



The ABC's of the PA State Board of Pharmacy

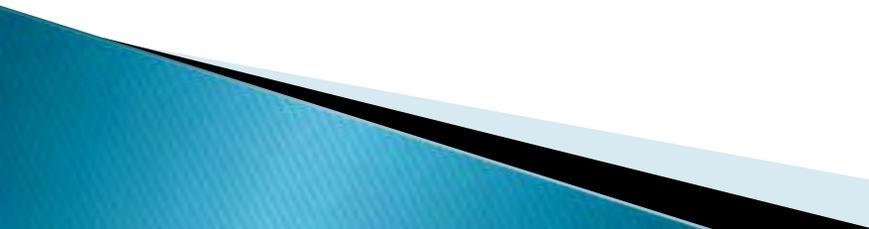
DEA Pharmacy Diversion Awareness Conference
August 27, 2016

Jason McMurry – Pharmacy Board Counsel
Keith Bashore – Pharmacy Board Prosecutor

Presentation Learning Objectives

- } Learn the structure/function of the PA State Board of Pharmacy and its related entities

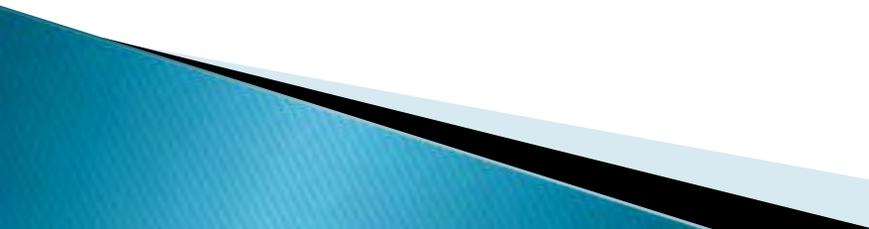
 - } Pennsylvania's Response to the Heroin and Prescription Opioid Crisis – A Pharmacy View
 - ABC-MAP
 - Licensing of Non-Resident Pharmacies
 - Naloxone/Act 139

 - } Review of pending laws and regs
- 



“New laws, rules, regulations...sometimes I don't know what to think of all this paperwork!”

PA State Board Of Pharmacy

- ∅ Is the entity created by and empowered to enforce and execute the Pharmacy Act.
 - ∅ Issues licenses, registrations and certificates to pharmacies/pharmacists who meet the qualifications set forth in the Pharmacy Act.
 - ∅ Promulgates regulations to give further definition and detail to the Pharmacy Act.
 - ∅ Enforces the standards and rules set forth in the Pharmacy Act and regulations.
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Department of State – BPOA

Bureau of Professional and Occupational Affairs provides administrative and legal support to 29 professional and occupational licensing boards and commissions. Professional licensing protects the health, safety and welfare of the public from fraudulent and unethical practitioners. Professions range from Physicians and Cosmetologists to Accountants and Pharmacists.



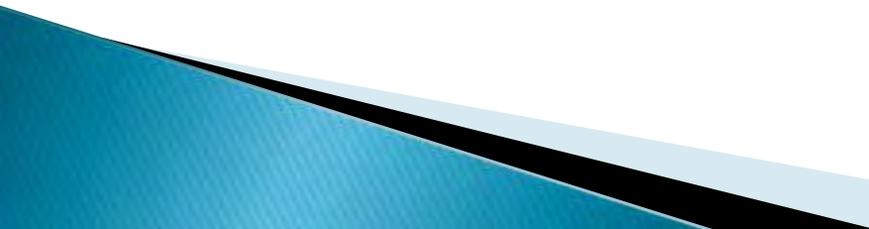
One Penn Center



BPOA “Umbrella” Functions

- } Administrative Licensing Divisions
 - } Professional Compliance Office
 - } Prosecution Division
 - } Board Counsel Division
 - } Office of Hearing Examiners
 - } Bureau of Enforcement and Investigation (BEI)
 - } Professional Health Monitoring Program (PHMP)
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Bureau of Enforcement and Investigation

