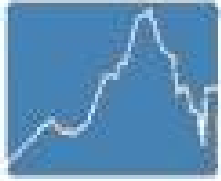


Department of Health Professions

Virginia Board of Pharmacy Law Update

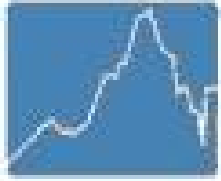
134th Virginia Pharmacists Association
Annual Convention
July 26, 2015

Caroline Juran, Executive Director



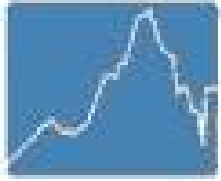
Disclosures

- No real or apparent conflicts of interest during the past two years 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



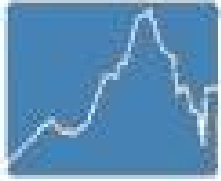
Current Board Members

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



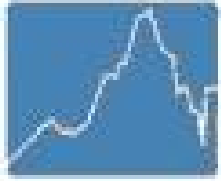
2015 NABP Fred T. Mahaffey Award

- Awarded to Virginia Board of Pharmacy
- Recognizes a board of pharmacy that has made substantial contributions to the regulation of the practice of pharmacy over the past year
- Significant contributions in protecting the public and ensuring that compounding is performed in a safe and compliant manner



Objectives

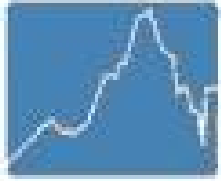
- Highlight ongoing efforts of Virginia Governor's Prescription Drug and Heroin Abuse Task Force
- Briefly review select pharmacy-related bills passed by 2015 General Assembly
- Briefly explain 2016 legislative proposals
- Provide information on miscellaneous topics and reminders



Department of Health Professions

Governor's Prescription Drug and Heroin Abuse Task Force

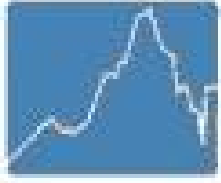
- Since 2000, deaths in VA from prescription drug overdoses have more than doubled
- In 2013, 468 Virginians died from prescription opioid overdose



Department of Health Professions

Governor's Prescription Drug and Heroin Abuse Task Force

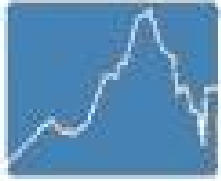
- **Question:**
 - What percentage of all drug/poison deaths were attributed to opioids from 2007 to 2013?



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Governor's Prescription Drug and Heroin Abuse Task Force

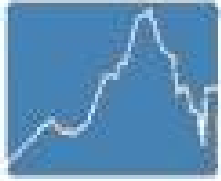
- **Answer:**
 - Nearly 70%.



Department of Health Professions

Governor's Prescription Drug and Heroin Abuse Task Force

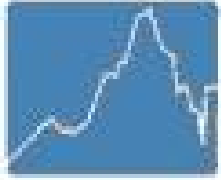
- Deaths from heroin in VA have doubled in past 2 years
- In 2013, 213 people died from heroin overdose
- Affects all regions of VA



Department of Health Professions

Governor's Prescription Drug and Heroin Abuse Task Force

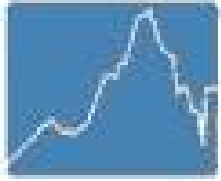
- **Question:**
 - Between 2006-2012, seizures of prescription opioids during an arrest increased by what percentage?



Department of Health Professions

Governor's Prescription Drug and Heroin Abuse Task Force

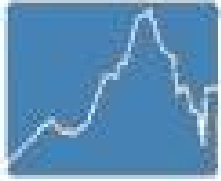
- **Answer:**
 - 437%



Department of Health Professions

Governor's Prescription Drug and Heroin Abuse Task Force

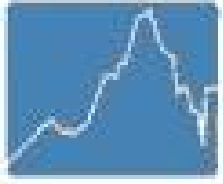
- Heroin seizures increased by 79%, then increased again by over 48% from 2012 to 2013.



