



Department of Health Professions

Virginia Board of Pharmacy Law Update

**VPhA Annual Convention
September 8, 2017**

**Caroline D. Juran, Executive Director
Beth O'Halloran, Deputy Executive Director**



Disclosures

- No real or apparent conflicts of interest that may have a direct bearing on the subject matter of this continuing education program.
- No financial relationships or commercial interest that need to be disclosed.
- Speaking to you today as the executive director and deputy executive director of the Board of Pharmacy.



Current Board Members

Department of Health Professions

Ryan K. Logan, *Chairman*

2nd term ends June 30, 2021

Fairfax, VA

Michael I. Elliott, *Vice Chairman*

1st term ends June 30, 2018

Forest, VA

Freeda Cathcart, *Citizen*

1st Term Ends June 30, 2019

Roanoke, VA

Sheila K. W. Elliott

1st Term ends June 30, 2018

Hampton, VA

Ellen B. Shinaberry

2nd term ends June 30, 2018

Harrisonburg, VA

Jody H. Allen

2nd term ends June 30, 2018

Midlothian, VA

Melvin L. Boone, Sr., *Citizen*

1st term ends June 30, 2018

Chesapeake, VA

Rebecca Thornbury

2nd Term ends June 30, 2020

Grundy, VA

Rafael Saenz

1st Term Ends June 30, 2019

Crozet, VA

Cynthia Warriner

2nd Term ends June 30, 2020

Chester, VA



Overview of Program

- Briefly review select pharmacy-related bills passed by the 2017 General Assembly
- Summarize recent Board of Pharmacy and PMP regulatory activity
- Describe implementation plan for overseeing pharmaceutical processors
- Review 2018 legislative proposals
- Review process for performing routine pharmacy inspections and discuss most commonly cited deficiencies
- Discuss information on miscellaneous topics and frequently asked questions



Department of Health Professions' Mission

- To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.



Department of Health Professions

2017 Legislation Passed by General Assembly



SB1027 Pharmaceutical Processors

- Amended §§ [18.2-250.1](#) and [54.1-3408.3](#); created [54.1-3442.5](#) through [54.1-3442.8](#)
- Effective March 16, 2017
- Authorizes licensing of a pharmaceutical processor to cultivate, produce, and dispense cannabidiol oil and THC-A oil for treatment of intractable epilepsy
- Must have pharmacist-in-charge



SB1027 Pharmaceutical Processors

- Emergency regulations effective August 7, 2017
- Infrastructure for oversight being implemented
 - Licensing software
 - Ability to report to PMP
 - Formation of committee to review applications and award permits
 - Hiring of staff
 - Educational materials



SB1027 Pharmaceutical Processors

- Board will register patients, parents/guardians of minors or incapacitate adults
- Competitive application process for up to 5 permits in state; one per health district
- Will be a separate cost center from the Board
- Estimated timeframe for board readiness to begin accepting applications is 2Q 2018



SB 1009

- Amended §§ [54.1-3303](#) and [54.1-3423](#)
- Effective February 20, 2017
- Emergency regulations effective May 8, 2017 through November 7, 2018
- Board will issue controlled substance registration to certain entities who don't otherwise meet federal requirements to participate in telemedicine for prescribing drugs in Schedules II-V.



HB1453/SB848

- Amended §§ [8.01-225](#) and [54.1-3408](#)
- Effective February 23, 2017
- Continues expansion of access to naloxone by allowing persons teaching REVIVE! training program in community settings to dispense naloxone free of charge to persons who have successfully completed training program
 - Must obtain controlled substances registration certificate from Board of Pharmacy



HB2165

- Amended §§ [54.1-3401](#), [54.1-3408.02](#), and [54.1-3410](#)
- Effective Feb 21, 2017
- Requires opiate prescriptions to be e-prescribed by 2020
- Required convening of workgroup to discuss challenges and implementation
 - Interim report to be submitted to legislators in November



HB2165

- Interim report to be submitted to legislators in November w/ recommendations to amend law to:
- Create exceptions for mandate, e.g., prescribed drug is for administration, temporary technological or electrical failure, prescription issued to out-of-state pharmacy
- Create certification that prescriber only prescribes a low volume of opiates annually



HB2165 (cont.)

- Strike statement in §54.1-3410 E that no pharmacist may dispense opiate unless e-prescribed
- Insert statement that pharmacist is not required to verify if prescriber satisfies an exception and has issued the otherwise valid prescription in compliance with the mandate.



HB2164

- Amended § [54.1-3456.1](#)
- Effective February 23, 2017
- Designated gabapentin “drug of concern”
 - Must now be reported to PMP



SB1178/HB2163

- Created § 54.1-3408.4
- Effective July 1, 2017
- Indicates buprenorphine without naloxone shall be issued only
 - (i) for patients who are pregnant,
 - (ii) when converting a patient from methadone to buprenorphine containing naloxone for a period not to exceed seven days, or
 - (iii) as permitted by regulations of the Board of Medicine, Nursing, or Veterinary Medicine.



