ASK YOUR DOCTOR IF OXYCODONE IS RIGHT FOR YOU!!

Side effects may include: Empty Pockets, Theft, Lying, Withdrawl, Nose-bleeds, Fits of Rage, Depression, Uncontrollable Itching and Sniffling, Prostitution, Jail-Time, Heroin Use, Loss of Friends, etc.
OPIOIDS AND CONTROLLED SUBSTANCES

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2nd Vice President, Florida Osteopathic Medical Association
Associate Professor, Internal Medicine University of Central Florida
Clinical Associate Professor, Internal Medicine, Nova Southeastern University
Disclosure

• No financial or other material conflicts of interest

• Not representative of any institution or organization
The I Love Me Slide:
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- 20 years private practice, board certified in pain medicine and addiction medicine
- Current Chair, American Osteopathic Pain Medicine Conjoint Exam Committee
- Administrative Director for Chronic Pain Management, John T. Mather Hospital, Port Jefferson, NY
- Core faculty, PM&R residency program, Mercy Medical Center, Catholic Health System
- Leadership Council, Long Island Council on Alcoholism and Drug Dependence (LICADD)
- Medical Director, LICADD Opioid Overdose Prevention Program
- Member, Nassau County, NY, County Executive’s Task Force on Heroin and Prescription Drug Abuse
- Former Medical Director, Town of Babylon Drug and Alcohol Program

Disclosures: Speaker Bureau, US WorldMeds, Lucemyra
Outline-1

- Pharmacology of opiates
- Epidemiology of opioid crisis
- Current Florida statistics regarding M&M of controlled substance-related deaths
- Current standards, laws and rules on prescribing controlled substances
- Proper prescribing of opiates
- Risks, diagnosis and treatment of opioid addiction
Outline-2

- Prescribing emergency opioid antagonists
- Alternatives to controlled substance prescribing
  - Non-pharmacological therapies
- Physician liability for overprescribing controlled substances
- Controlled substance disposal
• Pharmacology of opiates
• Epidemiology of opioid crisis
• Current Florida statistics regarding M&M of controlled substance-related deaths
• Current standards, laws and rules on prescribing controlled substances
• Proper prescribing of opiates
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Definitions

• Opiate
• Opioid
• Narcotic
• Controlled substance
Morpheus: God of Dreams

- Winged creature
- Many siblings
- Communicator
- Dream: human form
- Hypnos
- “In the arms of Morpheus”
Mechanism of action
## Receptor activity

<table>
<thead>
<tr>
<th></th>
<th><strong>Mu</strong></th>
<th><strong>Delta</strong></th>
<th><strong>Kappa</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesia</td>
<td>Analgesia</td>
<td>Analgesia with fewer adverse effects</td>
<td>Mild analgesia</td>
</tr>
<tr>
<td>Sedation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Euphoria</td>
<td></td>
<td></td>
<td>Dysphoria</td>
</tr>
<tr>
<td>Respiratory</td>
<td></td>
<td></td>
<td>Less respiratory depression</td>
</tr>
<tr>
<td>depression</td>
<td>Constipation</td>
<td></td>
<td>Decreased dependence</td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dependence</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Opioid classification

<table>
<thead>
<tr>
<th>Full agonist</th>
<th>Partial agonist</th>
<th>Agonist-antagonist</th>
<th>Antagonist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>Buprenorphine</td>
<td>Pentazocine</td>
<td>Naloxone</td>
</tr>
<tr>
<td>Fentanyl</td>
<td></td>
<td>Butorphanol</td>
<td>Naltrexone</td>
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<tr>
<td>Oxycodone</td>
<td></td>
<td></td>
<td>Nalbuphine</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
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</table>
## Opioid comparison

<table>
<thead>
<tr>
<th>Medication</th>
<th>Onset</th>
<th>Duration</th>
<th>Equi-analgesic dose</th>
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</thead>
<tbody>
<tr>
<td>Fentanyl patch</td>
<td>12-24 hrs</td>
<td>72 hrs/patch</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>15-30 mins</td>
<td>4-6 hrs</td>
<td>7.5mg po</td>
</tr>
<tr>
<td>Methadone</td>
<td>30-60 mins</td>
<td>&gt; 8 hrs</td>
<td></td>
</tr>
<tr>
<td>Morphine IR</td>
<td>30-60 mins</td>
<td>3-6 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>MS Contin®</td>
<td>30-90 mins</td>
<td>8-12 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>Kadian®</td>
<td>30-90 mins</td>
<td>12-24 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>Oxycodone IR</td>
<td>10-15 mins</td>
<td>4-6 hrs</td>
<td>20mg po</td>
</tr>
<tr>
<td>Oxycodone CR</td>
<td>1 hr</td>
<td>12 hrs</td>
<td>20mg po</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>30-60 mins</td>
<td>4-6 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>Codeine</td>
<td>30-60 mins</td>
<td>4-6 hrs</td>
<td>200mg po</td>
</tr>
<tr>
<td>Meperidine</td>
<td>10-15 mins</td>
<td>2-4 hrs</td>
<td>300mg po</td>
</tr>
<tr>
<td>Phenanthrenes</td>
<td>Piperidine/phenylpiperadine</td>
<td>Deiphenylheptanes</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------------------------</td>
<td>-------------------</td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td>Fentanyl*</td>
<td>Methadone*</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone*</td>
<td>Meperidine</td>
<td>Propoxyphene</td>
<td></td>
</tr>
<tr>
<td>Oxymorphone*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodone*</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Controlled Substances Act replaced all the previous regulations and classified controlled substances in five categories:

I. Substances that have no accepted medical use in the United States and have a high abuse potential (e.g.-heroin, L.S.D., etc.)

II. Substances that have a high abuse potential with severe psychic or physical dependence liability but with an accepted medical use (e.g.-Dilaudid, Morphine, Ritalin, etc.)