Department of Health Professions

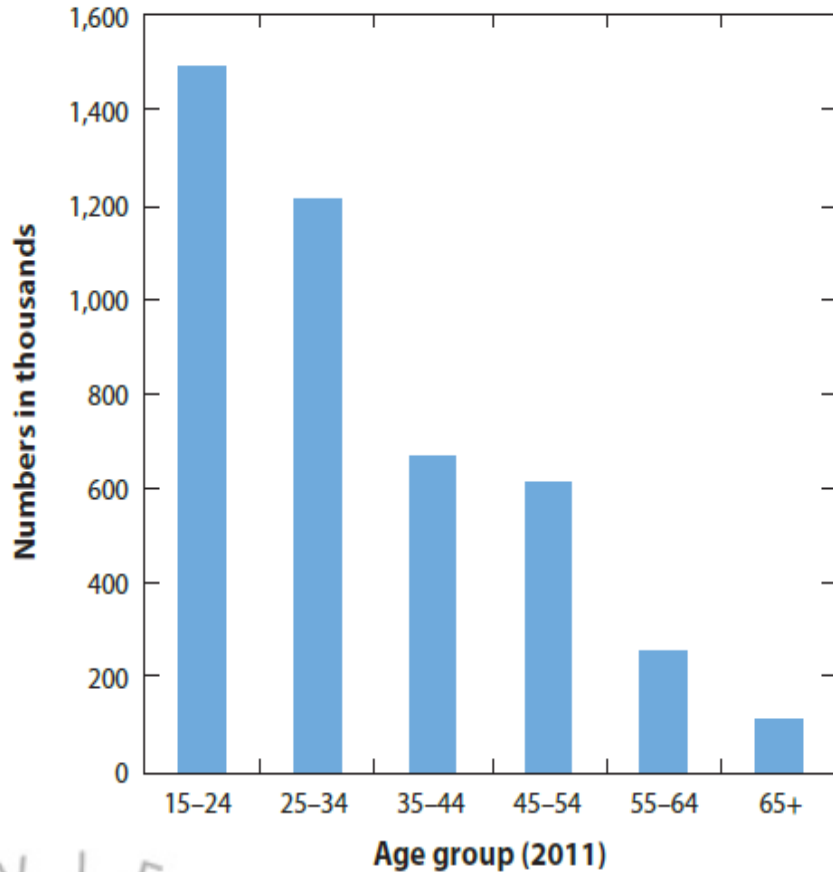
Governor's Prescription Drug and Heroin Abuse Task Force

- Workgroups: Data monitoring, storage and disposal, treatment, and education
- Implementation Plan sent to Governor June 30, 2015
- <http://www.dhp.virginia.gov/taskforce/default.htm>
- Final meeting September 21, 2015



Department of Health Professions

a Past month nonmedical OPR use by age



b OPR-related unintentional overdose deaths by age

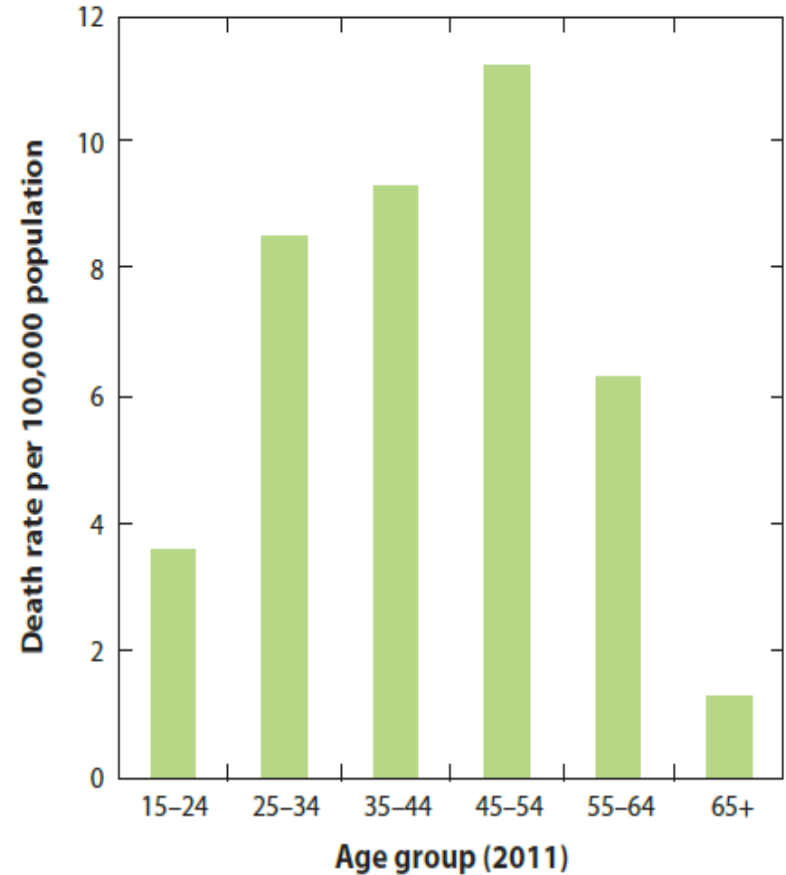
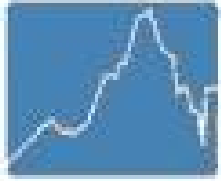


