



**Department of Health Professions**

---

# **Virginia Board of Pharmacy Update**

VSHP Webinar  
February 18, 2015

Caroline Juran, Executive Director



# Current Board Members

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



## Board Member Expiring Terms

- Empsy Munden's 1<sup>st</sup> term to expire June 30, 2015
- Dinny Li's (citizen) 1<sup>st</sup> term to expire June 30, 2015



**Department of Health Professions**

---

# Pharmacy-related DHP Bills



## Scheduling Bill

- HB 1839; conforms state law with federal regulation
- 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



**Department of Health Professions**

---

## 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
- Propose creation of 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



**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



**Department of Health Professions**

---

# New Regulations



**Department of Health Professions**

---

# Continuous Quality Improvement Regulations

- Replacement regulations effective December 31, 2014
- Inspections – no sanction until July 1, 2015



# Continuous Quality Improvement Regulations

- 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



### EMS Drug Kits

- “method of sealing the kits such that once the seal is broken; it cannot be reasonably resealed without the breach being detected”
  - unique numeric or alphanumeric identifier; record
  - built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy



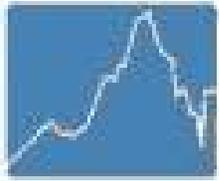
### EMS Drug Kits

- Requires pharmacist, pharmacy technician, or nurse to reconcile C II-V drugs at the time the opened kit is returned
- Record of reconciliation, to include any noted discrepancies, to be maintained by the pharmacy for a period of two years from the time of exchange
- Theft or any other unusual loss to be reported to Board and DEA



### EMS Drug Kits

- Record of filling/verifying kit to include drug contents, initials of pharmacist verifying contents, date, record of identifier if seal used, and assigned expiration date for kit
- record of exchange of kit to include date of exchange, name of EMS agency and EMS provider receiving the kit
- Authorizes exchange of kit in ED by pharmacist, nurse or prescriber



### EMS Drug Kits

- Authorizes 1:1 exchange of CVI drugs or devices
- Controlled Substances Registration issued to EMS agency or multiple agencies within single jurisdiction
- EMS provider may directly obtain CVI drugs and devices from automated drug dispensing device, if authorized by PIC



## Department of Health Professions

---

### EMS Drug Kits

- If CVI obtained via 1:1 exchange from nurse, pharmacist, or prescriber, must record date of exchange, name of licensed person providing drug or device, name of EMS agency and provider receiving the drug or device, and assigned expiration date
- Record maintained by pharmacy for one year from the date of exchange
- If perform 1:1 of CVI drugs or devices, CII-V drugs shall remain in a separate, sealed container



### EMS Drug Kits

- 54.1-3408 amended July 1, 2014 by General Assembly
- Authorizes EMS to administer drug via oral or written order *or standing protocol*
- Record of administration must accompany kit during exchange
- Record is not required to be signed by prescriber if pharmacy has copy of protocol covering administration of the drug
- If drug administered via oral order, then record must be signed



## EMS Drug Kits

- Nothing prohibits pharmacy from obtaining prescriber signature or patient-specific prescription for drugs in CII-V



**Department of Health Professions**

---

# Recently Amended Guidance Document



### Guidance Document 110-36 - Compounding

- Single dose vial (SDV) punctured outside ISO Class 5 environment, BUD not to exceed 1 hour, unless specified otherwise by manufacturer
- SDV punctured within and stored within ISO 5, BUD not to exceed 6 hours
- 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



# 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

- Document provides guidance for under what conditions stability may be estimated.
- Provides guidance that surface sampling should be performed at least quarterly.
- Guidance on air sampling to be reconsidered during March 24<sup>th</sup> full board meeting. USP requires air sampling to be performed at least every 6 months.



**Department of Health Professions**

---

# Reminders



**Department of Health Professions**

---

## Pharmacy Renewals

- Expire April 30<sup>th</sup>
- In-state renewal forms to be mailed early March



## 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



## 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



**Department of Health Professions**

---

# Pharmacy Diversion Awareness Conference

- Hosted by DEA with guest speakers
- May 30<sup>th</sup> and repeated May 31<sup>st</sup>, 8:30am-5pm
- Sheraton Norfolk Waterside Hotel
- No registration fee
- To register: [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov), click on “Meetings & Events” then “Pharmacy Diversion Awareness Conferences” then “Upcoming Conferences”



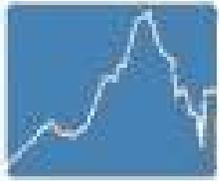
## Required CE for 2015

- 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



## Department of Health Professions

---

### 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)



**Department of Health Professions**

---

# Possible Future Topics



## Possible Future Topics

- Governor's Prescription Drug and Heroin Abuse Task Force
  - Prescription Monitoring Program, storage and disposal, education
- Inspection Process for Physician Selling
- March 24<sup>th</sup> – Full Board Meeting



## Possible Future Topics

- Regulation Committee – May 11<sup>th</sup>, 9AM
  - Requiring PTCB for Pharmacy Technician Registration
  - Compounding – closed system transfer devices to extend BUD of single dose vials
  - 2016 Legislative Proposals
- Drug Supply Chain Security Act – Track and Trace of Drugs; Licensure of 3PLs



## 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
- Use professional judgment, taking “red flags” into consideration
- Red Flags video at <http://www.dhp.virginia.gov/pharmacy/>



## Board E-newsletters

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



## Department of Health Professions

---

[www.dhp.virginia.gov](http://www.dhp.virginia.gov)

Tel: (804) 367-4456

[pharmbd@dhp.virginia.gov](mailto:pharmbd@dhp.virginia.gov)