III. Substances that have an abuse potential less than those in Schedules I and II, and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs (e.g.-Tylenol #3, paregoric, Marinol, etc.)

IV. Substances that have an abuse potential less than those in Schedules I, II and III (e.g.-Restoril, Darvocet, Ambien, etc.)

V. Substances that have a relatively low potential for abuse (e.g.-Lyrica, Lomotil, Hycotuss, etc.)
1970
The *Controlled Substances Act* replaced all the previous regulations and classified controlled substances in five categories:

1994
The *Uniform Controlled Substances Act* is proposed and enacted by all 50 states.
## Controlled substance examples

<table>
<thead>
<tr>
<th>C-II</th>
<th>C-III</th>
<th>C-IV</th>
<th>C-V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>Lower dose of codeine</td>
<td>Tramadol</td>
<td>Lowest dose of codeine</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Anabolic steroids</td>
<td>Chloral hydrate</td>
<td>Robitussin-AC®</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>Lower dose of hydrocodone</td>
<td>Chlordiazepoxide</td>
<td>Lomotil®</td>
</tr>
<tr>
<td>Morphine</td>
<td>Ketamine</td>
<td>Clorazepate</td>
<td>Phenergan with codeine®</td>
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<tr>
<td>Oxycodone</td>
<td>Dronabinol</td>
<td>Carisoprodol</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td>GHB</td>
<td>Meprobamate</td>
<td></td>
</tr>
<tr>
<td>Amphetamine</td>
<td></td>
<td>Phentermine</td>
<td></td>
</tr>
<tr>
<td>Pentobarbital</td>
<td></td>
<td>Phenobarbital</td>
<td></td>
</tr>
</tbody>
</table>
• Pharmacology of opiates
• Epidemiology of opioid crisis
• Current Florida statistics regarding M&M of controlled substance-related deaths
• Current standards, laws and rules on prescribing controlled substances
• Proper prescribing of opiates
• Risks, diagnosis and treatment of opioid addiction
Why are we talking about this?

• Statistics

• Leading cause of injury death

• Headlines

• Legislation
From 1999 to 2013, the amount of prescription opioid pain relievers prescribed & sold in the U.S. nearly QUADRUPLED.

Yet there has not been an overall change in the amount of pain that Americans report.

Source: Centers for Disease Control and Prevention
ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients1 who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,2 Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154

Boston University Medical Center

Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases

Russell K. Portenoy and Kathleen M. Foley
Pain Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center, and Department of Neurology, Cornell University Medical College, New York, NY 10021 (U.S.A.)
(Received 10 June 1985, accepted 28 October 1985)

Summary

Thirty-eight patients maintained on opioid analgesics for non-malignant pain were retrospectively evaluated to determine the indications, course, safety and efficacy of this therapy. Oxycodeone was used by 12 patients, methadone by 7, and levorphanol by 5; others were treated with propoxyphene, meperidine, codeine, pentazocine, or some combination of these drugs. Nineteen patients were treated for four or more years at the time of evaluation, while 6 were maintained for more than 7 years. Two-thirds required less than 20 morphine equivalent mg/day and only 4 took more than 40 mg/day. Patients occasionally required escalation of dose and/or hospitalization for exacerbation of pain; doses usually returned to a stable baseline afterward. Twenty-four patients described partial but acceptable or fully adequate relief of pain, while 14 reported inadequate relief. No patient underwent a surgical procedure for pain management while receiving therapy. Few substantial gains in employment or social function could be attributed to the institution of opioid therapy. No toxicity was reported and management became a problem in only 2 patients, both with a history of prior drug abuse. A critical review of patient characteristics, including data from the 16 Personality Factor Questionnaire in 24 patients, the Minnesota Multiphasic Personality Inventory in 23, and detailed psychiatric evaluation in 6, failed to disclose psychological or social variables capable of explaining the success of long-term management. We conclude that opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse.
How did we get here?

• 1980s: opioids for non-malignant pain
• 1996: the 5th vital sign; OxyContin released
• 1998: FSMB protection
• 2001: TJC weighs in
• 2004: failure to treat is punishable
• 2007: Purdue is guilty of misbranding

Multiple Contributing Elements

- Annual volume of opioid prescriptions steadily on the rise throughout the 1990's
- Aggressive marketing by opioid manufacturers
- Rise of internet sales
- Birth of pill mills
- Low prescriber awareness / low public awareness
- Initially weak regulatory environment
- Pain as a vital sign
- HCAHPS pain question
Source of pain relievers for non-medical use, users aged 12 or older: 2012-2013

Image from SAMHSA, as cited in Tetrault and Butner, 2015.
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

1999 (range 1 - 50)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Some states have more opioid prescriptions per person than others.
NUMBER OF BABIES DIAGNOSED WITH NEONATAL ABSTINENCE SYNDROME (NAS)

Source: Reuters analysis of U.S. Department of Health and Human Services data
• Pharmacology of opiates
• Epidemiology of opioid crisis
• Current Florida statistics regarding M&M of controlled substance-related deaths
• Current standards, laws and rules on prescribing controlled substances
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• Risks, diagnosis and treatment of opioid addiction
Oxycodone Deaths in Florida

Source: Drugs Identified in Deceased Persons by Florida Medical Examiners 2016 Annual
## Drug overdose deaths

