquisitions with regard to inspection and inventory

- Allowing Board to rescind pharmacy permit if not opened within 60 days of issuing permit.

18VAC110-20-150 Physical standards for all pharmacies

- Specifying acceptable refrigeration facilities based on Center for Disease Control guidance for vaccine storage, require calibrated thermometer, weekly temperature logs or documentation; exemption of sink requirement if pharmacy does not stock prescription drugs.

18VAC110-20-180 Security system

- Requiring security system to have at least one hard wired communication method for transmitting breach as is required for wholesale distributors.
- Clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient.

18VAC110-20-190

- Amending physical requirements for a prescription department's enclosure.
- Amending requirement for locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

18VAC110-20-200 Storage of drugs, devices, and controlled paraphernalia; expired drugs

- Adding language from Guidance Document 110-40 regarding dispersion of Schedule II drugs.

PART VI. Drug Inventory and Records.

18VAC110-20-240 Manner of maintaining records, prescriptions, inventory records

- Adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Deleting language in subsection B regarding the red "C" unless this is based on federal rules.
- Clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

PART VII. Prescription Order and Dispensing Standards.

18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians

- Separating subsections A and B from the rest of the regulation.
- Addressing concern in subsection B by the Virginia Pharmacist Association with pharmacists not being provided adequate pharmacy technician support.
- Reviewing appropriateness of requiring pharmacists to not return a forged prescription.
- Regarding subsection F and on-hold prescriptions, revising requirement for pharmacy to pull the originally filed prescription and refile it.
- Adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

18VAC110-20-275 Delivery of dispensed prescriptions

- Addressing concerns with white bagging and brown bagging.
- Revising section 275 for more clarity.

18VAC110-20-277 Prescription Requirements

- Adding new regulation in section 277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

18VAC110-20-280 Transmission of a prescription order by facsimile machine

- Clarifying that a requirement for a signature to be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Considering whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

18VAC110-20-290 Dispensing of Schedule II drugs

Adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

PART VIII. Labeling and Packaging Standards for Prescriptions.

18VAC110-20-355 Pharmacy repackaging of drug; records required; labeling requirements

Amending requirement for how to identity pharmacist verifying accuracy of the process.

PART X. Unit Dose Dispensing Systems.

18VAC110-20-425 Robotic Pharmacy Systems

- Streamlining robotic pharmacy system regulations by striking #5 and simplifying #4.
- Strengthening requirements for pharmacist accountability in assigning bar codes.

Part XI Pharmacy Services to Hospitals

18VAC110-20-470 Emergency room

In #2, consider changing "practitioner" to "prescriber"

18VAC110-20-490 Automated devices for dispensing and administration of drugs

- Streamlining requirements for automated dispensing devices in hospitals.
- Clarifying that drug for emergency use may include drugs for first doses.
- Clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.

Part XII Pharmacy Services to Long-Term Care Facilities

18VAC110-20-550 Stat-drug box

- Clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarifying that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

18VAC110-20-555 Use of automated dispensing devices

Considering whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

PART XIII Other Institutions and Facilities

18VAC110-20-580 Humane societies and animal shelters

- Amending regulation based on recent amendments to §54.1-3423; changing term for humane societies to public or private animal shelters.

PART XV Medical Equipment Suppliers (MES)

18VAC110-20-630 Issuance of a permit as a medical equipment supplier

- Adding requirement that applications must include name of responsible party
- Requiring MES to notify the Board within 14 days of a change in the responsible party

18VAC110-20-680 Medical equipment suppliers

- Adding language from Guidance Document 110-19 for MES to transfer prescriptions.
- Adding requirement to provide Board with hours of operation and notification to board and public when hours change.

PART XVI Controlled Substance Registration for Other Persons or Entities

18VAC110-20-710 Requirements for storage and security for controlled substance registrants

- Amending schedules to include Schedule I

The Board considered whether there is a better method for identifying the responsible pharmacist as initials are required 23 times throughout regulations of the Board. It is likely the Board review all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

18VAC110-50-40 Safeguards against diversion of drugs

- Amending B, 2 that communication line must be hardwired, but sensors may be wireless.
- Amending B, 3 to require the security system to be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operable.

