

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

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 Warehousemen, 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 Warehouse*s, 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 identify 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.