FEDERAL & STATE LAWS RELATED TO THE PRESCRIBING OF CONTROLLED SUBSTANCES

Marc G. Kaprow, DO, FACOI

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DISCLOSURE

• ANY OPINIONS STATED HEREIN ARE SOLEY MY OPINIONS AND DO NOT REFLECT THE OPINIONS, POSITIONS OR STATEMENTS OF MY EMPLOYER.

• NOT CURRENTLY RECEIVING REMUNERATION (LAVISH OR OTHERWISE) FROM ANY PHARMA CUETICAL COMPANY, ETC.
OBJECTIVES

- Fulfill the requirement of 64B15-13(3)(e), Florida Administrative Code
  - Review of the applicable laws and rules
  - Current Florida Statistics re: Morbidity and Mortality of controlled substances
  - Opiate Pharmacology
  - Proper prescribing of Opiates
  - Review of Physician Liability
  - Diagnosis of Opioid Addiction / Treatment Options (New for 2016-2018)

- NOT GOING TO READ THE SLIDES TO YOU
FEDERAL LAWS AND RULES - SUMMARY

- Schedule II prescriptions must be filled within 1 year.
- No refills are permitted (can post date and indicate when fillable)
- MUST BE WRITTEN

- Schedule III prescriptions must fill within 6 months
- Up to 5 refills in 6 months allowed
- Written or telephone

- Physicians must be registered with the US DEA.
STATE RULES - SUMMARY

- Chapter 456 – Florida Statutes (General Health Professions Provisions)
- Chapter 459 – Florida Statutes (Osteopathic Medicine)
- Chapter 893 – Florida Statutes (Drug Abuse Prevention and Control)
- 64B-15 – Florida Administrative Code (Osteopathic Medicine)
- 64B-7 – Florida Administrative Code (Pain Management Clinics)
- 64-4 – Florida Administrative Code (Compassionate Use)
MAJOR CHANGES SINCE LAST BIENNIIUM

- Compassionate Use
- “Medical marijuana” course
- Low THC cannabis implementation
- “Right to Try” passed
- Amendment 2
UNCHANGED - PRIORITY

- State Approved Vendor for Rx Pads
- Controlled substance designation on Online Physician Profile
- PDMP Database NOT required
- Must follow documentation rules, including H&P, documentation of efficacy and social contract
- Telemedicine restriction
UNANTICIPATED CONSEQUENCES – PILL MILL

National Overdose Deaths
Number of Deaths from Heroin

Source: National Center for Health Statistics, CDC Wonder
Heroin, Codeine, GHB, PCP, Ketamine, Freon, Meperidine, all tracked inhalants, and Buprenorphine constituted less than 2% of the drug frequencies.

Note: Many of the deaths were found to have several drugs contributing to the death; thus, the count of specific drugs is greater than the number of cases.
Heroin, Codeine, GHB, PCP, Ketamine, Freon, Meperidine, all tracked inhalants, and Buprenorphine constituted less than 2% of the drug frequencies.

Note: Many of the deaths were found to have several drugs contributing to the death; thus, the count of specific drugs is greater than the number of cases.
Frequency of Occurrence of Drugs in Decedents
January – June 2015

- Oxycodone 5.3%
- Morphine 6.8%
- Ethanol 23.1%
- Codeine 2.1%
- Benzodiazepines 22.1%
- Cannabinoids 7.9%
- Cocaine 9.5%
- Fentanyl 4.0%
- Hydrocodone 3.6%
- Heroin 3.5%
- Hydrocodone 3.6%
- Methamphetamine 1.3%
- Methadone 2.4%
- Oxymorphone 1.7%
- Tramadol 2.4%
- Zolpidem 1.1%
- Amphetamine 1.8%

Buprenorphine, carisoprodol/meprobamate, cathinones, GHB, ketamine, meperidine, other sympathomimetic amines, synthetic cannabinoids, all tracked inhalants, and all tracked hallucinogenics individually constituted less than 1% of the drug frequencies and were not included.

