

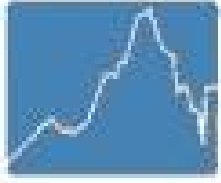
Department of Health Professions

Virginia Board of Pharmacy

VPhA Annual Meeting

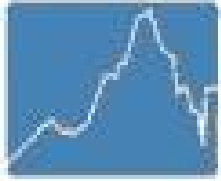
August 3, 2014

Caroline D. Juran, Executive Director
Sammy Johnson, Deputy Exec Director



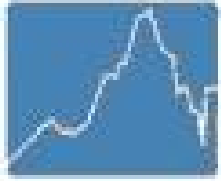
Financial Disclosures

- Caroline Juran and Sammy Johnson
- We have no relevant financial relationships or conflicts to disclose.
- No sources of support to disclose.



Overview of Program

- Highlight new laws enforced by the Department of Health Professions which may impact pharmacy
- Provide a summary of recent regulatory action
- Highlight guidance recently adopted by the Board of Pharmacy
- Summarize legislative proposals adopted by the Board of Pharmacy



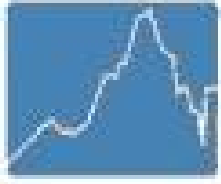
Overview of Program

- Briefly summarize board-related projects, e.g., REVIVE naloxone pilot, prescription drug abuse, compounding work group, hosting of NABP/AACP Districts 1 & 2 meeting, physician selling inspection program
- Answer questions regarding board-related activities



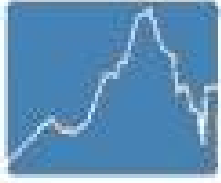
Pre-test Questions

1. Should you be reporting the dispensing of tramadol to the PMP currently?
2. How many minor deficiencies must be cited during a routine pharmacy inspection prior to a monetary penalty being imposed?
3. May a pharmacist provide a compounded drug to a veterinarian intended for further distribution to his patients?



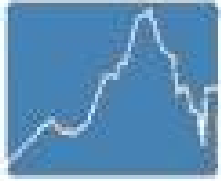
Current Board Members

- Ellen B. Shinaberry, Chairman
- Empsy Munden, Vice-Chairman
- R. Crady Adams
- Jody H. Allen
- Dinny Li (citizen)
- Ryan Logan
- Robert M. Rhodes
- Pratt P. Stelly (citizen)
- Rebecca Thornbury
- Cynthia Warriner



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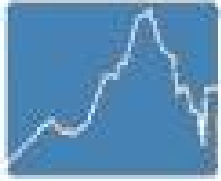
New Laws Enforced by DHP that Impact Pharmacy



Department of Health Professions

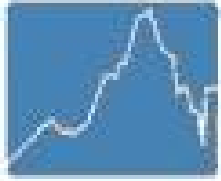
Compounding Drugs for Vet Dispensing

- HB 1035 amended §§54.1-3301 and 54.1-3410.2
- Effective July 1, 2014
- Pharmacists may provide veterinarian with compounded drug intended for:
 - administration to his patients, and
 - Further distribution by vet to his patients under certain circumstances (see next slide for circumstances)



Compounding Drugs for Vet Dispensing

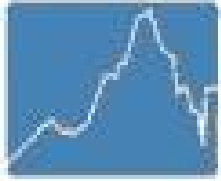
- Further distribution by vet to his patients when....
 - companion animal
 - limited to drugs necessary to treat emergent condition
 - timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian
 - Quantity dispensed by vet limited to 72-hour supply



Compounding Drugs for Vet Dispensing

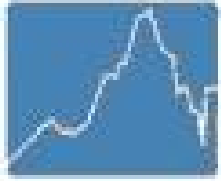
Labeling requirements:

- name and strength of the compounded medication or list of the active ingredients and strengths;
- facility's control number;
- appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding;
- name and address of the pharmacy; and,
- quantity.