<table>
<thead>
<tr>
<th>USA</th>
<th>2016</th>
<th>2017</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>696,602</td>
<td>825,016</td>
<td>18</td>
</tr>
<tr>
<td>Florida</td>
<td>48,380</td>
<td>65,428</td>
<td>35</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>2016</th>
<th>2017</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cocaine</td>
<td>101,860</td>
<td>152,650</td>
<td>50</td>
</tr>
<tr>
<td>Heroin</td>
<td>173,183</td>
<td>191,315</td>
<td>10</td>
</tr>
<tr>
<td>Semi-synthetic opioids</td>
<td>163,138</td>
<td>177,901</td>
<td>9</td>
</tr>
<tr>
<td>Opioids</td>
<td>452,369</td>
<td>554,974</td>
<td>23</td>
</tr>
<tr>
<td>Psychostimulants</td>
<td>80,589</td>
<td>109,652</td>
<td>36</td>
</tr>
<tr>
<td>Synthetic opioids</td>
<td>170,776</td>
<td>302,130</td>
<td>77</td>
</tr>
</tbody>
</table>

CDC, National Center for Health Statistics, National Vital Statistics System,
Painkiller Sales and Overdose Deaths

The nation’s rising overdose death rate from painkillers such as Vicodin, Percocet and OxyContin closely parallels an increase in opioid prescription sales over the past 15 years.

† Sales data is unavailable for 2012.

Source: U.S. Drug Enforcement Administration and Centers for Disease Control and Prevention
© 2016 The Pew Charitable Trusts
Relationship Between Opioid Prescribing and Drug Overdose Death Rates

Source: Death rate, 2008, CDC/NVSS. Opioid pain reliever sales rate, 2010, DEA’s ARCOS
Number of Deaths from Prescription Opioid Pain Relievers

USA

Source: National Center for Health Statistics, CDC Wonder
Drug overdose deaths continue to increase in the United States.
From 1999 to 2016, more than 630,000 people have died from a drug overdose. (Average of 247 deaths per day, 10 people per minute.)
Around 66% of the more than 63,600 drug overdose deaths in 2016 involved an opioid.
In 2016, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 5 times higher than in 1999.
From 1999-2016, more than 350,000 people died from an overdose involving any opioid, including prescription and illicit opioids.¹
On average, 115 Americans die every day from an opioid overdose²

The onset can be described as occurring in 3 distinct waves:

I. Increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids (natural and semi-synthetic opioids and methadone) increasing since at least 1999.

II. The second wave began in 2010, with rapid increases in overdose deaths involving heroin.

III. The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids – particularly those involving illicitly-manufactured fentanyl (IMF). The IMF market continues to change, and IMF can be found in combination with heroin, counterfeit pills, and cocaine. 1,3

3 Waves of the Rise in Opioid Overdose Deaths

- **Wave 1**: Rise in Prescription Opioid Overdose Deaths
- **Wave 2**: Rise in Heroin Overdose Deaths
- **Wave 3**: Rise in Synthetic Opioid Overdose Deaths

**Other Synthetic Opioids**
e.g. Tramadol and Fentanyl, prescribed or illicitly manufactured

**Commonly Prescribed Opioids**
Natural & Semi Synthetic Opioids and Methadone

• Pharmacology of opiates
• Epidemiology of opioid crisis
• Current Florida statistics regarding M&M of controlled substance-related deaths
• Current standards, laws and rules on prescribing controlled substances
• Proper prescribing of opiates
• Risks, diagnosis and treatment of opioid addiction
• C-II prescriptions do not have an expiration
  • Florida Rx must be filled within 1yr
  • No refills allowed

• C-III prescriptions expire 6mos post date written
  • Max of 5 refills within 6mos

• Physicians who write or dispense controlled substances for detoxification must be separately registered for that purpose

• Emergencies

• Partial fills
"Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.
The 2016 Florida Statutes

Title XXXII
REGULATION OF PROFESSIONS AND OCCUPATIONS

459.0137 Pain-management clinics.—

(4) REGISTRATION

Training requirements

64B15-14.0051 Training Requirements for Physicians Practicing in Pain Management Clinics.
Effective July 1, 2012, physicians who have not met the qualifications set forth in subsections (1) through (6), below, shall have successfully completed a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or a pain medicine residency that is accredited by ACGME or the AOA. Prior to July 1, 2012, physicians prescribing or dispensing controlled substance medications in pain management clinics registered pursuant to Section 459.0137(1), F.S., must meet one of the following qualifications:

(1) Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a subspecialty certification in pain medicine; or a Certificate of Added Qualification in Pain Management by the American Osteopathic Association;

(2) Board certification in pain medicine by the American Board of Pain Medicine (ABPM);

(3) Successful completion of a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or a pain medicine residency that is accredited by the ACGME or the AOA;

(4)(a) Successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, neurology, neurosurgery, or psychiatry approved by the ACGME or the AOA;

(b) Successful completion of a residency program in family practice, internal medicine, or orthopedics approved by the AOA; or

(c) Current Certificate of Added Qualification approved by the AOA in hospice, palliative medicine or geriatric medicine.

(5) Current staff privileges at a Florida-licensed hospital to practice pain medicine or perform pain medicine procedures;

(6) Three (3) years of documented full-time practice, which is defined as an average of 20 hours per week each year, in pain-management and attendance and successful completion of 40 hours of in-person, live-participatory AMA Category I or AOA Category IA CME courses in pain management that address all the following subject areas:

7) Upon completion of the 40 hours of CME set forth above, physicians qualifying under subsection (6) above, must also document the completion of 15 hours of in-person, live participatory AMA Category I or AOA Category IA CME in pain management for every year the physician is practicing pain management.