Part II Wholesale Distributors

18VAC110-50-60 Special or limited-use licenses

- Expanding ability to issue limited use for other entities such as third party logistic providers if law passed during 2016 General Assembly session to create this licensing category.

18VAC110-50-70 Minimum required information

- Placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

18VAC110-50-80 Minimum qualifications, eligibility, and responsible party

- Requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.
- For consistency, considering similar requirements in 18VAC110-20-80 for responsible party of manufacturers.

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING – PERIODIC REGULATORY REVIEW

November 3, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The meeting was called to order at 1:09pm
PRESIDING:	Ellen B. Shinaberry, Chairman
MEMBERS PRESENT:	Ryan Logan Cynthia Warriner Melvin Boone
MEMBER ABSENT:	Rebecca Thornbury
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Deputy Executive Director Cathy M. Reiniers-Day, Deputy Executive Director Beth O'Halloran, Individual Licensing Manager Elaine J. Yeatts, Senior Policy Analyst
APPROVAL OF AGENDA:	The agenda was approved as presented.
PUBLIC COMMENT:	There was no public comment offered.
ISSUANCE OF CONTROLLED SUBSTANCES REGISTRATIONS TO MULTIPLE MEDICAL CLINICS LOCATED WITHIN A MEDICAL OFFICE BUILDING WITH SAME OWNERSHIP:	Ms. Juran provided background on previous discussion at the September 2015 full board meeting and the previous historical discussions surrounding the requests for the issuance of a single Controlled Substance Registration (CSR) to multiple clinics that are located within a medical office building with the same owner. She stated she surveyed several states and that most do not issue CSRs for the purpose of stocking drugs. They issue the CSRs for prescriber purposes. Delaware, however, issues CSRs in a manner similar to Virginia and it currently does not issue a single CSR to a building of multiple clinics. It issues CSRs to individual clinics within the building.
RECOMMENDATION:	**The Committee voted unanimously to recommend to the full board that it not issue a single controlled substances registration (CSR) to multiple medical clinics that are located within the same medical**

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office building with shared ownership.

- Review of Parts I-IV and XIII-XVII of *Regulations Governing the Practice of Pharmacy, Chapter 20*

Ms. Yeatts reviewed the procedure with the Committee for the periodic regulatory review process. She stated a notice of periodic regulatory review has been posted on Town Hall and shared with the public participation guidelines list maintained by board staff. The public comment period is from November 30, 2015 until December 30, 2015. She indicated the Committee must first identify regulations that it will consider amending and that these regulations will be listed in the Notice of Intended Regulatory Action (NOIRA) once the board completes its review of the regulations in chapters 20 and 50. Because chapter 20 has become quite lengthy, she also recommended the board consider breaking chapter 20 into 3 separate chapters: one chapter for addressing individuals such as pharmacists, pharmacy technicians, and interns; one for addressing pharmacies; and one for addressing facilities other than pharmacies. The Committee then began identifying such regulations in chapter 20 (Attachment 1) and will continue this work at subsequent Regulatory Committee meetings until this first step is completed.

ADJOURN:

Next meeting will take place on January 6, 2016.

With all business concluded, the meeting concluded at approximately 5:00 pm.

Ellen B. Shinaberry, Chairman

12/28/15
DATE:

Caroline D. Juran, Executive Director

12/1/15
DATE:

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Attachment 1

Below are regulations in Chapter 20, Parts I-IV and XIII-XVII identified by the Regulation Committee to be considered by the full board for inclusion in the Notice of Intended Regulatory Action (NOIRA) as part of the periodic regulatory review.

Part I. General Provisions

18VAC110-20-10 Definitions.

18VAC110-20-15 Criteria for delegation of informal fact-finding proceedings to an agency subordinate

- Should be moved to its own separate chapter

18VAC110-20-20 Fees

- Consider staggering renewals for pharmacist licenses and pharmacy technician registrations. Committee recommended no change to facility renewals. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-25 Unprofessional conduct

- Ms. Reiniers-Day to research other boards' language.