Department of Health Professions

Regulations and Guidance Recently Enacted



Partial Filling of CII Prescriptions, 18VAC110-20-310

- Fast-track regulatory amendment effective September, 7, 2017
- Conforms State regulation to federal allowance in recently enacted CARA Act
- *A prescription for a Schedule II drug may be filled in partial quantities if the partial fill is requested by the patient or by the practitioner who wrote the prescription provided:*



Partial Filling of CII Prescriptions, 18VAC110-20-310, *cont.*

- 1. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;*
- 2. The prescription is written and filled in accordance with state and federal law; and*
- 3. The remaining portions are filled not later than 30 days after the date on which the prescription is written.*



18VAC110-20-110 Hours Worked

- Would state “Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day
- and shall allow at least six hours of off-time between consecutive shifts.
- A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.”
- Effective February 2017



Guidance Document 110-39

- March 2017 - Adoption of guidance document on hours of continuous work and breaks for pharmacists



Guidance Document 110-20

- “Practice by a Pharmacy Technician Trainee”
- Revised in March 2017
- Board now interprets “nine month” allowance in 18VAC110-20-101 to mean 9 consecutive months from the date the pharmacy technician trainee begins performing duties restricted to a pharmacy technician as part of a Board-approved pharmacy technician training program



Guidance Document 110-9

- March 2017 - Deficiency 21b amended to read “Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better”.



Department of Health Professions

***Pending* Regulatory Activity**
(not yet final)



Periodic Regulatory Review

- Chapters 20 and 50
- Board adopted proposed amendments in three parts – December '16, March '17, & June '17
- Refer to agenda packets and minutes on board website for proposed language
- Once Governor approves publishing of compilation, a 60-day comment will soon follow.



Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- Examples of proposed amendments:
- Regulations for individuals (pharmacists, pharmacy technicians, interns) would be moved to new Chapter 21
- Regulations for facilities (pharmacies, medical equipment supplies) would remain in Chapter 20
- Would place language from guidance documents into regulation



Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-90, Continuing education:
 - Would required at least 5 hours in live or real-time interactive CE which may include:
 - 1 hour attendance at board meeting;
 - 1 hour serving as preceptor for pharmacy student or resident in accredited school or program.



Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-110, PIC eligibility:
 - Would require minimum two years experience practicing as pharmacist in VA or another state;
 - Board could grant exception for good cause shown.
- 18VAC110-20-140, New pharmacies
 - Would state if pharmacy not operational within 90 days from date permit issued, board shall rescind permit unless extension granted for good cause shown.



Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-150, Physical standards
 - Would state pharmacies stocking drugs requiring cold storage temperature shall record temperature daily and adjust temperature as necessary;
 - Would require record to be maintained manually or electronically for two years.
- 18VAC110-20-180, Security System
 - Would require breach in alarm to be communicated to PIC or pharmacist working at the pharmacy



Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-10, Definitions
 - Would define “Initial or initials” to mean the first letters of a person’s name or other unique personal identifier
- 18VAC110-20-425, Robotic pharmacy systems
 - Would further streamline requirements
 - Would acknowledge use of IV admixture robotics, but require pharmacist verification of each compound



Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-530, Long Term Care
 - Would allow pharmacy to share copy of CVI prescription or order with another pharmacy for immediately dispensing up to 7-day supply without transferring prescription if:
 - Have written contract in place with other pharmacy outlining services, recordkeeping, and responsibilities of each pharmacy



Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-550, Stat-drug box
 - Would allow one unit of liquid, not to exceed 30ml, to be substituted for a solid dosage unit in each drug schedule



Refilling CVI Prescriptions In Quantity up to Total Amount Prescribed

- March 2017 – Board adopted proposed amendment resulting from petition.
- Proposed language: *Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for drugs of concern as defined in § 54.1-2519, a pharmacist, using professional judgement and upon request by the patient, may refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration.*



Refilling CVI Prescriptions In Quantity up to Total Amount Prescribed, *cont.*

- Public hearing on proposed amendment to be held September 26th at 9am



Use of Automated Dispensing Devices

- Proposed amendment: clarifies authority to use automated dispensing systems as emergency drug kits and stat drug boxes.
- Eliminates need for controlled substances registration if only using for emergency purposes
- Public hearing on proposed amendment to be held September 26th at 9am



18VAC110-20-25 Coupons

- Would prohibit incentives to transfer prescription
- Would be unprofessional conduct to advertise or solicit in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing the transfer of a prescription absent professional rationale by use of coupons, rebates, or similar offerings.
- Final regulations adopted 3/17
- In Governor's Office; not final yet.