Rulemaking Authority 459.0137(4) FS. Law Implemented 459.0137 FS. History—New 11-8-10, Amended 3-16-11, 3-26-12, 7-3-12.
Regulatory/Agency Actions

- **2014-17**: Approval of a new formulations of naloxone for community use, including autoinjector and intranasal products

- Development of abuse deterrent (AD) opioid formulations

- Much more...
• Jun 10, 2015 – FL HB751, Emergency Treatment and Recovery Act


• Mar 16, 2016 – CDC Guideline for Prescribing Opioids for Chronic Pain

• Jul 7, 2016 – National Governors Association: Finding Solutions to the Prescription Opioid and Heroin Crisis: A Roadmap for States

• Jul 22, 2016 – US S.524, Comprehensive Addiction and Recovery Act

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm
http://www.cdc.gov/drugoverdose/prescribing/guideline.html
State of Emergency Issued


Original Post: May 3rd @ 3:20pm

Dear Florida Pharmacists and Pharmacies:

Today following Governor Scott’s Executive Order declaring the opioid epidemic a state of emergency in Florida, Dr. Philip, State Surgeon General, declared a public health emergency and issued a naloxone standing order for emergency responders. 

The order authorizes pharmacists who maintain a current active license practicing in a pharmacy located in Florida that maintains a current active pharmacy permit to dispense naloxone to emergency responders for administration to persons exhibiting signs of opioid overdose. Emergency responders include law enforcement officers, firefighters, paramedics and emergency medical technicians.

The pharmacy must maintain a copy of the Naloxone Standing Order if dispensing naloxone pursuant to the order.

Incorporated in the Naloxone Standing Order is the expectation that the SAMHSA Opioid Overdose Response Technical Assistance Center will follow-up.

Florida HB 21

- Signed by Gov. Scott on March 19, 2018
- Mostly effective July 1, 2018

- Impact on key areas
  - Prescription Drug Monitoring Program (PDMP)
  - Controlled substance prescribing
  - Pain management clinic registration
  - Continuing medical education
E-FORCSE

- Electronic - Florida Online Reporting of Controlled Substances Evaluation program: Florida’s Prescription Drug Monitoring Program (PDMP)

- Created by the 2009 legislature, an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the State

- Operational 9/1/11; Health care practitioner (HCP) access 10/17/11; law enforcement access 11/14/11

- Health Information Designs, Inc. developed a database that collects and stores prescribing and dispensing data for controlled substances in Schedules II, III, and IV

- PDMP purpose: to provide information to HCPs to guide their decisions in prescribing and dispensing controlled substances
Florida’s PDMP:
http://www.e-forcse.com

As of December 31, 2017-

- Dispensing records uploaded: > 250M
- Total registrants: 85,318
- Number that have queried: 71,726
- Total reports requested: > 4M
## Registration and utilization, 2017

<table>
<thead>
<tr>
<th>License type</th>
<th>Total licensees (no.)</th>
<th>Registered users (no.)</th>
<th>Registered users (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARNP</td>
<td>25,740</td>
<td>3,828</td>
<td>14.9</td>
</tr>
<tr>
<td>DN</td>
<td>14,283</td>
<td>1,178</td>
<td>8.3</td>
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<tr>
<td>ME</td>
<td>75,729</td>
<td>16,287</td>
<td>21.5</td>
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<tr>
<td>OPC</td>
<td>3,332</td>
<td>20</td>
<td>0.6</td>
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<tr>
<td>OS</td>
<td>9,120</td>
<td>3,552</td>
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<tr>
<td>PA</td>
<td>8,687</td>
<td>2,336</td>
<td>26.9%</td>
</tr>
<tr>
<td>PO</td>
<td>1,904</td>
<td>242</td>
<td>12.7</td>
</tr>
<tr>
<td>PS</td>
<td>31,606</td>
<td>18,611</td>
<td>58.9</td>
</tr>
<tr>
<td>Designee</td>
<td>---</td>
<td>1,616</td>
<td>---</td>
</tr>
</tbody>
</table>

PDMP: 7/1/2018

- E-FORSCE remains intact
- Prescriber or dispenser (or designee) must consult the database for all patients 16 or older
- Applies to **ALL** controlled substances, not just opioids
- Document reason for not consulting (cannot dispense more than 3d supply)
- Dispensing must be reported by next day’s EOB


http://www.fl senate.gov/Session/Bill/2018/21/BillText/er/PDF
https://www.drugs.com/schedule-5-drugs.html

Florida Medical Association brief on HB 21
Controlled substance Rx: 7/1/2018

• Added treatment of acute pain to F.S.456.44
• Board rule-making
• Acute pain: “the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.”

Injury Severity Score

<table>
<thead>
<tr>
<th>Body system</th>
<th>Injury severity</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head and neck</td>
<td>No injury</td>
<td>0</td>
</tr>
<tr>
<td>Face</td>
<td>Minor</td>
<td>1</td>
</tr>
<tr>
<td>Chest</td>
<td>Moderate</td>
<td>2</td>
</tr>
<tr>
<td>Abdomen</td>
<td>Serious</td>
<td>3</td>
</tr>
<tr>
<td>Extremity, inc pelvis</td>
<td>Severe</td>
<td>4</td>
</tr>
<tr>
<td>External</td>
<td>Critical</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Unsurvivable</td>
<td>6</td>
</tr>
</tbody>
</table>

[http://www.trauma.org/archive/scores/iss.html](http://www.trauma.org/archive/scores/iss.html)
• 3 day limit on C-II opioid
• Up to 7 day supply IF...
  • Medically necessary
  • “Acute pain exception” is written on Rx
  • Documents acute condition and lack of alternatives

**Note that all 3 criteria must be met**

• Emergency opioid antagonist
• “Nonacute pain”
Pain management clinic: 1/1/2019

- Pain management clinic registration
- Exempt entities
  - Clinic in which the majority of physicians there primarily provide surgical services
  - Clinic held by a publicly traded company whose most recent total quarterly assets exceed $50M
  - Clinic affiliated with a medical school at which training is provided
- Certificate of exemption

http://www.flsenate.gov/Session/Bill/2018/21/BillText/er/PDF
CME: 1/31/2019

- DEA registrants
- Controlled substance prescribers
- 2 hour, board-approved, CME
- Part of biennial license renewal
- Within the number of CE hours required by law
- Failure to complete course = no license renewal
- By Jan 31, 2019 and each subsequent renewal
- Submit confirmation of course completion

http://www.flsenate.gov/Session/Bill/2018/21/BillText/er/PDF
Laws Setting Limits on Certain Opioid Prescriptions

* Note: The map displays the state's primary opioid prescription limit and does include additional limits on certain providers or in certain settings. Arizona allows prescriptions up to 14 days following surgical procedures and North Carolina allows up to 7 days for post-operative relief. Maryland requires the "lowest effective dose." Minnesota's limit is for acute dental or ophthalmic pain. The map also does not reflect limits for minors that exist in at least eight states.

