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
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
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
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.
Governor’s Prescription Drug and Heroin Abuse Task Force

– Workgroups: Data monitoring, storage and disposal, treatment, and education
– Recommendations considered by TF in June
(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
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
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
- .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
- Published 3-4 times annually
- Provide current email address to Board – RENEWALS