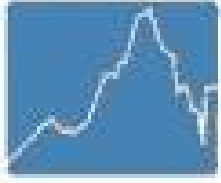
Selling Dextromethorphan to Minors

- Effective January 1, 2015
- HB 505 created 18.2-265.20 and 18.2-265.21
- Illegal for pharmacy and retail distributor to sell DMX to minor, i.e., less than 18 years
- Must ID person unless outward appearance reasonably presume person 25 years or older
- Knowingly violate = \$25 civil penalty
- Violate provision for reviewing ID = notice of noncompliance; \$25 for subsequent violation



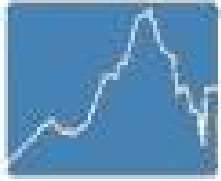
Drugs of Concern

- HB 874 defined “drug of concern”, amended 54.1-2520 and created 54.1-3456.1
- Effective July 1, 2014
- Any drug or substance, including any controlled substance or other drug or substance, where there has been or there is the potential for abuse and that has been identified by the Board of Pharmacy
- Board may promulgate regs designating drugs of concern where there has been or there is the actual or relative potential for abuse



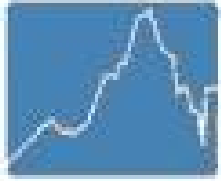
Drugs of Concern

- Designated tramadol as a drug of concern
- Drugs of concern must be reported to the PMP
- **DEA final rule places tramadol into Schedule IV effective August 18, 2014



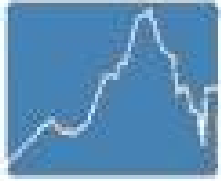
Prescriber Registration and Use of PMP

- HB 1249 created 54.1-2522.1 effective July 1, 2015
- Prescribers shall be registered to use PMP upon filing application for license or renewal
- Prescribers shall query PMP under certain circumstances for humans



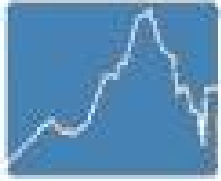
Prescriber Registration and Use of PMP

- Circumstances:
 1. At the time of initiating new course of treatment which includes benzo or opiate anticipated to last > 90 consecutive days and treatment agreement entered into
 2. Prescriber with special ID from DEA to treat opioid addiction therapy shall query prior to or as part of execution of treatment agreement



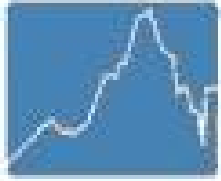
Prescriber Registration and Use of PMP

- 2 exceptions for querying PMP:
 1. If benzo or opiate on list published by Secretary of Health and Human Resources that has low potential for abuse for humans
 2. if the course of treatment arises from pain management relating to dialysis or cancer treatments



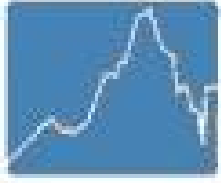
Pharmacist May Delegate Access to PMP

- HB 539, effective July 1, 2014
- Any dispenser authorized to access PMP may delegate his or her authority to health care professionals who are:
 - (i) licensed, registered, or certified by a health regulatory board and
 - (ii) employed at the same facility and under the direct supervision of the dispenser



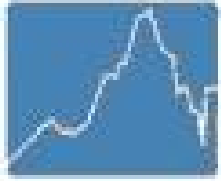
Pharmacist May Delegate Access to PMP

- Submit application to PMP
- Delegate will have own user name and password
- Pharmacist will be able to review reports requested by their delegates



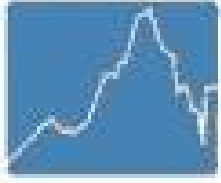
Scheduling Bill

- HB 575
- Effective July 1, 2014
- Added lorcaserin (weight loss) to Schedule IV
- Added perampanel (antiepileptic) to Schedule III



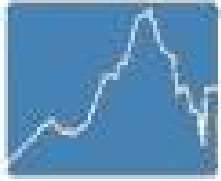
Cannabimimetic Agents

- HB 1112 and SB 594
- Renamed synthetic cannabinoids
- Placed them into Schedule I – same penalties except simple possession = class I misdemeanor
- Authorizes Board to expeditiously place drugs into Schedule I or II for up to 18 months