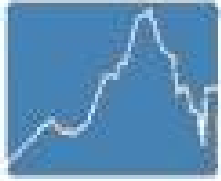
Figure 4

(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.



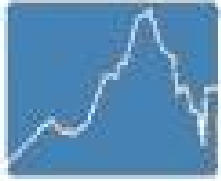
New Increased Access to Naloxone

- 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



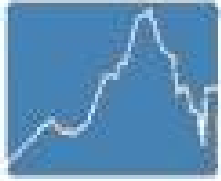
New Increased Access to Naloxone

- Board-approved protocol requires:
 - Counsel on opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety
 - Patient cannot waive counseling, unless pharmacist is able to verify successful completion of REVIVE! training program



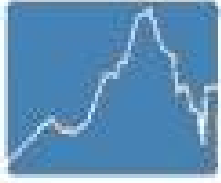
New Increased Access to Naloxone

- Dispensing brochure must be provided-
<http://www.dhp.virginia.gov/pharmacy/>
- Kits (minus drug) for intranasal administration available through Department of Behavioral Health and Developmental Services -
REVIVE@dbhds.virginia.gov
- Each vial or syringe of naloxone shall be labeled
 - name of person receiving drug does not have to appear on the label



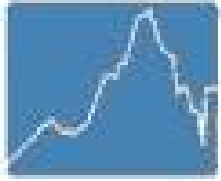
New Increased Access to Naloxone

- Pharmacies may wholesale distribute naloxone via invoice to law enforcement or fire fighters who have completed training program as required by law enforcement agency or fire department



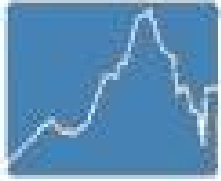
Recently Scheduled Drugs

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



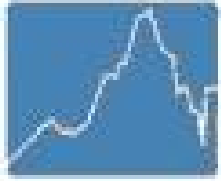
Pharmacist Possession of Epinephrine and Oxygen

- HB 1914; amended § 54.1-3408
- Effective July 1, 2015
- Authorizes pharmacist to possess and administer pursuant to oral, written order, or protocol to treat medical emergencies



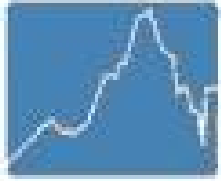
Licensing of Physician Dispensing Location

- HB 2192
- Amended § 54.1-3304.1
- Authorizes Board to license facility from where physicians are dispensing
- Emergency regulations for implementing to be adopted by Board in September



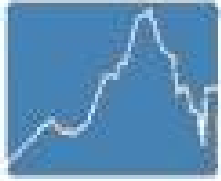
Wholesale Distributor Notification Requirement

- HB 1736
- Amended § § 54.1-3435 and 54.1-3435.01
- Requires wholesale distributors to notify Board when cease distributing Schedule II-V drugs to dispenser based on suspicious activity



Wholesale Distributor Notification Requirement

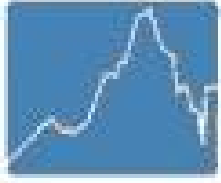
- "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency
- Similar to federal requirement



