

**Department of Health Professions**

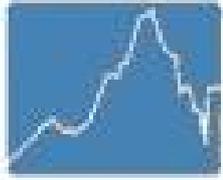
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# **Virginia Board of Pharmacy Update**

**DEA Pharmacy Diversion Awareness  
Conference**

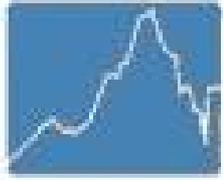
**May 30 & 31, 2015**

**Caroline Juran, Executive Director**



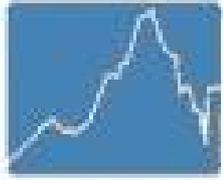
# Current Board Members

- Ellen B. Shinaberry,  
Chairman
- Empsy Munden, Vice-  
Chairman
- Jody H. Allen
- Dinny Li (citizen)
- Cynthia Warriner
- Sheila Elliott
- Rebecca Thornbury
- Ryan K. Logan
- Melvin L. Boone (citizen)
- Michael Elliott



# Objectives

- Highlight ongoing efforts of Virginia Governor's Prescription Drug and Heroin Abuse Task Force
- Briefly review select pharmacy-related bills passed by 2015 General Assembly
- Briefly discuss new CQI requirements, 2G to 3G/4G alarm technology, 2015 CE requirement

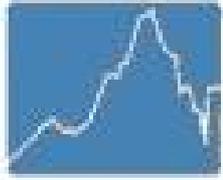


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# Governor's Prescription Drug and Heroin Abuse Task Force

- Since 2000, deaths in VA from prescription drug overdoses have more than doubled
- In 2013, 468 Virginians died from prescription opioid overdose
- From 2007 to 2013, nearly 70% of all drug/poison deaths were attributed to opioids

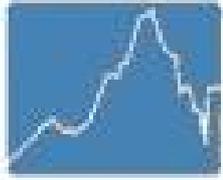


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# Governor's Prescription Drug and Heroin Abuse Task Force

- Deaths from heroin in VA have doubled in past 2 years
- In 2013, 213 people died from heroin overdose
- Affects all regions of VA

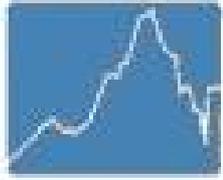


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# Governor's Prescription Drug and Heroin Abuse Task Force

- 2006-2012 - Prescription opioid seizures during an arrest increased by 437%
- Heroin seizures increased by 79%, then increased again by over 48% from 2012 to 2013.



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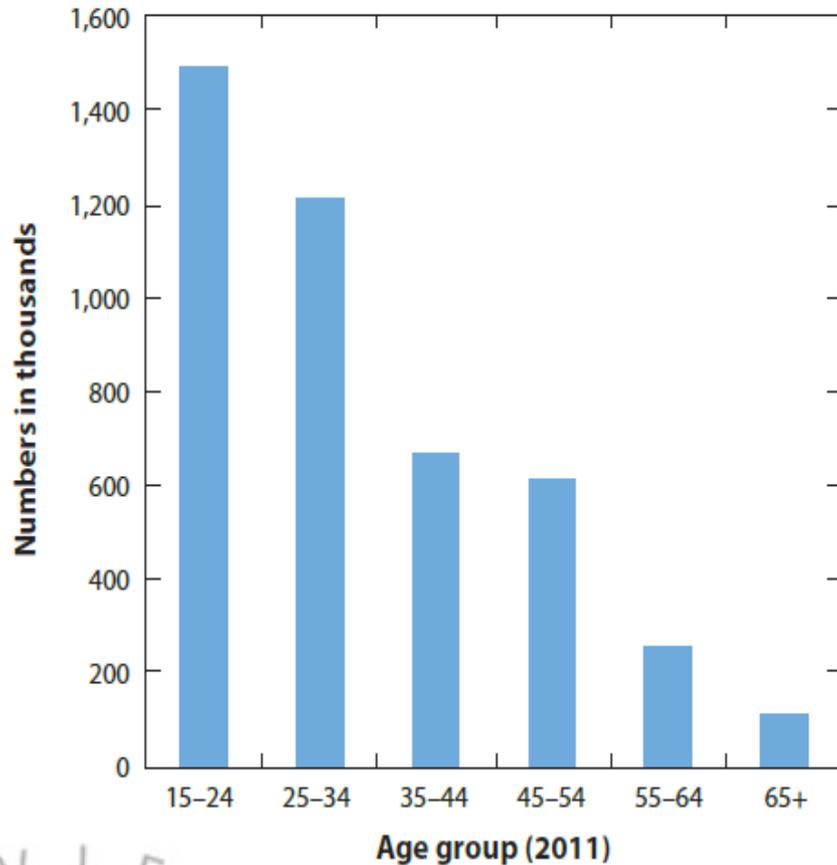
# Governor's Prescription Drug and Heroin Abuse Task Force

- Workgroups: Data monitoring, storage and disposal, treatment, and education
- Recommendations considered by TF in June