When does dependence begin?

Days' supply of the first opioid prescription

*Days' supply of the first prescription is expressed in days (1–40) in 1-day increments. If a patient had multiple prescriptions on the first day, the prescription with the longest days' supply was considered the first prescription.

http://www.newsweek.com/cdc-opiate-addiction-572498
https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm
www.flhealthsource.gov/FloridaTakeControl
• Pharmacology of opiates
• Epidemiology of opioid crisis
• Current Florida statistics regarding M&M of controlled substance-related deaths
• Current standards, laws and rules on prescribing controlled substances
• **Proper prescribing of opiates**
• Risks, diagnosis and treatment of opioid addiction
Counterfeit-proof Rx pads

• Controlled substance Rx must be written on a counterfeit-resistant pad produced by an approved vendor, or electronically prescribed

• Otherwise, risk of Rx rejection and confiscation

http://www.floridashealth.com/mqu/counterfeit-proof.html

http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.html
Components of a legitimate controlled substance Rx

- Legible printed/typed on counterfeit-proof Rx
- Date in textual format
- Patient name & address
- Name and strength of medication
- Dispense amount in both textual and numeric format
- Sig: directions should be legibly written out
- Number of refills, if any
- DEA number legibly written
- Signature – ink or typed (no signature stamps)
- Doctor office name and contact information (e.g., address, phone)
Example

Date: September 21, 2016
Patient Name: Jasmine Akrabah   DOB: 05/29/1966
Address: 1111 Center Lane, Anytown, Florida 33312
Percocet (5/325)
Disp. # 10 (Ten)
Sig: Take one tab by mouth every 6 hours PRN post-op pain
No Refills
DEA # _____   Signature _______
WHY GUIDELINES FOR PRIMARY CARE PROVIDERS?

Primary care providers account for approximately
50% of prescription opioids dispensed.

Nearly 2 million Americans, aged 12 or older, either abused or were dependent on prescription opioids in 2014.

An estimated 11% of adults experience daily pain.

Millions of Americans are treated with prescription opioids for chronic pain.

Primary care providers are concerned about patient addiction and report insufficient training in prescribing opioids.

MYTH VS TRUTH

1. Myth: Opioids are effective long-term treatments for chronic pain.
   Truth: While evidence supports short-term effectiveness of opioids, there is insufficient evidence that opioids control chronic pain effectively over the long term, and there is evidence that other treatments can be effective with less harm.

2. Myth: There is no necessity of opioids as long as opioids are titrated slowly.
   Truth: Only opioid designs whose user greater than 50 MME/day are associated with significant risks, and lower designs are safer.

3. Myth: The risk of addiction is minimal.
   Truth: Up to one quarter of patients receiving prescription opioids long term in a primary care setting struggle with addiction. Certain multi-dose boxes are suspiciously associated.

WHAT CAN PROVIDERS DO?

First, do no harm. Long-term opioid use has uncertain benefits but known serious risks. CDC’s Guideline for Prescribing Opioids for Chronic Pain will support informed clinical decision making, improved communication between patients and providers, and appropriate prescribing.

PRACTICES AND ACTIONS

USE NONOPIOID TREATMENT

Opioids are not first-line rational therapy for chronic pain (Recommendation E1)

In a systematic review, opioids and other treatments were equally effective in improving pain and functional status when used in addition to physical therapy. (Recommendation E3)

REVIEW PUMP

Check prescription drug monitoring program data for high strengths and prescriptions from other providers. (Recommendation E8)

A lack of need for opioids is one of the most significant factors in switching patients to non-opioids, 2014 prescription, or design. (Recommendation E8)

OFFER TREATMENT FOR OPIOID USE DISORDER

Other or additional evidence-based treatment (e.g., medication-assisted treatment and behavioral therapy) for patients with opioid use disorders (Recommendation E15)

A study found patients prescribed higher doses of opioids had twice the risk of developing opioid addiction compared to patients prescribed opioids.

START LOW AND GO SLOW

Were opioids are started, prescribe them at the lowest effective dose (Recommendation E7)

Use stepped care high-dose, 2014, and an associated 12% to 36% higher risk of overdose compared to low-dose alone.

AVOID CONCURRENT PRESCRIBING

Avoid prescribing opioids with benzodiazepines or nonprescription opioids contemporaneously whenever possible (Recommendation E13)

Data from prescription-side prescribing in a managed care setting with a mean score of risk for overdose risks compared to open prescriptive provider.

