



Virginia Department of
Health Professions

Virginia Board of Pharmacy Law Update

Virginia Society of Health-System
Pharmacists

April 13, 2018

Caroline D. Juran, Executive Director



Virginia Department of
Health Professions

- No financial interests or conflicts of interest to declare.
- Speaking to you as the executive director of the Virginia Board of Pharmacy.



Objectives

- Summarize select pharmacy-related bills passed by the 2018 General Assembly
- Describe recent Board of Pharmacy action related to regulations and board guidance
- Review ongoing and upcoming projects related to pharmaceutical processors, e-prescribing, routine pharmacy inspections, and PMP-generated investigations



Pre-Test Questions

- 1) According to State law, CBD oil may only be used to treat intractable epilepsy. True or False



Pre-Test Questions

- 2) When must you comply with USP Chapter <800>?
- a) July 1, 2018
 - b) December 1, 2018
 - c) December 1, 2019



Department of Health Profession 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.



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

Resigned, now staff

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



Virginia Department of
Health Professions

Legislation



HB313/SB728

- Requires DHP Director, in consultation with Advisory Panel, to review controlled substances prescribing and dispensing patterns using PMP
- Panel includes reps from boards, VDH, DMAS, DBHDS
- Report findings and best practices to JCHC annually



HB501

- Requires hospice programs to develop policies for disposal of unwanted drug
- Disposal shall be (i) performed by a nurse, PA, or physician employed by or contracted with the hospice program; (ii) witnessed by member of patient's family or second hospice employee licensed by DHP; and (iii) documented in the patient's medical record.



HB520

- Creates licensing category for nonresident warehouseers and nonresident third party logistics providers that ship prescriptions drugs and devices into Virginia



HB793

- Eliminates need for nurse practitioner to have practice agreement with patient care team physician if:
 - 5+ years clinical experience
 - Physician submits attestation
 - Consult, collaborate, and develop plan for referral to physician of complex cases or emergencies
 - Boards of Medicine & Nursing to develop joint regulations



HB842

- Authorizes REVIVE! Trainers dispensing naloxone pursuant to 54.1-3408(Y) to dispense hypodermic needles and syringes for administering naloxone



HB878/SB413

- Authorizes manufacturers, wholesale distributors, 3PLs, warehouse users to deliver CVI prescription devices directly to ultimate user if:
 - agreement entered with medical equipment supplier who has received valid order; or,
 - Agreement entered with medical director of home health, nursing home, ALF, or hospice and he/she has directed devices to be distributed directly to patient's residence and administered to patient



HB1173/SB632

- Currently, prescriber not required to query PMP for opioid prescription written for up to 14 days if for treatment of surgical or invasive procedure
- These bills eliminate this exception



HB1251/SB726

- Expands treatment with CBD or THC-A oil to treatment of any disease or condition as determined by physician
- Expands allowance from 30-day supply to 90-day supply
- (Recommendations of JCHC)



SB330

- Several authorizations to include:
- Requires dispensing of CBD and THC-A oil to be reported to PMP
- Requires physician to query PMP prior to issuing written certification
- Requires FBI criminal background check of pharmaceutical processor applicant
- Requires processor to establish stability testing to ensure percentage of THC in THC-A oil on-site remains within 10% of level measured when labeled



HB1556/SB832

- Requires reporting of naloxone and Schedule V drugs dispensed pursuant to a prescription to the PMP



SB544

- Further clarifies donation of unwanted drugs for redispensing as means of increasing participation in current program
- Refer to Regulations 18VAC110-20-740 through 18VAC110-20-800



SB882

- Provides prescriber may authorize nurse to approve additional refills for CVI drug for no more than 90 days if:
 - No changes to drug
 - Prescriber has current written protocol identifying when nurse may approve additional refills
 - Nurse documents in patient chart
 - Additional refills transmitted to pharmacy orally or by facsimile



Virginia Department of
Health Professions

Actions related to Regulations and Board Guidance

E-Profile ID

- March 2018 – Board adopted proposed regulations requiring pharmacists, pharmacy technicians, and pharmacy interns to provide board with E-profile ID when applying for new license or renewing
- Free of charge from NABP
- Most already have one
- Will facilitate exchange of information between board and NABP



Increase in Fees

- March 2018 – Board adopted proposed regulations to increase licensure fees
- First increase since 2002
- 2002 license count approximately 12,000; currently approximately 35,000



Brown Bagging/White Bagging

- Notice of Intended Regulatory Action at Governor's Office
- Board will consider regulations for:
 - Brown bagging of drugs requiring special storage, reconstitution or compounding prior to administration
 - Requiring specialty pharmacies to notify receiving pharmacy of shipment to ensure coordination of patient care
 - Providing estimated arrival date and exact address where product has been shipped



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 proposed regulations, 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 require 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.



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



Pharmaceutical Processors

- Emergency regulations to be readopted likely in June based on recent statutory changes
- Final regulations to be adopted later this year



USP <800>

- Guidance Document 110-36 amended December 2017.
- Practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection
- <800> first published in 2014. Published as an official standard in February 2016 with a delayed implementation date of July 1, 2018.
- Delayed to December 1, 2019 to align with next revision of <797>.



Other Guidance Documents Recently Amended

- 110-2 Pharmacist Licensure
- 110-4 Continuing Education
- 110-5 Theft and Loss
- 110-46 Delivery of Drugs
- 110-47 Counseling regarding Disposal



Department of Health Professions

Ongoing and Upcoming Projects



Projects: Pharmaceutical Processors

- RFA for conditional approval of permits
- Emergency and final regulations
- Registering physicians, patients, parents, guardians
- Development of inspection form



Projects: E-prescribing

- HB2165 (2017) mandates e-prescribing of opiates, effective July 1, 2020
- 2017 Work Group Report available at - <https://rga.lis.virginia.gov/Published/2017/RD431/PDF>
- Work group may reconvene this summer to finalize 2019 legislative fixes



Department of Health Professions

Projects: Routine Pharmacy Inspections

- Board to convene ad hoc committee to review and potentially revise current routine pharmacy inspection form or process



Department of Health Professions

Projects: PMP-generated Investigations

- Ongoing efforts to identify optimal criteria to identify unusual dispensing

Post-Test Questions

- 1) According to State law, CBD oil may only be used to treat intractable epilepsy. True or False



Post-Test Questions

1) False. CBD oil may now be used to treat any disease or condition identified by the physician to benefit the patient.



Post-Test Questions

- 2) When must you comply with USP Chapter <800>?
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Resources

Board website: www.dhp.virginia.gov

Regulatory Town Hall:

Become registered user –

<http://townhall.virginia.gov/L/Register.cfm>

Actions underway -

<http://townhall.virginia.gov/L/NowInProgress.cfm>

Charts for Regulatory Actions-

<http://townhall.virginia.gov/UM/charts.cfm>

DEA website: <https://www.dea diversion.usdoj.gov/>



Virginia Department of
Health Professions

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