Safe and Sound Prescribing During the Opioid Epidemic: Update on Legal and Regulatory Issues

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CENTER FOR EVIDENCE-BASED PRACTICES

A partnership between the Mandel School of Applied Social Sciences & Department of Psychiatry at the School of Medicine

www.centerforebpbp.case.edu
Our Mission

The Center for Evidence-Based Practices at Case Western Reserve University is a technical-assistance organization that promotes knowledge development and the implementation of evidence-based practices (EBPs) for the treatment and recovery of people diagnosed with mental illness or co-occurring mental illness and substance use disorders.

Our technical-assistance services include the following:
- Service-systems consultation
- Program consultation
- Clinical consultation
- Training and education
- Program evaluation (fidelity & outcomes)
- Professional peer-networks
- Research
Service innovations for people with mental illness, substance use disorders

- **SAMI**
  - Substance Abuse & Mental Illness
  - Strategies for co-occurring disorders
- **IDDT**
  - Integrated Dual Disorder Treatment
  - The evidence-based practice
- **DDCAT**
  - Dual Diagnosis Capability in Addiction Treatment
  - An organizational assessment & planning tool
- **DDCMHT**
  - Dual Diagnosis Capability in Mental-Health Treatment
  - An organizational assessment & planning tool
- **ACT**
  - Assertive Community Treatment
  - The evidence-based practice
- **SE/IPS**
  - Supported Employment/Individual Placement & Support
  - The evidence-based practice
- **IPBH**
  - Integrated Primary & Behavioral Healthcare
- **TRAC**
  - Tobacco: Recovery Across the Continuum
  - A stage-based motivational model

**Case Western Reserve University**

www.centerforebp.case.edu
Learning Objective 1

- Review the key legal and regulatory issues related to the opioid epidemic, especially as related to safe prescribing of opioid medications
  - HB 93, including enhancements to OARRS
  - Emergency and Acute Care Facility Opioid and Other Controlled Substances Prescribing Guidelines (ED Guidelines)
  - Ohio’s Opioid Prescribing Guidelines (80 MED Guidelines)
  - Laws related to Project DAWN (HB 170 and HB 363)
  - opioidprescribing.ohio.gov
Learning Objective 2

- List important educational resources related to the opioid epidemic which are available to particular audiences, including patients, families, clinicians, and administrators
  - SAMHSA Opioid Overdose Toolkit
  - FDA How to Dispose of Unused Medications
  - VA Guidelines: Taking Opioids Responsibly
  - https://pharmacy.osu.edu/outreach/generation-rx-initiative
  - Dontgetmestartedohio.org
  - www.starttalking.ohio.gov
Gov. Kasich signs into law House Bill 93 (the "pill mill bill") surrounded by members of SOLACE, a support group for those who have lost loved ones due to prescription drug abuse. (May 20, 2011)
HB 93: “The Pill Mill Bill”

- Became law on May 20, 2011
- Wide-ranging law including multiple areas:
  - Pain management clinics must be licensed by Pharmacy Board
  - In-office physician dispensing limits
  - Medicaid and Bureau of Worker’s Comp Lock-in Programs
  - Enhancements to OARRS
  - Drug Take-Back Programs
  - Patient safety and education fund
Licensure of Pain Management Clinics

- Primary component of practice is treating pain or chronic pain and >50% of patients are prescribed controlled substances, tramadol, carisoprodol, or other drugs specified by the Medical Board.

