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Prescription Drug Regulation in PA

- Shared administrative oversight by the State Board of Pharmacy (Pharmacies) and the Department of Health (Drug manufacturers, Distributors, Reverse Distributors).

- Criminal enforcement and oversight by the Office of Attorney General and local law enforcement.
Who has access to the data in Pennsylvania’s current Prescription Drug Monitoring Program?

a. Pharmacists  
b. Prescribers  
c. Board of Pharmacy/Department of Health  
d. Attorney General  
e. All of the above
New Laws Affecting PA Pharmacies

- Cancer Drug Repository Program – Enables eligible persons to receive cancer drugs at minimal or no cost. Controlled substances are excluded from the program.

- National Precursor Log Exchange (NPLEEx) – Real time on-line tracking of, and law enforcement access to, purchases of OTC cold and allergy medications used in the manufacture of Methamphetamine. Pennsylvania joined NPLEEx effective April 5, 2004.
What happened with sterile compounding?

- Legislation was introduced in the PA General Assembly to increase regulation and enhance inspections and standards of sterile compounding in PA, but did not become law.

- The State Board of Pharmacy recently approved the first publishable draft of new sterile compounding standards for pharmacies in PA. These regulations will be published for comment shortly, but will only affect pharmacy compounding.
Prescription Drug Monitoring Program in Pennsylvania - Current

- Current PDMP system was one of the earliest in the US
- Data collection and access are limited to the Office of Attorney General
- Data is only collected on Schedule II controlled Substances
- The Criminal History Records Information Act prevents the AG from sharing any PDMP data or access with the Board of Pharmacy or Department of Health
Enhanced PDMP???

- **House Bill 1694**
  - Limits access to PDMP data by law enforcement and regulatory agencies
  - Discusses allowable access to PDMP and mandatory reporting, but does not mandate use

- **Senate Bill 1180**
  - Better access to PDMP data for enforcement/regulatory purposes
  - Requires prescribers to query the database for new patients or when clinically indicated
The Evolution of DDAP

- Formerly the Office, then Bureau of Drug and Alcohol Programs, now a Cabinet level Department
- As of July 2012, the Department of Drug and Alcohol Programs (DDAP), formerly under the Department of Health, has become a department in its own right. This change reflects a strong commitment by the Commonwealth to provide education, intervention and treatment programs to reduce the drug and alcohol abuse and dependency for all Pennsylvanians.
Welcome to the Department of Drug and Alcohol Programs

As of July 2012, the Department of Drug and Alcohol Programs (DDAP), formerly under the Department of Health, has become a department in its own right. This change reflects a strong commitment by the Commonwealth to provide education, intervention and treatment programs to reduce the drug and alcohol abuse and
Other PA Initiatives Addressing Heroin and Opioid Abuse

- Overdose Rapid Response Taskforce
- Naloxone Workgroup/Legislation
- Methadone Death and Incident Review
- Opioid Prescribing Practices and Pain Management Taskforce
- Governor’s Taskforce on Heroin and Other Opioid Abuse
- Joint State Government Taskforce on Opioid Prescription Drug Proliferation and Heroin Use
PA Prescribing Guidelines

- Guidelines on the Use of Opioids to Treat Chronic Noncancer Pain – Issued July 10, 2014
- Still to come:
  - Guidelines for Prescribing Opioids in the Emergency Room
  - Guidelines for Prescribing Opioids for Acute Pain Relief
  - Guidelines for Dental Prescribing of Opioids
  - ????
“Chronic pain is best treated using an interdisciplinary, multi-model approach. The treatment team often includes the patient and his or her family, the primary care provider, a physical therapist, a behavioral health provider and one or more specialists.”

Query: What prominent group of healthcare professionals is conspicuously absent from that quote? 

((Hint – look to your left and right))

The real answer is that you need to stay involved
Drug Diversion by Pharmacists and Other Healthcare Professionals

- The primary cause of drug diversion by healthcare professionals in Pennsylvania is personal substance abuse/impairment.
- Healthcare professionals with substance abuse/impairment issues represent a serious public danger.
- Healthcare professionals who prescribe and/or dispense prescription drugs and suffer from addiction are prone to divert drugs to themselves and others.
Where to get help with substance abuse issues?

The Division of Professional Health Monitoring Programs (PHMP) of the Bureau of Professional & Occupational Affairs (BPOA) provides a method by which professionals suffering from a physical or mental impairment, such as chemical dependency, 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)**.
Voluntary Recovery Program

- The VRP provides a method by which professionals suffering from a physical or mental impairment, such as chemical dependency, can be directed to appropriate treatment and receive monitoring to ensure that they remain capable of practicing safely.

- To be eligible for VRP enrollment, a licensee must agree to enter into a confidential consent agreement with the licensing board for a period of no less than three years. The consent agreement stipulates that disciplinary action will be deferred so long as the licensee adheres to the terms and conditions of the agreement and maintains satisfactory progress in the program.

- When a licensee successfully fulfills the terms of the consent agreement and completes the VRP, no disclosure, publication or public record is made of the participant’s involvement in the VRP or the events precipitating their enrollment.

If you are a licensed health care professional who wishes to be considered for VRP enrollment, or suspect a licensee is impaired, please contact the VRP for further assistance at (800) 554-3428 or (717) 783-4857.
Pharmacist Peer Assistance SARPH

http://www.sarph.org/
SARPH at a glance

- Chemical Dependency; Psychological and/or mental disabilities such as depression and bi-polar disorder
- Since its inception in 1984 through December 2006, over 590 participants have enrolled in the program. Eighty Five % of our participants have satisfactorily completed. 158 participants are currently being monitored, 93% are in full compliance without any contract violations.
Post-Test Questions

- Who has access to the date in Pennsylvania’s current Prescription Drug Monitoring Program?
  a. Pharmacists
  b. Prescribers
  c. Board of Pharmacy/Department of Health
  d. Attorney General
  e. All of the above

- Is Pennsylvania a participating state in the NPLEx?

- What is the primary cause of drug diversion by healthcare professionals in Pennsylvania?