Department of Health Professions

Licensing of Outsourcing Facilities/Compounding

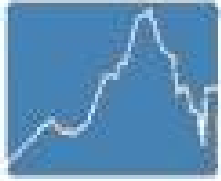
- HB 1737; effective July 1, 2015
- Creates new licensing category
- Compliance with cGMPs and federal law
- Require pharmacy permit also when dispensing patient-specifically
- Emergency regulations to be adopted by board in September



Department of Health Professions

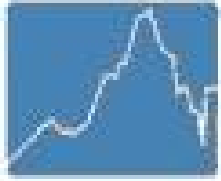
Licensing of Outsourcing Facilities/Compounding

- Also, amended § 54.1-3410.2
- Restricts pharmacy compounding for office use to a reasonable amount if there is a critical need to treat an emergency condition



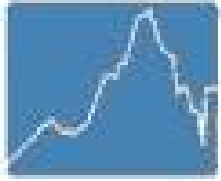
PMP bill – HB 1841

- Until January 1, 2016 – DHP to register prescribers upon initial licensure or renewal
- Effective January 1, 2016 - DHP to automatically register all licensed prescribers and pharmacists
- Need current email addresses!!!
- Effective July 1, 2015 - Requirement for prescribers to query PMP under certain circumstances



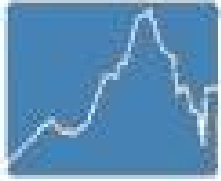
PMP bill – HB 1841

- Prescriber must query PMP when initiating new course of treatment with benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days
- Prescriber with Data 2000 waiver ID for prescribing controlled substances for opioid addiction must query PMP prior to or as part of execution of treatment agreement



PMP bill – HB 1841

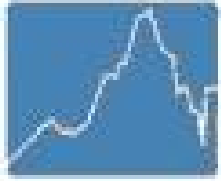
- Exceptions:
 - If benzo or opiate on list published by HHR Secretary with low potential for abuse
 - If course of treatment arises from pain management relating to dialysis or cancer treatments



Department of Health Professions

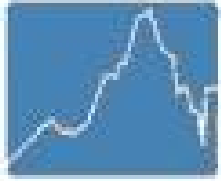
Virginia General Assembly Legislative Information System

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



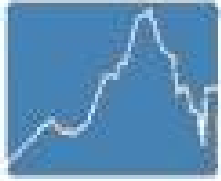
Regulations Effective July 16, 2015

- 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



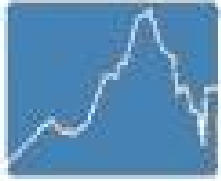
Regulations Effective July 16, 2015

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



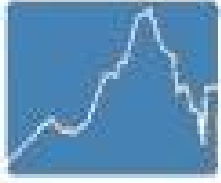
Regulations Effective July 16, 2015

- 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



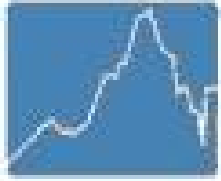
Regulations Effective July 1, 2015

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



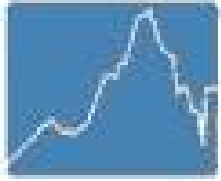
Department of Health Professions

2016 Legislative Proposals



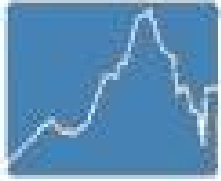
Legislative Proposal Process

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



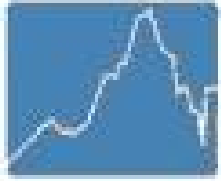
3PL, Track and Trace, etc.

- Would require wholesale distributors to comply with federal track and trace requirements
- Would create new licensing categories for in-state and nonresident third party logistics providers and nonresident manufactures
- Would clarify that manufacturers may distribute drug without an additional license as a wholesale distributor
- Would clarify in §54.1-3410.2 the use of bulk drug substances in compounding



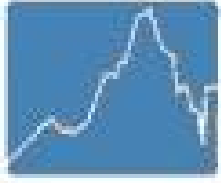
Nonresident Medical Equipment Suppliers

- Would create new licensing category for non-resident medical equipment suppliers
- Would formalize the Board's existing process and hold out-of-state MES facilities to a similar licensure oversight as in-state MES facilities



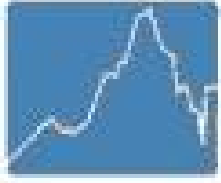
PTCB Certification

- Would require certification from the Pharmacy Technician Certification Board (PTCB) as a prerequisite for initial registration as a pharmacy technician
- Would waive initial application fee for board registration and subsequent renewals fees for a limited-use pharmacy technician registration who works exclusively in a free clinic pharmacy
- Delayed implementation date of July 1, 2017 is proposed.



