FEDERAL AND STATE LAWS RELATING TO THE PRESCRIBING OF CONTROLLED SUBSTANCES

64B15-13.001 CONTINUING EDUCATION FOR BIENNIAL RENEWAL.

Joel B. Rose, DO
Member Florida Board of Osteopathic Medicine
Fellow American Association of Osteopathic Medical Examiners
Fellow Federation of State Medical Board
FSMB Model Opioid Policy Contributor 2013, 2017

FOMA Mid-Year Seminar
Hyatt Regency Westshore
September 15, 2017
8:30 am – 9:30 am
- Review of the applicable federal and state laws and rules
- Review of the current Florida statistics regarding morbidity and mortality of controlled substance related deaths
- Pharmacology of opiate drugs
- Proper prescribing of opiate drugs
- Review of physician liability for overprescribing controlled substances
- Diagnosis of opioid addiction and treatment options
THE OPIATE PROBLEM
91 AMERICANS die every day from an opioid overdose (that includes prescription opioids and heroin).
Nearly 2 million Americans abused or were dependent on prescription opioids in 2014.
As many as 1 in 4 people who receive prescription opioids long term for non-cancer pain in primary care settings struggle with addiction.
Each day, more than 1,000 people are treated in emergency departments for not using prescription opioids as directed.
From 1999 to 2015, more than 180,000 people died from overdoses related to prescription opioids.

- In US 500,000 people have died from drug overdoses 1999-2015
- In US 15,000 people died in 2015 from drug overdoses
Drug overdose deaths have nearly tripled in the US since 1999

- Americans dying of a drug overdose
  - 1999: 6 out of every 100,000
  - 2015: > 16 out of every 100,000
    - Heroin and other opioids account for about half of these deaths

- Drug overdose deaths are rising:
  - 7% each year for whites (up 3.5 x 1999 rate)
  - 2% for blacks and hispanics

- Drug overdose deaths increased from 1999 to 2015 in all age groups
  - Adults aged 45-54 had the highest death rate at about 30 fatalities per 100,000 people
Heroin accounts for \( \frac{1}{4} \) overdose deaths in 2015
  - *Triple the rate from 2010*

Other opioids such as oxycodone and hydrocodone accounted for another 24% of overdose deaths in 2015
  - *Down from 29% in 2010*

Highest overdose death rate in
  - WV
  - KY
  - NH
  - OH

*91% of people who overdose and survive are given another Rx for opioids*
How did we get here?

- Pain, the 5\textsuperscript{th} vital sign 1996 American Pain Society
- Urged to treat pain more aggressively
- The pain level is what the patient says it is
- Wider use of opioids for chronic non malignant conditions
- Financial empowerment of diversion
- Heavy marketing of opioid medications
How did we get here?

- Threat of being sued for under treatment of pain
- Asked to treat pain without the proper training or support to do so
- Belief that addiction does not occur if there is a true need for analgesia
- Poor education on addiction and mental health issues
- Patient satisfaction surveys?
  - Under the gun to write for meds
State Laws

- FAC 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain – Definitions

- FS 456.44 Controlled substance prescribing

REVIEW OF THE APPLICABLE STATE LAWS AND RULES
Pain

- An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage

Acute Pain

- The normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness
- It is generally time-limited and is responsive to opioid therapy, among other therapies

Chronic Pain

- A pain state which is persistent
  - Duration of 3 or more months

Chronic Nonmalignant Pain*

- 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
Addiction aka drug dependence and psychological dependence

- A neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm
  - Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction
  - A chronic relapsing brain disease
**Analgesic Tolerance**

- The need to increase the dose of opioid to achieve the same level of analgesia
  - Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction

**Tolerance**

- A physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or
- A reduced effect is observed with a constant dose
Physical Dependence

- A physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered.
- An expected result of opioid use.
- Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction

- A pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse

- The use of any substances for non-therapeutic purposes or
- Use of medication for purposes other than those for which it is prescribed.
Addiction medicine specialist*

- A board-certified psychiatrist with
  - a subspecialty certification in addiction medicine or
  - who is eligible for such subspecialty certification in addiction medicine

- An addiction medicine physician certified or eligible for certification by the ASAM

