

# CDS Prescribing for Acute and Chronic Pain

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# Conflict of Interests

*I have no relevant  
financial relationships to  
disclose.*

# Controlling the Opioid Epidemic: A *Three-pronged Approach Using Medical Regulation*

- **Prevent** new cases of opioid addiction.
- **Reduce supply** from pill mills and the black-market.
- **Treat** people who are already addicted.

# Role of Prescribing: CDC Data

- Prescribing practices related to prescription drug abuse and play an important role in opioid analgesic abuse
- Deaths involving prescription opioids in US increased from > 22,000 in 2015 = about 62 deaths per day in 2015 to the most recent estimate of 144 deaths/day
- Taking opioids for longer periods of time or in higher doses increases the risk of addiction, overdose, and death
- Amount opioids prescribed/person 3x higher in 2015 than 1999

# Prescribing Problems and Solutions

- **Problem:** High prescribing
  - **Solution:** Safer prescribing practices
- **Problem:** Too Many Prescriptions
  - In 2015, the amount of opioids prescribed was enough for every American to be medicated **around the clock for 3 weeks**
  - **Solution:** Fewer prescriptions - Use opioids **only** when benefits are likely to outweigh risks

# Prescribing for Too Many Days

- **Problem: Too many days**
  - Even at low doses, taking an opioid for > than 3 months increases the risk of addiction by **15x**
  - Avg day supply/prescription increased from 13.3 in 2006 to 17.7 in 2015
- **Solution: Fewer days** - For acute pain, prescriptions should only be for the expected duration of pain severe enough to need opioids
- Acute pain  $\leq 3$  days usually enough; > 7 days rarely needed

# Prescribing Problems and Solutions: Too High a Dose

- **Problem: Too high a dose**

- A dose of 50 morphine milligram equivalents (MME) or more per day **doubles** the risk of opioid OD death, compared to 20 MME or less per day
- At  $\geq 90$  MME, the risk increases **10 times**.
- Avg daily MME/prescription decreased from 59.7 in 2006 to 48.1 in 2015

- **Solution: Lower doses**

- Use the lowest effective dose of immediate-release opioids when starting, and reassess benefits and risks when considering dose increases
- Avoid a daily dose of  $\geq 90$  MME
- If already taking high doses, offer the opportunity to gradually taper to safer doses

# Morphine Milligram Equivalents

- CDC Guidelines define (MME)/day as the amount of morphine an opioid dose is equal to when prescribed
- Often used as a gauge of the abuse & overdose potential of the amount of opioid that is being given at a particular time
- Although neither the rule nor the statute reference MME, practitioners may find it helpful in assessing the dosages given, particularly when the patient may be taking more than one opioid
- CDC website includes information to assist in calculating Morphine Milligram Equivalents

# Prescribing, Overdoses and Deaths in New Jersey

- CDC in 2014 62 prescriptions/100 residents = 5.4 million prescriptions for pain killers in NJ
  - 1<sup>st</sup> half 2016 total ODs up 41% over 2015, heroin up 43%, oxycodone were up 46%, and fentanyl (not including fentanyl analogs) up 120%
  - NJ OD deaths 2015
    - 1,587 people including
    - 918 involving heroin
    - 417 involving fentanyl
    - 302 involving oxycodone
- | 1 <sup>st</sup> half 2016 |
|---------------------------|
| 1,022 people including    |
| 594 involving heroin      |
| 394 involving fentanyl    |
| 177 involving oxycodone   |

# Transition Pills to Heroin: Brand to Generic

- Medicine cabinet dry
- Price: Cheap \$5-8
- Purity: 40%-76%
- Direct Importation
- Availability
- Inhaling to IDU

• DEA/Domestic Monitoring Program



# 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

# Opioid Prescribing Law

- On February 15, 2017, P.L. 2017, c. 28, was signed into law, imposing certain restrictions on how opioids and other Schedule II CDS may be prescribed.
- In response to the new law, the Attorney General and New Jersey's prescribing boards adopted new emergency rules that went into effect on 3/1/17.
- On 5/1/17 the emergency rules were readopted.
- These rules concern limitations on prescribing, administering or dispensing of CDS, with specific limitations for opioid drugs, and establish special requirements for the management of acute and chronic pain.