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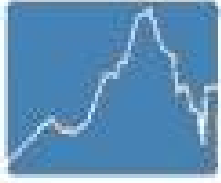
Proposed Regulatory Action
(Not yet in effect)



Department of Health Professions

Administrative fees for duplicate licenses and verification

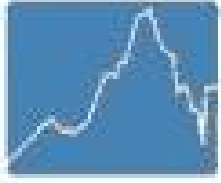
- Proposed regulation
- Public comment ended July 18, 2014
- \$10 – duplicate
- \$25 - verification



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Maintaining floor stock of certain drugs onsite at correctional facilities

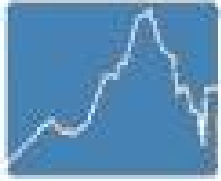
- Fast-track proposed regulation
- At Secretary's Office
- Would allow facility to floor-stock IV fluids, irrigation fluids, sterile water, sterile saline



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CQI Regulations

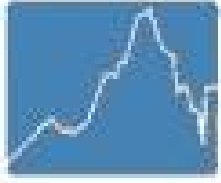
- Emergency regs expired 9/30/13
- Permanent replacement proposed regs under review, at Secretary's Office



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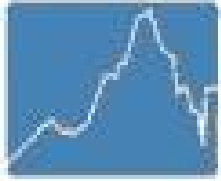
Prohibition against incentives to transfer prescriptions

- Notice of Intended Regulatory Action recently published, at Secretary's Office



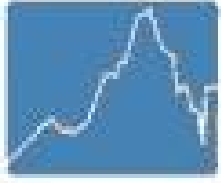
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Final Regulations for Collaborative Practice Agreements



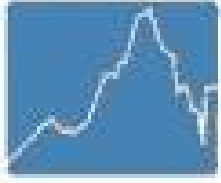
Collaborative Practice Agreements

- §§54.1-3300 and 54.1-3300.1 amended in 2013
- **Joint BOM and BOP regulatory changes effective 4/23/14**
- Clarifies with whom pharmacist may enter into agreement (adds nurse practitioners, PAs, and physician's office)
- Prescriber may elect for patient to not participate by contacting pharmacist or documenting on prescription



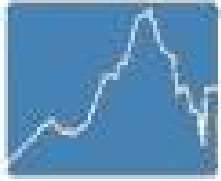
Collaborative Practice Agreements

- Clarifies agreement may be in writing or electronic
- Authorizes pharmacist to implement drug therapy following diagnosis by prescriber



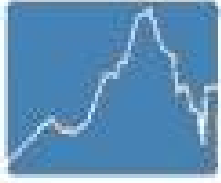
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Guidance Recently Adopted by Board



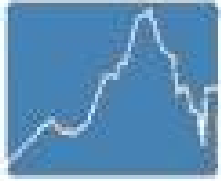
Guidance Document 110-17

- Minimum passing score for Internet Based Test of English as a Foreign Language (TOEFL ibt) exam increased in March 2014



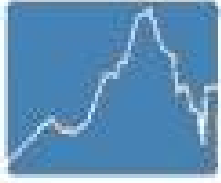
Guidance Document 110-27

- Amended in December 2013 and mailed to all pharmacists-in-charge
- Added suggested best practices to safeguard against diversion of controlled substances



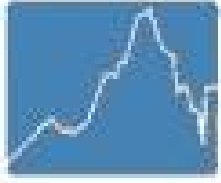
Guidance Document 110-9

- Amended in December 2013
- Number of minor deficiencies resulting in monetary penalty increased from 3 to 5
- Bifurcated several major deficiencies into a major and a minor



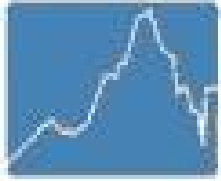
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Legislative Proposals



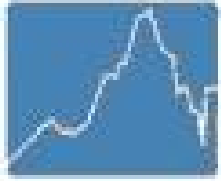
Scheduling Proposal

- Propose placing alfaxalone (anesthetic for animals) and tramadol into Schedule IV
- Would conform state law with federal regulations



