Federal and State Laws Relating to Prescribing of Controlled Substances

FOMA

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Purpose & Disclosures

• If one is not residency trained in pain fellowship or anesthesia once a prescription is written for a controlled substance your care is viewed as those of a pain management expert.

• As a physician it is your duty to care for your patient’s pain safely, however if treatment goals are not met have your patient re-evaluated by another consultant.

• I am not here to give you legal advice nor tell you how to treat pain

• I am not here representing the BOOM

• No disclosures
5 Most Misdiagnosed Cases for Preceding Biennium (64B15-13)

**** 1. Inappropriate opioid prescribing to patients of undiagnosed psychiatric condition and/or diversion.
2. Failure / delay in diagnosing cancer.
3. Retained foreign body/ wrong site/ wrong patient
4. Surgical complications/ errors / pre op evaluations
5. Prescribing, dispensing, administering or using non FDA meds or devices.
Purpose

– Knowledgeable about the controlled substance prescriber registration and standards of practice

– Inform you about the requirements for pain management clinics

– Overview of federal laws
Pre test questions?

• A board certified FP/GP/internist are working part-time in a pain clinic. Who is responsible to register the pain clinic?
  – A. The pain clinic owner
  – B. The lawyer for the pain clinic
  – C. You as an employee must verify that the clinic is registered.
  – D. You should not worry because the lawyer/medical director for the pain clinic will take care of it.
Pre test questions

• Who are not exempt from registering when practicing in a pain management clinic?
  • 1. anesthesiologists
  • 2. physiatrists
  • 3. neurologists
  • 4. rheumatologists
  • 5. family medicine physicians
  • 6. surgeons who perform surgical interventions
Pre test questions

• If working in a pain management clinic how many days do you have to notify the board in writing of your termination with the pain management clinic?
  – 1. 7 days
  – 2. 10 days
  – 3. 14 days
  – 4. 30 days
Pre test questions

• What is the minimum amount of time must a doctor see a chronic pain management patient for periodic review and refills?
  • 1. 30 days
  • 2. 60 days
  • 3. 90 days
  • 4. 120 days
Pre test

• What is the best way to protect your medical license – property asset?

1. Maintain your medical records
2. Good communication with patients- be their friend-give them your cell phone #
3. Utilize universal precautions
4. None of the above
Controlled substances

• Chapter 893, F.S. sets forth the Florida Comprehensive Drug Abuse Prevention & Control Act

• The act also provides requirements for the px and administrating of CS by health care practitioners & proper dispensing by pharmacists & health care practitioners
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
Pain Management Clinics

• Any facility that:
  • Advertises in any medium for any type of pain management services; or
  • Where any month, a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

• S.459.0137 FS (DO)
Pain management clinic

• Only a physician licensed under FS chapter 458 or 459 may dispense medication or prescribed CS regulated under Chapter 893, F.S. on the premises of a registered pain management clinic

• PA’s and ARNPs are not allowed to px CS, regulated under Chapter 893 in PMC
Physician assistant

• Effective January 1, 2017 PAs are authorized to prescribe CS
• A supervising physician may delegate to a fully licensed PA, the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed a formulary established section F.S. 458.347 (4) (f) or F.S. 459.022
PA formulary

• Includes general anesthetics and radiographic contrast materials
• The formulary must also limit the prescription of CS II as listed in Section 893.03 F.S. to a 7 day supply
• Formulary must restrict the prescribing of psychiatric mental health CS for children < 18yo
Advanced registered nurse practitioners

• Effective January 1, 2017 ARNPs are authorized to px, dispense, administer, or order any drug within an established supervisory protocol.

• May px, or dispense CS as defined in s (893.03), FS only if he or she had graduated from a program leading to a master’s or doctoral degree in clinical nursing specialty area with training in specialized practitioner skills.
Controlled substance formulary

- Rule 64B9-4.016 FAC become effective 10/16/2016
- Rule provides ARNP may only prescribe CS to the individual’s education, training, experience and protocol
- Must restrict px of CS listed 893.03 FS to 7 day supply
- Does not apply to psychiatric medications px by a psychiatric nurse in 394.455. FS
ARNP formulary

• Only ARNP who meet the definition of a psychiatric nurse, 394.455 may prescribe psychiatric mental health controlled substances to children younger than 18 years of age.
Drug enforcement administration