# The CDS Prescribing Regulation

- 13:35-7.6 LIMITATIONS ON PRESCRIBING, ADMINISTERING OR DISPENSING OF CONTROLLED DANGEROUS SUBSTANCES; SPECIAL EXCEPTIONS FOR MANAGEMENT OF ACUTE AND CHRONIC PAIN
- Available on-line at the BME website  
<http://www.njconsumeraffairs.gov/prescribing-for-pain/Documents/BME-Rule-Language.pdf>

# Definitions: Acute and Chronic Pain

- “Acute pain” means the pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time.
- “Acute pain” does not include chronic pain, pain being treated as part of cancer care, hospice or other end of life care, or pain being treated as part of palliative care.
- “Chronic pain” means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause, it continues, either continuously or episodically.

# Definitions: Initial Prescription

- A prescription issued to a patient who:
- (1) has never previously been issued a prescription for the drug or its pharmaceutical equivalent; or
- (2) was previously issued a prescription for the drug or its pharmaceutical equivalent, and the date on which the current prescription is being issued is more than one year after the date the patient last used or was administered the drug or its equivalent
- To determine if a patient was previously issued a prescription for a drug or its pharmaceutical equivalent, the practitioner shall consult with the patient, review prescription monitoring information, and, to the extent it is available to the practitioner, review the patient's medical record

# Exceptions to the Prescribing Requirements for CDS

- The requirements for prescribing controlled dangerous substances set forth below shall not apply to a prescription for a patient who is
  - currently in active treatment for cancer,
  - or receiving hospice care from a licensed hospice,
  - or receiving palliative care,
  - or is a resident of a long term care facility,
  - or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

# When Prescribing, Dispensing or Administering CDS a Practitioner Shall

- Thorough medical history which reflects the
  - nature, frequency, and severity of any pain,
  - the patient's history of substance use or abuse, and
  - The patient's experience with non-opioid medication and non-pharmacological pain management approaches;
- PE is appropriate to the practitioner's specialty, including
  - an assessment of physical and psychological function, and
  - an evaluation of underlying or coexisting diseases or conditions

# When Prescribing, Dispensing or Administering CDS a Practitioner Shall

- Access relevant PMP
- Develop a treatment plan
  - Identifies the objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and
  - Any further diagnostic evaluations or other treatments planned, with particular attention focused on determining the cause of the patient's pain;
- Prepare a medical record

# The Medical Record Shall reflect

- Medical history, findings on PE, relevant PMP Data and Treatment Plan
- A recognized medical indication for the use of the controlled substance;
- The complete name of the controlled substance;
- The dosage, strength and quantity of the controlled substance; and
- 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.
- Shall be at the lowest effective dose as determined by the directed dosage and frequency of dosing

# Multiple Prescriptions Schedule II CDS

- Notwithstanding the 30-day supply limitation, a practitioner may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90 -day supply 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.

# Signs of Potential Patient Drug Diversion

- Doctor shopping (use the PMP!)
- Using multiple pharmacies
- Lost or stolen prescriptions
- Lost or stolen medication
- Early renewals

# Prior to Issuing Initial Prescription Schedule II or any Opioid for Pain

- Discuss with patient or parent or guardian if < 18 yo & not emancipated minor (< 18 also for each subsequent opioid prescription for adults reiterate prior to issuing 3<sup>rd</sup> schedule II prescription)
- Note in chart discussion took place
  - Reason medication being prescribed
  - Possible alternative treatments
  - Risks associated with medication
  - Opioids include but not limit to risks of addiction, physical or psychological dependence, & OD associated with opioids and danger of taking opioids with alcohol, benzodiazepines and other CNS depressants and requirements for proper storage and disposal