- An osteopathic physician who holds a certificate of added qualification in addiction medicine through the AOA
Board-certified pain management physician*

A physician who

- Possesses board certification in pain medicine by the American Board of Pain Medicine
- Has board certification by the ABIPP
- Has board certification or sub-certification in pain management
- Has board certification in pain medicine by a specialty board recognized by the AAPS or the ABMS
- Is an osteopathic physician who holds a certificate in Pain Management by the AOA
Board eligible*

- Successful completion of an a residency program approved by the ACGME or the AOA for a period of 6 years from successful completion of such residency program in the following areas:
  - Anesthesia
  - Physical medicine and rehabilitation
  - Rheumatology
  - Neurology
State Laws

- FAC 64B15-14.005 – Guidelines
- FS 456.44 Controlled substance prescribing*
- FAC 64B16-27 Pharmacy Practice**
Compliance with Controlled Substances Laws and Regulations

To prescribe, dispense, or administer controlled substances, the osteopathic physician must be:

- Licensed in the state
- Designate himself or herself as a controlled substance prescribing practitioner on his or her practitioner profile*
- Comply with applicable federal and state regulations

Osteopathic physicians are referred to the *Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970*, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.
Medical Records

Must keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate
2. Diagnostic, therapeutic, and laboratory results
3. Evaluations and consultations
4. Treatment objectives
5. Discussion of risks and benefits
6. Treatments
7. Medications (including date, type, dosage, and quantity prescribed)
8. Instructions and agreements
9. Drug testing results
10. Periodic reviews
Medical Records

- 11. A photocopy of the patient's government-issued photo identification*
- 12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription*
- 13. The registrant’s full name presented in a legible manner

Records must:

- Remain current
- Maintained in an accessible manner
- Readily available for review
- Must be in full compliance with Rule 64B15-15.004, F.A.C., and Section 459.015(1)(o), F.S.
Evaluation

- A complete medical history and physical examination must be conducted and documented in the medical record before beginning any treatment*

- The medical record shall document:
  - The nature and intensity of the pain
  - Current and past treatments for pain
  - Underlying or coexisting diseases or conditions
  - The effect of the pain on physical and psychological function
  - A review of previous medical records*
  - A review of previous diagnostic studies*
  - History of alcohol* and substance abuse
  - The presence of one or more recognized medical indications for the use of a controlled substance
Treatment Plan

- State objectives that will be used to determine treatment success such as
  - Pain relief
  - Improved physical function
  - Improved psychosocial function

- Indicate if any further diagnostic evaluations or other treatments are planned

- After treatment begins adjust drug therapy, if necessary, to the individual medical needs of each patient.

- Are other treatment modalities needed such as:
  - Osteopathic manipulative treatment and applications
  - Rehabilitation program
Treatment Plan

- Aberrant Behaviors*
  - Each registrant must develop a written plan for assessing each patient’s risk of aberrant drug-related behavior, which may include patient drug testing
  - Registrants must assess each patient’s risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan
Informed Consent and Agreement

Discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient’s surrogate or guardian if the patient is incompetent.

The patient shall receive prescriptions from one osteopathic physician and one pharmacy where possible.

If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the osteopathic physician shall:

- Employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:
  - 1. Urine/serum medication levels screening when requested;
  - 2. Number and frequency of all prescription refills; and
  - 3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement)
Informed Consent and Agreement*

The registrant shall discuss with the patient, persons designated by the patient, or the patient’s surrogate or guardian if the patient is incompetent:

- Risks and benefits of the use of controlled substances including
  - The risks of abuse and addiction,
  - Physical dependence and its consequences

The registrant shall use a written controlled substance agreement between the registrant and the patient outlining the patient’s responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills
2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.
3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating registrant unless otherwise authorized by the treating registrant and documented in the medical record
Periodic Review

Based on the individual circumstances of the patient, the osteopathic physician shall review the course of treatment and any new information about the etiology of the pain.

Continuation or modification of therapy shall depend on the osteopathic physician’s evaluation of progress toward stated treatment objectives such as improvement in:

- Patient’s pain intensity
- Improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life

If treatment goals are not being achieved, despite medication adjustments, the osteopathic physician shall reevaluate the appropriateness of continued treatment.