- Any health care profession wishing to px CS must apply for a registration # from the DEA housed within the US DOJ
- Registration # are linked to state licenses & may be suspended or revoked upon any disciplinary action taken against a licensee.
Prescribing practitioners

• A pharmacist in good faith in the course of professional practice only, may dispense CS upon a written or oral prescriptions of a practitioner.
• Prescription – order for drugs written, signed, or transmitted by word of mouth, telephone or other means of communication by a duly licensed practitioner licensed to prescribe such drugs, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so.
F.S. 456.44 (2) prescribing

A **physician** licensed under Chapter 458, 459, 461, or 466,

**PA** licensed under Chapter 458 or 459, or an

**ARNP** certified under Chapter 464-Part 1 who prescribes any CS, listed in Schedule II, III, or IV, in Section 893.03

FS must designate himself or herself as a CS prescribing practitioner on his or her practitioner profile, for the treatment of chronic nonmalignant pain.
www.flhealthsource.com

- Click on “Licensee/provider”
- Click on “update profile”
- Log in selecting your profession
- User ID and Password were mailed with your physical license
- If you do not recall your user id “Get login help” 1-850-488-0595 option 3
Standards of practice 64B15-14.005

• (3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.
Guidelines- evaluation

• (a) **A complete medical history and a physical examination** must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, 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, previous diagnostic studies, and history of alcohol and substance abuse.
• The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. 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.
(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.
64B15-14.005-informed consent

• (c) The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient’s surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician 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 physician unless otherwise authorized by the treating physician and documented in the medical record.
(d) The patient shall be seen by the physician 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, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician’s evaluation of the patient’s progress.
64B15-14.005

• If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.
(e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and 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 co-morbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addictionologist or psychiatrist.
64B15-14.005

• (f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:
1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.
64B15-14.005

• 7. Medications, including date, type, dosage, and quantity prescribed.
• 8. Instructions and agreements.
• 9. Periodic reviews.
• 10. Results of any drug testing.
• 12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.
• 13. The physician’s full name presented in a legible manner.
Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant’s report, a prescribing physician 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 physician 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. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient’s medical record.
E-Forcse- PDMP

- The Electronic - Florida Online Reporting of Controlled Substances Evaluation program
- Safer prescribing of controlled substances
- Reduce drug abuse and diversion by identifying the doctor shoppers or trying to obtain multiple px for CS from multiple healthcare px (felony)
- Guide doctors in their decision making
- Recent updates- one can check their DEA prescribing history for accuracy
- Link to Alabama PDMP
- Icon EMR for E-Forsce
E-forcse

- Section 893.055, Florida Statutes, requires health care practitioners to report to the PDMP each time a controlled substance is dispensed to an individual.
- This information is to be reported through the electronic system as soon as possible but not more than 7 days after dispensing.
- This reporting timeframe ensures that health care practitioners have the most up-to-date information available.
- E-FORCSE will comply with the Health Insurance Portability and Accountability Act (HIPAA)
FS 893.0551  drug abuse prevention & control

• I certify that the person for whom I am requesting a Patient Advisory Report for is under my care.

• I understand that inappropriate access or disclosure of PDMP data is a violation of section 893.0551, Florida Statutes, and a third degree felony
• E-forcse

• In addition to practitioners and pharmacists, law enforcement agency may request confidential CS dispensing information in the database during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed CS

• DOH ISU & Medicaid Fraud Unit may request info from the database investigation of cases involving CS
• E-forcse delegated authority

• As of 2/14/2017 a designee or a prescriber or dispenser may have direct access to CS dispensing information in the PDMP

• Rule 64K-1.003 (3) F.A.C. sets for the requirements

• Also allows consultants of PRN to review data
HB 557

• As of 1/1/2018 requires a dispenser to upload CS dispensing inform no later than the close of the business the day following the dispensing of a CS to a PDMP

• Also expands access to employee of the VA to review a patient’s CS hx
HB 5203

- AUTHORIZES THE USE OF GENERAL REVENUE STATE FUNDS FOR ADMINISTRATION OF PDMP
Other states PDMP

• As of July 2017, thirty-six states and the District of Columbia require prescribers to query the PDMP in specified circumstances, with 27 states requiring it at the initial prescribing of a designated substance and nine states at each prescribing of a substance.
What generates administrative complaint (AC)?

