



The ABC's of the PA State Board of Pharmacy

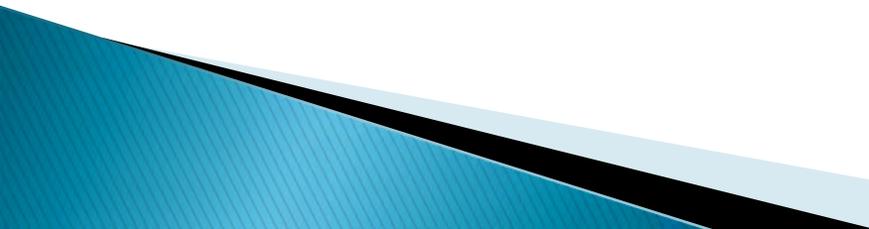
DEA Pharmacy Diversion Awareness Conference
December 10-11, 2015

Ray J. Michalowski – Pharmacy Board Senior Prosecutor

Presentation Learning Objectives

- ▶ Learn the structure/function of the PA State Board of Pharmacy and its related entities
 - Bureau of Professional and Occupational Affairs
 - Bureau of Enforcement and Investigation
 - Professional Health Monitoring Program
- ▶ Review and coming attractions of Pharmacy related legislation and regulation in PA
 - ABC-MAP
 - Licensing of Non-Resident Pharmacies
 - Naloxone
 - Pharmacy Technicians
 - Sterile Compounding Regulations

PA State Board Of Pharmacy

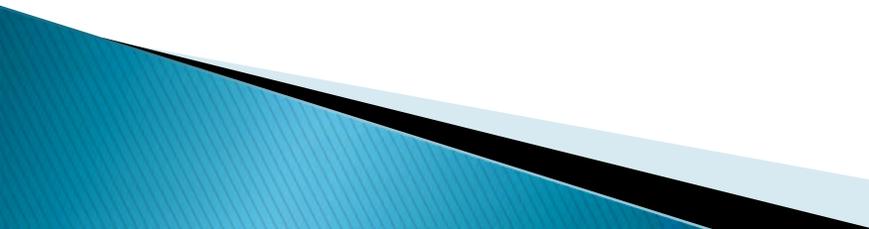
- The State Board of Pharmacy regulates the practice of pharmacy in Pennsylvania.
 - The Board registers pharmacy interns, licenses pharmacists and pharmacies and issues authorizations to administer injectable medications, biologicals and immunizations.
 - The Board is charged with passing upon initial qualifications for licensure and with imposing sanctions against persons and businesses who violate the Pharmacy Act.
- 



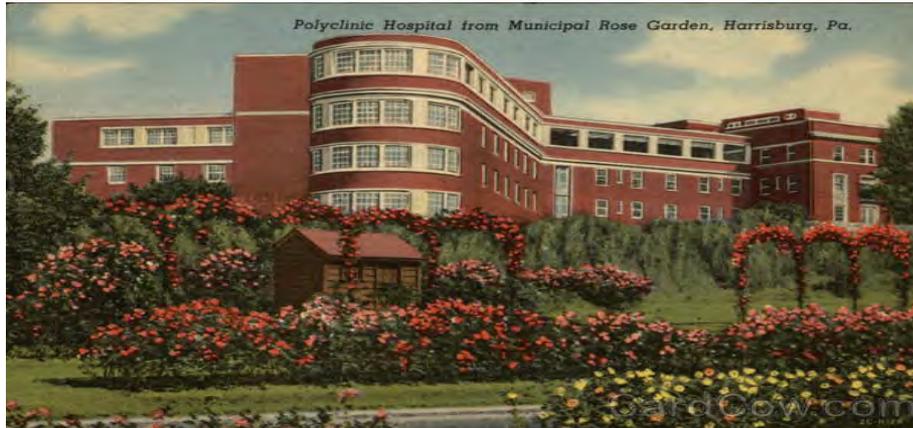
“New laws, rules, regulations...sometimes I don't know what to think of all this paperwork!”

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. Professionals range from Physicians and Cosmetologists to Accountants and Pharmacists.



One Penn Center



BPOA “Umbrella” Functions

- ▶ Administrative and 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)
- 

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 legal and investigative documents.
- 