The osteopathic physician shall monitor patient compliance in medication usage and related treatment plans.
Consultation

- The osteopathic physician shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives

- Special attention to:
  - Pain patients who are at risk for misusing their medications
  - Those whose living arrangements pose a risk for medication misuse or diversion

- The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients

  - the management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or a psychiatrist
What do you do if the patient shows signs or symptoms of substance abuse?*

- Unless the registrant is a physician who is board-certified or board-eligible in pain management immediately refer patients to:
  - A board-certified pain management physician
  - An addiction medicine specialist
  - Mental health addiction facility

- Throughout the period of time before receiving the consultant’s report, a prescribing registrant shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient

- Upon receipt of the consultant’s written report, the prescribing registrant shall incorporate the consultant’s recommendations for continuing, modifying, or discontinuing controlled substance therapy

- The resulting changes in treatment shall be specifically documented in the patient’s medical record
What to do you do if their evidence of diversion?

- Evidence or behavioral indications of diversion shall be followed by *discontinuation of controlled substance therapy*

- The *patient shall be discharged*, and all results of testing and actions taken by the registrant shall be documented in the patient’s medical record
Who is exempt from 456.44?*

This subsection does not apply to:

- A board-eligible or board-certified:
  - Anesthesiologist
  - Physiatrist
  - Rheumatologist
  - Neurologist

- A board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services
Who is exempt from 456.44?*

This subsection does not apply to:

- A board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the ACGME or AOA
- A board eligible or board certified specialists in pain medicine by the American Board of Pain Medicine
- American Board of Interventional Pain Physicians, American Association of Physician Specialist
- A board approved by the ABMS or the AOA and performs interventional pain procedures of the type routinely billed using surgical codes
- A registrant who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395
How often must a patient be re-evaluated?

- The patient shall be seen by the registrant at regular intervals, *not to exceed 3 months*, to
  - Assess the efficacy of treatment
  - Ensure that controlled substance therapy remains indicated
  - Evaluate the patient’s progress toward treatment objectives
  - Consider adverse drug effects
  - Review the etiology of the pain
  - Monitor compliance in medication usage
  - Monitor compliance for related treatment plans
  - Monitor compliance with controlled substance agreements
  - Monitor for indications of substance abuse or diversion

- Continuation or modification of therapy shall depend on the registrant’s evaluation of the patient’s progress

- If treatment goals are not being achieved, despite medication adjustments, the registrant shall reevaluate the appropriateness of continued treatment
What are behaviors that will red flag a RX by a pharmacist?

The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

- (a) Frequent loss of controlled substance medications
- (b) Only controlled substance medications are prescribed for a patient
- (c) One person presents controlled substance prescriptions with different patient names
- (d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time
- (e) Patient always pays cash
- (f) Patient always insists on brand name product
Federal Laws

From DEA

State Laws***

FS 893

REVIEW OF THE APPLICABLE FEDERAL LAWS AND RULES
What is a prescription?

- A prescription is an order for medication which is dispensed to or for an ultimate user.
- A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user.
  - An order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription.
- To be valid, a prescription for a controlled substance must:
  - Be issued for a legitimate medical purpose by a registered practitioner.
  - Practitioner must be acting in the usual course of sound professional practice.
What information is required on a prescription for a controlled substance?

- A prescription for a controlled substance must include the following information:

  - Date of issue
    - A notation of the date in
      - Numerical, month/day/year format, or
      - Abbreviated month written out, or
      - Month written out in whole
What information is required on a prescription for a controlled substance?

- A prescription for a controlled substance must include the Patient’s name and address
- Practitioner’s name, address, and DEA registration number
- Drug name
- Drug strength
- Dosage form
- Quantity prescribed

   - Each prescription written by a practitioner in this state for a controlled substance listed in Schedule II, III, or IV must include:

     - a written notation of the quantity of the controlled substance prescribed and
     - a numerical notation of the quantity of the controlled substance prescribed
What information is required on a prescription for a controlled substance?

- Directions for use
- Number of refills (if any) authorized
- Manual signature of prescriber
What information is required on a prescription for a controlled substance?