Part II. Licensure Requirements For Pharmacists

18VAC110-20-50 Curriculum and approved schools of pharmacy

- Consider striking subsection B to eliminate language for "first" professional degree. Staff to do further research on implications of this recommendation and will discuss at future meeting.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Discussed limiting validity of law exam score to 2 years, but recommended limiting to 3 years based on record retention.

18VAC110-20-80 Renewal and reinstatement of license

- Recommended clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee as staff is currently requiring and not the current active renewal fee.
- Staff will review to ensure the terms "reactivate" and "reinstate" are being used correctly.

18VAC110-20-90 Requirements for continuing education

- Consider ability to accept inter-professional continuing education; staff to research how it is currently being awarded and by whom.

FINAL/APPROVED
Attachment 1

- Suggested wording in (B) (2) be changed from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of CE
- Consider striking ability for board to approve and accept board-approved CE programs
- Committee discussed recommendations for requiring live CE and having ability to carry over hours into subsequent year, but concluded a statutory amendment would be necessary. Staff will research what other state boards of pharmacy may require live CE.
- Committee discussed recommendation for requiring CE annually in the subject of opioids. Statutory ability to specify topic for CE annually also discussed. No final recommendation was made.

18VAC110-20-100 Approval of continuing education programs

- Suggestion to remove ability for board to approve CE programs.

PART III Requirements For Pharmacy Technician Registration

18VAC110-20-102 Criteria for approval of training programs

- Consider including training program approval number to be printed on certificate awarded by training program.
- Consider requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.

18VAC110-20-106 Requirements for continued competency

- Consider changing "certificates" to "documentation" in both sentences of subsection D.

PART IV Pharmacies

18VAC110-20-110 Pharmacy permits generally

- Consider specifying minimum number of hours PIC must practice at the location listed on the pharmacy permit application
- Consider requiring minimum number of years of experience for PIC eligibility. There was discussion for a possible ability for exceptions, but no final recommendation made.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider requirement for inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider amending to allow Board to rescind pharmacy permit if not opened within 60 days of issuing permit. Concern raised that board counsel may recommend criteria if the term "may" is used as proposed in the agenda packet.

FINAL/APPROVED
Attachment 1

18VAC110-20-150 Physical standards for all pharmacies

- Consider specifying acceptable refrigeration facilities based on CDC guidance for vaccine storage, require calibrated thermometer, weekly temperature logs or documentation; exemption of sink requirement if pharmacy does not stock prescription drugs.

18VAC110-20-180 Security system

- Consider requiring security system to have at least one hard wired communication method for transmitting breach as is required for wholesale distributors.
- Consider clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient. Committee discussed whether pharmacist must practice at the pharmacy or if acceptable to notify district supervisor pharmacist who does not necessarily practice at location. No final recommendation made.
- Discussed whether regulation should clarify how long security system auxiliary source of power must last, but concluded that it may be problematic to address this issue.

18VAC110-20-200 Storage of drugs, devices, and controlled paraphernalia; expired drugs

- Add language from Guidance Document 110-40 regarding dispersion of Schedule II drugs
- Discussed clarifying subsection D to include old chemicals used for compounding, but concluded that the board should consider adopting guidance indicating subsection D includes old chemicals and that it will be a violation of this regulation to use old chemicals that exceed the expiration date that is assigned based on USP standards.

PART XIII Other Institutions and Facilities

18VAC110-20-580 Humane societies and animal shelters

- Amend regulation based on recent amendments to §54.1-3423 changing term for humane societies to public or private animal shelters.

PART XV Medical Equipment Suppliers

18VAC110-20-630 Issuance of a permit as a medical equipment supplier

- Add language to regulation that applications must include name of responsible party
- Requirement to notify the Board within 14 days of a change in the responsible party

18VAC110-20-680 Medical equipment suppliers

- Consider adding language from Guidance Document 110-19 for MES to transfer prescriptions based on amended handout.
- Consider adding requirement to provide Board with hours of operation and notification to board and public when hours change.