- Requires criminal records check:
  - any person with ownership of the facility [w/ results directly to the Pharmacy Board]
  - all employees of the facility
  - Cannot have been convicted of, or pleaded guilty to, any felony in Ohio, another state, or the United States
In-Office Dispensing Limits

- Limits on the amount of controlled substances that may be personally furnished by prescribers
  - "personally furnish" → term used to describe the action of a prescriber who provides a whole or partial supply of drugs to a patient for the patient's personal use.
- **Monthly**: no more than an a total of 2,500 dosage units of all controlled substances combined
- **72-hour period**: no more than the amount of controlled substances necessary for the patient's use in a 72-hour period
Medicaid and Worker’s Comp Lock-In

- Recipients abusing the Medicaid program
  - Utilize Medicaid services at a frequency or amount that is not medically necessary, as determined by utilization guidelines
  - May be locked into a primary care physician, pharmacy, and hospital/emergency room Medicaid agency for a specific period of time
  - Limits the recipient’s ability to obtain drugs
- May also identify providers who may be engaging in unsound medical practices
- “Safety net approach” which varies from state to state
Enhancements to OARRS

- Medical Board rule 4731-11-11: accessing OARRS prior to prescribing or personally furnishing a controlled substance or tramadol to a patient
  - (1) If a patient is exhibiting signs of drug abuse or diversion
    - See next 2 slides for MUST-check vs. MAY-check situations
  - (2) When you have a reason to believe the treatment of a patient with controlled substances or tramadol will continue for twelve weeks or more
  - (3) At least once a year thereafter for patients receiving treatment with controlled substances or tramadol for twelve weeks or more
MUST check an OARRS Report:

- Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen
- Forging or altering a prescription
- Stealing or borrowing reported drugs
- Having been arrested, convicted or received diversion, or intervention in lieu of conviction for a drug related offense while under the physician’s care
- Increasing the dosage of reported drugs in amounts that exceed prescribed amount
- Selling prescription drugs
- Receiving reported drugs from multiple prescribers, without clinical basis
- Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient’s use of illegal or reported drugs
MAY check an OARRS Report:

- A known history of chemical abuse or dependency
- Appearing impaired or overly sedated during an office visit or exam
- Requesting reported drugs by specific name, street name, color, or identifying marks
- A history of illegal drug use
- Frequently requesting early refills of reported drugs
- Frequently losing prescriptions for reported drugs
- Recurring emergency department visits to obtain reported drugs
- Sharing reported drugs with another person
ED Guidelines
Why Focus on EDs?

- Emergency rooms are a major source of the nation’s opiate prescriptions, accounting for 39% of all opioids prescribed, administered or continued in the U.S.
- Of 374,891 ED visits in the U.S. during 1993-2005, 42% were related to pain and almost one-third (29%) of patients received an opioid
- Overall number of opioid prescriptions written increased 14%
  - 1993: 23% of patients in pain got an opioid prescription
  - 2005: 37% of patients in pain got an opioid prescription
  - Source: *JAMA, Trends in Opioid Prescribing by Race/Ethnicity for Patients Seeking Care in US EDs, 2008*
Why Focus on EDs?

- From 2001-2010, the percentage of overall ED visits where an opioid analgesic was prescribed increased from 20.8% to 31%.
- Prescription rates of Dilaudid increased dramatically, up 668.2%.
- Percentage of visits for painful conditions only increased by 4%, from 47.1% in 2001 to 51.1% in 2010.
- Opioid prescribing up across all age groups and all payers.
- Largest proportional increase in opioid prescriptions in Midwestern states.
- Greatest relative increases in use of hydromorphone (known as Dilaudid) and morphine; Hydromorphone and oxycodone had the greatest relative increases from 2005-2010.

### Summary of Ohio ED Guidelines when managing chronic pain

- Look for emergency or urgent conditions
- No pain pills if you already have a prescriber
  - May contact primary MD to confirm information
  - Only enough until you can see primary MD
- Valid photo ID or take your picture before getting prescription
- May ask for a urine sample
- Check OARRS
- No shots or IVs,
- No refills on lost/stolen Rx, no replacement of MAT meds
- No long-acting pain meds
- Care plans for frequent utilizers of EDs
- Referral for treatment information
80 MED Guidelines

CDC Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic January 13, 2012 / 61(01);10-13
### CDC: Percentage of U.S. patients and prescription drug overdoses, by risk group

- **Among patients who are prescribed opioids,**
  - 80% are prescribed low doses (<100 mg morphine equivalent dose [MED] daily) by a single practitioner, and account for 20% of all prescription drug overdoses
  - 10% of patients are prescribed high doses (≥100 mg MED) of opioids by single prescribers and account for 40% of prescription opioid overdoses
  - 10% of patients seek care from multiple doctors, are prescribed high daily doses, and account for another 40% of opioid overdoses
2008: 14,800 prescription painkiller deaths

For every 1 death there are...