# Initial Opioid Drug Prescription for Treatment of Acute Pain

- A practitioner shall not issue an initial prescription in a quantity exceeding a 5 day supply as determined by the directed dosage and frequency of dosage
- The initial prescription shall be for the lowest effective dose of an immediate-release opioid drug
- A practitioner shall not issue an initial prescription for an opioid drug that is for an extended-release or long-acting opioid
- When a practitioner issues an initial prescription for an opioid drug for the treatment of acute pain, the practitioner shall so indicate it on the prescription

# What is meant by the lowest effective dose?

- According to the 3/16 *CDC Guidelines*, practitioners should:
  - (1) use caution when prescribing opioids at any dosage;
  - (2) carefully reassess evidence of individual benefits and risks when considering increasing dosage to  $\geq 50$  MME/day; and
  - (3) avoid increasing dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/day.

# Subsequent Prescription for Acute Pain

- No less than 4 days after issuing the initial prescription, upon request of the patient, a practitioner may issue a subsequent prescription for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription provided the following conditions are met:
  - The practitioner consults (in person, via telephone, or other means of direct communication) with the patient;
  - After the consultation with the patient, the practitioner, in the exercise of his or her professional judgment, determines that an additional days' supply of the prescribed opioid drug is necessary and appropriate to the patient's treatment needs and does not present an undue risk of abuse, addiction, or diversion;

# Subsequent Prescription - Continued

- The practitioner documents the rational for the authorization in the patient record
- The subsequent prescription for an additional days' supply of the prescribed opioid drug is tailored to the patient's expected need at the stage of recovery, as determined on the previous slide, and
- Any subsequent prescription for an additional days' supply shall not exceed a 30-day supply as a result, the maximum allowable "days' supply" for the first two prescriptions would be a 35-day supply
- Prescribers should make every effort to limit the 2nd prescription to the patient's actual needs and avoid providing more than is reasonably expected to be needed at that stage of recovery

## What if I expect to be unavailable on the day the patients supply expires because I will not be on call?

- You can authorize the 2nd prescription on the 4th day, just as you would on the 5<sup>th</sup> day - you consult with the patient, in your professional judgment determine that an additional “days’ supply” is needed and there is no undue risk of abuse, addiction or diversion
- There may be some circumstances, for example, after major surgery or major traumatic injuries, including long bone fractures and severe burns, where the practitioner should plan ahead and make arrangements to consult with the patient on the 4th or 5th day following the initial prescription to assure that the patient has a sufficient supply of medication to meet his or her specific needs
- The prescriber issuing the initial prescription may deem it appropriate to alert a covering prescriber that the patient may need an additional limited supply that will provide pain relief until the original prescriber is available

# How can I get the 2<sup>nd</sup> prescription to the patient so he/she can fill it?

- If you & the pharmacy can engage in e-prescribing, the patient won't need to physically obtain the prescription from you
- The patient or someone authorized by the patient will need to pick up the medication
- If you or the pharmacy can't engage in e-prescribing, & after the requisite consultation, you conclude that the patient's needs can be met by a medication that is classified as a Schedule III controlled substance, you can call in that prescription
- If you conclude that the patient has an emergency need for a Schedule II controlled substance, you can call in a *72-hour emergency supply*, for which the pharmacist will generate a prescription with all the pertinent information, except your signature & you will need to follow-up with a written prescription within 7 days

# Pain Management Agreement: At Time of 3<sup>rd</sup> Schedule II Prescription

- Written contract or agreement between prescriber & patient, signed and dated as a means to:
  - Prevent possible development of physical or psychological dependence
  - Document understanding of practitioner & patient regarding the pain management plan;
  - Identify the specific medications & other modes of treatment including PT or exercise, relaxation, or psychological counseling as part of the treatment plan

# Pain Management Contract

## Continued

- Establish the patient's rights in assoc. with treatment, and the patient's obligations in relation to the responsible use, discontinuation of use, and storage of Schedule II CDS, including any restrictions on the refill of prescriptions or the acceptance of Schedule II prescriptions from practitioners;
- Specify the measures to monitor compliance including but not limited to random specimen screens and pill counts; &
- Delineate the process for terminating the agreement including the consequences if the practitioner has reason to believe that the patient is not complying with the agreement

# How should opioids be stored?

- If children at home – from a toddler to a teenager – consider a lockbox for medications
- Even one accidental dose of an opioid pain medicine meant for an adult can cause a fatal overdose in a child
- Teenagers and others in the home or who are visiting may seek out opioid pain medicines for non-medical use e.g. look in bathroom medicine cabinets for a chance to steal these medicines
- If you are selling your home or having work done in your home, make sure your medications are secure.