LEARN MORE: www.cdc.gov/drugoverdose/prescribing/guideline.html
2016 CDC guidelines

- 18yoa+, chronic pain treatment (3mos+)
- Use non-opioid therapies
  - Nonpharmacological therapies
  - Non-opiate treatments
- Start low and go slow
- Follow up

http://www.cdc.gov/drugoverdose/prescribing/guideline.html
Opioid Prescribing Recommendations: Summary of 2016 CDC Guidelines

**Determining when to initiate or continue opioids for chronic pain**

- Opioids are not first-line or routine therapy
- Establish treatment goals before starting opioid therapy and a plan if therapy is discontinued
- Only continue opioid if there is clinically meaningful improvement in pain and function
- Discuss risks, benefits and responsibilities for managing therapy before starting and during treatment

**Opioid selection, dosage, duration, follow-up and discontinuation**

- Use immediate-release (IR) opioids when starting therapy
- Prescribe the lowest effective dose
- When using opioids for acute pain, provide no more than needed for the condition
- Follow up and review benefits and risks before starting and during therapy
- If benefits do not outweigh harms, consider tapering opioids to lower doses or taper and discontinue

**Assessing risk and addressing harms of opioid use**

- Offer risk mitigation strategies, including naloxone for patients at risk for overdose
- Review PDMP* data at least every 3 months and perform UDT** at least annually***
- Avoid prescribing opioid and benzodiazepines concurrently when possible
- Clinicians should offer or arrange MAT**** for patients with OUD†

*Prescription drug monitoring program
**Tissue drug testing
***Some VA facilities may require more frequent testing
****Medication-assisted treatment
†Opioid use disorder
• Determine when to initiate/continue opioids
  • Non-Rx and non-opioid tx is preferred
  • Establish tx goals; discuss realistic risks and benefits

• Opioid logistics
  • Rx IR instead of ER/LA
  • Begin w/ lowest effective dose; consider quantity and duration
  • Monitor

• Assessing risk & addressing harms
  • Consider risk mitigation
  • Consult PDMP
  • Urine drug screen
  • Avoid opiate/BZD combos
  • Treat opioid use disorder

http://www.cdc.gov/drugoverdose/prescribing/guideline.html
Clinically meaningful improvement

• 30%+ improvement
• Assess and document
• Validated tools

• What is not CMI?

• Rx – CMI = inappropriate care

STEP 2  Develop and Select Policies

PREVENTING OPIOID MISUSE AND OVERDOSE

HEALTH CARE STRATEGIES FOR PREVENTION AND EARLY IDENTIFICATION

- Develop and update guidelines for all opioid prescribers.
- Limit new opioid prescriptions for acute pain, with exceptions for certain patients.
- Adopt a comprehensive opioid management program in Medicaid and other state-run health programs.
- Remove methadone for managing pain from Medicaid preferred drug lists.
- Expand access to non-opioid therapies for pain management.
- Enhance education and training for all opioid prescribers.
- Maximize the use and effectiveness of state prescription drug monitoring programs.
- Use public health and law enforcement data to monitor trends and strengthen prevention efforts.
- Enact legislation that increases oversight of pain management clinics to reduce “pill mills.”
- Raise public awareness about the dangers of prescription opioids and heroin.

RESPONDING TO OPIOID MISUSE AND OVERDOSE

HEALTH CARE STRATEGIES FOR TREATMENT AND RECOVERY

- Change payment policies to expand access to evidence-based MAT and recovery services.
- Increase access to naloxone.
- Expand and strengthen the workforce and infrastructure for providing evidence-based MAT and recovery services.
- Create new linkages to evidence-based MAT and recovery services.
- Consider authorizing and providing support to syringe service programs.
- Reduce stigma by changing the public’s understanding of substance use disorder.

In The News...

- **Aug 2016**: influx of fentanyl-laced counterfeit pills and toxic compounds further increases risk of fentanyl-related ODs and fatalities
- **Sep 2016**: FDA adds boxed warnings to Rx opioids and BZDs
  - DEA issues carfentanil warning
Open letter to all Medical Providers:

“Years from now, I want us to look back and know that, in the face of a crisis that threatened our nation, it was our profession that stepped up and led the way.”

TurnTheTideRx.org website
Launched Aug. 8, 2016
Platform with resources for physicians and their patients

http://turnthetiderx.org/
Presidential Proclamation -- Prescription Opioid and Heroin Epidemic Awareness Week, 2016

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 18 through September 24, 2016, as Prescription Opioid and Heroin Epidemic Awareness Week. I call upon all Americans to observe this week with appropriate programs, ceremonies, and activities that raise awareness about the prescription opioid and heroin epidemic.

IN WITNESS WHEREOF, I have hereunto set my hand this sixteenth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

BARACK OBAMA
In The News...

- **Aug 2017**: As of Jan 2018, GA docs will be required to take 3hrs of CME on opioid prescribing before license renewal
- **Sep 2017**: FDA requires 74 opioid manufacturers to develop physician training
- **CDC awards $28.6M to help states fight opioid overdose epidemic**
- **States and cities sue opioid manufacturers and distributors**

• Pharmacology of opiates
• Epidemiology of opioid crisis
• Current Florida statistics regarding M&M of controlled substance-related deaths
• Current standards, laws and rules on prescribing controlled substances
• Proper prescribing of opiates
• Risks, diagnosis and treatment of opioid addiction
Economic burden of opioid abuse

- Nonmedical use of opioid pain relievers cost insurance companies up to $72.5 billion annually in health-care cost

- Social & economical consequences
  - Cost of prevention and treatment
  - Increased incidences of opioid overdose deaths
  - Safety risk to the public due to drug affected driving
  - Environmental contamination due to inappropriate disposal and illicit cultivation
  - Loss of productivity at work
  - Neonatal abstinence syndrome

Consequences

- Opioid use disorder
- Addiction
- Addiction treatment
- Withdrawal
- Toxicity/overdose
- Overdose treatment
Risks of Opioid Therapy

- **Mortality** (of all-causes)
  - Hazard ratio (HR) 1.64 for long acting opioids for non-cancer pain
- **Overdose deaths** (unintentional)
  - HR 7.18-8.9 for MED > 100 mg/d
- **Opioid use disorder**
  - For patients on long-term opioids (> 90 days)
    - HR 15 for 1-36 mg/d MED
    - HR 29 for 36-120 mg/d MED
    - HR 122 for > 120 mg/d MED

*MED=Morphine Equivalent Daily Dose (in mg/d)*
### DSM-5 Criteria for OUD (Rx opioids)
(2 or more criteria)