- Death of patient
- Ex-employee – angry
- Another physician
- Angry patient
- Newspaper article
- Pharmacy
- Arcos data (automation of reports and consolidated orders system)—one pharmacy in Boca Raton had more controlled substances delivered there one year that the state of California. This will alert law enforcement.
- Medicaid AHCA drug utilization review – Medicaid fraud dept.
What generates complaint?

- Complaints by nearby business owners regarding patient loitering in the parking lots.
- 459.016 reports of disciplinary actions by medical organizations
- Civil case which them may become an administrative complaint
- FL dept. of law enforcement

To conduct an investigation the complaint is usually signed by the individual. These pain clinics are processed in a coordinated effort with Florida law enforcement, DEA, and DOH investigators.
• **Cases are built**

• When a probable cause panel meet 
PSU will have brought sufficient evidence 
to file an administrative complaint. Undercover cops 
wire taps, records, prescriptions, pharmacy files, 
testimony, are used to build a case.

• If there is concern of patient safety The State Surgeon 
General may have already issued ESO/ERO to protect 
the public before the PCP meets.
Cases

• Undercover cops may pose as patients wire tapped for audio/visual
• Interesting to see on video surveillance that the physician did not even touch the patient
• Charts documents complete exam??
Red flags in the medical records

- Charts templates all very similar-written or EHR
- after 30-40 hours of review they appear to look very similar – a pattern
- Muscular-skeletal exam is deficient as it related to the chief complaint
- medical record documentation has no request for old records
- Initial urine drug testing, periodic duty for compliance
- Declines PE or permission to obtain old records or undergo diagnostic testing or periodic udt
Red flags

• MRI templated reports
• For example one diagnostic center reporting schmorl’s nodes (after review of 7-8 patient cases they all had schmorl’s nodes)
• Bullet on x-ray films (old records) and MRI done?
• Validity of report questionable from the MRI center
Red flags in the medical record

• Current Medical history indicating alprazolam, hydrocodone from previous physician but urine drug screening
  – positive THC-no benzo no metabolite of hydrocodone
  – Dispensing controlled substances in patient with positive udt for THC and Cocaine or Barbiturate?
Red Flags in the Medical Record

- Copies of Prescription illegible
  violation of federal law
CII prescriptions to be written on separate prescription and not with another legend drug
Textual format when writing prescriptions.
Red Flags

• Surveillance tapes- Office staff addressing the physician- as ”Percocet queen”
• Old records not requested
• Out of state government id cards
• No drivers licenses - had this patient had a DUI?
Red flags

• Treatment plan related
• Resists changes in treatment plan despite clear evidence of adverse physical or psychological effects
• Refuses to sign or fail to comply with opioid agreement
Red Flags-Board of Pharm/DEA

- Indicative of substance abuse or diversion
- DEA/National Association of Boards of Pharmacy/Stakeholders- consensus statement-
- red flags maybe raised by the pharmacist
Red flags @Pharmacy

• Initial visit
  – Patients travel to office or pharmacy as a group
  – Request CS the same day
  – Unexplained long distance travel
  – Pt appears seated, confused, intoxicated or exhibits withdrawal symptoms
Red flags@Pharmacy

• Patients behavior/communication
• PDMP indicates pt is obtaining CS rx from multiple providers without prescriber’s knowledge
Red flags

• Illicit/ illegal
• Altered prescription, fraudulent prescription, or patient rewrites a prescription
• Prescription not correctly written on fraud proof paper
• Incomplete Prescription
Other issues found

• Administrative complaint may have other aspects of care addressed besides inappropriate prescribing
• Pre-signed prescription pad 459.015 (1)z (ee)
• 459.0137 (2) 1(a) Not working in a registered pain clinic
AC issues

- 459.015 (o) medical records failing to keep legible medical records that justify the course of treatment including but not limited to patient histories, examination results, test results, records of drugs prescribed, dispenses or administered and reports of consultations and hospitalization.
Other issues AC

- 459.015 (t) Inappropriate prescribing, dispensing, administering, supplying, selling, giving, mixing of controlled substances, not in the best interest of the patient.