PART XVI Controlled Substance Registration for Other Persons or Entities

FINAL/APPROVED
Attachment 1

18VAC110-20-710 Requirements for storage and security for controlled substance registrants

- Amend schedules to include Schedule I

Additional subjects recommended for inclusion in board regulations:

18VAC110-20-22 (as proposed by staff in 11/3/15 agenda packet) – Submission of corrective action related to inspections

- Consider adding requirement in the General Provisions for PIC, responsible party, or owner to respond to inspection deficiencies within 14 days. This would be added to all relevant facility chapters.

18VAC110-20-10

- Review definition for "robotic pharmacy system"; appears to encompass more than traditional robot addressed in 18VAC110-20-425.

General ability for pharmacist to delegate to someone else to enter pharmacist's initials when required for recordkeeping purposes

Regulations discussed but <u>not</u> recommended for inclusion in the NOIRA:

18VAC110-20-40 Procedure for gaining practical experience

- Discussed adding requirement for licensees to submit certain documents when individual's name changes. However, decided not to require licensee change name in regulation, but to continue addressing in policy the documents needed to change a licensee's name.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING – PERIODIC REGULATORY REVIEW

January 5, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:15pm

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT: Ryan K. Logan
Cynthia Warriner
Melvin L. Boone, Sr.
Rebecca Thornbury

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Elaine J. Yeatts, DHP Senior Policy Analyst
Beth O'Halloran, Individual Licensing Manager

APPROVAL OF AGENDA: The agenda was approved as presented.

MOTION: **The Committee voted unanimously to approve the agenda as requested for the Regulation Committee meeting (motion by Warriner, second by Boone)**

PUBLIC COMMENT: Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) provided further explanation of the written comments submitted to the Board requesting a strengthening of 18VAC110-20-270 to address concerns with pharmacists not being provided adequate pharmacy technician support.

AGENDA ITEMS: Ms. Yeatts reviewed the procedure with the Committee of this periodic review process. The Committee is to consider the public comment recently received and recommend regulations to the full board for its consideration which should be drafted or amended. If the full board agrees, a Notice of Intended Regulatory Action (NOIRA) will be adopted which simply identifies the areas of regulation the board may address. Once the executive branch review is completed and approval to publish

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the NOIRA is received, another public comment period will be opened for 30 days. Based on the comment received, the Board will then develop the proposed regulatory language. After review and approval by the Governor, the proposed regulations will be published and another public comment period will be opened for 60 days. Comment will be reviewed by the Board, final regulation will be adopted, and once the Governor approves the final regulation, a 30-day final adoption period will begin.

The Committee reviewed written comments, provided as a handout by staff, regarding areas of regulation to consider amending during the periodic review. The handout included comments from pharmacist Jon Horton and pharmacist Jamin Engel submitted to Regulatory Town Hall, an email from VPhA, and a letter from NACDS. The committee determined it would not recommend the drafting of a regulation to allow for pharmacy technicians checking pharmacy technicians when using unit dose dispensing systems since this process could be considered on a case-by-case basis through the submission of an innovative pilot program application. Additionally, the Committee determined it would not recommend an allowance for regionalization of hospital packaging and compounding as this does not appear to be permissible under federal or state law. The Committee recommended including 18VAC110-20-190 and 18VAC110-20-270 in the NOIRA and will ensure the rulemaking aligns with any federal changes resulting from the Drug Quality and Security Act.

- Review of Parts V - XII of *Regulations Governing the Practice of Pharmacy, Chapter 20*

The Committee discussed this agenda item and considered staff's recommendations. The Committee's decisions regarding which regulations to include in the NOIRA are captured in Attachment 1.

- Review of *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers, Chapter 50*

The Committee discussed this agenda item and considered staff's recommendations. The Committee's decisions regarding which regulations to include in the NOIRA are captured in Attachment 1.

The Committee rejected staff's proposed amendment of 18VAC110-20-330 to require an expiration date on a prescription label.

- Draft regulatory language for NOIRA regarding unprofessional conduct to induce or incentivize a patient to transfer prescriptions.

Ms. Juran reviewed the excerpt of the Regulation Committee minutes from May 12, 2014 included in the agenda packet and the research summary presented at the time. The committee reviewed the proposed amendment prepared by staff for the Regulation Committee's review on May 12, 2014 as well as an excerpt from the full board meeting minutes from June 4, 2014.