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**a** Past month nonmedical OPR use by age



**b** OPR-related unintentional overdose deaths by age

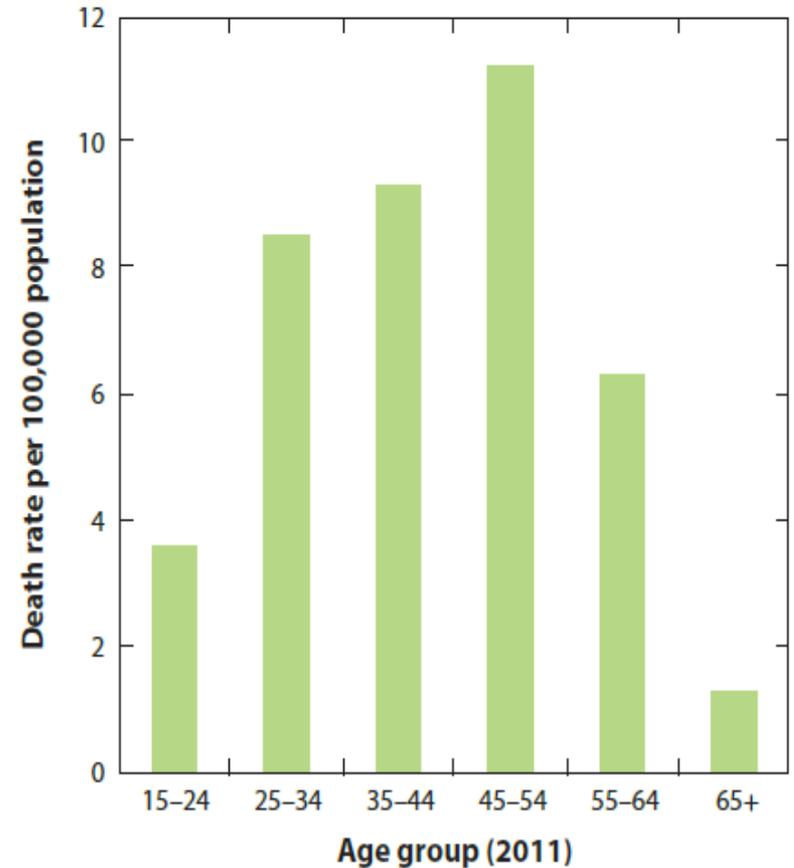
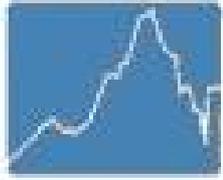


Figure 4

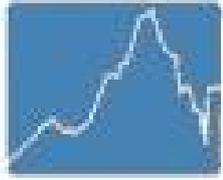
(a) Past month nonmedical OPR use by age versus (b) OPR-related unintentional overdose deaths by age. Abbreviation: OPR, opioid pain reliever. Sources: 58, 68.



# HB 1458 Naloxone

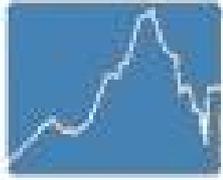
- REVIVE!
- 54.1-3408; bill signed into law; immunity

X. Notwithstanding the provisions of § 54.1-3303 and only for the purpose of participation in pilot programs conducted by the Department of Behavioral Health and Developmental Services, a person may obtain a prescription for a family member or a friend and may possess and administer naloxone for the purpose of counteracting the effects of opiate overdose, pursuant to an oral, written or standing order issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist may dispense naloxone or other opioid antagonist used for overdose reversal and a person may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose. Law-enforcement officers as defined in § 9.1-101 and firefighters who have completed a training program may also possess and administer naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.



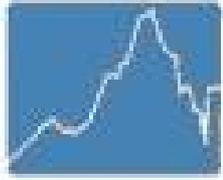
## Scheduling Bill

- HB 1839; conforms state law with federal regulation; effective July 1, 2015
- Schedule IV
  - alfaxalone (anesthetic for animals)
  - suvorexant (insomnia)
  - tramadol (pain)
- Schedule II
  - Hydrocodone combination products



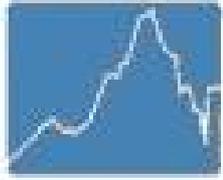
# Pharmacist Possession of Epinephrine and Oxygen

- HB 1914
- Would authorize pharmacist possession pursuant to oral, written order, or protocol to treat medical emergencies



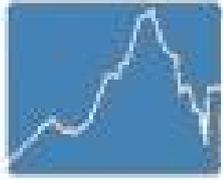
# Licensing of Physician Dispensing Location

- HB 2192
- Would authorize Board to license facility from where physicians are dispensing



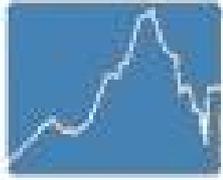
# Wholesale Distributor Notification Requirement

- HB 1736
- Would require wholesale distributors to notify Board when cease distributing Schedule II-V drugs to dispenser based on suspicious activity



