Federal and State Laws Relating to Prescribing of Controlled Substances

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Disclosure

- No financial or other material conflicts of interest
- This is not legal advice
- These comments are not representative of any institution or organization
Outline

- Federal laws on prescribing controlled substances
- Florida laws and rules on prescribing controlled substances
- Current Florida statistics regarding M&M of controlled substance-related deaths
- Pharmacology of opiates
- Proper prescribing of opiates
- Physician liability for overprescribing controlled substances
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- 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 prescribe controlled substances are required to obtain a DEA certificate
- Physicians who write or dispense controlled substances for detoxification must be separately registered for that purpose
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“Chronic nonmalignant pain”

- Pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery

Fla. Stat. Section 456.44 controlled substance prescribing
Physician requirements – 1

- Identify as a controlled substance providing practitioner on DOH profile
- Satisfy medical records req’s
  - Conduct and document a physical exam before tx
  - Document current and past tx for pain, inc Rx from prior physicians
  - Show a review of previous medical records (must request them if immediately unavailable)
- Records must be individualized (no template)
- Photocopy of gov’t-issued photo ID (usually DL)
- Drugs prescribed
Physician requirements – 2

- Document a tx plan with pt-specific objectives
- With pt, co-sign controlled substance agreement
- Discuss abuse and addiction risks with pt
- Meet with pt no more frequently than q3mos
  - Assess tx
  - Monitor addiction risk
  - Evaluate potential drug-related aberrant behavior
  - Unless certified in pain mgmt, pts with abuse sx must be referred
    - Board-certified pain mgmt physician
    - Addiction medicine specialist
    - Mental health facility for abuse/addiction
Physician requirements – 3

- If referred, physician must document medical justification for ongoing prescriptions
- After receiving report from consultant, physician must incorporate recs in further tx of pt

Exceptions

- Neoplastic pain may be tx with C-II – IV agents without necessitating registration as a controlled substance provider nor does it require abiding by the other reqs
- Pain prompted by injury that follows its usual course
- Prescription for indication other than chronic nonmalignant pain (e.g., BZD for anxiety)
Pain Management Clinics

- Any location that:
  - Advertises pain mgmt services...must register
  - In any month, prescribes opiates, BZDs, barbs, or carisoprodol for tx chronic nonmalignant pain for most of its pts...must register

- Even if the owner/mgmt/business name is the same, each clinic...must register separately

- Physicians generally must own the clinic

- Exception: if most physicians primarily do surgeries...does not have to register

Fla. Stat. Section 459.0137 pain-management clinics
Physician responsibilities

- Notify BOOM within 10 days of beginning/ending practice in a pain mgmt clinic
- Comply with the clinic’s physical & operational, infx prevention & control, health & safety, QA, and data collection & reporting req’s
  - Each DO is responsible for ensuring clinic’s compliance with above
- Pain mgmt clinics must designate a physician as the responsible party for its registration & operational req’s
March 2010 – June 2012 registrations

Number of Pain Clinics

0 200 400 600 800 1000 1200

Mar-10 May-10 Jul-10 Sep-10 Nov-10 Jan-11 Mar-11 May-11 Jul-11 Sep-11 Nov-11 Jan-12 Mar-12 May-12
Training requirements

- Effective 7/1/12
  - Successful completion of an AOA- or ACGME-accredited pain mgmt residency or fellowship

Fla. Admin. Code Ann. r. 64B15-14.0051
Prior to 7/1/12 (one of the following)

1. Specialty certification in pain medicine
2. Completion of post-graduate pain mgmt training
3. Completion of AOA/ACGME residency in PM&R, anesthesiology, neurology, neurosurgery, or psychiatry
4. Completion of AOA residency in FM, IM, or orthopedics
5. AOA certification in hospice, pall care, or geriatrics
6. Current hospital staff privileges for pain medicine
7. 3yrs of documented full time practice
   - 20hrs/wk each year in pain mgmt
   - 40hrs, live, in-person AMA-I/AOA-Ia CME in pain mgmt
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## Drugs Identified in Deceased Persons by Florida Medical Examiners

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2014*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5,647</td>
<td>3.4%</td>
</tr>
<tr>
<td></td>
<td>2,710</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>7.4</td>
<td>24.2%</td>
</tr>
<tr>
<td></td>
<td>1,516</td>
<td>102.9%</td>
</tr>
<tr>
<td></td>
<td>27.9% (2009)</td>
<td>16.3%</td>
</tr>
<tr>
<td></td>
<td>$3.6B</td>
<td></td>
</tr>
</tbody>
</table>

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## Receptor activity

<table>
<thead>
<tr>
<th></th>
<th>Mu</th>
<th>Delta</th>
<th>Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesia</td>
<td>Analgesia with fewer adverse effects</td>
<td>Mild analgesia</td>
<td></td>
</tr>
<tr>
<td>Sedation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Euphoria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory depression</td>
<td></td>
<td>Less respiratory depression</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical 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>Butorphanol</td>
<td></td>
<td>Naltrexone</td>
</tr>
<tr>
<td>Oxycodone</td>
<td></td>
<td>Nalbuphine</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Opioid comparison

<table>
<thead>
<tr>
<th>Medication</th>
<th>Onset</th>
<th>Duration</th>
<th>Equianalgesic dose</th>
</tr>
</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>
</tbody>
</table>
# Opioid allergy

<table>
<thead>
<tr>
<th>Phenanthrenes</th>
<th>Piperidine/phenylpiperadine</th>
<th>Deiphenylheptanes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>Fentanyl*</td>
<td>Methadone*</td>
</tr>
<tr>
<td>Hydromorphone*</td>
<td>Meperidine</td>
<td>Propoxyphene</td>
</tr>
<tr>
<td>Oxymorphone*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodone*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Controlled substance class 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>Chlortal 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>
</tr>
<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>
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- Be sensitive to psychological issues
- Adhere to pain mgmt contract
  - Sincere ongoing communication
  - Consider regular urine drug testing
- Note signs of abusive behavior
  - Nuisance office calls
  - Lost Rx
  - Early refills
- CAGE-like screening each visit
- Adherence to prescription-writing requirements
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.htm
Components of a legitimate 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 (eg, address, phone)
Example

Dr. John Smith
1234 Main Street
Anytown, Florida
954-555-1948

Date: February 11, 2014
Patient Name: Jane Smith                        DOB: 05/29/1966
Address: 1111 Center Lane, Anytown, Florida 33312
Percocet (5/325)
Disp. # 60 (Sixty)
Sig: Take one tab by mouth every 6 hours PRN post-op pain
No Refills
DEA #_________  Signature_________
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 June 30, 2015 -

- Dispensing Records Uploaded
  - 145,696,235

- TOTAL Practitioner Registrations
  - 30,339

- Total Patient Advisory Reports Requested
  - 19,389,253
Fla. Stat. Section 893.055, requires reporting to the PDMP each time a controlled substance is dispensed to an individual.

Reporting via the electronic system as soon as possible, but not more than 7 days after dispensing.

Reporting timeframe ensures that health care practitioners have the most up-to-date information available.

E-FORCSE complies with the Health Insurance Portability and Accountability Act (HIPAA).
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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
Conclusion

- Medical history & physical exam prior to beginning treatment
- Detailed medical records are a must
- Written treatment plan for assessing and monitoring risk
- Controlled substance agreement
- Regular follow up as least every three months
- Referral as necessary
Thank you

Special thanks to David A. Lips, attorney
Hall, Render, Killian, Heath & Lyman, P.C.
Indianapolis, IN

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