Virginia Board of Pharmacy Law Update

DEA Pharmacy Diversion Awareness Conference
November 19 & 20, 2016

Caroline Juran, 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 needs to be disclosed
• Speaking to you today as the executive director of the Board of Pharmacy.
Current Board Members

- Rebecca Thornbury, Chairman
- Ryan K. Logan, Vice-Chairman
- Jody H. Allen
- Melvin L. Boone (citizen)
- Freeda Cathcart (citizen)
- Michael Elliott
- Sheila Elliott
- Rafael Saenz
- Ellen B. Shinaberry
- Cynthia Warriner
Objectives

• Briefly review select pharmacy-related bills passed by 2016 General Assembly
• Overview of recently enacted regulations and pending regulatory action
• Briefly explain 2017 legislative proposals
• Provide information on miscellaneous topics and reminders
New Laws Passed in 2016
General Assembly
HB 528 - 3PL, Track and Trace, etc.

- Requires wholesale distributors to comply with federal track and trace requirements
- Creates new licensing category for in-state third party logistic providers and nonresident manufacturers
- Clarifies that manufacturers may distribute drug without an additional license as a wholesale distributor
- Clarifies in §54.1-3410.2 the use of bulk drug substances in compounding
HB 527 - Nonresident Medical Equipment Suppliers

- Creates new licensing category for non-resident medical equipment suppliers
- Formalizes the Board’s existing process and holds out-of-state MES facilities to similar licensure oversight as in-state MES facilities
HB 293/SB 513 – PMP
(Until July 1, 2019)

• Expands mandatory requests to the PMP
  – §54.1-2522.1; Prescriber or delegate, at time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than 14 consecutive days
  – Physicians with DATA 2000 waiver IDs must query PMP prior to or as a part of execution of a treatment agreement with the patient
HB 293/SB 513 – PMP
(Until July 1, 2019)

• Exceptions:
  – Patient receiving hospice or palliative care;
  – Treatment for surgical or invasive procedure and such prescription is not refillable;
  – Prescribed during inpatient hospital admission or at discharge;
  – Patient in nursing home or assisted living facility that uses a sole source pharmacy;
HB 657 - PMP

- §54.1-2523.1; PMP advisory panel/disclosure
- DHP Director to develop, in consultation with advisory panel (representatives of Boards of Medicine and Pharmacy) criteria for:
  - indicators of unusual patterns of prescribing or dispensing;
  - misuse of covered substances; and
  - method for analysis of data collected by PMP using the criteria
- Unusual prescribing or dispensing to be disclosed to DHP Enforcement Division
SB 287 -PMP

- §54.1-2521; Increased frequency for reporting
- Dispensers as of January 1, 2017 must report within 24 hours or next business day, whichever comes later
SB 701- Pharmaceutical Processors

- 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
- Board adopted emergency regulations
- Bill must be reconsidered by GA in 2017 prior to enactment of law or regulations
2017 Legislative Proposal

(Adopted by Board, but will NOT be included in 2017 Governor’s Packet)
PTCB Legislative Proposal

- Would have:
  - required PTCB for initial registration as a pharmacy technician
  - Grandfathered existing pharmacy technicians
  - Had a delayed effective date of July 1, 2018
Virginia General Assembly Legislative Information System

- [http://leg1.state.va.us/](http://leg1.state.va.us/)
- Can search and track any bill by bill number, subject, or patron
Recently Enacted Regulations
Licensing of Physician Dispensing Location

- Emergency regulations effective 12/7/15-6/6/17
- Authorizes Board to license facility from where physicians are dispensing
- Board currently working on permanent regulations
- Public hearing on 12/12/16
Licensing of Outsourcing Facilities/Compounding

- Emergency regulations effective 12/7/15 through 6/6/17
- Creates new licensing category
- Compliance with cGMPs and federal law
- Require pharmacy permit also when dispensing patient-specifically
- Public hearing for permanent regs on 12/12/16
Scheduling of Drug

• Several actions to place various illicit drugs into Schedule I via Regulation
• Descheduled after 18 months unless law passed to permanently place into Schedule I
• Public hearing on 12/12/16
Pending Regulatory Activity
(not yet final)
Periodic Regulatory Review

- Chapters 20 and 50
- Most recent comment period ended 8/10/16
- Next step = Board to draft proposed language
- Regulation Committee Meeting – November 29
- More opportunities to comment in future!
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.
- Public hearing on 12/12/16
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.”