- } Perform Inspections of licensed facilities, including most pharmacies.
 - } Investigate Complaints filed or generated by the public, other licensed professionals, law enforcement and regulatory agencies, and by the Board of Pharmacy.
 - } Serve and obtain legal and investigative documents.
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PHMP

- } The Professional Health Monitoring Program provides a method by which professionals suffering from a physical or mental disorder, such as a substance use disorder, may be directed to appropriate treatment and receive monitoring to ensure that they can safely practice their licensed profession.
 - } PHMP comprises two programs, the Voluntary Recovery Program (VRP) and the Disciplinary Monitoring Unit (DMU).
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Professional Health Monitoring Programs

} Voluntary Recovery Program

- Requires a Consent Agreement with the Board
- Confidential to all practical extents
- Discipline is deferred

} Disciplinary Monitoring Unit

- Via Consent Agreement or Adjudication
- Public Order of the Board
- Disciplinary in nature

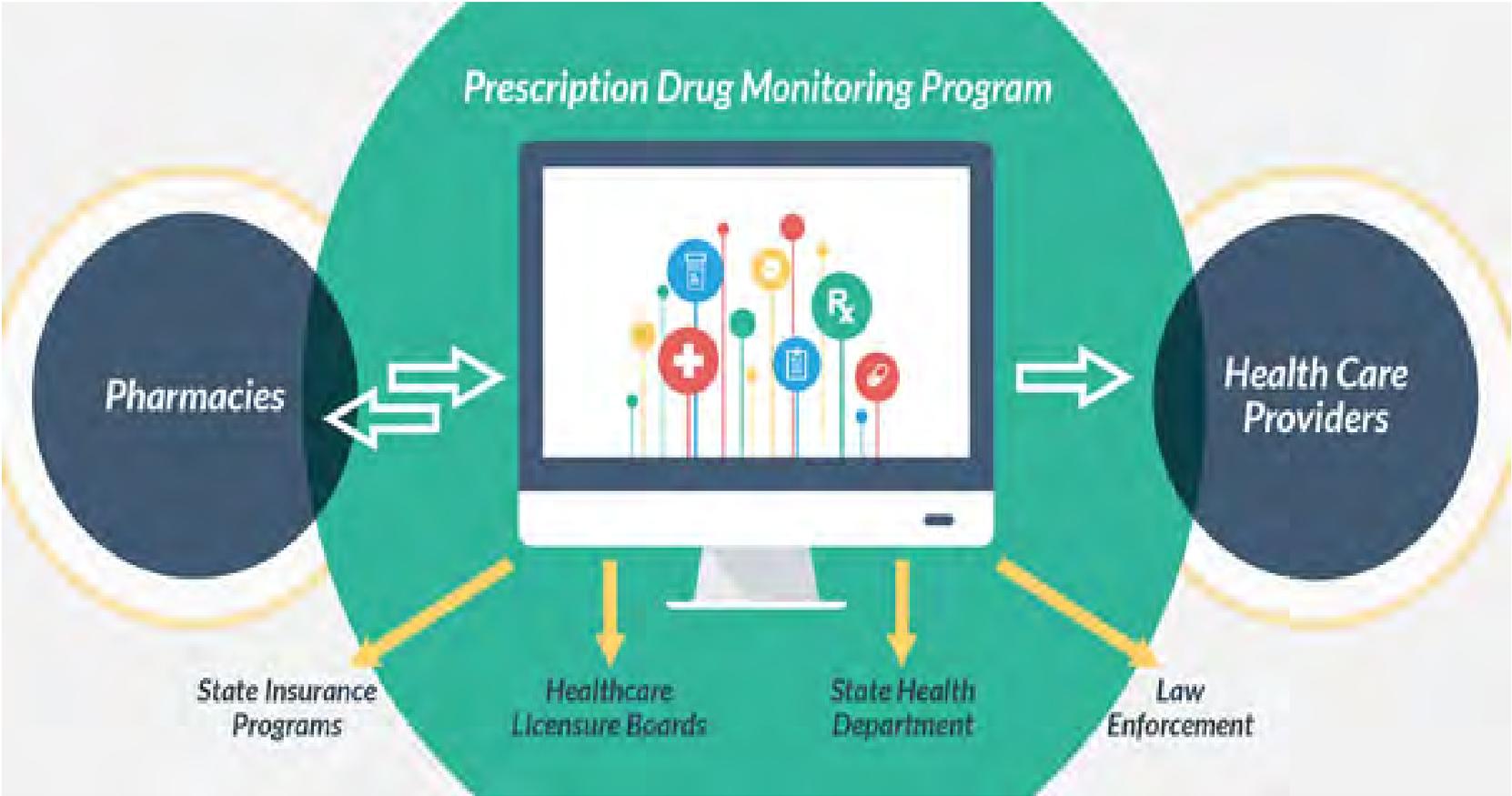


- } <http://sarph.org/>
- } Phone: 800-892-4484
- } FACT: The most frequent cause of pharmacy drug diversion is personal addiction.

S.A.R.P.H.

Secundum Artem Reaching Pharmacists with Help