- A prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner.
- An individual may be designated by the practitioner to prepare the prescriptions for his/her signature:
  - The practitioner is responsible for making sure that the prescription conforms in all essential respects to the law and regulation.
- Prescriptions for schedule II controlled substances must be written and be signed by the practitioner.
- Prescriptions for schedules III through V controlled substances may be written, oral or transmitted by fax.
- In emergency situations, a prescription for a schedule II controlled substance may be telephoned to the pharmacy.
What is an emergency situation?

Per § CFR 290.10 the term emergency situation means those situations in which the prescribing practitioner determines:

1. That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; **and**
2. That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, **and**
3. That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing

Must follow up with a written prescription being sent to the pharmacy within **seven days**

In an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled (FS 893.04 (F))***
Can controlled substance prescriptions be refilled?

- **Schedule II**
  - Cannot be refilled
  - A new prescription must be issued

- **Schedules III and IV**
  - May be refilled up to five times in six months
    - From date written***

- **Schedule V**
  - May be refilled as authorized by the practitioner
Can controlled substance prescriptions for hospice patients be faxed to a pharmacy?

- A prescription written for a schedule II narcotic substance for a patient enrolled in a
  - Hospice care program certified and/or paid for by Medicare under Title XVIII or
  - Hospice program which is licensed by the state
- May be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile
Can controlled substance prescriptions for hospice patients be faxed to a pharmacy?

- A pharmacist may dispense directly a controlled substance listed in schedules III, IV, or V pursuant to either:
  - A written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or
  - An oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist
    - A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state***
Is it appropriate to provide a DEA registration number on prescriptions written for medications other than controlled substances?

- DEA strongly opposes the use of a DEA registration number for any purpose other than the one for which it was intended, to provide certification of DEA registration in transactions involving controlled substances.

- The use of DEA registration numbers as an identification number is not an appropriate use and could lead to a weakening of the registration system.

- Although DEA has repeatedly made its position known to industries such as insurance providers and pharmacy benefit managers, there is currently no legal basis for DEA to prevent or preclude companies from requiring or requesting a practitioner’s DEA registration number.
Is it permissible to dispense a prescription for a quantity less than the face amount prescribed resulting in a greater number of dispensations than the number of refills indicated on the prescription?

- Yes. Partial refills of schedules III and IV controlled substance prescriptions are permissible under federal regulations provided that each partial filling is dispensed and recorded in the same manner as a refilling (i.e., date refilled, amount dispensed, initials of dispensing pharmacist, etc.)
  - The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
  - No dispensing occurs after six months past the date of issue

**NOTE:** This does not include schedule II
Can a practitioner prescribe methadone for the treatment of pain?

- Federal law and regulations do not:
  
  - Restrict the prescribing, dispensing, or administering of any schedule II, III, IV, or V narcotic medication, including methadone, for the treatment of pain, if
  
  - Such treatment is deemed medically necessary by a registered practitioner acting in the usual course of professional practice.

- If *methadone is used for the maintenance or detoxification* of opioid addicted individuals the practitioner is required to be registered with the DEA as a Narcotic Treatment Program (NTP)
Can a prescription be written for a patient to relieve acute withdrawal symptoms while arranging for the patient’s referral for treatment?

- An exception to the registration requirement, known as the "three day rule" [Title 21, Code of Federal Regulations, Part 1306.07 (b)]
  - Allows a practitioner who is not separately registered as a narcotic treatment program, to **administer (but not prescribe)** narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient’s referral for treatment, under the following conditions:
    - Not more than one day’s medication may be administered or given to a patient at one time
    - This treatment may not be carried out for more than 72 hours
    - This 72-hour period cannot be renewed or extended
What is meant by “acceptable medical practice?”

The legal standard that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice has been construed to mean:

- that the prescription must be “in accordance with a standard of medical practice generally recognized and accepted in the United States.”

Federal courts have long recognized that it is not possible to expand on the phrase “legitimate medical purpose in the usual course of professional practice” in a way that will provide definitive guidelines to address all the varied situations physicians may encounter.
What is meant by “acceptable medical practice?”

- While there are no criteria to address every conceivable instance of prescribing, there are recurring patterns that may be indicative of inappropriate prescribing:
  - An inordinately large quantity of controlled substances prescribed
  - Large numbers of prescriptions issued compared to other physicians in an area
  - No physical examination was given
  - Warnings to the patient to fill prescriptions at different drug stores
  - Issuing prescriptions knowing that the patient was delivering the drugs to others
What is meant by “acceptable medical practice?”