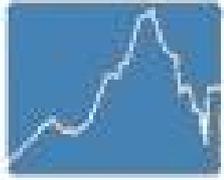
# Licensing of Outsourcing Facilities

- HB 1737
- Creates new licensing category
- Compliance with cGMPs and federal law
- Require pharmacy permit also when dispensing patient-specifically
- Restricts pharmacy compounding for office use to a reasonable amount if there is a critical need to treat an emergency condition



# PMP bills

- Requires DHP to automatically register prescribers and pharmacists by January 1, 2016
- Need for current email addresses!!!
- Requirement for prescriber to query PMP under certain circumstances – July 1, 2015

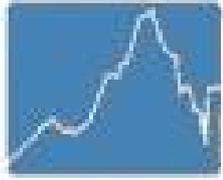


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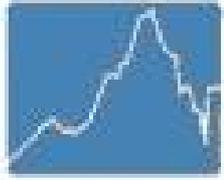
# Virginia General Assembly Legislative Information System

- <http://leg1.state.va.us/>
- Can search and track any bill by bill number, subject, or patron



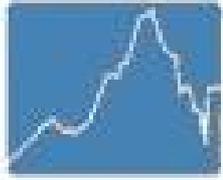
# Regulations Effective July 16, 2015

- 18VAC110-20-190
- PIC or pharmacist on duty shall not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.



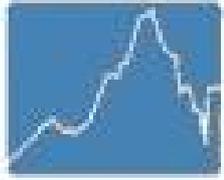
# Regulations Effective July 16, 2015

- 18VAC110-20-20
- Renewal of nonresident pharmacy registrations   
due no later than the date of initial registration



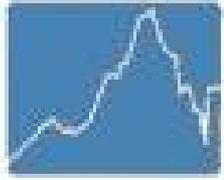
# Regulations Effective July 16, 2015

- 18VAC110-20-590
- Per listing determined by provider pharmacist in consultation with medical or nursing staff, correctional facility may stock IV fluids, irrigation fluids, sterile water, and sterile saline
- Accessed only by those licensed to administer drugs and administered pursuant to valid prescription or lawful order



# Regulations Effective July 1, 2015

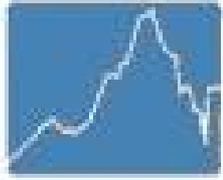
- 18VAC110-20-20
- Duplicate license/registration - \$10
- Verification of license/registration - \$25



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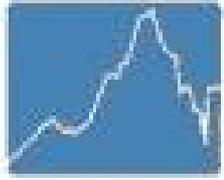
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# Reminders



# Continuous Quality Improvement Regulations

- § 54.1-3434.03 effective 2011
- Replacement regulations effective December 31, 2014
- Regulations 18VAC110-20-418 and 18VAC110-20-10



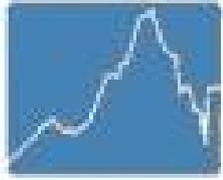
## Diversion

- Red Flags video
- PMP
- Perpetual inventory



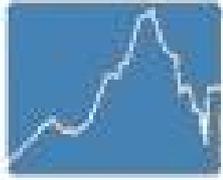
# Continuous Quality Improvement Regulations

- Inspections – no sanction until July 1, 2015
- Guidance Document 110-9
- Minor Deficiency 42
- No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports.
- Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance.
- 20% Threshold



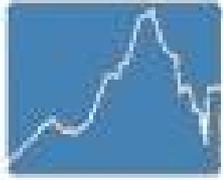
## Required CE for 2015

- 1-hour CE requirement for 2015 only
- Subject of *opioid use or abuse*
- Applicable only for pharmacists



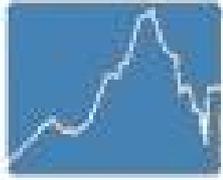
# 2G to 3G-4G, Security Systems

- 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



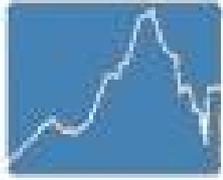
# Selling Dextromethorphan to Minors

- 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



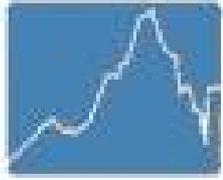
# Counterfeit Drugs

- Ensure prescription drugs are purchased only from properly licensed entities
- Verify licensure through License Lookup at Board's website – [www.dhp.virginia.gov](http://www.dhp.virginia.gov)
- .pharmacy Generic Top Level Domain (gTLD) with National Association of Boards of Pharmacy (NABP)



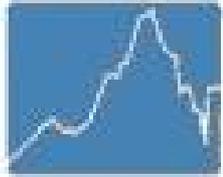
# License Verifications

- 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



# Board E-newsletters

- Recent publication = May 2015
- Available at <http://www.dhp.virginia.gov/pharmacy/newsletters/2015/VA022015.pdf>
- Published 3-4 times annually
- Provide **current email address** to Board – **RENEWALS**



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