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

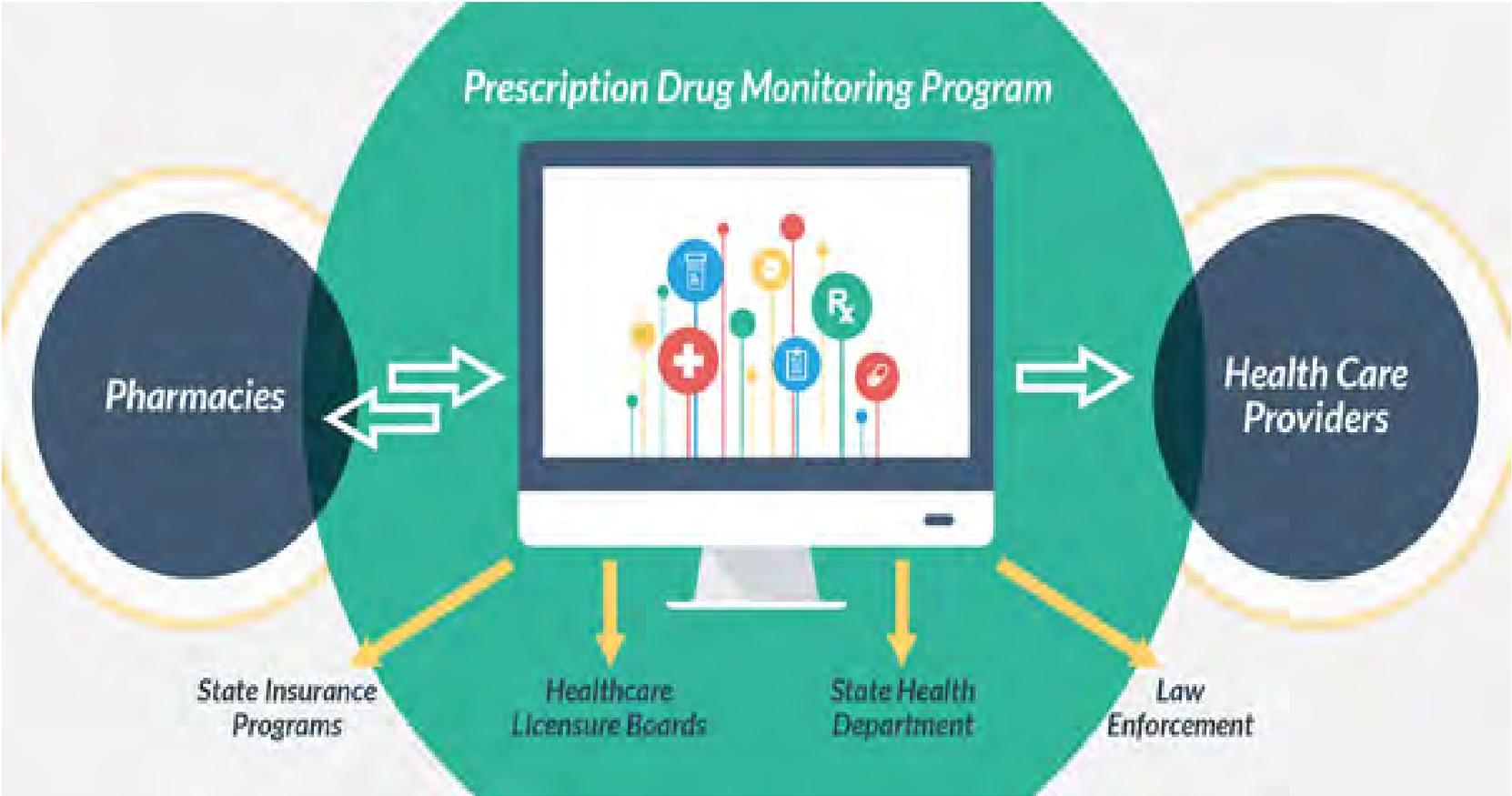


- ▶ <http://sarph.org/>
- ▶ Phone: 800-892-4484
- ▶ The most frequent cause of pharmacy drug diversion is personal addiction.

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

- ▶ Pennsylvania's new Prescription Drug Monitoring Program Legislation
- ▶ Act 191 of 2014 – Effective June 30, 2015
- ▶ Highlights:
 - Will be housed in the Department of Health
 - Data System – Currently in the procurement and development phase
 - When ABC-MAP is implemented the current PDMP system will switch over to ABC-MAP
 - Law enforcement must go through OAG – Court Order
 - Reporting timeframe will be 72 hours or less after dispensing of the medication

ABC-MAP Highlights (Cont.)

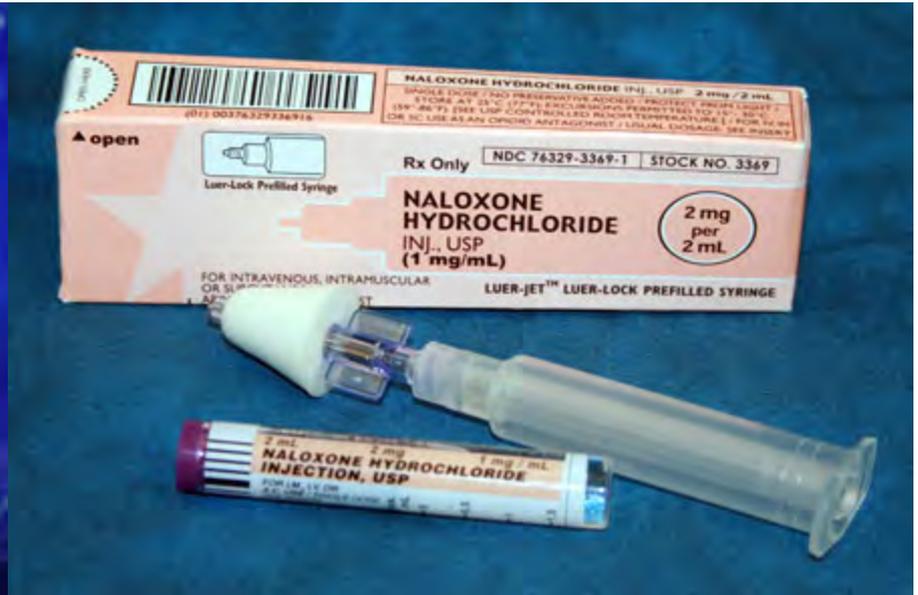
- ▶ All drugs in Schedules II – V are covered
- ▶ Dispenser reporting requirements include all health care practitioners
- ▶ Pharmacies can query the system whenever potentially dispensing for a patient
- ▶ Prescribers can query new or existing patients, but are not mandated to query
- ▶ Prescribers may query on their DEA number
- ▶ Licensing Boards can query for investigations
- ▶ Will be part of the National Interconnect