- 459.015 (rr) 8 dispensing any medicinal drug not based upon a valid practitioner-patient relationship
Administrative complaint

- 459.015 (rr) 9
- Failing to notify the board of the date of his or her termination from a pain management clinic as required by s.459.0137 (2)
- 459.015 9 (ss) Failure to timely notify the department of the theft of prescription blanks from a pain management clinic or a breach of other methods from prescribing within 24 hours
Administrative complaint

- 459.015 (rr) 9
- Failing to notify the board of the date of his or her termination from a pain management clinic as required by s.459.0137 (2)
- 459.015 9 (ss) Failure to timely notify the department of the theft of prescription blanks from a pain management clinic or a breach of other methods from prescribing within 24 hours
Most common AC

• 459.015 (1)(x) committing malpractice by violation of
• 459.015 (1)(l) by prescribing, dispensing, administrating, supplying, selling, giving, mixing or otherwise preparing a legend drug including any CS other than in the course of DO professional practice (inappropriate or excessive)
• Failing to follow the guidelines for use of CS 459.015(1)(pp)
• Failing to maintain legible treatment records 459.015 (1)(o)
Impact of legislation

- Judicious use of controlled substances
- Increased use of nonscheduled medications to treat chronic pain
- Increased modalities incorporating lifestyle changes & physical therapy
- Less physician inertia regarding reevaluation of chronic pain patients
Impact of legislation

- Referral for consultation when goals not met-as part of your re-evaluation
- Re-evaluate your patient with additional diagnostic testing
- Access to care may be a problem especially for Medicaid recipients. Neurologist, orthopedic, heme/oncologist assist in the community to fill the niche.
Impact on legislation

- Active D.O. 5494 total 7759
- Active M.D. 49514 total 73441
- PMC 2015-2016 emergency action 1
- 54 complaints probable cause 9
- 22 legally sufficient AC 5

< 1% of physicians disciplined CS violations.
Prescribers of controlled substances for the treatment of chronic pain

- MD 24.939% registered
- DO 32.770%
- Dentist 15.853%
- Podiatrist 33.909%
Privacy breach undermines pill mill database

- Names, addresses, phone numbers, pharmacies and drug dosages prescribed to about 3300 Floridians found its way into the hands of lawyers involved in the prosecution of six prescription-drug fraud cases in Central Florida.
27% Decrease in Oxycodone Deaths in Florida Between 2012-2013

Source: Drugs Identified in Deceased Persons by Florida Medical Examiners 2013 Report
Figure 11 depicts the mortality rate per 100,000 population for five classes of prescription drugs from 2003 to 2013.

The oxycodone-caused death rate steadily increased since 2005 and peaked in 2010 (8.0 per 100,000). In the subsequent three years, the rate decreased to 2.7 per 100,000 (2013), the lowest since 2006. The mortality rate for methadone and the benzodiazepine, Alprazolam, have also declined since 2010. Deaths from methadone are at their lowest rate (2.0 per 100,000) since 2003. The trend for hydrocodone has been relatively stable over the ten-year period.

Figure 11. Annual mortality rates caused by the major prescription drugs in Florida, 2003-2012
Treatment addiction-unintended consequence

- **Florida Addiction Treatment Statistics**
  - In 2009, the government's lead agency on substance abuse, SAMHSA reported a total of 79,322 admissions into Florida alcohol and drug rehabilitation centers. Of that number, 61.7% were male and 38.3% female.

- **Florida Alcohol & Drug Rehab Admission Statistics for 2009**
  - Drug admissions for treatment have increased from 21% in 1992 to 46% in 2006.

- For all those seeking comprehensive treatment, the National Survey of Substance Abuse Treatment Services reported that in 2006, only 228 facilities of all the treatment programs in the state offered some type of residential care.
Total Admissions = 79,322
Comparison of Drug Caused Deaths
January 2015 – June 2016

Note: Not all drugs are included in the above chart.
Deaths Caused by Hydrocodone, Oxycodone and Methadone
2005 to 2014
Abuse deterrent opioids

Studies have demonstrated a 25% to 45% reduction of OxyContin abuse and a reduction of 20% in the estimated prescription opioid overdose rate.

Despite these encouraging statistics, there are other factors to be considered with regard to abuse- deterrent opioids (ADOs). Unfortunately, no opioid formulation can prevent people from swallowing a large number of intact tablets or capsules, which is the most common method of abuse.

