

# BME Role in Response to Opiate Abuse: Developing Solutions

Sindy M. Paul, MD, MPH, FACPM

New Jersey Board of Medical Examiners

June 10, 2016

# Abuse and Misuse of Prescription Drugs: A Major Public Health Issue

- OD has become the #1 cause of injury death in the US (CDC, 2015)
- 2010 US prescription painkillers prescribed to medicate every adult around-the-clock for 1 month
- Transition to heroin (name to generic)
- NJ has a comprehensive approach including regulation, education, disposal opportunities, PMP, Naloxone, new prescription blanks, and treatment expansion

# At Risk Populations

- 2 major at risk populations in the US:
  - Estimated 9 million persons who report long-term medical use of opioids
  - Approximately 5 million persons who report nonmedical use in the past month
- Nonmedical use is defined as opioid analgesic use without a prescription or a medical need to take an opioid

# Role of Prescribing

- Prescribing practices related to prescription drug abuse and play an important role in opioid analgesic abuse
- 80% of patients receive low dose (<100 mg morphine equivalent dose/day) prescriptions from a single provider
  - Account for 20% of the overdoses

# Role of Prescribing - Continued

- 10% of patients who get prescriptions for high doses ( $\geq 100$  mg morphine equivalent dose/day) from single prescriber
  - 40% of the opioid overdoses
- 10% get high daily dose prescriptions from multiple providers
  - 40% of the opioid overdoses and likely diverting to people who use them without a prescription

# Non-Medical Users

- Among nonmedical users
  - 76% take medication prescribed for someone else
  - only 20% indicate they received the medication through a prescription from their physician

# What is the Board's Responsibility?

- 1894 Medical Practice Act: BME authorized to regulate the practice of medicine
- Protection of the public health and welfare
- Public assurance that licensees are:
  - qualified
  - Competent
  - Honest
- Regulations, including CDS prescribing

# The CDS Prescribing Regulation

- **13:35-7.6 LIMITATIONS ON PRESCRIBING, ADMINISTERING OR DISPENSING OF CONTROLLED SUBSTANCES; SPECIAL EXCEPTIONS FOR MANAGEMENT OF PAIN**
- **Available on-line at the BME website**  
<http://www.njconsumeraffairs.gov/regulations/Chapter-35-Board-of-Medical-Examiners.pdf>

# What to Ensure When Prescribing, Dispensing or Administering CDS

- Patient's medical history has been taken
- PE is conducted
- Assess physical & psychological function,
- Assess underlying or coexisting diseases or conditions, any history of substance abuse
- Nature, frequency and severity of any pain

# The Medical Record Shall reflect

- 1) A recognized medical indication for the use of the controlled substance;
- 2) The complete name of the controlled substance;
- 3) The dosage, strength and quantity of the controlled substance; and
- 4) The instructions as to frequency of use.

# Schedule II Authorization Limitation

- With respect to Schedule II controlled substances, unless the requirements below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less.
- Changes to Schedule II

# Exception: Schedule II

## Limitation 120 Dosage Units

- For the 120 dosage unit limitation, the practitioner follows a treatment plan
  - Designed to achieve effective pain management, which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness
  - The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall
  - Indicate if any further diagnostic evaluations or other treatments are planned
  - The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative;

# 30 Day Supply Limitation: Implantable Infusion Pump

- With regards to the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump which is utilized to achieve pain management for patients suffering from cancer, intractable pain or terminal illness.
- A prescription for such an implantable infusion pump may provide up to a 90-day supply, as long as the physician evaluates and documents the patient's continued need at least every 30 days; and

# 30 Day Supply Limitation: Multiple Prescriptions

- A practitioner may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II CDS provided that:
  - i) Each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice;
  - ii) The practitioner provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;
  - iii) The practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and
  - iv) The practitioner complies with all other applicable State and Federal laws and regulations.

# Continuous Prescription 3 Months or More for Pain Management

- The practitioner:
  - 1) Shall review, at a minimum of every 3 months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;
  - 2) Shall remain alert to problems associated with physical and psychological dependence; and
  - 3) Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the CDS, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

# If the Treatment Objectives are not Being Met

- The practitioner:

- 1) Shall assess the appropriateness of continued CDS treatment or undertake a trial of other drugs or treatment modalities; and

- 2) Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives

# Be Aware of the Potential for Misuse or Diversion of CDS

- A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse

# The Medical Record

- The practitioner shall keep accurate and complete records including that information required by (a) above as well as:
  - 1) The patient's medical history and PE
  - 2) Other evaluations and consultations;
  - 3) Treatment plan objectives;
  - 4) Evidence of informed consent;
  - 5) Treatments and drugs prescribed or provided, as described in an earlier slide;
  - 6) Any agreements with the patient; and
  - 7) Periodic reviews conducted