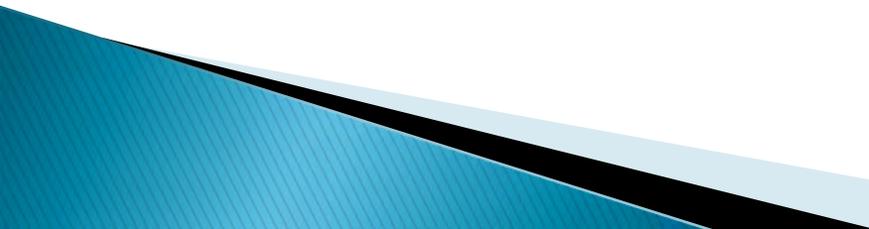
Non-Resident Pharmacies

- ▶ 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 will be subject to ABC-MAP requirements and standards

NALOXONE SAVED MY LIFE



Naloxone

- ▶ Act 139 of 2014 (David's Law)
 - ▶ Allows first responders including law enforcement, fire fighters, EMS or other organizations the ability to administer a medication known as naloxone, a life-saving opioid reversal medication, 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.
- 

Naloxone Law Implementation

- ▶ Effective date November 29, 2014
- ▶ Standing Order For First Responders written by the Physician General on June 10, 2015
- ▶ Authorized explicitly by Act 139
- ▶ Standing Orders written by various physicians for specific pharmacies
- ▶ Standing Order For all “eligible persons” written by the Physician General on October 28, 2015
- ▶ Authorized implicitly by Act 139?

Naloxone Law immunity provisions 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. See 49 Pa. Code § 27.18(c):
 - 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 not knowingly fill or refill a prescription for a controlled substance or nonproprietary drug or device if the pharmacist knows or has reason to know it is for use by a person other than the one for whom the prescription was written, or will be otherwise diverted, abused or misused.
 - 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.

Misc. PA Pharmacy Legislation

- ▶ Act 8 of 2015
 - Lowered the age for pharmacy flu vaccinations
- ▶ Act 147 of 2014
 - Added personal care homes and assisted living facilities to the law allowing pharmacies to repackage and relabel VA medications for veterans
 - 49 Pa. Code §27.102. Return to stock of undelivered medication—statement of policy.
 - An exception to the rule against returning medications to stock, and strictly limited by the guidelines in the statement of policy



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

 PHARMACY

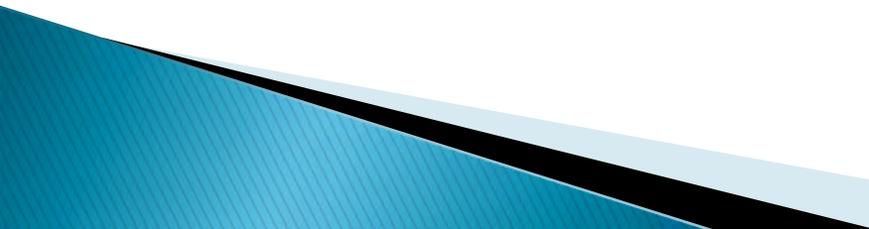
Pending Laws and Regs

- ▶ House Bill 854 – Pharmacy Technician Registration **crosses fingers**
 - Passed handily by the House, currently in the Senate Professional Licensure Committee
- ▶ Pharmacy Board regulations on Sterile Compounding
 - Currently in proposed form and winding their way through the regulatory review process
 - Explicitly adopts USP 797 (and successor) standards for pharmacies performing sterile compounding
 - Is USP 797 the de facto standard of care already?

Other PA Government Agencies with drug/drug treatment oversight

- ▶ Pennsylvania Department of Human Services
 - Office of Mental Health and Substance Abuse Services
 - ▶ Pennsylvania Department of Health
 - Inspects Hospital Pharmacies
 - Registers drug manufacturers and distributors
 - ▶ Pennsylvania Department of Drug and Alcohol Programs
 - Coordinates state-wide drug take back programs
 - Methadone death review panel/licenses methadone clinics
- 

Knowledge Check

- True or False: The PA State Board of Pharmacy regulates pharmacists, pharmacies, drug distributors and manufacturers doing business in Pennsylvania?
 - True or False: Naloxone may be dispensed to eligible persons 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!!
rmichalows@pa.gov