Note: In many deaths, several drugs contributed to the death; thus, the count of specific drugs is greater than the number of cases.
### Comparison of Drug Occurrences in Decedents (continued)

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<thead>
<tr>
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<tbody>
<tr>
<td><strong>Inhalants</strong></td>
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<tr>
<td>Halogenated</td>
<td>19</td>
<td>25</td>
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<td>Helium</td>
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<td>13</td>
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<td>Hydrocarbon</td>
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<td>Nitrous Oxide</td>
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<tr>
<td>Buprenorphine</td>
<td>17</td>
<td>29</td>
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<tr>
<td>Codeine</td>
<td>128</td>
<td>209</td>
<td>63.3%</td>
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<td><strong>Opioids</strong></td>
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<tr>
<td>Fentanyl</td>
<td>201</td>
<td>397</td>
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<tr>
<td>Heroin</td>
<td>165</td>
<td>343</td>
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<tr>
<td>Hydrocodone</td>
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<td>0.0%</td>
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<tr>
<td>Hydromorphone</td>
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<tr>
<td>Meperidine</td>
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<td>5</td>
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<tr>
<td>Methadone</td>
<td>251</td>
<td>239</td>
<td>-4.8%</td>
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<tr>
<td>Morphine</td>
<td>540</td>
<td>670</td>
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<tr>
<td>Oxycodone</td>
<td>485</td>
<td>525</td>
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<tr>
<td>Oxymorphone</td>
<td>127</td>
<td>171</td>
<td>34.6%</td>
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<tr>
<td>Tramadol</td>
<td>309</td>
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<td>Cannabinoids</td>
<td>509</td>
<td>785</td>
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<tr>
<td>Carisoprodol/Meprobamate</td>
<td>93</td>
<td>64</td>
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<tr>
<td>Cathinones</td>
<td>74</td>
<td>89</td>
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<tr>
<td>Cocaine</td>
<td>749</td>
<td>840</td>
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<td>GHB</td>
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<td>Ketamine</td>
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<td>Sympathomimetic Amines</td>
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<td>Synthetic Cannabinoids</td>
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<tr>
<td>Zolpidem</td>
<td>116</td>
<td>104</td>
<td>-10.3%</td>
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</tbody>
</table>

*Due to the small number of occurrences, percent changes were not calculated.

Note: Many of the deaths were found to have several drugs contributing to the death, thus the count of specific drugs listed is greater than the number of cases.
TAKE HOMES

• Heroin, Fentanyl, Cocaine, Methadone biggest culprits for death

• Co-ingestant concerns:
  • Alcohol
  • Benzos
  • Marijuana

• Trending:
  • Heroin, Fentanyl, Cannabis

TRUST NO ONE – Check everyone
CITY AREAS

• Which area leads for deaths with:

  • Methadone
  • Fentanyl
  • Heroin
  • Cocaine
CITY AREAS

• Which area leads for deaths with:
  
  • Methadone – TAMPA / ST. PETE
  
  • Fentanyl
  
  • Heroin
  
  • Cocaine
CITY AREAS

• Which area leads for deaths with:

  • Methadone – TAMPA / ST. PETE

  • Fentanyl - ORLANDO

  • Heroin

  • Cocaine
CITY AREAS

• Which area leads for deaths with:
  • Methadone – TAMPA / ST. PETE
  • Fentanyl - ORLANDO
  • Heroin – WEST PALM BEACH
  • Cocaine
CITY AREAS

- Which area leads for deaths with:
  - Methadone – TAMPA / ST. PETE
  - Fentanyl - ORLANDO
  - Heroin – WEST PALM BEACH
  - Cocaine - MIAMI
NOWHERE IS SAFE
OPIATE 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

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

- **δ-receptor** (Enkephalins)
  - Analgesia
  - Dysphoria
OPIATES

- CNS effects (sedation / euphoria / dysphoria)
- All opiates bind opiate receptors
- Methadone also binds NMDA
- Non-Opiates may involve:
  - 5HT, GABA, cAMP, COX / PG, others
APPROACHING PAIN

• History

• Physical

• Assess and Classify

• Develop Plan of Care
HISTORY

- Palliating / Precipitating Factors
- Quality
- Radiation
- Severity
- Timing

Pain Scale

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<tr>
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<tr>
<td>0</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
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</table>

0-10 Scale
ASSESSMENT

- Primary vs. Secondary
- Etiology
  - Somatic
  - Neuropathic
  - Visceral
- Acute vs. Chronic
- Prognosis
PLAN

• Diagnostics
• Patient Education

• Treatment
  • Medications
    • Non-Opitate
    • Opiate
    • Adjunct
  • Non – Medication
    • OMT
    • Therapy
PRIMARY VS. SECONDARY

