Virginia Department of Health Professions

Virginia Board of Pharmacy Law Update

Virginia Pharmacists Association

138th Annual Convention

August 16, 2019

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Virginia Department of
Health Professions

- No financial interests or conflicts of interest to declare.

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Objectives

- Summarize select pharmacy-related bills passed by the 2019 General Assembly
- Describe recent Board action related to regulations, guidance, and other miscellaneous subjects
- Review 2020 legislative proposals

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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.

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2019 Legislation
(effective July 1, 2019)

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HB1743 Counseling

- Amended §54.1-3319
- Emphasizes that pharmacist may counsel on proper drug disposal

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HB1952 Physician Assistant Supervision Model

- Establishes patient care team model for supervising physician assistants
- Board of Medicine directed to adopt emergency regulations to implement

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HB2158 & HB2318 Naloxone Dispensing

- Amended §54.1-3408 (X and Y)
- Authorizes health care providers in emergency departments and EMS to dispense naloxone
- Authorizes school nurses, local health department employees assigned to schools, and other school employees to possess, administer, & dispense naloxone
- All pursuant to an oral, written, or standing order issued by a prescriber or Health Commissioner

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HB2158 & HB2318 Naloxone Dispensing

- For lay persons dispensing on behalf of an organization, must provide instruction to person being dispensed naloxone; no longer requires patient to complete REVIVE! training program
- Eliminates requirement for Controlled Substances Registration, except for those organizations dispensing injectable naloxone with hypodermic syringe
- Allows organization to charge fee to cover cost of drug

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HB2557 Gabapentin

- Amended §§ 54.1-3454 and 54.1-3456.1
- Places gabapentin into Schedule V as of 7/1/19

HB2557 Gabapentin, cont.

- Initial and biennial inventory required as of July 1, 2019
- Refill, dispense, and report to PMP as a Schedule V (valid for 6 months, no > 5 refills)
- E-prescriptions received July 1 or later will need to comply with federal law, although not yet scheduled by DEA
- Wholesale distributors have until July 1, 2020 to comply with storage requirements

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HB2559 E-prescribing Opioids

- Amended §§ 54.1-3408.02 and 54.1-3410
- Provides exceptions to e-prescribing requirement for opioids which becomes effective July 1, 2020
- Authorizes prescriber board to grant a one-year waiver based on demonstrated economic hardship, technological limitations outside control of prescriber, or other exceptional circumstance

HB2559 E-prescribing Opioids, cont.

- States pharmacist not required to determine if an exception to e-prescribing applies
- Secretary of Health and Human Resources to convene workgroup to identify successes, challenges, offer recommendations for expanding to other controlled substances; report to General Assembly by 11/1/2022

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HB2563 Fentanyl Testing

- Amended §§ 18.2-265.1 and 54.1-3466
- Clarified that products used to test for fentanyl or fentanyl analogs are not drug paraphernalia

SB1289 Seizure of Drugs

- Amended §§ 54.1-2408.1, 54.1-3424, and 54.1-3434
- Clarified process for board or law enforcement to place drugs and devices under seal, transfer, and disposal if subject to forfeiture
- Authorized Director of DHP or law enforcement to dispose of seized drugs and devices when owner has not claimed them

SB1366 Inspections

- Amended § 32.1-126.5
- Requires Commissioner of Health to identify state inspections of a medical care facility (Title 32.1) and collaborate with state entities to consolidate as much as practicable to minimize interruption of care being provided

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SB1557 Pharmaceutical Processors

- Amended §§ 54.1-3408.3 and 54.1-3442.6
- Authorized PAs and NPs to issue written certifications for CBD and THC-A oils
- Restricted dispensed dose to no > 10mg THC
- Secretaries of HHR and Agriculture to convene workgroup to review appropriate oversight

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SB1632 CBD/THC-A Oils in Schools

