DRAFT/UNAPPROVED

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**

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.

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Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

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.
- 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

Attachment I

- 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.

18VAC110-20-150 Physical standards for all pharmacies

Attachment 1

- 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

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

- Amend schedules to include Schedule I

Attachment 1

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.

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