Department of Health Professions

Miscellaneous Topics and Reminders

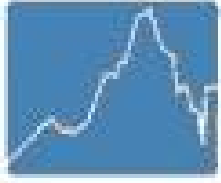


Department of Health Professions

Most Commonly Cited Major Deficiencies

Question:

- What is the most commonly cited deficiency?

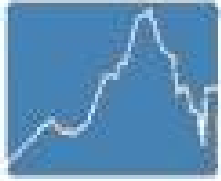


Department of Health Professions

Most Commonly Cited Major Deficiencies

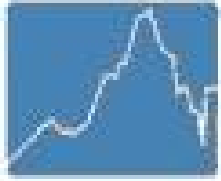
Answer:

- Not performing perpetual inventory of Schedule II drugs.



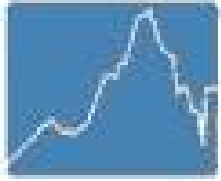
Most Commonly Cited Major Deficiencies

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



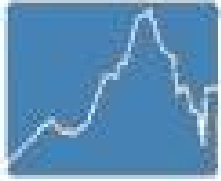
Most Commonly Cited Minor Deficiencies

1. Minor 13: Inventories taken on time but not in compliance
2. Minor 19: Partial filling of prescriptions not properly documented
3. Minor 30: Required compounding/dispensing/distribution records not complete and properly maintained
4. Minor 8: Emergency access alarm code/key not maintained in compliance
5. Minor 24: Labels do not include all required information



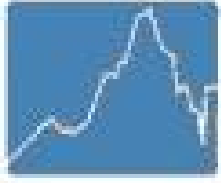
Change of PICs

- PIC must immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC
- New application shall be filed within 14 days of the original date of resignation or termination of the PIC
- Seizure letter will be sent after 14 days



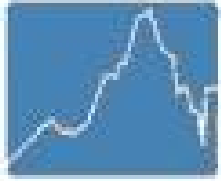
Compounding Pharmacies

- Every PIC or owner (includes nonresident pharmacies) must notify Board of intent to dispense or deliver compounded sterile drug in VA
- Upon renewal, must notify board of intent to continue
- Law requires Board to have ability to produce list of those performing sterile compounding
- Guidance Document 110-36 – FAQs on compliance with USP-NF standards



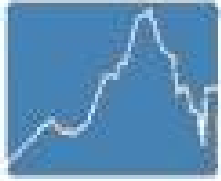
Guidance Document 110-36 - Compounding

- **Question:**
- What is the BUD of a single dose vial (SDV) punctured outside of a ISO Class 5 environment



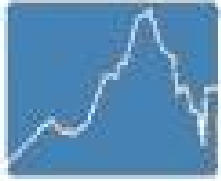
Guidance Document 110-36 - Compounding

- **Answer:**
- BUD cannot exceed 1 hour, unless specified otherwise by manufacturer



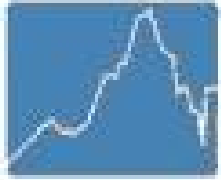
Guidance Document 110-36 - Compounding

- SDV punctured within and stored within ISO 5, BUD not to exceed 6 hours



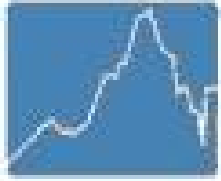
Guidance Document 110-36 - Compounding

- Punctured SDV removed from ISO 5, e.g., for final verification purposes, BUD not exceed 1 hour from being removed from ISO 5 or originally assigned BUD of 6 hours within the ISO Class 5 environment, whichever is shorter
- Board advises not to use a closed system transfer device to extend the BUD of a single dose vial



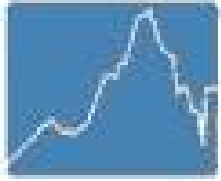
Guidance Document 110-36 - Compounding

- Stability information for multiple drugs may be considered when combining drugs, assuming shortest BUD is used to assign stability to the compound.
- Peer-review or reference source literature shall be consulted and professional judgment of the pharmacist exercised when assigning BUD of compound containing multiple drugs.
- Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.