- Amended § 22.1-277 and 18.2-251.1:1
- Requires school boards to adopt policies for permitting students with written certification to use CBD and THC-A oil while at school
- Prohibits suspending or expelling
- Prohibits nurse or others at school administering oils from being prosecuted
- Requires development of form to assist with administering oils to students

SB1719 CBD/THC-A Oils

- Amended §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7
- Creates “registered agent” for receiving oil
- Addresses personnel qualifications for cultivation and extraction
- Authorizes wholesale distribution of oils between pharmaceutical processors
- Requires Board to adopt emergency regulations for implementing

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Recently Enacted Regulations

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Nonresident 3PL and Warehousers

- Authorized the registration of nonresident third party logistic providers and nonresident warehousers
- Effective 3/22/19

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E-Profile ID

- Added 18VAC110-20-22, amended 18VAC110-20-80 and 18VAC110-20-105
- Requires pharmacists, pharmacy interns and pharmacy technicians to provide board with e-profile number when applying for or renewing licensure/registration
- Free of charge from NABP, most already have one
- Facilitates exchange of information between board and NABP
- Effective June 26, 2019

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Cold Storage Temperature

- Fast-track, 18VAC110-20-10; Effective 7/25/19
- Amends “storage temperature” definition to conform to changes in USP definition
- “A freezer is a cold place in which the temperature is ~~maintained thermostatically between -20° and -10°C (-4° and 14°F)~~ controlled between -25° and -10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20°C (-4°F), the temperature of the storage location should be controlled to plus or minus 10 degrees.”

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Proposed Regulations

Operational within 90 days

- Amends 18VAC110-20-140
- “Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension.”
- Effective 8/22/19

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Increase in Fees

- March 2018 – Board adopted proposed regulations to increase licensure fees
- First increase since 2002
- Note: Two fee reductions since 2002
- 2002 license count approximately 12,000; currently approximately 35,000
- Comment period ended 7/26/19 – none received

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Increase in Fees, cont.

- Proposed fees:
  - pharmacist new license = from $180 to $235
  - Pharmacist renewal = from $90 active/$45 inactive to $120/$60
  - Pharmacy new permit = from $270 to $500
  - Pharmacy renewal = from $270 to $350

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Delivery of Prescriptions

- Petition for Rulemaking received
- In 2018, NOIRA adopted to amend 18VAC110-20-275
- Petitioner requests not to require label to identify a pharmacy solely involved in the holding of a prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions.
- Additional comment from senior consumer organizations being sought
- Adoption of proposed regs to be considered on 9/25/19

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Brown/White Bagging

- Board adopted proposed regulation to amend 18VAC110-20-275; at Secretary's Office
- Pharmacy shall not deliver drugs to a patient's residence intended to be subsequently transported by the patient to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration
- Exception for patients with hemophilia who may require emergent blood factor treatment

Brown/White Bagging, cont.

- Requires shipping pharmacy to notify alternate delivery site of anticipated arrival date, exact address where drug shipped, patient name, and any special storage requirements
- Shipping pharmacy shall provide counseling or ensure process in place for patient to receive counseling
- Drugs to be stored in secure manner at alternate delivery site
- Pharmacy to provide procedure for the return of any drugs not delivered or administered to patient

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Periodic Regulatory Review

- Chapters 20 and 50
- Board adopted final regulations
- In Governor's Office

Periodic Regulatory Review, *cont.*

- Examples of proposed final 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, *cont.*

- 18VAC110-21-120, Continuing education:
  - Would require at least 3 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, *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.
- 18VAC110-20-150, Physical standards
  - Would require pharmacies stocking drugs requiring cold storage temperature to record temperature daily and adjust temperature as necessary;
  - Would require record to be maintained manually or electronically for two years.

