

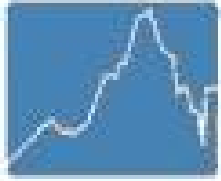


Department of Health Professions

Virginia Board of Pharmacy Law Update

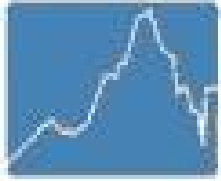
VPhA Annual Convention
September 11, 2016

Caroline Juran, Executive Director



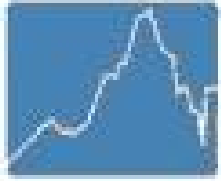
Disclosures

- 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.



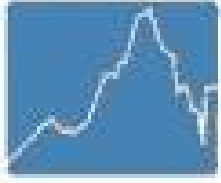
Current Board Members

- 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



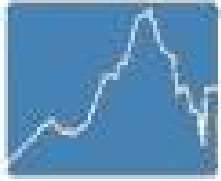
Objectives

- 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



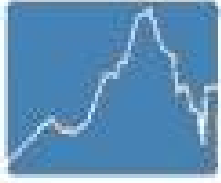
Department of Health Professions

New Laws Passed in 2016 General Assembly



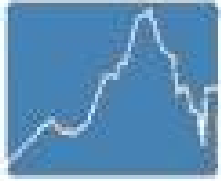
HB 528 - 3PL, Track and Trace, etc.

- 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



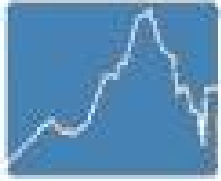
HB 527 - Nonresident Medical Equipment Suppliers

- 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)*

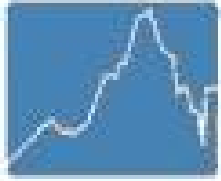
- Expands mandatory requests to the PMP
 - 54.1-2522.1; Prescriber or delegate, at time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than 14 consecutive days
 - Physicians with DATA 2000 waiver IDs must query PMP prior to or as a part of execution of a treatment agreement with the patient



Department of Health Professions

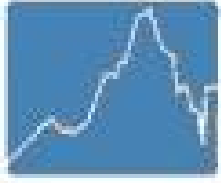
HB 293/SB 513 – PMP *(Until July 1, 2019)*

- 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;



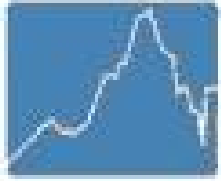
HB 657 - PMP

- 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



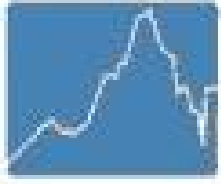
SB 287 -PMP

- 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

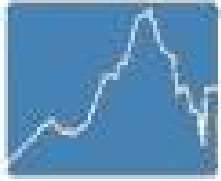
- Authorizes licensing of a pharmaceutical processor to cultivate, produce, and dispense cannabidiol oil and THC-A oil for treatment of intractable epilepsy
- Must have pharmacist-in-charge
- Board adopted emergency regulations
- Bill must be reconsidered by GA in 2017 prior to enactment of law or regulations



Department of Health Professions

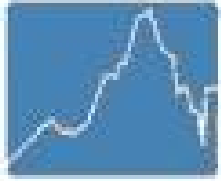
2017 Legislative Proposals

(Adopted by Board, but will NOT be included in 2017 Governor's Packet)



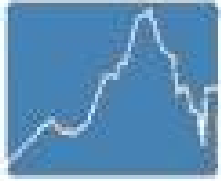
Legislative Proposal Process

- Board-adopted legislative proposal become DHP bills
- However, prior to introducing in GA, proposal must be approved by:
 - DHP Director,
 - Secretary HHR, and
 - Governor



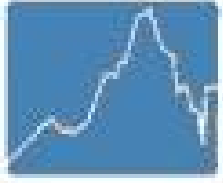
PTCB Legislative Proposal

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



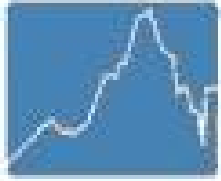
Collaborative Practice Legislative Proposal

- Would have:
 - Clarified existing law that a pharmacist may issue a prescription to implement, modify, continue, or discontinue drug therapy as part of the collaborative practice agreement
- Did not seek to expand existing authority; only to clarify how the process may be completed



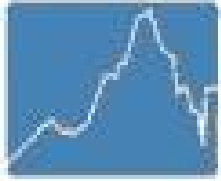
Department of Health Professions

Recently Enacted Regulations



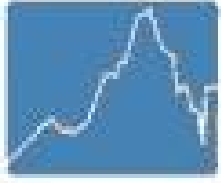
Licensing of Physician Dispensing Location