# When CDS are Continuously Prescribed for Management of Chronic Pain

- Review, at least every 3 months, the course of treatment, any new information about the etiology of the pain & the patient's progress toward treatment objectives, & document the results of that review;
- Assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, & document results of that assessment;
- Access relevant PMP information

# When CDS are Continuously Prescribed for Management of Chronic Pain- Continued

- Make periodic reasonable efforts, unless clinically contraindicated, to either stop using CDS, taper the dosage, try other drugs, such as NSAIDS, or utilize alternative treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence, and document, with specificity, the efforts undertaken
- Conduct random UDS at least every 12 months
- Monitor pain management agreement compliance & recommendations that the patient seek a referral, and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by other practitioners or prescribers, and document within the patient record the plan after that discussion

# When CDS are Continuously Prescribed for Management of Chronic Pain- Continued

- Advise the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, of the availability of an opioid antidote; and
- Refer the patient to a pain management or addiction specialist for independent evaluation or treatment in order to achieve treatment objectives, if those objectives are not being met

# Naloxone Waiver: BME Guidance to Allow Access for Administration

- 13:35-7.1A Examination prior to prescribing is waived or dispensing Naloxone (Narcan)
- 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



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



# Role of the Prescription Monitoring Program (NJPMP)

- Part of a comprehensive statewide approach to help reduce the risk of patient opioid misuse, abuse, addiction and diversion
- Quality of care/proper prescribing – patient look up
- Prevent doctor shopping and diversion
- Detection of medical identity theft with stolen, altered, or fraudulent prescriptions – self look up

# NJPDMMP Overview

- NJPMP went live in September 2011
- Database contains over 67.85 million prescriptions
- Averaged 247,000 searches by practitioners per month in 1<sup>st</sup> half 2017
- Linking with 14 other states: PA, NY, CT, DE, RI, VA, SC, MA, NH, ME, WV, OH, VT and MN
- Confidential data, HIPAA compliant
  - Possible \$10,000 civil penalty/offense, criminal conviction and/or Licensing Board disciplinary action

# Medications in New Jersey PMP

- CDS (Controlled and Dangerous Substances)  
Scheduled II -V
- HGH (Human Growth Hormone)
- Any other drug as determined by DCA Director

# NJPMP Approved Users

- “Practitioner” = an individual currently licensed, registered, or otherwise authorized by NJ or another state to prescribe drugs in the course of professional practice
- Has a current CDS registration and is authorized to prescribe, dispense, or administer CDS or HGH
- A pharmacist who is employed by a current pharmacy permit holder and is authorized to dispense CDS or HGH
- Users certify that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient

# NJPMP Approved Users: Delegates

- A practitioner may designate as a delegate a licensed health care professional (RN, LPN or dental hygienist) or a certified medical assistant who is employed at the practice setting at which the practitioner practices
- A delegate may be an authorized delegate for > 1 practitioner
- A NJ authorized delegate may not be able to access another state's PMP data
- A delegate no longer employed at the practice setting at which the practitioner practices is no longer authorized to be a delegate or to access the PMP on behalf of that practitioner

# Supervising Practitioner Responsibilities for Delegation

- Prior to delegate designation confirm education, training & license or certification requirement of each delegate
- Ensure delegate understands limitations on disclosure of PMP information and Federal and State laws, rules and regulations concerning patient information confidentiality including HIPAA
- At least every 6 months monitor delegate PMP use for potential misuse
- Report unauthorized access within 5 business days of discovery to DCA through PMP
- Terminate the delegate's access to the PMP when a delegate, for any reason, is no longer authorized to be a delegate