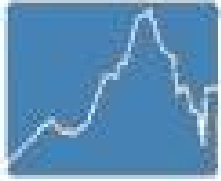
Guidance Document 110-36 - Compounding

- Provides guidance that surface sampling should be performed at least quarterly.
- USP requires air sampling to be performed at least every 6 months.



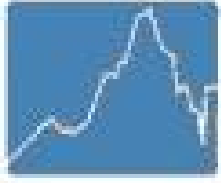
Continuous Quality Improvement Regulations

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



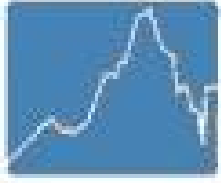
Continuous Quality Improvement Regulations

- Effective July 1, 2015 - Minor Deficiency 42
- Guidance Document 110-9
- 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



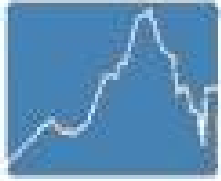
Required CE for 2015

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



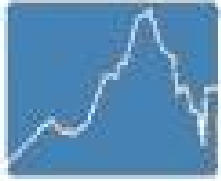
Diversion

- Red Flags video
- PMP
- Perpetual inventory



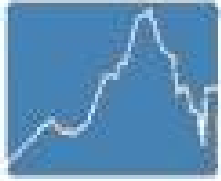
2G to 3G-4G, Security Systems

- 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



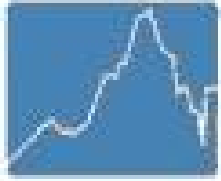
Selling Dextromethorphan to Minors

- 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



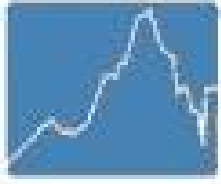
Counterfeit Drugs

- 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)



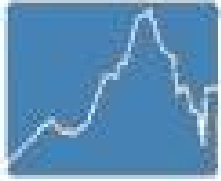
License Verifications

- Check License Lookup when hiring new pharmacists and pharmacy technicians
- Include questions on application regarding felony or misdemeanor convictions, pending charges, board action or pending disciplinary action



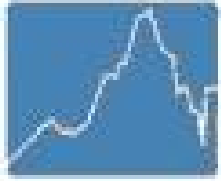
Pharmacy Technician Training

- **Question:**
- How long may a person perform duties restricted to a pharmacy technician when enrolled in a board-approved pharmacy technician training program prior to obtaining registration with the board?



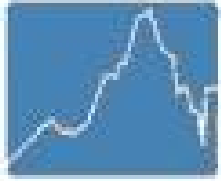
Pharmacy Technician Training

- **Answer:**
- Up to 9 months.



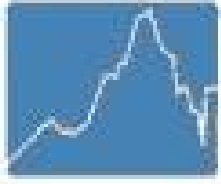
Pharmacy Technician Training

- Ensure training program is board-approved
- <http://www.dhp.virginia.gov/pharmacy/ptprograms.asp>
- Working for up to 9 months while enrolled in pharmacy technician training program only valid prior to initial registration



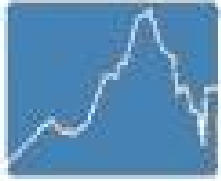
Prescription Validity

- Prescriptions being received in Virginia pharmacies from out of state prescriber and patient resides in a third state
- June 2012 Board e-newsletter article
- Use professional judgment, taking “red flags” into consideration
- Red Flags video at <http://www.dhp.virginia.gov/pharmacy/>



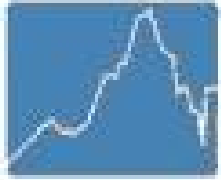
Board E-newsletters

- Recent publication = May 2015
- Available at <http://www.dhp.virginia.gov/pharmacy/newsletters/2015/VA022015.pdf>
- Published 3-4 times annually
- Notification of current publication via email



Electronic Renewal Notification

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



Department of Health Professions

www.dhp.virginia.gov

Tel: (804) 367-4456

pharmbd@dhp.virginia.gov