<table>
<thead>
<tr>
<th>DSM-5 Criteria</th>
<th>Example behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Craving or strong desire to use opioids</td>
<td>Describes constantly thinking about opioids</td>
</tr>
<tr>
<td>Recurrent use in hazardous situations</td>
<td>Repeatedly driving under the influence</td>
</tr>
<tr>
<td>Using more opioids than intended</td>
<td>Repeated requests for early refills</td>
</tr>
<tr>
<td>Persistent desire/unable to cut down or control opioid use</td>
<td>Unable to taper opioids despite safety concern or family’s concern</td>
</tr>
<tr>
<td>Great deal of time spent obtaining, using or recovering from the effects</td>
<td>Spending time going to different doctor’s offices and pharmacies to obtain opioids</td>
</tr>
<tr>
<td>Continued opioid use despite persistent opioid-related social problems</td>
<td>Marital/family problems or divorce due to concern about opioid use</td>
</tr>
<tr>
<td>Continued opioid use despite opioid-related medical/psychological problem</td>
<td>Insistence on continuing opioids despite significant sedation</td>
</tr>
<tr>
<td>Failure to fulfill role obligations</td>
<td>Poor job/school performance; declining home/social function</td>
</tr>
<tr>
<td>Important activities given up</td>
<td>No longer active in sports/leisure activities</td>
</tr>
</tbody>
</table>
Assessing and monitoring

• SBIRT

• “Universal Precautions” when prescribing opioids in chronic non-cancer pain (CNCP)

• ORT = Opioid Risk Tool

• PDMP = Florida’s Prescription Drug Monitoring Program
10 steps of “Universal Precautions”

1. Make a diagnosis with appropriate differential.
2. Perform a psychological assessment, including risk of addictive disorders.
3. Obtain informed consent.
4. Use a treatment agreement.
5. Conduct assessments of pain level and function before and after the intervention.
6. Begin an appropriate trial of opioid therapy with or without adjunctive medications and therapies.
7. Reassess pain score and level of function.
8. Regularly assess the “4 As” of pain medication (analgesia, ADLs, adverse events, aberrant drug-related behaviors).
9. Periodically review pain diagnosis and co-occurring conditions, including addictive disorders.
10. Document initial evaluation and follow-up visits.

Adapted from Gourlay et al., 2005. (SAMHSA TIP 54, page 49)
# Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

<table>
<thead>
<tr>
<th>Mark each box that applies</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Family history of substance abuse</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Rx drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Personal history of substance abuse</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Rx drugs</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>Age between 16—45 years</strong></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>History of preadolescent sexual abuse</strong></td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td><strong>Psychological disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADD, OCD, bipolar, schizophrenia</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Scoring totals**

Physical dependence vs. addiction

Physical Dependence
- Body is used to having a high level of opioid
- Abrupt discontinuation will result in withdrawal symptoms (nausea & vomiting, anxiety, etc.)

Addiction
- Uncontrollable craving and compulsive use, inability to control drug use
- There is no addiction without craving

Addiction is a chronic, progressive brain disease due to altered brain structure and function

Addiction

• Definition
  1. Tolerance
  2. Withdrawal
  3. Abuse
  4. Helplessness
  5. Compulsion
  6. Isolation
  7. Vicious circle of devastation

• Dependence

• Hyperalgesia

Addiction treatment

- Inpatient
  - Short term
  - Long term
  - Partial hospitalization
- Outpatient
  - Intensive programs
  - Clinics
- Medication-assisted treatment programs

http://www.samhsa.gov/medication-assisted-treatment
MAT (Medication Assisted Treatment)

• Component of comprehensive treatment

• Methadone
• Buprenorphine

• Naltrexone/naloxone?

<table>
<thead>
<tr>
<th></th>
<th>Buprenorphine/Naloxone*</th>
<th>Methadone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment setting</strong></td>
<td>Office-based</td>
<td>Specially licensed OTP</td>
</tr>
<tr>
<td><strong>MOA</strong></td>
<td>Partial opioid agonist*</td>
<td>Opioid agonist</td>
</tr>
<tr>
<td><strong>FDA-approved?</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Reduces cravings?</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>OUD classification?</strong></td>
<td>Mild—Moderate</td>
<td>Mild/Moderate/Severe</td>
</tr>
<tr>
<td><strong>Candidates</strong></td>
<td>None/few failed attempts</td>
<td>Many failed attempts</td>
</tr>
<tr>
<td><strong>Recommended for those using ongoing short-acting opioids?</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Psychosocial intervention recommendations</strong></td>
<td>Addiction-focused MM</td>
<td>Individual counseling and/or contingency management</td>
</tr>
</tbody>
</table>

http://buprenorphine.samhsa.gov/
http://www.opioidprescribing.com/naloxone_module_1-landing

http://www.pcssmat.org
https://www.samhsa.gov/medication-assisted-treatment
Withdrawal

- Rhinorrhea
- Diarrhea
- Yawning
- Anxiety
- Mydriasis

- Lacrimation
- Vomiting
- Hyperventilation
- Hostility

Clinical Opiate Withdrawal Scale

Opiate-induced constipation

• Dietary and lifestyle interventions
• OTC medications
  • Stimulant laxatives: bisacodyl, senna
  • Stool softeners: docusate, mineral oil, Mg citrate
  • Enemas
• Prescription medications
  • Lubiprostone (Amitiza)
  • Methylnaltrexone (Relistor)
  • Naloxegol (Movantik)
  • Naldemedine (Symproic)

https://www.uspharmacist.com/article/opioidinduced-constipation-clinical-guidance-and-approved-therapies
• Prescribing emergency opioid antagonists
• Alternatives to controlled substance prescribing
  • Nonpharmacological therapies
• Physician liability for overprescribing controlled substances
• Controlled substance disposal
Toxicity/overdose