# Delegate Responsibilities

- Share PMP information with only his/her supervising practitioner
- As with all persons granted PMP access delegates shall not share PMP login ID & password with any other person or entity
- All delegates shall identify the practitioner on whose behalf they are accessing the PMP information
- Follow the documentation procedures established by his or her supervising physician e.g. a summary notation of the information reviewed by the physician or the printed PMP report in the patient record

# When to Use the 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 (every 3 months) thereafter.

# Mandatory Look Up Exemptions that May Affect Practitioners

- Administering a CDS directly to a patient
- Prescribing a CDS to be dispensed by an institutional pharmacy
- Prescribing a CDS in the ED of a general hospital, provided that the quantity prescribed does not exceed a five-day supply
- Prescribing a CDS to a patient under the care of a licensed hospice

# Mandatory Look Up Exemptions that May Affect Practitioners

- A practitioner or the practitioner's agent administering methadone as interim treatment for a patient on a waiting list for admission to an authorized substance abuse treatment program
- A situation in which it is not reasonably possible for the prescriber to access the PMP in a timely manner, no other individual authorized to access the PMP is reasonably available, and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance

# Mandatory Look Up Exemptions that May Affect Practitioners

- A situation under which consultation of the PMP would result in a patient's inability to obtain a prescription in a timely manner, thereby, in the clinical judgment of the practitioner, adversely impacting the medical condition of the patient, and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance
- A situation in which the PMP is not operational as determined by the DCA or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance

# PMP Use: 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

# Proper Disposal of Medication for Unused Medication

- Project Medicine Drop Box 215 locations for safe secure disposal of household medications, over 157,000 pounds collected

<http://www.njconsumeraffairs.gov/meddrop>



- Take-back Program
- Drug disposal pouch

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

Among Other Things:

- The Medical Record and Related Documents
- Complete History, PE, imaging studies, lab tests, diagnosis
- 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

# Doctors Charged by the Attorney General's Prescription Fraud Investigation Strike Team

- Dr. Byung Kang – indicted 3/17 in a joint DEA investigation, charged with illegally distributing oxycodone and Xanax, allegedly **prescribed oxycodone to a patient he knew was abusing the drug, patient fatal OD** on pills he prescribed. Charged with 1st-degree strict liability for drug-induced death.
- Dr. James Ludden – charged 3/8/17 with illegally prescribing narcotics, including opiates, to a # of people **without legitimate medical purpose**

# Doctors Charged by the Attorney General's Prescription Fraud Investigation Strike Team

- Dr. Thomas Duffield –indicted 10/16 on charges he illegally wrote oxycodone prescriptions that he **exchanged for gift cards, often with people who were not his patients**. Twice he allegedly exchanged gift cards for prescriptions with an undercover police officer in Trenton.
- Dr. George Beecher –indicted in 12/15 for allegedly **conspiring with a drug dealer to operate a ring that distributed oxycodone pills with a street value of over \$1 million**. He is charged with first-degree strict liability for a drug-induced death in the death of a ring member's son.

# 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 Rx's 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**
- Mr. Roth sold the pills for about \$20 or \$30 each
- Dr. Evans pleaded guilty to 2nd degree drug distribution, surrendered medical license, sentenced to 5 years in prison
- Mr. Roth received a 7 year prison sentence

# Operation Oxy Highway: Dr. Craig Gialanella July 2017

- Investigation began 12/16 after Atlantic County pharmacist reported residents were using Dr. Gialanella, a GP whose office is > 100 miles away, to obtain large quantities of opiates
- **Between 1/14 & 5/17 Dr. Gialanella issued prescriptions for > 350,000 oxycodone 30 milligram tablets**
- Prescriptions included those for the alleged leaders and members of a 16 person drug ring
- If all pills were sold on the street for \$20 each, they would command more than \$7 million

# 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
- 40mg extended-release tabs oxymorphone not designed to resist crushing or dissolving, dissolved in non-sterile water & IDU insulin syringe
- HIV patients 18-57 yo (mean 35, median 32)
- 114 (84%) co-infected with HCV

EDITORIAL CARTOON By Nate Beeler/Examiner



# 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