Pharmacist Possession of Epinephrine and Oxygen

- Propose authorizing pharmacist possession pursuant to oral, written order or protocol to treat medical emergencies



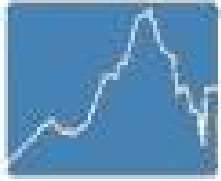
Licensing of Physician Dispensing Location

- Propose authorizing Board to license facility from where physicians are dispensing



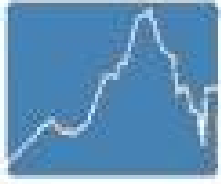
Wholesale Distributor Notification Requirement

- Propose requiring wholesale distributors to notify Board when cease distributing prescription drugs to entity based on suspicious activity



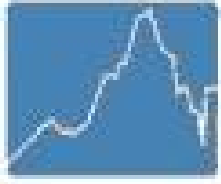
Licensing of Outsourcing Facilities

- Propose creation of new licensing category
- Compliance with cGMPs and federal law
- Conform state law to federal law by removing allowance to compound human drugs for office use
- Require pharmacy permit also when dispensing patient-specifically
- Change timeframe for current inspection report from nonresident pharmacies



Miscellaneous Topics

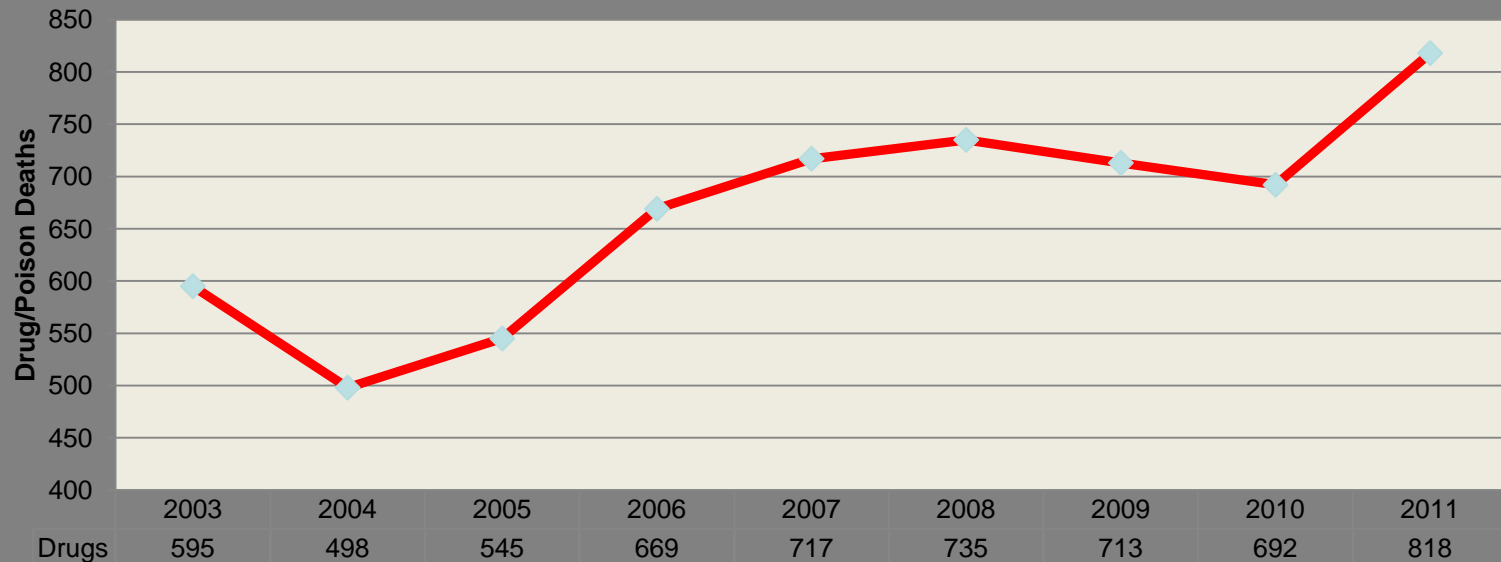
- Prescription drug abuse



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Drug/Poison Deaths of Virginia Residents: 2003-2011