There is also great concern about ADOs partially driving the current nationwide increase in heroin use. The same study demonstrating a 20% reduction in prescription opioid overdose rates also found a 23% rise in heroin overdoses during the same time period.
ADDO/ Opioid substitution

- 2016 Public health crisis SE Indiana
- 181 tested HIV +
- Close network of residents injecting Oxymorphone (opana) and sharing needles
- Chilling prescribing, PDMP check by dispensers
- 7 day initial supply for new patients (IN)
Unintended consequences

• 2012 Broward County addiction treatment centers have seen an 87% spike of admissions among addicts using heroin 169-316
  Supply and Demand Theory applies
    $10 dime bag of heroin
    30mg oxycodone $30-$80 per tablet

• Surge in the number of people now hooked on heroin. With crackdowns focusing on siphoning off supplies rather than treating addiction, people are finding that heroin, which yields a high similar to the oxycodone.

www.sunsentinel 2/15/13 Nicole Brochu “Heroin Taking Oxy’s Place for more Addicts”
Unintended consequences

• Broward County bath salt “Flakka” alpha PVP
• $3-$5 per dose
• Unpredictable synthetic stimulant
• No urine drug testing
• No reversal agent

• www.sunsentinel.8/10/15
456.0137 pain mgmt clinics

• 1. (a) Registration
• Advertise in any medium for any type of pain mgmt
• Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the tx of chronic nonmalignant pain.
• S459.0137
459.0137 pain clinic registration

- exemptions
- If licensed as facility chapter 395
- The majority of the physicians who provide services in the clinic provide surgical services
- The clinic is owned by a publicly held corporation who shares are traded on a national exchange or whose assets total >$50 Million
- Affiliated with an accredited medical school at which training is provided for medical students, residents or fellow
459.0137 pain clinic exemptions

Corporate entity under 26 U.S.C. s. 501 c(3)
Owned and operated by one or more board certified anesthesiologist, rheumatologists, physiatrists, neurologist or
If owned by a fellowship trained pain medicine
Each clinic shall be registered separately regardless of owner
459.0137

- The DOH shall deny registration to any clinic that is not fully owned by a physician licensed under chapter 458/459 or a group of physicians.

- Termination of employment - must notify DOH in writing of the date of termination within ten calendar days (return receipt).
Responsibilities-PMC facility & Physical operations

• Each physicians practicing a pain clinic is responsible for ensuring compliance with the facility and physical operations requirements

• Sign

• Hours

• Public listed telephone number and fax that is operational 24 hours per day
Pain Clinic Responsibilities

• Emergency lighting and communications
• Reception and waiting area
• Restroom
• Private patient exam room
Pain clinic responsibilities

- Infection control
- Health and safety hazards
- Quality assurance requirements
- Data collections and reporting requirements
  Repeat/new patients, discharged for drug abuse, drug diversion & out of state patients
- Inspection
Number of pain clinics registered

- 7/1/2009 921
- 7/1/2010 823
- 7/1/2011 444
  - 2013/2014 359
  - 2014/2015 309
  - 2015/2016 281

counterfeit proof prescription pads

- Requires any controlled substances prescription to be written on a counterfeit-resistance pad produced by an approved vendor or electronically prescribed.
- Risk of not using counterfeit-proof rx is reject unauthorized rx and patients are inconvenienced.
- www.floridashealth.com/mqu/counterfeit-proof.html
HB7095

- Bans dispensing Schedule II & III by a physician & made it a violation both a 3rd degree felony

- Created a standard of care for all physicians prescribing controlled substances to treat chronic pain
DEA

- Did not affect DEA controls on schedule III and schedule IV. Physicians may prescribe a six month supply of those drugs with a single rx indicating up to 5 one month refills.
- Signatures stamps not accepted
- However state laws supersede for chronic pain nonmalignant pain 90 interval office visit
Federal Law

- Under federal law this is no expiration on a rx for schedule II. States have tighter rules.
- Rx for schedule III substances expire 6 months after date written
- There may be 5 refills within the 6 month period.
Prescriptions
-schedule II

• A new prescription must be issued for scheduled II rx.