- 10 treatment admissions for abuse
- 32 emergency dept visits for misuse or abuse
- 130 people who abuse or are dependent
- 825 nonmedical users

http://www.cdc.gov/homeandrecreationalsafety/rxbrief/
Odds of an Overdose and the MED

- Research shows that patients who receive higher doses of prescribed pain medications are at increased risk for overdose and need close supervision and periodic reevaluation.
- Prescribed pain medication doses can be calculated as a Morphine Equivalent Daily Dose (MED), and the odds of an overdose at 50 – 99 MED are three times higher than at a dose under 50 MED.
The 80 MED “trigger point”: Press Pause

- Recommend that 80 milligrams MED for more than three months for patients with chronic, non-terminal pain should trigger the prescriber to reevaluate the effectiveness and safety of the patient’s pain management plan.
- The guidelines are intended to supplement, and not replace, the prescriber’s clinical judgment.
- 80 MED “trigger point” also provides an opportunity to further assess addiction risk or mental health concerns.
80 MED Guideline Recommendations

- Reestablish informed consent
- Review the patient’s functional status and documentation, including the 4A’s of chronic pain treatment
- Review the patient’s progress toward treatment objectives
- Utilize OARRS as an additional check on patient compliance
- Consider a treatment agreement
- Reconsider having the patient evaluated by one or more specialists
MED Calculator

- [https://www.ohiopmp.gov/portal/MED_Calculator.aspx](https://www.ohiopmp.gov/portal/MED_Calculator.aspx)

- Can calculate the MED automatically for several different opioid medications

- OARRS reports now include an “Active Cumulative Morphine Equivalent” in the top right-hand corner
Morphine Equivalent Table Used in OARRS

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*US Department of Health and Human Services, Center for Disease Control*
# Ohio Automated Rx Reporting System

**Patient Rx History Report**

Date: 9/9/2013 1:41:12 PM

**Patient: BETTY TESTPATIENT**

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1289 BETTY TESTPATIENT, DOB 01/01/1970; 234 WEST ST, WESTERVILLE, OH 43081  
5142 BETTY TESTPATIENT, DOB 01/01/1970; 123 BROADWAY, COLUMBUS, OH 43215 |

**Active Cumulative Morphine Equivalent**

**59.6**

**See explanation provided at the end of the report**

**Prescriptions**

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**Disclaimer:** The State of Ohio does not warrant the above information to be accurate or complete. The Report reflects the search criteria entered by the requestor, the data entered by the dispensing pharmacy, and the frequency at which the data is reported. For more information about any prescription, please contact the dispensing pharmacy or the prescriber.
HB 170: Before and After

- Only advanced paramedics and people addicted to prescription opioid drugs or heroin could access and carry naloxone
- Friends and family members of addicts now have access to naloxone
- All first responders, including police officers, firefighters and basic paramedics, can carry naloxone
- Persons who are now permitted to prescribe, provide, or administer naloxone, if acting in good faith and with reasonable care, are granted immunity from drug offenses, criminal prosecution, civil liability, or professional disciplinary action
Pending Legislation: HB 363

- The Good Samaritan Law
- HB 363 provides immunity from criminal liability for those who seek help for either themselves or others when involved in a drug-related medical emergency
- This immunity extends only to minor drug possession offenses, where evidence against a person is obtained as a result of that person seeking medical assistance
Ohio Legislation related to Opioids

- Since July of 2013:
  - 3 bills enacted into law
  - 15 bills in the House are pending (including HB 363)
  - 4 bills in the Senate are pending

- See handout for details

- Source:
Educational Resources
SAMHSA Opioid Overdose Toolkit

How to Dispose of Unused Medicines

Is your medicine cabinet filled with expired drugs or medications you no longer use? How should you dispose of them?