# Overdose Prevention Act (Good Samaritan Law)

- NJ = 12<sup>th</sup> state with Good Samaritan Law
- P.L.2013, c.46, N.J.S.A. 24:6J-1 et seq.
- Purpose: encourage OD witnesses & victims to seek medical assistance without fear of criminal or civil liability
- Recognizes increased access to Naloxone (Narcan) would reduce OD deaths in the best interest of public
- Distribution to family members or peers
- Requires change on BME prescribing regulations

# Naloxone Waiver: BME Guidance to Allow Access for Administration

- 13:35-7.1A Examination prior to prescribing is waived or dispensing Naloxone
- 13:35-7.2 Name and address of person to whom the prescription is issued rather than the name and address of the patient shall be included on each prescription
- 13:35-7.2 Follow-up not required for prescription issued to person not at OD risk, but who in physicians' judgment may be able to assist someone else during an OD and has received patient OD information on the indications for Naloxone administration as an opioid antidote



# NJ Prescription Monitoring Program (NJPMP)

New Jersey Division of Consumer Affairs



[DCA HOME](#) [NJMP INFO](#) [PRESCRIBERS / PHARMACISTS](#) [ENFORCEMENT](#) [TREATMENT](#) [MEDIA](#) [BE AWARE](#) [PROJECT MEDICINE DROP](#)



[www.NJConsumerAffairs.gov/pmp](http://www.NJConsumerAffairs.gov/pmp)

# Prescription Monitoring Program

- Unless an exemption applies, prescribers (or their delegates) will be required to review prescription monitoring information when they prescribe a Schedule II medication to a new or current patient for acute or chronic pain the first time they prescribe and quarterly thereafter. Additional details will be made available as the Division of Consumer Affairs proceeds with the process of creating regulations in support of the new statute.

# Prescription Monitoring Program

- Physician mandatory unless exemption
- Pharmacist required daily
- CDS & HGH
- Linking with other states
- Confidential data, HIPAA compliant
  - \$10,000 civil penalty/offense + Possible BME action
- [NJConsumerAffairs.gov/pmp](http://NJConsumerAffairs.gov/pmp)

# PMP Use

- Patient Look Up (>100,000/month)
- Self Look Up
- Mercer County Physician PMP Self Check
  - **Identity had been stolen**
  - **Criminals obtained prescription pad**
  - **Forged prescriptions for Oxycodone**
  - **1 month, 12 fraudulent patient names had been used to obtain over 1,300 pills**

# The Star-Ledger

PAGE 15 | TUESDAY, MAY 20, 2014 | NJ.COM

## Doctors can help fight drug abuse with Rx checks

By Steve C. Lee

**L**ast year, a Mercer County physician logged onto the New Jersey Prescription Monitoring Program database to search prescriptions written in his name. The results shocked him. The doctor discovered his identity had been stolen in a massive prescription fraud scheme.

One or more criminals had illegally obtained his prescription pad and were using it to forge prescriptions for oxycodone, a widely abused narcotic painkiller. Within a month, 12 fraudulent patient names had been used to obtain 1,300 pills, sellable on the streets for \$25,000. If this physician hadn't searched NJPMP records, this illegal opiate distribution scheme might never have been detected.

This week, during National Prevention Week, acting Attorney General John J. Hoffman and I call upon New Jersey's health care community to make regular use of the NJPMP, as an everyday part of their practice. Prescribers who do so play a tremendous role in New Jersey's fight against the nationwide opiate abuse epidemic. As has been well-documented, abuse of prescription painkillers like oxycodone leads to addiction and death, and has become a gateway drug for heroin.

Maintained by the state Division of Consumer Affairs, the NJPMP collects detailed information on every prescription filled in New Jersey for controlled drugs or human growth hormone — more than 32 million prescriptions to date. Each record includes names of the patient, doctor and pharmacy; purchase date; type, dosage, and amount of medication; and the method of payment.

The NJPMP is available to all licensed health care practitioners authorized to prescribe or dispense medications. Physicians can search individual patients' prescribing patterns and learn, for example, whether a patient has engaged in "doctor shopping" — deceptively visiting multiple

physicians, to obtain more narcotics than any one doctor would prescribe — or other patterns consistent with addiction or abuse.

Today, slightly more than 20 percent of New Jersey's eligible prescribers and pharmacists have registered to use the NJPMP. Given that the program is relatively new, that's an impressive adoption rate. It puts New Jersey on par with other states that make prescription-monitoring programs available to doctors for optional use.

But with the urgency of our drug-abuse crisis, New Jersey's health care community can and must do better. The NJPMP will not fulfill its potential to fight drug diversion until a significant majority of doctors register and consult it regularly when prescribing oxycodone and other controlled medications.