- Coma
- Miosis
- Bradypnea/hypoventilation
Overdose treatment

• BLS
• Naloxone
  • Injectable (Narcan)
  • Autoinjectable (Evzio)
  • Nasal spray (Narcan)
• Active monitoring

https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio
• Prescribing emergency opioid antagonists
• Alternatives to controlled substance prescribing
  • Nonpharmacological therapies
• Physician liability for overprescribing controlled substances
• Controlled substance disposal
• Pharmacological
  • Antidepressants
  • Anticonvulsants
  • Acetaminophen
  • NSAIDs
  • Anesthetics
  • Corticosteroids
  • Non-BZD muscle relaxers
• Non-pharmacological
  • Heat/cold
  • Osteopathic manipulation
  • Physical therapy
  • Chiropractic
  • Acupuncture
  • TENS?
  • Biofeedback
  • Cognitive behavioral therapy
  • Exercise
Timing is everything

• Low back pain
  • 40%-60% less likely to use opioids over 2 years if PT seen within 2 weeks of onset
    • Childs et al 2015; Fritz et al 2013

• Neck pain
  • 41% less likely to receive opioid therapy for neck pain in the next 12 months
    • Horn et al, 2018

• Knee pain
  • 33% less likely over 12 months
    • Stevans et al 2017
• Prescribing emergency opioid antagonists
• Alternatives to controlled substance prescribing
  • Non-pharmacological therapies
• Physician liability for overprescribing controlled substances
• Controlled substance disposal
• Minimum penalty for 1\textsuperscript{st} violation
  • 6mo license suspension, probation + $10,000 fine

• Minimum penalty for 2\textsuperscript{nd} violation
  • 1yr license suspension, probation + $10,000 fine

• Maximum penalty for either offense
  • License revocation + $10,000 fine
• Failure to check the PDMP
  • 1\textsuperscript{st} offense
    • Non-disciplinary citation from DOH

  • 2\textsuperscript{nd} offense
    • Subject to discipline from respective Board

• Willful malfeasance
  • 1\textsuperscript{st} degree misdemeanor
• Prescribing emergency opioid antagonists
• Alternatives to controlled substance prescribing
  • Non-pharmacological therapies
• Physician liability for overprescribing controlled substances
• **Controlled substance disposal**
Controlled substance disposal

• Small amounts

• Secure safely

• Safe disposal options
  • Veterans Health Administration
  • Return to pharmacist or prescriber?
Medication disposal per FDA

- Take-back programs
  - https://www.deadiversion.usdoj.gov/drug_disposal/takeback/

- DEA-authorized collectors
  - https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1
  - DEA Office of Diversion Control’s Registration Call Center: 1-800-882-9539

- Household trash (*not for controlled substances*)

- Flushing:
The opioid epidemic

33,000 Americans killed in 2015 by opioids, including prescription drugs and heroin—more than any previous year.

91 daily U.S. deaths from opioid overdose, including prescription drugs and heroin.

183,000 U.S. deaths from overdoses related to prescription opioids, 1999-2015.

6 out of 10 portion of total U.S. deaths by drug overdose that involve an opioid.

15,000 deaths in 2015 from overdoses involving such prescriptions.

2 million Americans in 2014 who abused or were dependent on prescription opioids.

25 to 54 age range for most U.S. deaths by overdose of a prescription opioid, 1999-2014.

13,000 number of U.S. deaths by heroin overdose in 2015.

20.6 percentage increase from 2014 to 2015 in deaths by heroin overdose.

Source: Centers for Disease Control and Prevention
Opioid epidemic strategy

• Improving access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments

• Targeting availability and distribution of overdose-reversing drugs

• Strengthening our understanding of the crisis through better public health data and reporting

• Providing support for cutting edge research on pain and addiction

• Advancing better practices for pain management

SO HOW DOES A PHYSICIAN GET IN TROUBLE?
SO HOW DOES A PHYSICIAN GET IN TROUBLE?

1. Regulatory
2. Civil
3. Criminal
SO HOW DOES A PHYSICIAN GET IN TROUBLE?

1. Regulatory
   • This involves the professional behavior of the practitioner
   • It impacts the ability and the scope of the practice of medicine
   • Ultimately it involves whether or not professional misconduct has occurred
   • Such as:
     • Practicing while impaired (e.g.-drug and/or alcohol abuse, etc.)
     • Practicing outside the scope of their specialty
     • Fraud
     • Abusive behavior
     • Neglect
     • Failure to document, etc.
   • Can result in:
     • License suspension, revocation, limitation, etc
     • Practice Monitor
     • Fines, etc.
     • You name it, you just don’t go to jail!
SO HOW DOES A PHYSICIAN GET IN TROUBLE?

2. Civil

• This is a malpractice suit
• At least in New York, before proceeding, an attorney must have another physician certify that it is a valid case or in the absence of this the attorney can attest to the validity
• In general harm must be shown
• Results in a financial award
• The financial award may be not only for lost wages, loss of consortium, etc. but also for punitive damages if the judge so chooses
SO HOW DOES A PHYSICIAN GET IN TROUBLE?

3. Criminal

• This is where criminal behavior has to be proven

• It used to be primarily cases of assault (sexual or otherwise) on the part of the provider, insurance fraud, etc..

• In 2006, however, the landscape of medicine changed...
Additional references

- American Society of Addiction Medicine Opioid Addiction 2016 Facts & Figures


- National Institute on Drug Abuse (NIDA) [https://www.drugabuse.gov/](https://www.drugabuse.gov/)


Thank you

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Hall, Render, Killian, Heath & Lyman, P.C.
Indianapolis, IN
"I'M MARRIED, SO I'M AN EXPERT IN PAIN MANAGEMENT."