- } S.A.R.P.H. is the dedicated pharmacy peer assistance program contracted through the Pennsylvania Department of State. Eligibility and monitoring are coordinated between S.A.R.P.H. and the Professional Health Monitoring Program.
- } Enrollment does not require a Board referral!!
- } <http://sarph.org/>
- } Phone: 800-892-4484



ABC-MAP

Achieving Better Care by Monitoring All Prescriptions

- } Act 191 of 2014 – Effective June 30, 2015
 - } PA Department of Health – AWA Rx E system
 - } All dispensers and pharmacies are now required to report to ABC-MAP system within 72 hours of dispensation of controlled substances (Schedule II to V) as of June 24, 2016.
 - } Registration for prescribers and their delegates began on August 8, 2016.
 - } The AWA Rx E system became available to all medical professionals and their delegates on August 25, 2016.
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ABC-MAP Highlights

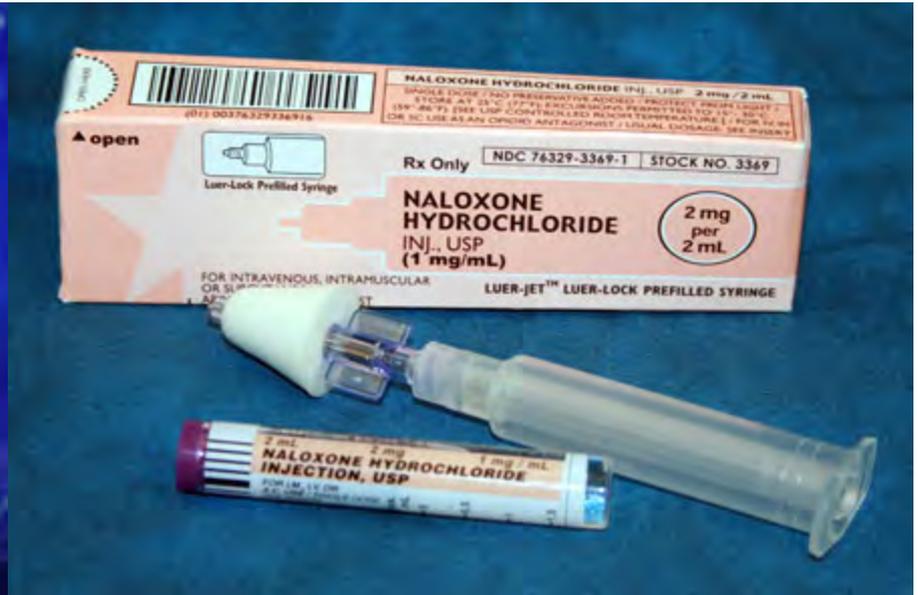
- } Pharmacies may query the system prior to dispensing for a patient
 - } Prescribers may query the system prior to prescribing for a patient
 - } Prescribers may query their number own DEA registration number
 - } ABC-MAP will be part of the PMP Interconnect
 - } The Board of Pharmacy and Law Enforcement can query the system with specific reasons and limitations.
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Non-Resident Pharmacies