The Division of Consumer Affairs is doing everything it can to increase the rate at which prescribers and pharmacists bring the NJPMP into their daily practice. We are working to make it easier to enroll by permitting state-licensed practitioners to automatically register every year when they renew their authority to prescribe or dispense controlled drugs.

An upcoming step will be to expand the data available to doctors. Prescribers who use the NJPMP today can only find prescriptions filled in New Jersey; they will not learn whether a patient engaged suspicious prescription-based activity across state lines. Through future partnerships with neighboring states, we'll soon be able to obtain data on prescriptions filled outside New Jersey.

The search of a patient's prescription-drug history takes less than a minute, even on a laptop during a patient visit. But none of our efforts will have a substantial impact until the health care community fully commits to the program.

As the Mercer County example shows, this database can help doctors protect the integrity of their medical licenses. More importantly, it is a powerful, lifesaving tool in the fight against prescription drug abuse.

*Steve C. Lee is acting director of the New Jersey Division of Consumer Affairs. Join the conversation at [nj.com/opinion](http://nj.com/opinion).*

**None of our efforts will have a substantial impact until the health care community fully commits to the program.**





# Proper Disposal: Project Medicine Drop



- 126 law enforcement locations, soon to add more
- > than 53,900 pounds (nearly 27 tons) collected since 11/11
- Safe, secure disposal of unused household medications



# Drug Take Back Program

## Notification: Effective 1/1/16

- P.L. 2015, c.66 Effective 1/1/16
- N.J.S.A. 45:9-22.11
  - Requires prescribers & pharmacies to provide a notice about drug take back programs upon dispensing to each patient a controlled dangerous substance (CDS) prescription medication.
  - Requires prescribers to furnish to each patient, with any CDS prescription drug or medicine dispensed for that patient as permitted pursuant to N.J.S.A. 45:9-22.11, a notice prepared by the Division of Consumer Affairs.

# Prescriber & Pharmacy Compliance

## P.L.2015, c.66: 1 of the Following

- Download the Division notice from the Division's website and provide a hardcopy to the patient;
- Download the Division notice from the Division's website and email an electronic copy to the patient; or
- Post a copy of the Division notice in a conspicuous location and insert the following text in another document (*for example, the prescription drug monograph*) that is provided to the patient:

# Text to be Inserted

- ***SAFE and SECURE MEDICINE DISPOSAL***

*Unused medications that remain in your medicine cabinet are susceptible to theft and misuse. To prevent medications from getting into the wrong hands, New Jersey's Office of the Attorney General and Division of Consumer Affairs urge you to properly dispose of your expired and unwanted prescription medicine at a nearby Project Medicine Drop location. **DROP OFF IS SIMPLE, ANONYMOUS AND AVAILABLE 24 HOURS A DAY – 365 DAYS A YEAR, NO QUESTIONS ASKED.** Simply bring in your prescription and over-the-counter medications and discard them in an environmentally safe manner. Always scratch out the identifying information on any medicine container you are discarding. For a list of Project Medicine Drop locations, please visit <http://www.njconsumeraffairs.gov/meddrop>.*

# Be Aware of the Potential for Misuse or Diversion of CDS

- A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse

# What Does the BME Look at During a CDS Prescribing Investigation

Among Other Things:

- The Medical Record and Related Documents
- Complete History and PE
- PMP Use
- Pain Management Contract
- Consideration/referral for other modalities ie PT, pain management specialist
- Ongoing evaluation, UDS
- Potential Diversion and Misuse
- Proper Termination Letter

# BME Investigation: It Starts with a Complaint

- BME website icon

<http://www.state.nj.us/lps/ca/bme/index.html>

- Email
- Phone
- Letter

# What is the Process for Handling Complaints?

- Screening Committee
- Investigation
- Priority Review Committee
- Preliminary Evaluation Committee
- Full Board Hearing
- Appeal process

