FINAL APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

May 10, 2017
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The meeting was called to order at 10:06am.
PRESIDING:	Ryan Logan, Committee Chairman
MEMBERS PRESENT:	Jody H. Allen Ellen B. Shinaberry Cynthia Warriner Freeda Cathcart
NON-VOTING MEMBER PRESENT:	Rafael Saenz
STAFF PRESENT:	Caroline D. Juran, Executive Director Cathy Reiniers-Day, Deputy Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Beth O'Halloran, Individual Licensing Manager Elaine J. Yeatts, Senior Policy Analyst
APPROVAL OF AGENDA:	Ms. Yeatts provided a one-page handout to the committee entitled *Report of Regulatory Actions* and requested the committee to include this additional item on the agenda so she may provide a status update of the Board's current regulatory actions.
MOTION:	**The Committee voted unanimously to approve the amended agenda as presented for the Regulation Committee meeting (motion by Allen, second by Warriner).**
PUBLIC COMMENT:	Lauren Schmitt, representing the Virginia Society of Health-System Pharmacists, provided comment on several items in the agenda regarding the periodic regulatory review. VSHP supports the deletion of the random check by a pharmacist for certain robotically picked orders and questioned if this included carousel technology. If so, then VSHP also supports that concept. VSHP also supports changing the wording on page 19 of the agenda packet to "prescriber". Lastly, VSHP supports streamlining 18VAC110-20-490 regarding automated dispensing devices, but also does not take issue with the current wording.

Pharmacist Gill Abernathy, speaking on her own behalf, provided comment regarding the suggested amendments in the agenda packet for the periodic regulatory review. Ms. Abernathy stated that there is now widespread use of automated dispensing machines and her suggestion is that the regulations may want to be more general, focusing on the security of drugs rather than a specific type of dispensing machine. Ms. Abernathy also stated that the Board may want to consider regulations that address the time allowed for a person to be terminated from access to the dispensing system once a violation is identified and who in an organization may grant access to the devices. Ms. Abernathy also suggested that the Board include language regarding the inventory of controlled substances in that it may not be clear to everyone that even if a pharmacy maintains no controlled substances, they are still required to have an inventory completed. Ms. Abernathy stated that on page 15 of the agenda, item D, may want to separate the last sentence into two sentences to be more concise in the wording. Ms. Abernathy would also like supervision to be clarified in the regulations, specifically for compounding devices and in ensuring product validation.

AGENDA ITEMS:

Report of Regulatory Actions:

Ms. Yeatts provided a brief overview of the regulatory actions that are pending for the Board of Pharmacy as indicated on the one-page handout. Several actions have become effective in the past three months and there are four that will become effective in June 2017.

Continue periodic regulatory review by developing draft amendments to Parts VI-VIII, X-XII of *Regulations Governing the Practice of Pharmacy*, Chapter 20 and Parts I-II of *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*, Chapter 50

The committee discussed the areas of regulations identified during the November 3, 2015 Regulation Committee Meeting for possible amendment (pages A-E of the agenda packet) and the suggested amendments for the periodic regulatory review, as prepared by staff and presented in the agenda packet (pages 7-37). The meeting was suspended at 1pm for a previously scheduled presentation of a possible summary suspension and resumed at 1:55pm.

- 18VAC110-20-10

The committee recommended that the definition for "robotic pharmacy system" be clarified to include intravenous (IV) admixture robotics.

- 18VAC110-20-20

The committee recommended striking the fees for humane society permits as the board no longer issues this type of permit.

- 18VAC110-20-50

The committee offered no amendments at this time.

- 18VAC110-20-112

Committee recommends moving the current language in 18VAC110-20-270 A and B into a new section 18VAC110-20-112 so to include this requirement affecting individuals in chapter 20, instead of the proposed new chapter 21 affecting pharmacy facilities. Additionally, the

committee recommends changing the word "acting" in subsection A to "performing duties".

- 18VAC110-20-240 — Committee agreed with the suggested amendments as presented in the agenda packet with the following exceptions: consider inserting a reference to 18VAC110-20-286 in subsection C; and, clarify that the procedures stated in subsection C, 1, b must be followed.

- 18VAC110-20-270 — Amendments considered by the committee include: separating subsections A and B from the rest of this regulation and creating a new section 18VAC110-20-112; in current subsection E change the wording from "shall" to "may" with regard to returning a prescription that is fraudulent; and, adding language from Guidance Document 110-32 regarding the use of drop boxes into a new subsection G, but editing the last sentence to regulate pharmacists and not the consumer with regard to leaving containers which contain drug or drugs in the drop box. It was suggested the language should state "pharmacists shall inform patients not to leave unused drugs" in the drop box. Regarding the second bullet on page B of the agenda packet, "Addressing concerns in subsection B by VPhA with pharmacists not being provided adequate support", the committee agreed that this should not be handled with a regulatory change, but rather handled at the corporate level. It was noted that VPhA did not offer the Board specific language for amending the regulation. The requirement for a pharmacy to pull the originally filled prescription and refile it when on-hold was already addressed in a previous regulatory action.

- 18VAC110-20-275 — The committee recommended no amendments to this section until it received the results of the NABP study on white/brown bagging and consider possible amendments at that time. No recommendations were considered for further clarifying this regulation.

- 18VAC110-20-277 — It was recommended in November 2015 that a new regulation 18VAC110-20-277 be created to clarify that all prescriptions unless electronically transmitted, must include manual signature, and a quantity or duration of treatment. The committee decided that this information was best addressed in 18VAC110-20-270.

- 18VAC110-20-280 — Committee agreed with the amendment as presented to insert "manual" into subsections B and D. No additional amendments were offered for this section as it was discussed that the long term care provider pharmacies originally requested the allowance in 18VAC110-20-280 A, 4, C and that staff was not aware of any request to remove the allowance.

