FINAL/APPROVED

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 Logan
Cynthia Warriner
Melvin Boone
Rebecca Thornberry

STAFF PRESENT: Caroline D. Juran
J. Samuel Johnson
Cathy Reiniers-Day
Elaine J. Yeatts
Beth O'Halloran

APPROVAL OF AGENDA: The agenda was approved as requested

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 of Virginia Pharmacists Association, provided a further explanation of his letter to the Board requesting to considering amending 18VAC110-20-270 to address the lack of adequate pharmacy technician staffing.

AGENDA ITEMS:

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

Ms. Yeatts reviewed the procedure with the Committee of this periodic review process. The Committee is to provide recommendations for possible additions, deletions, changes to the Regulations that will be available for public comment. From that point, items may be moved to a Notice of Intended Regulatory Action (NOIRA) and then sent to the

• Review of Parts I – IV of *Regulations governing Wholesale Distributors, Manufacturers, and Warehouses, Chapter 50*	Governor's office for review. Notes on all recommendations are included in these minutes as Attachment 1.
• Draft regulatory language for NOIRA regarding unprofessional conduct to induce or incentivize a patient to transfer prescriptions.	Ms. Juran presented an excerpt from Regulation Committee minutes from May 12, 2014 and the research summary presented at the time. The committee reviewed the proposed amendment prepared by staff for regulation committee's review on May 12, 2014 as well as an excerpt from Full Board meeting minutes from June 4, 2014.
MOTION:	**The Committee voted unanimously to approve the NOIRA as presented regarding unprofessional conduct to induce or incentivize a patient to transfer prescriptions (motion by Warriner, second by Thornberry)**
ADJOURN:	Next meeting will take place on March 24, 2016, TBD. With all business concluded, the meeting concluded at approximately 5:00 pm.

Ellen B. Shinaberry, Chairman

3/26/16
DATE:

Caroline D. Juran, Executive Director

3/25/16
DATE:

Notes from Regulation Committee Meeting
Periodic Regulatory Review and Small Business
Impact Review November 3, 2015
Attachment 1

Each Regulation includes bullets to be considered for regulatory change. If no bullet points are included then the Regulation was reviewed and no suggestions were discussed for changes to that Regulation.

Consider breaking Chapter 20 into smaller chapters, e.g., putting parts II, III, XVII, and relevant definitions in separate packet.

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 renewal for other permits and licenses.
- Committee concluded there may be a benefit to changing the date for renewal of pharmacist and pharmacy technician licenses and registrations. Facilities will remain the same.

18VAC110-20-21 Public address

18VAC110-20-22 – 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.

18VAC110-20-25 Unprofessional conduct

- May return to this Regulation after further review of other sections.

Part II Licensure Requirements For Pharmacists

18VAC110-20-30 Requirements for pharmacy practical experience

18VAC110-20-40 Procedure for gaining practical experience

- Initial suggestion to add requirements for submission of name change. Discussion revolved around licensees who do not wish to change their name on their professional license. Decision was made to not move forward with the suggestion.

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

- Consider striking reference to "first" professional degree in 18VAC110-20-50 (B). Suggestion to strike all of (B) from regulation. Staff to do further research on this subject and will be discussed at next meeting.

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

- Consider limiting validity of law exam score to 2 years. Agree to set a time period to expire scores.

18VAC110-20-70 Requirements for foreign-trained applicants

18VAC110-20-75 Registration for voluntary practice by out-of-state licensees

18VAC110-20-80 Renewal and reinstatement of license

- Suggestion to change wording to difference in active and inactive fee
- Note that if date of renewal changes for pharmacists and pharmacy technicians (A) and (B) would need to also change

18VAC110-20-90 Requirements for continuing education

- Explore accepting inter-professional continuing education
- Suggestion to change wording in (B) (2) to AMA to match current title

18VAC110-20-100 Approval of continuing education programs

- Suggestion to remove this approval from the Regulation

PART III Requirements For Pharmacy Technician Registration

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

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

- Consider including training program approval number to be printed on certificate
- Consider requiring copy of sample certificate with application and notify Board of changes to certificate.

18VAC110-20-103 Examination

18VAC110-20-104 Address of record; maintenance of certificate

18VAC110-20-105 Renewal and reinstatement of registration

- Note that if date of renewal changes for pharmacists and pharmacy technicians, section will need to be updated

18VAC110-20-106 Requirements for continued competency

- Consider amending "original" certificates or documentation.

PART IV Pharmacies

18VAC110-20-110 Pharmacy permits generally

- Consider clarifying the minimum number of hours PIC must practice at the location listed on the pharmacy permit application

- Consider if PIC's should have a minimum number of years of experience – NABP 2014 Model Act and Rules provided for information and review.

18VAC110-20-111 Pharmacy technicians
18VAC110-20-120 Special of limited-use pharmacy permits

18VAC110-20-121 Innovative program approval

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership
- Clarify requirements for acquisitions with regard to inspection and inventory

18VAC110-20-135 Change of hours in an existing pharmacy

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

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.

18VAC110-20-160 Sanitary conditions

18VAC110-20-170 Required minimum equipment or resources

18VAC110-20-180 Security system
- Consider requiring security system to have at least one hard wired communication method for transmitting breach. This is already in Wholesale Distributor Regulations
- Consider clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is not sufficient.
- Consider clarifying how long auxiliary source of power must last.

18VAC110-20-190 Prescription department enclosures; access to prescription department

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
- Consider adding prohibition in (D) for using "old" chemicals for compounding, reference USP <795>.

18VAC110-20-210 Disposal of drugs by pharmacies

PART XIII Other Institutions and Facilities

18VAC110-20-570 Drugs in infirmaries/first aid rooms

18VAC110-20-580 Humane societies and animal shelters

- Recent amendments to §54.1-3423 changed language of humane societies to public or private animal shelters. Language will be conformed in Regulation without the need for a NOIRA.

18VAC110-20-590 Drugs in correctional facilities

PART XIV Exempted Stimulant or Depressant Drugs and Chemical Preparations

18VAC110-20-600 Excluded substances

18VAC110-20-610 Exempted chemical preparations

18VAC110-20-620 Exempted prescription products

18VAC110-20-621 Exempted anabolic steroid products

18VAC110-20-622 Excluded veterinary anabolic steroid implant products

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

18VAC110-20-640 through 18VAC110-20-670 (repealed)

18VAC110-20-680 Medical equipment suppliers

- Consider adding language from Guidance Document 110-19 for MES to transfer prescriptions in to Regulation.
- 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

18VAC110-20-685 Definitions for controlled substance registration

18VAC110-20-690 Persons or entities authorized or required to obtain a controlled substance registration

18VAC110-20-700 Requirements for supervision for controlled substance registrants

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

- Amend schedules to include Schedule I

18VAC110-20-720 Requirements for recordkeeping

18VAC110-20-725 Repackaging by a CSB or BHA

18VAC110-20-726 Criteria for approval of repackaging training programs

18VAC110-20-727 Pharmacists repackaging for clients of a CSB or BHA

18VAC110-20-728 Drugs for immediate treatment in crisis stabilization units

18VAC110-20-730 Requirements for practitioner of medicine or osteopathy in free clinics

PART XVII Drug Donation Programs

18VAC110-20-740 Drug donation sites

18VAC110-20-750 Eligible drugs

18VAC110-20-760 Procedures for collecting eligible donated drugs

18VAC110-20-770 Procedure for transferring donated prescription drugs

18VAC110-20-780 Procedure for dispensing donated prescription drugs

18VAC110-20-790 Procedures for disposing of donated prescription drugs

18VAC110-20-800 Records