Medicines can be thrown in the household trash, but consumers should consult poison centers before disposing of drugs, according to the Food and Drug Administration (FDA). A few drugs should be flushed down the toilet and registered members of community-based "take-back" programs offer another safe disposal alternative.

Guidelines for Drug Disposal:
FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs issued by ONDCP in February 2007. The federal guidelines are summarized here:

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
- If no instructions are given, throw the drugs in the household trash, but:
  - Take them out of original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets and unrecognizable to people who may intentionally go through your trash.
  - Put them in a sealable bag, carry out, or other container to prevent the medication from leaking or breaking out of a garbage bag.

Take drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds...
VA Guidelines (May 2013)
https://pharmacy.osu.edu/outreach/generation-rx-initiative

Since 2007
Generation Rx Initiative: 6 Toolkits
Generation Rx: Other Programming

- The InterACT Theatre Project for Social Change partnered with Generation Rx to create an interactive drama.
- In 2011, Generation Rx partnered with the Cardinal Health Foundation and APhA-ASP to spread the program nationally.
- Generation Rx has partnered with Ohio State’s First Year Experience (FYE) program to educate incoming students.
- Generation Rx University Conference was launched in 2012 to enhance collegiate prescription drug abuse prevention and student recovery.
- Ohio State faculty, BSPS students, and PharmD students have presented prescription drug abuse prevention workshops to the Ohio Teen Institute Summer Conferences at Kenyon College since 2010.
- The Generation Rx Labs in Life exhibit was established at the Columbus Center of Science and Industry (COSI) in 2012.
DGMS: History and Vision

- **HISTORY:** The Ohio Association of County Behavioral Health Authorities (OACBHA), in conjunction with the Ohio Department of Mental Health and Addiction Services developed the statewide prescription drug abuse prevention campaign “Don't Get Me Started” (DGMS)

- **VISION:** Don’t Get Me Started (DGMS) works to bring awareness and understanding of prescription drug misuse and abuse in Ohio by fostering collaborative community outreach initiatives and engagement strategies that promote academic and personal excellence
5th Annual Conference: SAVE THE DATE

Ohio's 2014 Opiate Conference

June 30 - July 1

Don't Get Me Started

Hyatt Regency
Columbus, Ohio

Learn more at www.oacbha.org
Start Talking!

Parents, mentors and peers can make a difference just by talking to young people about drug abuse. The Start Talking! initiative provides tools for parents, guardians, educators and community leaders to start the conversation with Ohio’s youth about the importance of living healthy, drug-free lives.

Children of parents who talk to their teens about drugs are less likely to use.

50%

Ohio drug overdose deaths increased between 1999 and 2011, with prescription drugs driving that rise.

440%

1 in 10 high school students recently reported they had first tried marijuana before age 13.

For more information, visit starttalking.ohio.gov

Start Talking!
Building a Drug-Free Future
Start Talking! Major Programs
April 7 2014: 22 Grants totaling $1.5 million
Video Presentation:
http://www.youtube.com/watch?v=BGSoUG5joaQ

- **Parents360 Rx** is a program developed by the Partnership at Drugfree.org to increase parents’ knowledge of substance abuse and improve a parent’s confidence in their ability to speak with teens about substance abuse, particularly prescription drugs.

- **Parents360 Rx** is available to any school, community group or individual interested in hosting an informational session to educate adults about the dangers of substance abuse, with an emphasis on prescription drugs.
Questions and Comments?
Contact Us

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