- Issuing prescriptions in exchange for sexual favors or for money
- Prescribing of controlled drugs at intervals inconsistent with legitimate medical treatment
- The use of street slang rather than medical terminology for the drugs prescribed
- No logical relationship between the drugs prescribed and treatment of the condition allegedly existing
What is meant by “acceptable medical practice?”

- Each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient.

- What constitutes “an inordinately large quantity of controlled substances,” can vary greatly from patient to patient.
  
  - A particular quantity of a powerful Schedule II opioid might be blatantly excessive for the treatment of a particular patient's mild temporary pain, yet insufficient to treat the severe unremitting pain of a cancer patient.
What is meant by “date of issuance?”

- The date a prescription is issued is the same date that the prescribing practitioner actually writes and signs the prescription.

Is there a time limit for filling Schedule II prescriptions?

- There is no federal time limit for filling Schedule II prescription.
- Some state laws do set time limits.
Are separate registrations required for separate locations?

- A separate registration is required for each principal place of business or professional practice where controlled substances are stored or dispensed by a person.

Does a practitioner need a separate registration to treat patients at remote health care facilities?

- Separate registration is not required:
  - In an office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and
  - Where no supplies of controlled substances are maintained.
Can a prescription for a controlled II be written for a 90 day supply?

An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

2. The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.

3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

4. The issuance of multiple prescriptions is permissible under applicable state laws.

5. The individual practitioner complies fully with all other applicable requirements under the Controlled Substances Act and Code of Federal Regulations, as well as any additional requirements under state law.
Can a prescription for a controlled II be written for a 90 day supply?

- It should be noted that the implementation of this change in the regulation should not be construed as
  - Encouraging individual practitioners to issue multiple prescriptions
  - Encouraging individual practitioners to see their patients only once every 90 days when prescribing schedule II controlled substances
- Individual practitioners must determine on their own whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so
  - Based on sound medical judgment
  - In accordance with established medical standards
REVIEW OF THE CURRENT FLORIDA STATISTICS REGARDING MORBIDITY AND MORTALITY OF CONTROLLED SUBSTANCE RELATED DEATHS
Drugs Identified in Deceased Persons by Florida Medical Examiners

2015 Annual Report
Highlights:

- Total drug related deaths increased 13.9% (1,197 more) when compared to 2014
- 5,364 (12.4% more than 2014) individuals died with one or more Rx drugs in their system (either cause of death or merely present)
- Prescription drugs continue to be found more often than illicit drugs both as the cause of death and present at death
DRUGS THAT CAUSE THE MOST DEATHS

- Benzodiazepines (1,140)
  - Alpazolam (588)
  - Diazepam (163)
- Cocaine (967)
- Morphine (895)
- Ethyl alcohol (810)

- Heroin (733)
- Fentanyl (705)
- Oxycodone (565)
- Methadone (290)
- Hydrocodone (236)
Frequency of Occurrence of Drugs in Decedents¹
January – December 2015

1The following drugs individually constituted less than 1 percent of drug frequencies and are not included: chlordiazepoxide, estazolam, flunitrazepam, flurazepam, midazolam, triazolam, all hallucinogens, all inhalants, buprenorphine, meperidine, carisoprodol/meprobamate, GHB, ketamine, sympathomimetic amines, synthetic cannabinoids, and zolpidem.

Note: Percentages may not sum to 100 percent because of rounding.
Comparison of Drug Caused Deaths
2013 to 2015

Note: Not all drugs are included in the above chart.
Occurrences of Alprazolam and Diazepam
(Present and Cause)
2006 to 2015

Number of Occurrences


Alprazolam Diazepam

2015 Medical Examiners Commission Drug Report
Historical Overview of Heroin Occurrences\(^1\)
(Present and Cause)
2001 to 2015

Prior to 2013, only deaths caused by heroin were provided in this graph. The graph has been updated to reflect deaths in which heroin was the cause of death or merely present at the time of death.
Historical Overview of Fentanyl Occurrences
(Present and Cause)
2003 to 2015

The number of fentanyl occurrences indicated includes occurrences of fentanyl analogs.
Why is fentanyl more deadly than heroin?