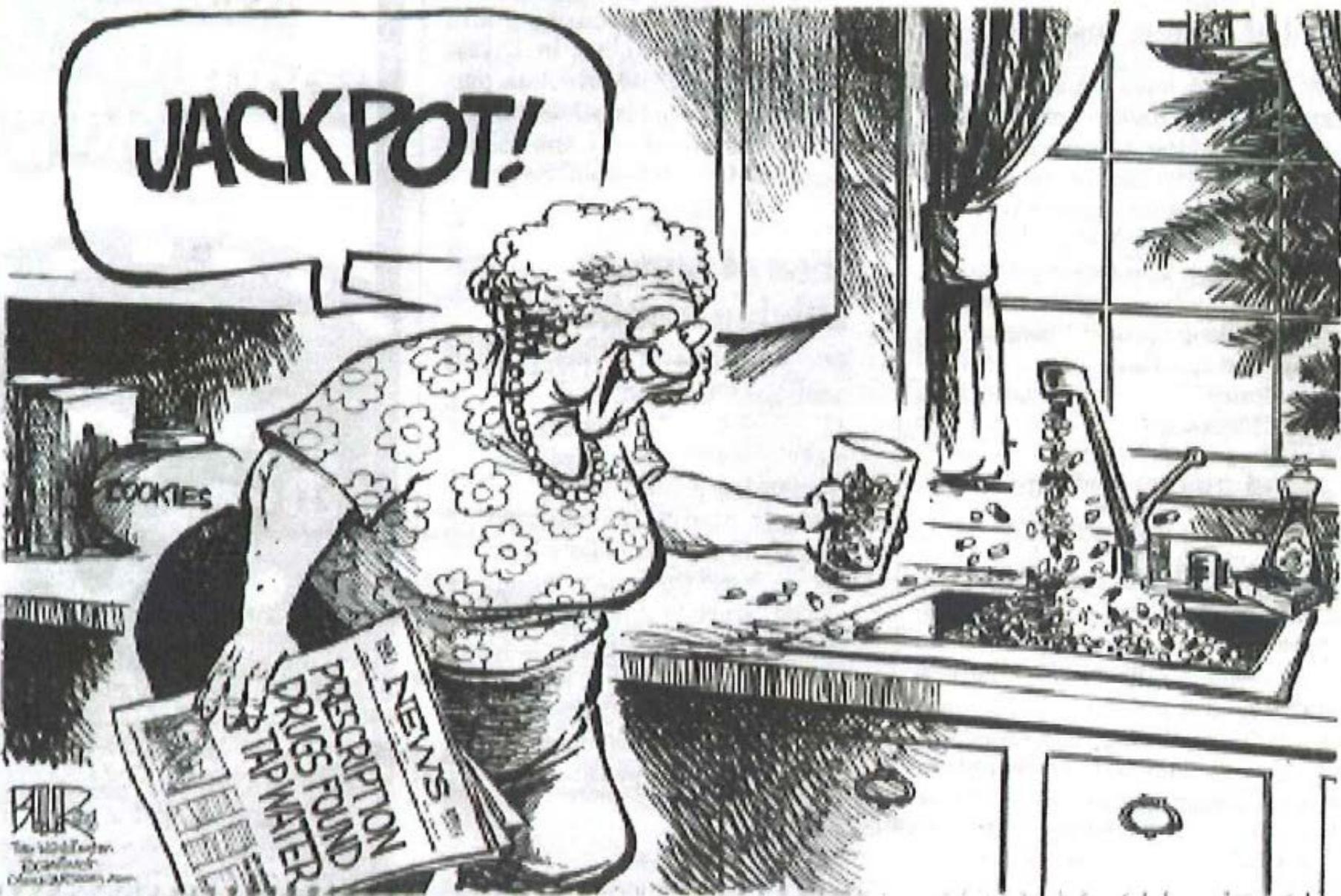
# New Jersey Man conspired with doctor to sell Oxycodone pills

- David Roth pleaded guilty to 2nd degree distribution of narcotics for selling oxycodone pills he got using false prescriptions written by Dr. Eugene Evans Jr.
- 1/12-3/14 Evans gave Roth Rxs for about 20,000 high dose 30mg tablets oxycodone in names of > 12 people he never examined, treated or even met in exchange for money
- Roth sold the pills for about \$20 or \$30 each
- Evans pleaded guilty to 2nd degree drug distribution, surrendered his medical license, authorities have recommended five year prison
- Roth received a 7 year prison sentence

# Community HIV Outbreak Linked to Oxymorphone IDU, Indiana 2015

- Historically < 5 HIV cases/yr diagnosed in county
- 135 diagnosed cases/4,200 people in community
- IDU multi-generational
- Daily # injections range 4-15, 1-6 partners/injection event
- 40mg extended-release tabs oxymorphone not designed to resist crushing or dissolving, dissolved in non-sterile water & IDU insulin syringe
- Other risk: IDU meth, heroin, & 10 female sex workers
- HIV patients 18-57 yo (mean 35, median 32)
- 114 (84%) co-infected with HCV

**JACKPOT!**



# Summary

- Role of the BME is to protect the public
- CDS regulations: part of a comprehensive prevention approach
- NJ addressing misuse and abuse of prescription medications through medical regulation, PMP, education, expanded access to care, safe disposal, and Good Samaritan protection
- Reduce the risk of premature death due to accidental drug overdose = # 1 cause of accidental death in NJ
- Reducing the risk of IDU is primary prevention for the syndemics of HIV, hepatitis, STI, and violence