• Final regs in Governor’s office
Miscellaneous Topics
Opioids
Figure 4

(a) Past month nonmedical OPR use by age versus (b) OPR-related unintentional overdose deaths by age. Abbreviation: OPR, opioid pain reliever. Sources: 58, 68.


OPR – opioid pain reliever
Opioid Statistics in Virginia

- Fatal overdoses during the first half of 2016 has increased 35% compared to same time period of 2015.
- By the end of 2016, number of fatal opioid overdoses is expected to increase by 77% compared to 5 years ago.
- Number of emergency department visits for heroin overdose between Jan and Sept 2016 increased 89% compared to same time period 2015.
Increased Access to Naloxone

• REVIVE! naloxone program
• § 54.1-3408 X authorizes pharmacist to dispense naloxone pursuant to oral, written, or standing order in accordance with protocol approved by BOP, in consultation with VDH and BOM
• Law enforcement and fire fighters may possess and administer; provides immunity
Increased Access to Naloxone

- Board-approved protocol requires:
  - Standing order issued to pharmacy, signed by physician, good for up to 2 years
  - Pharmacist to counsel unless pharmacist is able to verify successful completion of REVIVE! training program
  - Labeling, but do not have to include person’s name on the label
  - Dispensing brochure must be provided - [http://www.dhp.virginia.gov/pharmacy/](http://www.dhp.virginia.gov/pharmacy/)
Inside Diversion

- Diversion by staff
- Pharmacy technicians
- Pharmacists
External Diversion

• Use professional judgment to determine prescription validity, taking “red flags” into consideration
  – Prescriptions received in Virginia pharmacies from out of state prescriber and patient resides in a third state
  – Upon return, out of state patient brings friends
  – Paying cash
  – Justifies travel by saying your pharmacy has cheaper prices
  – Sleeping in car waiting for pharmacy to open
“Red Flags”

- June 2012 Board e-newsletter article
Internal Diversion

• Diversion by staff
  – Pharmacy technicians
  – Pharmacists
• Guidance Document 110-27
Suggested Best Practices

- Perform state and federal criminal background checks on those with access to drugs
- Require periodic urine drug screening
- Prohibit staff from bringing bags into Rx dept
- Prior to leaving, routine bag and smock checks
- Routinely review policies and procedures to prevent, identify, address internal and external theft
- Do not delegate management of inventory to solely one individual
- Review drugs received, drugs dispensed, monitor for adjustments or excessive ordering
- Install surveillance cameras
License Verifications

- Check License Lookup when hiring new pharmacists and pharmacy technicians
- Working for up to 9 months while enrolled in pharmacy technician training program only valid prior to initial registration
- Include questions on application regarding felony or misdemeanor convictions, pending charges, board action or pending disciplinary action
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. # 12: Storage of prescription drugs outside previously approved drug storage area
5. # 20: Pharmacist not checking and documenting repackaging and bulk packaging
Counterfeit Drugs

• Ensure prescription drugs are purchased only from properly licensed entities
• Verify licensure through License Lookup at Board’s website – www.dhp.virginia.gov
• .pharmacy Generic Top Level Domain (gTLD) with National Association of Boards of Pharmacy (NABP)
Appriss PMP Clearinghouse

- New PMP software platform
- Must submit data to Appriss as of 11/30
- Dispensers must register with clearinghouse prior to 11/30
- Questions – (855) 482-4767
Electronic Renewal Notification

• Provide current email addresses to Board
• Pharmacists and pharmacy technicians recently informed via email
• Paper notification will be mailed if not renewed by deadline identified in email
Reminders for Pharmacy Technicians

- Must obtain 5 hours of board-approved CE annually!
  - Cannot carry over from year to year
  - Must be ACPE, CME Category 1, or a board of pharmacy-approved program
  - Register for NABP CPE Monitor ID number
  - Do not attest to having completed CE if you did not
  - May request one-time extension for obtaining CE, then for good cause only
2G to 3G-4G, Security Systems

- 2G Sunset December 31, 2016
- Affects GSM technology; CDMA not affected
- Actions:
  - Contact alarm company, determine if action needed
  - Change to circuit board – no inspection needed
  - Any other change – submit remodel application
  - Maintain documentation describing technology in place, if upgrade necessary, and when it occurred
Board E-newsletters

• Recent publication = October 2016
• Next publication = December 2016
• Available at http://www.dhp.virginia.gov/pharmacy under “Newsletters and Presentations”
• Published 3-4 times annually
• Notification of current publication via email
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www.dhp.Virginia.gov/pharmacy

QUESTIONS?