**Lethal dose:**

- Heroin: 30 mg
- Fentanyl: 3 mg
Occurrences of Hydrocodone, Oxycodone, and Methadone
(Present and Cause)
2006 to 2015

Number of Occurrences
Hydrocodone Oxycodone Methadone

0 500 1000 1500 2000 2500 3000

Hydrocodone Oxycodone Methadone

2015 Medical Examiners Commission Drug Report
New laws and enforcement reverse trends in oxycodone prescribing and related deaths in Florida

Deaths per 100,000 population

Prescriptions per 100,000 population

- Oxycodone prescriptions fell by 24%
- Deaths fell by 52% after years of increases

Florida 22.7%
OPIOID PHARMACOLOGY
Mode of action

- Effects located in the Central Nervous System
- Specific receptors in the brain for different narcotics lead to different side effects

Action on:

- μ-receptor (*Endorphins*)
  - Analgesia  Euphoria

- τ-receptor (*Dynorphines*)
  - Analgesia  Sedation

- δ-receptor (*Enkephalins*)
  - Analgesia  Dysphoria
Schematic representation of nociceptive pain

(Used with permission from, Pasero C, Portenoy R. Neurophysiology of pain and analgesia and the pathophysiology of neuropathic pain. In: McCaffery M, Pasero C, eds. Pain Assessment and Pharmacologic Management. St. Louis: Mosby, 2011:4–5, Figure 1-2.)
Sites of action on the pain transmission pathway from the periphery to the higher centers are shown.

(A) Direct action of opioids on inflamed or damaged peripheral tissues.

(B) Inhibition also occurs in the spinal cord.

(C) Possible sites of action in the thalamus. Different thalamic regions project to somatosensory (SS) or limbic (L) cortex. Parabrachial nuclei (medulla/pons) project to the amygdala.

(D) Rostral ventral medulla

(E) Locus coeruleus indirectly control pain transmission pathways by enhancing descending inhibition to the dorsal horn.

Spinal sites of opioid action:
The μ, κ, and δ agonists reduce excitatory transmitter release from presynaptic terminals of nociceptive primary afferents.

The μ agonists also hyperpolarize second-order pain transmission neurons by increasing K⁺ conductance, evoking an inhibitory postsynaptic potential (IPSP).
ACUTE EFFECTS

- Analgesia
- Sedation
- Euphoria
- Respiratory Depression
- Antitussive Actions
- Nausea & Vomiting

- GI Effects
- Smooth Muscle
- Miosis
- Flushing & Pruritis
- ADH & Prolactin release
- LH Inhibition
PROPER PRESCRIBING OF OPIATE DRUGS
Figure C. Risk of Overdose Events in Four Different Populations

Risk of Overdose Event

- Dunn 2010
- Bohnert 2011
- Gomes 2011
- Zedler 2014

Risk Ratio vs. Dose in mg MED

- <20 mg/day
- 20-49 mg/day
- 50-99 mg/day
- >=100 mg/day
CDC GUIDELINE

PROPER PRESCRIBING OF OPIATE DRUGS
An estimated 1 out of 5 patients with non cancer pain-related diagnosis are prescribed opioids.

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

Since 1999, sales of prescription opioids in the US quadrupled.

From 1999 to 2015 more than 180,000 people died from overdoses related to prescription opioids.

**PROPER PRESCRIBING OF OPIATE DRUGS**
CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

PROPER PRESCRIBING OF OPIATE DRUGS
Acute Pain: Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

- When opioids are used for acute pain, clinicians should:
  - Prescribe the lowest effective dose of immediate-release opioids and
  - Should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids
    - Three days or less will often be sufficient
    - *More than seven days* will rarely be needed
  - Long-term opioid use often begins with treatment of acute pain

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016
Recommendations and Reports / March 18, 2016 / 65(1);1-49
Chronic Pain: Determining When to Initiate or Continue Opioids

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
- If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
Chronic Pain: Determining When to Initiate or Continue Opioids

Before starting opioid therapy for chronic pain, clinicians should:

- Establish treatment goals with all patients, including realistic goals for pain and function, and
- Should consider how therapy will be discontinued if benefits do not outweigh risks