- 18VAC110-20-290 — An amendment considered by the committee was to include language from Guidance Document 110-41 regarding changes a pharmacist may make to a Schedule II prescription. The committee agreed with the suggested amendment in concept, but requested staff to clarify the language in the last sentence.

- 18VAC110-20-355 — The committee discussed the suggested amendment in subsection A and suggested changing it to read "or other unique identifier" to identify the pharmacist who verified the accuracy of the process. Committee also agreed to include a requirement in a new subsection C to require repackaging to be performed in compliance with USP-NF standards.

- 18VAC110-20-425 — The committee discussed streamlining the robotic pharmacy regulations by: striking the requirement in subsection 5 for a 5% random check of all dispensed drugs from a robotic pharmacy system; changing 7 to remove requirement for reporting to board and instituting a manual check of all doses or compliance packages, but recommended requiring a manual check of all affected doses or compliance packages, require performance of a root cause analysis, and compliance with policies and procedures prior to resuming operations of the device for the affected drug; striking 8 b, c, and d; addressing downtime in policies and procedures; focusing oversight on the front end of the process with packaging and assignment of bar codes to ensure accuracy; and, clarify expectation for complying with any policy and procedures.

- 18VAC110-20-470 — The committee supported the amendment in subsection 2 to change the word "practitioner" to "prescriber".

- 18VAC110-20-490 — Amendments supported by the committee included: adding the word "ensuring" to subsection C, 2 wherein the pharmacist is responsible for ensuring reconciliation of the discrepancy or reporting of the loss; subsection D, 1, adding language to allow for the record to maintained electronically; subsection E, included an amendment to clarify that the requirement for discrepancy reports are for Schedule II-V drugs and drugs of concern; subsection F, 3, included an amendment to state that the PIC or designee shall conduct at least a monthly audit to "review dispensing and administration records" of Schedule II-V drugs; and subsection F, 3, a, the word "from" was recommended to be changed to "for".

- 18VAC110-20-530 — The committee supported the amendment to create a new subsection B as presented in the agenda packet to allow a pharmacy providing services to a long term care facility to provide prescription information of Schedule VI drugs to a back-up pharmacy without constituting the need for transferring the prescription, with the following exception: in subsection B, 1, after "to be provided" insert ", recordkeeping associated with the dispensing,". The committee concluded amendments to 18VAC110-20-530 sufficiently addressed the issue and amendments to 18VAC110-20-515 and 18VAC110-20-360 were not necessary.

- 18VAC110-20-550 — The committee supported the following amendments as presented: clarifying in subsection 5, b that the allowance for substituting one unit of liquid for a solid dosage form is allowable for each drug schedule, and that a pharmacy may provide a facility with more than one stat-drug box and that the contents of the multiple boxes do not need to be uniform.

• 18VAC110-20-555	The committee concluded that 18VAC110-20-490 should remain as written, with the following exception: The first sentence should be amended to also include residential facilities licensed by the Department of Behavioral Health and Developmental Services and hospice programs licensed by the Virginia Department of Health wherein only licensed nurses, pharmacists, or prescribers are administering drugs.
• 18VAC110-50-40	The committee supported an amendment to subsection B, 2 as presented, with the following exception: the beginning word in the sentence, "The", should be changed to "One". During discussions, the committee also agreed that a hard-wired communication line would include a Voice over Internet Protocol (VoIP) communication method. The committee supported an additional amendment in subsection 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 operational.
• 18VAC110-50-60	An amendment was supported by the committee as presented to expand the ability to issue a limited-use permit for certain entities.
• 18VAC110-50-70	The committee did not recommend amending this regulation as the information from Guidance Document 110-34 regarding the submission of a social security number or control number has already been addressed in a previous regulatory action.
• 18VAC110-50-80	The committee supported an amendment to require a federal criminal history check, not simply a criminal history record check through the Virginia criminal records as this database generally would not have information on individuals associated with non-resident facilities.
• 18VAC110-20-70 through 18VAC110-20-140	The committee concluded additional amendments to 18VAC110-20-70 through 18VAC110-20-140 to require similar requirements for manufacturers were not needed at this time as the risk for introducing counterfeit drugs into the supply chain does not appear as high with manufacturers as it is with other types of facilities.

ACTION ITEM:

Staff to amend 18VAC110-20-425, as referenced in this document, and the definition of robotic pharmacy system in 18VAC110-20-10 to include carousels and intravenous (IV) admixture robotics and present to the full Board for consideration at the June full board meeting.

MOTION:

As part of the periodic regulatory review, the committee voted unanimously to recommend to the full board to amend regulations in Parts VI-VIII, X-XII of *Regulations Governing the Practice of Pharmacy*, Chapter 20 and Parts I-II of *Regulations Governing Wholesale Distributors, Manufacturers and Warehousers,* Chapter 50

as summarized in this document. (motion by Warriner, second by Allen)

Legislative Proposal for dispensed Schedule V drugs to be reported to the Prescription Monitoring Program	The committee reviewed a legislative proposal for requiring dispensers to report the dispensing of Schedule V drugs to the Prescription Monitoring Program. An identical recommendation was adopted by the Board in June 2016, but legislation was not advanced to the General Assembly.
MOTION:	**The committee voted unanimously to recommend to the full board that it request the Prescription Monitoring Program advance a legislative proposal to amend the definition of "covered substance" in §54.1-2519 and its reference in §54.1-2520 to include Schedule V controlled substances (motion by Allen, second by Warriner).**
ADJOURN:	With all business concluded, the meeting adjourned at approximately 2:53 pm.

for **Ryan Logan, Chairman**

6/27/17
DATE

Caroline D. Juran, Executive Director

6/27/17
DATE