Periodic Regulatory Review, *cont.*

- 18VAC110-20-425
  - Would remove 5% daily random check of meds picked by robot
  - Would require analysis of any errors, prior to resuming operations
  - Would clarify IV Admix robots may be used, however, pharmacist must verify accuracy

Periodic Regulatory Review, *cont.*

- 18VAC110-20-490
  - Would require P&P for granting and terminating access for automated dispensing devices
  - Allows record of distribution to be maintained electronically
  - Limits discrepancy report requirements to Schedules II-V and drugs of concern

Periodic Regulatory Review, *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, *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

Delivery of Devices

- Board adopted proposed amendment of 18VAC110-50-55
- Would allow a distributor to ship prescription device to ultimate user on behalf of medical equipment supplier
- Would allow medical director of home health, LTC, or hospice to direct distributor to ship Rx device to ultimate user

Pharmaceutical Processors

- Final regulations effective 8/8/19
- Most recent changes focused on clarifying testing standards of products prior to dispensing

Miscellaneous Updates

Pharmaceutical Processors

- Board issued conditional approval for 5 permits
- To be operational by December 21, 2019 but may take at least 4-6 months to cultivate and produce oils
- Registrations as of 7/29/19:
  - 310 physicians
  - 750 patients
  - 15 parent/guardians

USP <800>

- 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>.
- Board amended Guidance Document 110-36 in June 2019; published for public comment.

Revised Routine Pharmacy Inspection Report

- April 2018 - Convened meeting with pharmacist inspectors
  - Comprehensive review of inspection report
  - pros/cons to current version
- June 2018 - Convened ad hoc committee of board
  - Revised & shortened inspection report
  - Added educational items on chapter <800>

Amended Guidance Document 110-9

- Effective July 1, 2018
- Identified 10 deficiencies that if cited will no longer result in an automatic monetary penalty, but must still correct deficiency.
- If “repeat deficiency” during the next subsequent routine or focused inspection, then will result in monetary penalty.
- Refer to guidance document or September 2018 e-newsletter on board website

Paperless Licensing Initiative

- Agency moving away from issuing licenses with an expiration date.
- Verify status of license on Board's website via *License Lookup* feature.
- Paper will have enhanced security features.
- Process implemented for pharmacy technicians as of July 1, 2019; Implemented for others by end of year
- Ensure board has current email address on file!

Identifying Board-Registered Outsourcing Facilities

- From Board's website, click on *LicenseLookup* in menu options https://dhp.virginiainteractive.org/Lookup/Index
- For *occupation*, select *Nonresident Outsourcing Facility*
- Click on facility name to view current status of license

2020 Legislative Proposals

Process for Introducing Legislative Proposals

- No guarantee board-approved legislative proposals will be introduced during General Assembly Session.
- Legislative proposals must first be approved by DHP Director, Secretary HHR, and Governor prior to being included in Governor's legislative packet.

Pharmacy Technician Education Standards

- Would create authority for board to register “pharmacy technician trainees” with fee to be established in regulations
- Would require pharmacy technician to complete training program that is either:
  - (a) an accredited training program approved by the Board, or
  - (b) operated through a federal agency or branch of the military

Pharmacy Technician Education Standards, cont.

- Would require pharmacy technician to pass national certification exam administered by the Pharmacy Technician Certification Board or National Healthcareer Association.

Pharmacy Technician Education Standards, cont.

- Would require regulations to establish minimum standards for issuing a registration through credentialing to:
  - persons previously practicing as a pharmacy technician and
  - for issuing a registration to those persons enrolled in a board-approved pharmacy technician training program prior to the effective date of such regulations.

Pharmacy Technician Education Standards, cont.

- Would eliminate waiving of first examination fee for limited-use pharmacy technicians working exclusively in free clinic pharmacy.
- Enactment clause would require regulations within 280 days of enactment.

Compounding of Essentially Copies of Approved Products

- Would amend §54.1-3410.2 to clarify what a pharmacist may compound.
- Currently states pharmacist shall not engage in the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products.

Compounding of Essentially Copies of Approved Products, cont.

- Currently, there are several exceptions.
- Proposal would eliminate the exception for “the mixing of two or more commercially available products regardless of whether the end product is a commercially available product.”

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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.deadiversion.usdoj.gov/

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