• However multiple rx on the same day with instructions to fill on different dates up to three rx so the patient must be seen within ninety days.
Controlled substances

• More than one narcotic can be written on a single prescription, but they cannot be mixed (in writing) with non-narcotics. That is, if a patient is to receive a prescription for a C-II and a C-III, or some non-controlled substance, the C-II must be on its own prescription, alone. However, if the patient is to receive a prescription for two C-II agents, both can be written on a single prescription.

• C-II Narcotic prescriptions have no refills by law.

• C-III, C-IV, and C-V prescriptions can have no more than 5 refills and are only valid for 6 months.
DEA 12-19-2007

- DEA permissive regulation expanded 30 day to 90 ninety day for scheduled II controlled substances.
- However three separate px
- Date of prescription clearly written out and fill dates for pharmacy fills clearly written
How to write a prescription

- Legible printed/typed on counterproof prescription produced by a vendor approved by DOH
- Date must be textual format
- Patient name & address
- Name of medication, strength of med
- Dispense # in both textual and numeric format
- Sig: directions should be legibly written out and format
- Number of refills if any
- DEA # legibly written
- Signature-clearly ink or typed
- Doctor name & address
“Valid Prescription for internet prescribing means a prescription that is for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least 1 in person medical evaluation of the patient or a covering physician....”

STANDARDS FOR TELEMEDICINE

• NUMEROUS PETITIONS FOR WAIVERS CAME TO BOARD OF MEDICINE

• ACCESS FOR ADOLESCENT PSYCHIATRY

(4) CONTROLLED SUBSTANCES SHALL NOT BE PRESCRIBED THROUGH THE USE OF TELEMEDICINE EXCEPT FOR THE TREATMENT OF PSYCHIATRIC DISORDERS.
RULE 64B15-14.0081
TELEMEDICINE

• NO CONTROLLED SUBSTANCES ARE TO BE PRESCRIBED UNLESS THE PATIENT IS IN A HOSPITAL SETTING.

• THIS RULE DOES NOT APPLY TO EMS PROVIDED BY ER DOCTORS
ELECTRONIC PRESCRIBING

• "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."
64B16-27.831 FAC

- Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of s. 456.42(2), Fla. Stat. (2015), and pursuant to applicable federal law. For more information related to the federal requirements, access http://www.deadiversion.usdoj.gov/ecomm/index.html
DEA

- **21 CFR 1306.04(a).** A prescription serves both as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed, and as a record of the dispensing, providing the pharmacy with the legal justification and authority to dispense the medication prescribed by the practitioner.
Collaboration to resolve red flags

- 64B16-27.831 updated December 2015
- Pharmacist validates a Prescription
- Conversation not overheard by anyone
- May access PDMP
- Pharmacist 2 hour CME on the validation of prescription controlled substances
Dispensing practitioners

• Today registered dispensing practitioners are prohibited from dispensing CII or CIII
Exceptions Dispensing practitioners

- Exceptions to dispensing prohibition for Schedule II and Schedule III Controlled
- Complimentary packages/samples
- Department of corrections
- Surgical procedures
- Clinical trails
- Methadone facility
- Hospices  F.S.893.03
Federal

- May prescribe any opioid for pain
- Sublingual buprenorphine is off label for pain
- Refer to the DEA practitioners’ manual

addiction

• Buprenorphine must have 8 hours of training and CSAT waiver/DEA x-number
• Methadone must be part of licensed opioid treatment program
addiction

SAMHSA NATIONAL HELPLINE
1-800-662-HELP (4357) or 1-800-487-4889

https://findtreatment.samhsa.gov/
Addiction

- Learn how to prevent & manage opioid overdose
- Access tx misusers or addicted
- Ensure ready access to naloxone
- Encourage the public 911
- Encourage px to use PDMP
Tramadol rescheduled

• Previously Nonscheduled to now schedule IV
• Periodic exam to 90 days if used for chronic nonmalignant pain.

• On April 20, 2017, The Food and Drug Administration (FDA) issued a warning that is restricting the use of codeine and tramadol medicines in children. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. These medicines should also be limited in some older children.

• Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.
Hydrocodone rescheduled

DEA moved HCP from schedule III to schedule II. Means no refills.

Scheduling of CS is done by the Florida Legislature.
States

• Remember Florida has stricter rules than Federal regulations. Florida rules supersede because DOH grants you the license to practice thus can regulate and discipline.
• Benefits of high-dose opioids for chronic pain are not established.

