FINAL/APPROVED

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

March 24, 2016
Second Floor
Board Room 4

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
NON-COMMITTEE MEMBERS PRESENT:	Freeda Cathcart Rafael Saenz
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Deputy Executive Director Cathy Reiniers-Day, Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst Beth O'Halloran, Individual Licensing Manager
APPROVAL OF AGENDA:	Amended agenda presented for review which included consideration for amendments to Guidance Documents 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide* and 110-15 *Delegation of Authority for Disciplinary Matters*
MOTION:	**The Committee voted unanimously to approve the amended agenda as presented. (motion by Boone, second by Logan)**
PUBLIC COMMENT:	John Lubkowski, Pharmacy Operations Manager of RMH Sentara Hospital, provided a handout with two suggestions for amending sections 18VAC110-20-250 and 18VAC110-20-275 of the Regulations. In section 18VAC110-20-250(4) the suggestion was to allow a system to capture a secure identification of the pharmacist responsible for each phase of the prescription processing record to include a daily generated barcode or other acceptable measure. In section 18VAC110-20-275(B)(1) the suggestion was to allow delivery of specialty pharmacy prescriptions to a clinic or hospital based outpatient center to comply with all requirements in this regulation. Stated reasons for the request

included: tighter regulation of insurers and the requirement that patients obtain certain specialty medications from select specialty pharmacies that has created a gap in care for these patients, delays in patient care, patient inconvenience, inability to assure drug security and storage, patient safety issues, and pedigree tracking concerns.

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

Ms. Yeatts reviewed the procedure with the Committee of this periodic review process.

Ms. Shinaberry led the Committee through a review of each suggested area for amendment in chapters 20 and 50 that had previously been identified by the Committee at the November 2015 and January 2016 meetings, and encouraged members to identify any additional areas that may need consideration. A summary of the regulations agreed upon by the Committee for possible amendment are included in Attachment 1.

MOTION:

The Committee voted unanimously to recommend to the full Board that it adopt a Notice of Intended Regulatory Action (NOIRA) for the periodic review of chapters 20 and 50, and include the identified regulatory subjects listed in Attachment 1 of these minutes in the NOIRA packet. (motion by Warriner, second by Boone)

- Amendment to Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide*

Ms. Juran and Mr. Johnson reviewed the suggested amendments to Guidance Document 110-9 which included: striking references to the terms "major" and "minor" throughout the document; removing the subheadings in the document that reference categories of deficiencies since any recently added deficiencies were placed at the end of the document and not within the appropriate subcategory; amending Deficiencies #25c and #26a to include gloved fingertip testing; and considerations for increasing the monetary penalty for Deficiencies #1 and #2 based on a noticeable increase in non-compliance with pharmacy owners not assigning new pharmacists-in-charge within the required timeframe. Ms. Juran also provided information that NABP is asking states to pilot the newly developed uniform inspection form and provide feedback to NABP. Virginia has agreed to pilot the form in the near future.

- Amendment to Guidance Document 110-15

Ms. Juran and Mr. Johnson reviewed the suggested amendments to Guidance Document 110-15 to delegate the authority for the Executive

Delegation of Authority for Disciplinary Matters

Director to have the ability to issue a pre-hearing consent order to impose the recommended monetary penalty as listed in Guidance Document 110-9 for either not having a pharmacist-in-charge fully engaged in the practice of pharmacy or not having a pharmacist-in-charge in place and application filed within the required time frame. Presently, when these violations are identified, staff requests the inspector to cite the deficiency during the next routine inspection, but that inspection may not occur for approximately 18-24 months. Staff is requesting the ability to issue the pre-hearing consent order when the violation occurs and to not have to wait until the next routine inspection.

MOTION:

The Committee voted unanimously to recommend to the full board the following amendments, as presented and amended, to Guidance Document 110-9:

- **Increase the monetary penalty for Deficiency #1 to $2,000 and Deficiency #2 to $1,000;**
- **Remove reference to the terms "major" and "minor" throughout the document;**
- **Remove the subheadings of deficiency categories;**
- **Renumber the previously termed "minor" deficiencies to begin with number 101; and,**
- **Add reference to "gloved finger tip test" to Deficiencies #25c and #26a.**

It further recommended to the full board that it amend Guidance Document 110-15 as presented by including the following language in #4:

- **"Application for a change in pharmacist-in-charge (PIC) is submitted beyond the required timeframe for designating a new PIC-PHCO would impose recommended monetary penalty as indicated in Guidance Document 110-9 for either not having a PIC fully engaged in the practice at the pharmacy location or having a PIC in place, inventory taken, but application not filed with Board within the required timeframe." (motion by Boone, second by Logan)**

ADJOURN:

With all business concluded, the meeting adjourned at approximately 5:15 pm.

Ellen B. Shinaberry, Chairman

6/14/16
Date

Caroline D. Juran, Executive Director

6/14/16
Date

Attachment 1

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", "pharmacy technician program" and "storage temperature."

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 "Accreditation Council for Medical Education" 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.
- Deleting #3 which references programs approved by the Board.

18VAC110-20-100 Approval of continuing education programs

- Deleting ability for board to approve CE programs.

PART III. Requirements For Pharmacy Technician Registration.

18VAC110-20-101 Application for registration as a pharmacy technician

- Clarify that the 9 month time frame for allowance of a person to perform the duties of a pharmacy technician can begin after completion of didactic training rather than at the time of initial enrollment in the program.

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.
- Setting some minimum standard for the length as well as the content of a training program.
- Include in the student record the date on which the student began performing duties of a pharmacy technician as a part of the program.

18VAC110-20-106 Requirements for continued competency

- Changing "original 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.

18VAC110-20-111 Pharmacy technicians

- Including in the documentation of a technician's training the date on which the technician began training that constitutes performance of pharmacy technician tasks.

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, 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.
- 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.
- 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.

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.

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

- 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.
- 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 for researchers who are allowed to store and use Schedule I drugs.

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 will review all regulations that require a pharmacist's initials to determine if there is a better method or use of technology, such as the use of unique identifiers, for accurately identifying the responsible pharmacist.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

In section 30, 40 and 50 –Including prescription devices in addition to prescription drugs.

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 consistent with the law that 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.

18VAC110-50-70 through 18VAC110-20-140

- For consistency, considering similar requirements in section 70 through 140 for manufacturers.