Regulatory Town Hall

- Become registered user - Receive email notifications regarding regulatory actions and meetings
- Submit online comments during open comment periods
- <http://townhall.virginia.gov/L/Register.cfm>
- Charts of Regulatory Processes - <http://townhall.virginia.gov/UM/charts.cfm>



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PMP Integration into Pharmacy Software



PMP Integration into Pharmacy Software

- Grant opportunity for up to 400 pharmacies on a first-come, first served basis
- Grant does not provide for upgrading software or technical work to implement the necessary connection requirements
- Grant pays the annual license fee for the life of the grant which is currently scheduled to end December 31, 2018
- Goal to improve performance, access and usability of PMP program



PMP Integration into Pharmacy Software

- QS1, RX30, and Pioneer have completed development work that enables the NarxCare integration
- 62 Krogers in VA have piloted first generation version for past two years and have been very pleased!
- Complete form at <http://info.apprisshealth.com/vanarxcareinforequest>



Department of Health Professions

Possible 2018 Legislative Proposals



Department of Health Professions

Nonresident 3PL and Nonresident Warehouses

- Would create licensing category for these two entities and authorize the shipping of prescriptions drugs and devices into Virginia



Reporting Naloxone and Schedule V to PMP

- Would amend definition of “covered substance” to include naloxone and Schedule V drugs dispensed pursuant to a prescription
- Would require dispensers to report dispensing of these drugs to the PMP
- Would assist prescribers in knowing if patients are obtaining the naloxone required to be co-prescribed by Board of Medicine regulations
- Satisfies VPhA’s request to report CV drugs



Department of Health Professions

Inspection Process and Commonly Cited Deficiencies



What is the #1 most commonly cited deficiency so far in 2017?



Most Commonly Cited Deficiencies with Automatic Monetary Sanction

1. # 15: Perpetual Schedule II inventory
2. # 14: Incoming PIC inventory
3. # 20a: Pharmacist not documenting final verification of non-sterile compounding
4. # 32: Have a clean room but not all physical standards in compliance
5. # 26: No documentation of media-fill testing for low and medium risk level compounding.



Inspection Form

- March 2017, inspectors began using the NABP universal inspection form

https://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm



Prohibition on Compounding Commercially Available Products

§54.1-3410.2 prohibits the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. There are a few exceptions to this..



Who is authorized to possess the key?

- Pharmacists!
- Just a reminder – NEVER give the pharmacy key to someone not authorized to possess it.



Department of Health Professions

Miscellaneous Topics and Frequently Asked Questions



Healthcare Workforce Surveys

- 2016 Pharmacist and Pharmacy Technician Surveys
- <https://www.dhp.virginia.gov/hwdc/findings.htm#Pharm>



Healthcare Workforce Surveys

Pharmacists

- Majority female, median age 45
- 41% carry educational debt, median debt \$100-110K
- 93% employed
- Earn \$120- 130K
- 7% expect to retire in next 2 years; ½ expect to retire by 2041
- Residencies or specialization slightly reduced; 24% at least one residency in 2013, 20% in 2016
- 25% immunization specialty in 2013, 18% in 2016



Healthcare Workforce Surveys

Pharmacy Technicians

- 84% female, 64% under age of 40
- 74% nationally certified; 66% PTCB, 9% ExCPT
- 59% high school degree or GED; 21% Associates degree
- 39% educational debt, between \$14-16K
- Median annual income \$20-25K
- 8% expect to leave profession in next 2 years with another 4% moving to another state; ½ expect to retire by 2041
- Slightly more employed last year and tended to work more hours



Suspicious Job Offers

- Offers to be PIC that are too good to be true usually are
 - Out of state pharmacies offering pay to be PIC “on paper”
 - Owner paying a pharmacist to sit in an empty pharmacy that is not operational for an extended period of time



Pharmacy Technician Examination

- Board ceased administering the Virginia Pharmacy Technician Examination on August 31, 2017
- 2 options for registration remain:
 - PTCB + submission of pharmacy tech application to board
 - Board-approved training program + ExCPT exam + submission of pharmacy tech application to board



Electronic Renewal Notification

- Provide current email addresses to Board – pharmbd@dhp.virginia.gov
- Pharmacists and pharmacy technicians will be informed via email in mid-October
- Please spread the word!



Continuing Education

- **Board required CE** in 2017 for pharmacists
 - At least one hour in proper opioid use, opioid overdose prevention, or naloxone administration
- NABP CPE Monitor – Required to receive credit for ACPE-accredited courses



Upcoming Meetings

- Full Board Meeting – September 26, 2017
- Ad Hoc Committee – September 18, 2017
 - USP <800>
 - Developing guidelines for counseling regarding proper disposal of unused dispensed drugs (HB2046)
 - Consideration of requiring temperature monitoring devices when dispensing drugs requiring cold temperature storage (HB1956)



Department of Health Professions

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QUESTIONS?