- } Act 43 of 2015
- } Effective as of December 6, 2015
- } Requires licensing of all Non-Resident Pharmacies dispensing to patients in PA
- } Licenses are currently being processed
- } Requires inspection by home state or VPP
- } Allows for reciprocal discipline to be imposed against PA licensed pharmacies
- } Non-Resident pharmacies are subject to ABC-MAP reporting standards

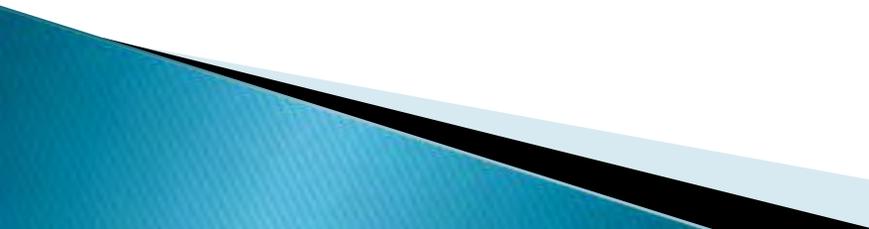
NALOXONE SAVED MY LIFE



Naloxone

- } Act 139 of 2014 (David's Law)
 - } Allows first responders such as law enforcement, fire fighters/EMTs to administer naloxone to individuals experiencing an opioid overdose.
 - } Allows individuals such as friends or family members that may be in a position to assist a person at risk of experiencing an opioid related overdose to obtain a prescription for naloxone.
 - } Provides immunity from prosecution for those responding to and reporting overdoses.
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Naloxone Law Implementation

- } Effective date November 29, 2014
 - } Standing Order For First Responders written by the Physician General on June 10, 2015
 - } Standing Orders written by various physicians for specific pharmacies
 - } Standing Order For all "eligible persons" written by the Physician General on October 28, 2015
 - } You may obtain a copy of either standing order from the PA Dept of Health Website
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Overdose Deaths and Naloxone

- } Documented drug overdose deaths in PA:
 - 2014 – 2,489
 - 2015 – 3,505 (30% increase)
 - 2016 – rate is still increasing!!
 - See <http://www.pacoroners.org/> for the entire 2014 and 2015 reports.

- } As of August 11, 2016, since the enactment of the Naloxone Law there have been 1,291 overdose reversals due to Naloxone administration by law enforcement alone.

The Naloxone Law – Immunity for healthcare professionals

- } Section 13.8(e)(1) A licensed health care professional who, acting in good faith, prescribes or dispenses naloxone shall not be subject to any criminal or civil liability or any professional disciplinary action for:
 - } (i) such prescribing or dispensing; or
 - } (ii) any outcomes resulting from the eventual administration of naloxone.
- } (2) The immunity under paragraph (1) shall not apply to a health professional who acts with intent to harm or with reckless indifference to a substantial risk of harm.

What the Naloxone Law does not do or change

- } It does not provide immunity from or lessen standards for the handling, dispensing, records keeping or storage of Naloxone.

- } It does not abrogate or limit a pharmacist's professional judgment and discretion.
 - A pharmacist may decline to fill or refill a prescription if the pharmacist knows or has reason to know that it is false, fraudulent or unlawful.

 - A pharmacist may decline to fill or refill a prescription if, in the pharmacist's professional judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled.



I like using my hands
to compound. It's fun!

 PHARMACY

Pending Laws and Regs

- } House Bill 854 – Pharmacy Technician Registration
 - } Pharmacy Board regulations on Sterile Compounding
 - } Pharmacy Board regulatory update
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Knowledge Check

- ∅ True or False: The PHMP Voluntary Recovery program is confidential and non-disciplinary?
- ∅ True or False: Naloxone may be dispensed without a physician's order?
- ∅ After a scheduled drug is dispensed a report must be made by the dispenser to the ABC-MAP system:
 - a. In Real Time
 - b. Daily by midnight
 - c. Within 72 Hours



Thank you!!