Clinicians should continue opioid therapy only if:

- There is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.
**Chronic Pain: Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation**

- Within 1 to 4 weeks of starting opioid therapy clinicians should evaluate benefits and harms with patients for chronic pain or of dose escalation
  - Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently
  - If benefits do not outweigh harms of continued opioid therapy:
    - Clinicians should optimize other therapies and
    - Work with patients to taper opioids to lower dosages or
    - To taper and discontinue opioids

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016
Recommendations and Reports / March 18, 2016 / 65(1):1–49
Chronic Pain: Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

- When starting opioid therapy for chronic pain, clinicians should:
  - Prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids
  - When opioids are started, prescribe the lowest effective dosage
  - Use caution when prescribing opioids at any dosage
  - Carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day
  - Avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016
Recommendations and Reports / March 18, 2016 / 65(1):1–49
Assessing Risk and Addressing Harms of Opioid Use

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.

- Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as:
  - History of overdose
  - History of substance use disorder
  - Higher opioid dosages (≥50 MME/day)
  - Concurrent benzodiazepine use, are present
Assessing Risk and Addressing Harms of Opioid Use

- Use state prescription drug monitoring program (PDMP) data to determine whether the patient is:
  - Receiving opioid dosages or
  - Dangerous combinations that put him or her at high risk for overdose
- Clinicians should review PDMP data:
  - When starting opioid therapy for chronic pain
  - Periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months
Assessing Risk and Addressing Harms of Opioid Use

- When prescribing opioids for chronic pain, clinicians should:
  - Use urine drug testing before starting opioid therapy and
  - Consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs
  - Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible
  - Offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder
Safeguarding your prescriptions

- Keep all prescription blanks in a safe place where they cannot be stolen, minimize the number of prescription pads in use.
- Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
- Use prescription blanks only for writing a prescription order and not for notes.
- Never sign prescription blanks in advance.
- Assist the pharmacist when they telephone to verify information about a prescription order;
  - A corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.
- Use tamper resistant prescription pads.
FS 893.13 Criminal Consequences

REVIEW OF PHYSICIAN LIABILITY FOR OVERPRESCRIBING CONTROLLED SUBSTANCES
A physician could be charged with culpable negligent homicide if one of his patients dies from a drug overdose.

A Florida doctor was found guilty of manslaughter yesterday in connection with the deaths of four patients from drug overdoses involving the powerful painkiller OxyContin.

A jury in a state circuit court in Milton, Fla., deliberated for a day before finding the doctor, James Graves, guilty of four counts of manslaughter, one count of racketeering and five counts of unlawful delivery of a controlled substance. Dr. Graves, who was once Florida's biggest prescriber of OxyContin, faces 30 years in prison.
A prescribing practitioner commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084 if they knowingly:

- Assist a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner’s professional practice
- Write a prescription for a controlled substance for a fictitious person
Third degree felonies:

- Employ a trick or scheme in the practice of the prescribing practitioner’s professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance

- Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner
Third degree felonies:

- A health care practitioner may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact with the intent to:
  - Provide a controlled substance or combination of controlled substances that are not medically necessary to his or her patient or
  - An amount of controlled substances that is not medically necessary for his or her patient,

For purposes of this paragraph, a material fact includes whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph
DIAGNOSIS OF OPIOID ADDICTION
<table>
<thead>
<tr>
<th>POTENTIAL ABERRANT DRUG-RELATED BEHAVIOR/EVENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Purposeful oversedation</td>
</tr>
<tr>
<td>• Negative mood change</td>
</tr>
<tr>
<td>• Appears intoxicated</td>
</tr>
<tr>
<td>• Increasingly unkempt or impaired</td>
</tr>
<tr>
<td>• Involvement in MVA or other accident</td>
</tr>
<tr>
<td>• Requests frequent or early refills</td>
</tr>
<tr>
<td>• Increased dose without authorization</td>
</tr>
<tr>
<td>• Reports lost or stolen Rx</td>
</tr>
<tr>
<td>• Demanding &amp; verbally abusive to staff</td>
</tr>
<tr>
<td>• Threatening; may be dangerous</td>
</tr>
<tr>
<td>• Attempts to obtain Rx from other doctors</td>
</tr>
<tr>
<td>• Changes route of administration</td>
</tr>
<tr>
<td>• Uses pain medication in response to stress</td>
</tr>
<tr>
<td>• Insists on Rx by name</td>
</tr>
<tr>
<td>• Contact with street drug culture</td>
</tr>
<tr>
<td>• Abusing ETOH or other drugs</td>
</tr>
<tr>
<td>• Hoarding Rx</td>
</tr>
<tr>
<td>• Arrested by police</td>
</tr>
<tr>
<td>• Victim of abuse</td>
</tr>
<tr>
<td>• Requests refills when office is closed</td>
</tr>
</tbody>
</table>
**EARLY SYMPTOMS**