MOTION:

The Committee voted unanimously to approve the proposed amendment to 18VAC110-20-25 as presented which would add "#11. Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not limited to, incenting or inducing the transfer of a prescription absent professional rationale" to the regulation on unprofessional conduct. (motion by Warriner, second by Thornbury)

ADJOURN:

Next Regulation Committee meeting is tentatively scheduled for March 24, 2016.

With all business concluded, the meeting adjourned at approximately 5:00 pm.

Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

Below are regulations in *Regulations Governing the Practice of Pharmacy*, Chapter 20, Parts V-XII and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*, Chapter 50 identified by the Regulation Committee to be considered by the full board for inclusion in the Notice of Intended Regulatory Action (NOIRA) as part of the periodic regulatory review.

18VAC110-20-10

- Review definition for "robotic pharmacy system".

18VAC110-20-190

- Consider amending physical requirements for a prescription department's enclosure.
- Consider amending A, 2 to not allow locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

Part VI Drug Inventory and Records

18VAC110-20-240 Manner of maintaining records, prescriptions, inventory records

- Consider adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Consider deleting language in subsection B regarding the red "C" unless this is based on federal rules.
- Consider clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

Part VII Prescription Order and Dispensing Standards

18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians

- Consider separating subsections A and B from the rest of the regulation.
- Consider addressing VPhA's concern with pharmacists not being provided adequate pharmacy technician support in subsection B.
- Regarding subsection E, consider appropriateness of requiring pharmacists to not return a forged prescription.
- Regarding subsection F and on-hold prescriptions, Warriner questioned if a pharmacist is required to pull the originally filed prescription and refile it. Staff to review issue.
- Consider adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

18VAC110-20-275 Delivery of dispensed prescriptions

- Consider amending to address delivery of Schedule II-VI drugs to a central desk at other facilities, e.g., assisted living facilities, hotels, places of employment, etc. Staff to consult DEA.
- Consider addressing concerns with white bagging and brown bagging.

18VAC110-20-277 Prescription Requirements

- Consider adding new regulation 18VAC110-20-277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

18VAC110-20-280 Transmission of a prescription order by facsimile machine

- Determined that staff's suggested amendments to clarify that signature must be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Consider whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

18VAC110-20-290 Dispensing of Schedule II drugs

- Consider adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

Part VIII Labeling and Packaging Standards for Prescriptions

18VAC110-20-355 Pharmacy repackaging of drug; records required; labeling requirements

- Consider amending requirement for how to identity pharmacist verifying accuracy of the process.
- Consider reviewing all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

Part X Unit Dose Dispensing Systems

18VAC110-20-425 Robotic Pharmacy Systems

- Consider streamlining robotic pharmacy system regulations by striking #5 and simplifying #4. May also need to amend the definition of robot.
- Consider strengthening requirements for pharmacist accountability in assigning bar codes.

Part XI Pharmacy Services to Hospitals

18VAC110-20-470 Emergency room

- In #2, consider changing "practitioner" to "prescriber".

18VAC110-20-490 Automated devices for dispensing and administration of drugs

- Consider streamlining requirements for automated dispensing devices in hospitals.
- Consider clarifying that drug for emergency use may include drugs for first doses.
- Consider clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.

Part XII Pharmacy Services to Long-Term Care Facilities

18VAC110-20-550 Stat-drug box

- Consider clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarify that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

18VAC110-20-555 Use of automated dispensing devices

- Consider whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

18VAC110-50-40 Safeguards against diversion of drugs

- Consider amending B, 2 that communication line must be hardwired, but sensors may be wireless.
- Consider amending B, 3 to require the security system to be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operable.

Part II Wholesale Distributors

18VAC110-50-60 Special or limited-use licenses

- Consider expanding ability to issue limited use for other entities such as third party logistic providers if law passed during 2016 General Assembly session to create this licensing category.

18VAC110-50-70 Minimum required information

- Consider placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

18VAC110-50-80 Minimum qualifications, eligibility, and responsible party

- Consider requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.
- For consistency, consider similar requirements in 18VAC110-20-80 for responsible party of manufacturers.