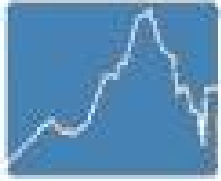
Rate in 2011 was 9.6 per 100,000



Source: Office of the Chief Medical Examiner Annual Report 2011

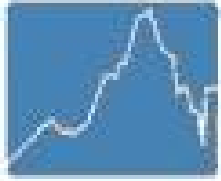
Source: Virginia Office of the Chief Medical Examiner

www.dhp.virginia.gov



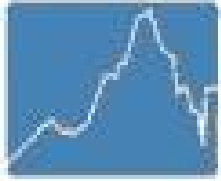
Prescription Drug Abuse

- Be sure to properly secure drug stock
- Perform monthly perpetual inventories of CII
- 54.1-3404 – requires immediate notification of theft or unusual loss of drugs in CII-V with complete listing of kind, quantity and strength of such drugs lost within 30 days of discovery
- Notify DEA as well



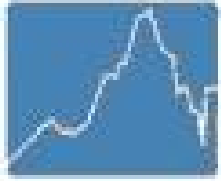
Prescription Validity

- Prescriptions being received in VA pharmacies from out of state prescriber and patient resides in a third state
- June 2012 Board e-newsletter article
- Red Flags video



Use the PMP to Assist in Determining Validity of Prescription!!

- Stores dispensing data of CII-IV
- Tool to identify doctor shoppers and potential abuse
- VPMP = >21,000 users; >5079 pharmacists
- Interoperable with 17 states



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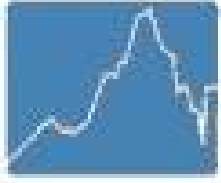
Use the PMP to Assist in Determining Validity of Prescription!!

- Tennessee, Ohio, Indiana, Connecticut, Delaware, Illinois, Michigan, South Carolina, North Dakota, Arizona, Kansas, New Mexico, South Dakota, Minnesota, Kentucky, West Virginia and Louisiana
- 1,313,861 requests were processed in 2013



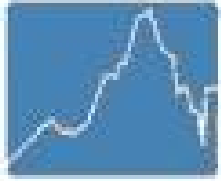
REVIVE Naloxone Pilot

- §54.1-3408 amended 2013
- Within pilot program, allows person to obtain prescription for naloxone to administer to family member or friend
- Counteract opiate overdoses
- Pilot at OTP in Richmond and southwest Virginia
- DBHDS to report back to GA in December 2014



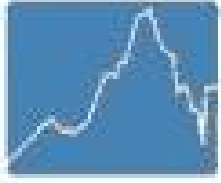
Counterfeit Drugs

- Ensure prescription drugs are purchased only from properly licensed entities
- Verify licensure through License Lookup at Board's website
- .pharmacy gTLD with NABP



Miscellaneous Topics

- Compounding work group (guidance, pharmacists compounding in MD office)
- Hosting of NABP/AACP Districts 1 & 2 meeting
- Physician selling inspection program
- Concern from vets – appropriate drug therapy for animals and humans may be different



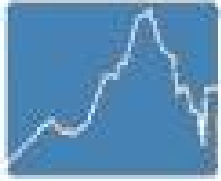
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Board of Pharmacy Website Address

www.dhp.virginia.gov/pharmacy

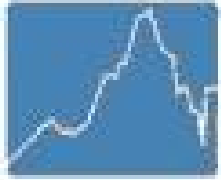
Board of Pharmacy E-mail Address

pharmbd@dhp.virginia.gov



Post-test Questions

1. Should you be reporting the dispensing of tramadol to the PMP currently? **Yes.**
2. How many minor deficiencies must be cited during a routine pharmacy inspection prior to a monetary penalty being imposed? **Five.**
3. May a pharmacist provide a compounded drug to a veterinarian intended for further distribution to his patients? **Yes, under certain circumstances.**



Department of Health Professions