- Agitation
- Anxiety
- Muscle Aches
- Increased tearing
- Insomnia
- Runny nose
- Sweating
- Yawning

**LATE SYMPTOMS**

- Abdominal cramping
- Diarrhea
- Dilated pupils
- Goose bumps
- Nausea
- Vomiting

**OPIOID WITHDRAWAL**
OPIOID ADDICTION TREATMENT OPTIONS
Methadone since 1965
  - Only in Opioid Treatment Program (OTP)
Office Based Opioid Treatment (OBOT)
  - Buprenorphine since 2002
    - Various Forms
    - Implantable
      - Probuphine
Adjunctive medications
  - Clonidine
Combined with other forms of individual or group counseling

OPIOID ADDICTION TREATMENT OPTIONS
FACING ADDICTION IN AMERICA

The Surgeon General’s Report on Alcohol, Drugs, and Health

U.S. Department of Health & Human Services
DISCUSSION
osteopathic physicians shall maintain written legible records on each patient. Such written records shall contain, at a minimum, the following information about the patient:

(a) Patient histories
(b) Examination results
(c) Test results
(d) Records of drugs prescribed, dispensed or administered
(e) Reports of consultations
(f) Reports of hospitalizations
64B15-15.004 Written Records; Minimum Content; Retention.

Medical records in which compounded medications are administered to a patient in an office setting must contain, at a minimum, the following information:

- (a) The name and concentration of medication administered
- (b) The lot number of the medication administered
- (c) The expiration date of the medication administered
- (d) The name of the compounding pharmacy or manufacturer
- (e) The site of administration on the patient
- (f) The amount of medication administered
- (g) The date medication administered
64B15-15.004 Written Records; Minimum Content; Retention

Whenever patient records are released or transferred, the osteopathic physician releasing or transferring the records shall:

- maintain either the original records or copies thereof
- a notation shall be made in the retained records indicating to whom the records were released or transferred

Whenever patient records are released or transferred directly to another Florida licensed physician, or licensed health care provider

- it is sufficient for the releasing or transferring osteopathic physician to maintain a listing of each patient whose records have been so released or transferred
- which listing also includes the physician or licensed health care provider to whom such records were released or transferred. Such listing shall be maintained for a period of five (5) years
64B15-15.004 Written Records; Minimum Content; Retention

In order that the patients may have meaningful access to their records pursuant to Section 456.058, F.S.:

- an osteopathic physician shall maintain the written record of a patient for a period of at least five (5) years from the date the patient was last examined or treated by the osteopathic physician

- However, upon the death of the osteopathic physician, the provisions of Rule 64B15-15.001, F.A.C., are controlling.
459.015 Grounds for disciplinary action; action by the board and department

- Failing to keep legible, as defined by department rule in consultation with the board, medical records that:
  - identify the licensed osteopathic physician or the osteopathic physician extender and supervising osteopathic physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that
  - justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.
What can be done? (CDC)

- Improve opioid prescribing to reduce exposure to opioids, prevent abuse, and stop addiction
- Expand access to evidence-based substance abuse treatment, such as Medication-Assisted Treatment, for people already struggling with opioid addiction
- Expand access and use of naloxone—a safe antidote to reverse opioid overdose
- Promote the use of state prescription drug monitoring programs, which give health care providers information to improve patient safety and prevent abuse
- Implement and strengthen state strategies that help prevent high-risk prescribing and prevent opioid overdose
- Improve detection of the trends of illegal opioid use by working with state and local public health agencies, medical examiners and coroners, and law enforcement

Appendix