• Pain is the primary symptom of a condition (usually not treatable)
  • Post herpetic neuropathy
  • Fibromyalgia
  • Diabetic neuropathy
• Pain that is secondary to a treatable condition
  • Pseudotumor cerebri
  • Bone metastasis
  • Renal calculi

ALWAYS EVALUATE FOR AN UNDERLYING CAUSE AND TREAT
GENERAL PRINCIPLES

- Acute pain is treated acutely
  - Short acting agents
    - APAP
    - NSAIDS
  - Short acting opiates
- Chronic Pain is treated chronically
  - Long Acting Agents + Breakthrough
    - Long lasting NSAIDs
    - Long acting opiates
  - Consider adjunct treatments
SOMATIC

• Usually acute

• Responds well to NSAIDs

• Responds well to OMT

• Responds well to therapy

• Consider Opiates only when last option or post surgical repair (e.g. ORIF)
VISCERAL

- Often secondary
- Must address underlying cause
- Moderate response to opiates
- Structural exam may be of benefit for diagnosis or later treatment
NEUROPATHIC

• Chronic, often progressive

• Poor response to opiates (except methadone)

• Anticonvulsants / Antidepressants / Other adjuvants most beneficial

• OMT may have limited benefit
SIDE EFFECTS

- Histamine release
- Pupillary Miosis
- CONSTIPATION
- Muscle spasm / fasiculation
- Somnolence
TO TREAT OR NOT TO TREAT?

• Is there a history of or high risk for addiction or abuse?

• Are there any high risk co-ingestants?

• How many cooks are in the kitchen?

• E-Forsce

• Have I CLEARLY documented why I am doing what I am doing?
SELECTION POINTS

- Morphine
  - Gold standard
  - PO / IV
  - Short / Long Acting
  - Pronounced histamine release
  - METABOLICALLY ACTIVE METABOLITES

- Consider other meds / forms as appropriate
  - Oxycodone, Hydrocodone, Codiene,
  - Fentanyl
  - Hydromorphone
SUBSTANCE USE DISORDERS

- DSM-V no longer refers to addiction; SUBSTANCE USE DISORDERS
- Defined by
  - Clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.
- Criteria
  - Evidence of impaired control
  - Social impairment
  - Risky use
  - Pharmacological criteria
SOME FLAGS OF OPIOID USE DISORDER

- Doctor shopping (check E-FORSCE)
- Jittery / Secretive / Belligerent
- Track marks if injecting / Other physical signs of smoking or inhaling / Paraphernalia
- Risk taking (sex for money, sharing needles, new STIs)
- Shifts in Grooming / Support system / Moods
- Physical manifestations
- Co ingestants
TREATMENT OPTIONS

- Should be multi-modal and include:
  - Detoxification
  - Behavioral healthcare / Counseling
  - Screening for co-morbid mental health conditions (depression, anxiety, etc.)
  - Medication (e.g. Methadone, Suboxone)
  - Long term follow up

- Specific training and certification available for Suboxone
- Behavioral health referral
FOR EXPERIENCED CLINICIANS ONLY

- Methadone
- Morphine / Naltrexone
- Oxymorphone
- Buprenorphine
- Tapentadol (Nucynta)
- Meperidine
THINGS TO REMEMBER

• Always use the gut if you can
• Co-administered diphenhydramine is for the histamine release, not the high
• EVERYONE GETS A STOOL SOFTENER / LAXATIVES
• Itch does not equal allergy
• True opiate allergy excludes ALL opiates
• 15 is not a number on the pain scale
• The PDMP is your friend
• The Pharmacist is an even better friend
• You are a physician, not a drug dealer – even though you both carry a “pager”
• The PDR is not a menu
ORANGE IS THE NEW WHITE (COAT)

• Don’t clone your notes
• Don’t prescribe if your gut tells you not to
• Beware the medical marijuana – document as if your license depends on it
• Keep copies of everything (Rx, etc.) and write what every drug is for
• Be aware for inappropriate behavior
• When in doubt – refer to a behavioral health specialist

• Don’t prescribe opiates for anyone you are not willing to discharge from your practice.

• Physicians charged are NOT doing the right thing – very small percentage. Don’t be afraid of the meds.
QUESTIONS?