- 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



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
- Board currently working on permanent regulations



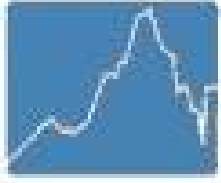
18VAC110-20-540

- Amends regulation to allow emergency drug kit to contain diazepam rectal gel
- Effective date 8/11/16



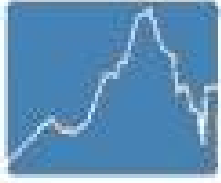
Scheduling of Drug

- Several actions to place various illicit drugs into Schedule I
- Descheduled after 18 months unless law passed to permanently place into Schedule I



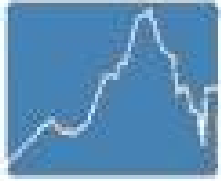
Department of Health Professions

Pending Regulatory Activity (not yet final)



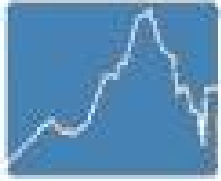
Periodic Regulatory Review

- Chapters 20 and 50
- Most recent comment period ended 8/10/16
- Next step = Board to draft proposed language
- More opportunities to comment!



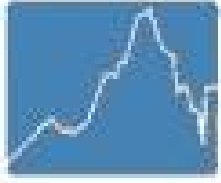
18VAC110-20-25 Coupons

- 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.
- Proposed regs in the Governor's office for review



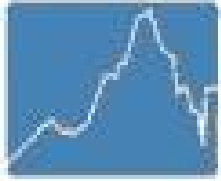
18VAC110-20-110 Hours Worked

- 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 Secretary’s office



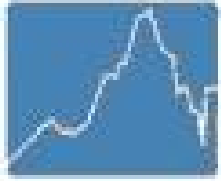
Department of Health Professions

Miscellaneous Topics and Reminders



Inspection Process

- Guidance Document 110-9
 - No longer “major” and “minor”
 - Bifurcated deficiencies to decrease monetary sanctions



Most Commonly Cited Deficiencies with Automatic Monetary Sanction

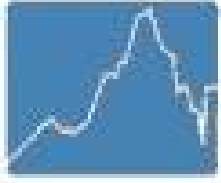
1. # 15: Perpetual Schedule II inventory
2. # 14: Incoming PIC inventory
3. # 20a: Pharmacist not documenting final verification of non-sterile compounding
4. # 12: Storage of prescription drugs outside previously approved drug storage area
5. # 20: Pharmacist not checking and documenting repackaging and bulk packaging



Department of Health Professions

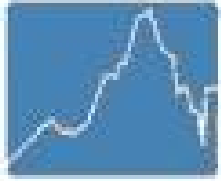
Most Commonly Cited Deficiencies without Automatic Monetary Sanction

1. # 113: Inventories taken on time but not in compliance
2. # 119: Partial filling of prescriptions not properly documented
3. # 130: Required compounding/dispensing/ distribution records not complete and properly maintained
4. # 108: Emergency access alarm code/key not maintained in compliance
5. # 124: Labels do not include all required information



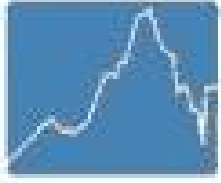
Universal Inspection Form

- Draft form developed by member states of NABP
- VA piloted form, offering feedback



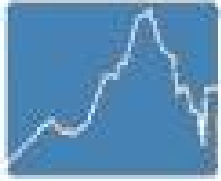
Board E-newsletters

- Recent publication = May 2016
- Available at http://www.dhp.virginia.gov/pharmacy/pharmacy_newsletters.htm
- Published 3-4 times annually
- Notification of current publication via email



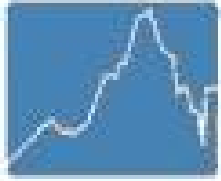
Electronic Renewal Notification

- Provide current email addresses to Board
- Pharmacists and pharmacy technicians informed via email when time to renew
- Paper notification mailed if not renewed by deadline identified in email



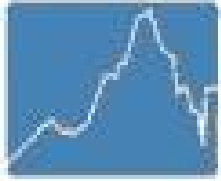
Reminders for Pharmacy Technicians

- 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



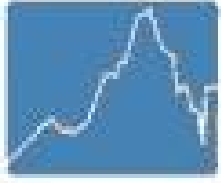
Increased Access to Naloxone

- 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/>



Department of Health Professions

www.dhp.virginia.gov

Tel: (804) 367-4456

pharmbd@dhp.virginia.gov

www.dhp.Virginia.gov/pharmacy

QUESTIONS?