• The CDC clinical evidence review found that higher opioid dosages are associated with increased risks for motor vehicle injury, opioid use disorder and overdose.

• According to the CDC guideline, the clinical and contextual evidence reviews found that opioid overdose risk increases in a dose-response manner, that dosages of 50 to less than 100 MME/day have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages of 1 to less than 20 MME/day.

• In March 2016, the CDC released guidelines intended for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, or end-of-life care. The goal of the guidelines is to ensure clinicians provide safe and effective treatment, improve patient outcomes, and reduce the incidence of opioid use disorder, overdose, and opioid-related adverse events.

  https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
cdc

- Determination of when to initiate and continue opioids for chronic pain:

  - Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Opioid therapy should be used only if benefits are considered to be greater than the risks to the patient. If opioids are used, they should be used as part of an integrated pain management strategy including non-pharmacologic therapy and non-opioid pharmacologic therapy.

  - Before starting opioid therapy for chronic pain, goals for treatment should be set with each patient, including a plan for discontinuation of the opioid if treatment goals are not met.

  - Clinicians should ensure that patients are aware of the risks of opioid therapy before initiation or continuation of opioid therapy.
• Opioid selection, dosage, duration, follow-up, and discontinuation:

• Clinicians should initiate opioid therapy with immediate-release opioids instead of extended-release or long-acting opioids.

• Clinicians should prescribe the lowest effective opioid dosage. Careful consideration should be given when increasing dosage to ≥ 50 morphine milligram equivalents (MME) per day, and doses ≥ 90 MME per day should generally be avoided.

• For acute pain, clinicians should prescribe quantities limited to the expected duration of pain severe enough to require opioids. Generally, 3 days or less is sufficient with durations up to 7 days rarely required.

• Clinicians should evaluate risks and benefits of therapy 1 to 4 weeks after initiation or dose escalation for all patients treated with opioids for chronic pain. Monitoring should occur at least every 3 months while on opioid therapy.
• **Assessment of risks and addressing harms of opioid use:**

  Clinicians should evaluate patients for opioid-related harm prior to starting and periodically during therapy. Clinicians should consider offering naloxone to patients with an increased risk of opioid overdose.

  Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program(s) before initiation of opioid therapy and at least every 3 months, thereafter.

  Clinicians should perform urine drug testing prior to initiation of opioid therapy with consideration given to annual drug testing.

  Concurrent prescribing of opioids and benzodiazepines should be avoided.

  Patients with opioid abuse or dependence should receive treatment, including buprenorphine, methadone, and behavioral therapies.

  In an effort to address our crisis in Florida, The Agency for Health Care Administration will implement a morphine milligram equivalent daily dose of **90 MME.** Dosages above 90 MME per day will require a prior authorization.
The Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain recommends avoiding prescribing opioid pain medications and benzodiazepines concurrently whenever possible.

The FDA is requiring boxed warnings – the FDA’s strongest warning – and patient-focused Medication Guides for prescription opioid analgesics, opioid containing cough products, and benzodiazepines with information about the serious risks associated with using these medications at the same time. Risks include extreme drowsiness, respiratory depression, coma, and death.

On September 24, 2016, the DUR Board voted to create a soft edit to deny all prospective drug utilization review (ProDUR) therapeutic duplication (TD) and drug to drug interaction (DD) edits for any benzodiazepine (BZP) and opioid combinations.
Marijuana

• Marijuana is the most commonly used illicit drug in the United States for the population overall and for youths in particular.

• Although the laws regarding marijuana use have changed in a number of states over the past decade, marijuana use remains illegal under federal laws in all states (e.g., the Controlled Substances Act; http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm).
• Medical marijuana
  64B15-14.013

  • Senate bill 8A, passed during the 2017 Special Session, created section 381.986, Florida Statutes, Medical use of Marijuana.

  • Medical marijuana may be used for patient care if it is prescribed by a qualified Florida physician licensed under Chapter 459 or Chapter 458, F.S., in a manner that is consistent with the standard of care.

  • Qualified physicians clear & active license, 2hour course $250
  • mandatory standardized informed consent & for comparable conditions

http://flboardofmedicine.gov/pdfs/OCUmmedicacannabis.pdf
DEA update disposal act

- Do not accept/collect CS from a patient – example allergic rx
- Do not require a particular method of destruction “non-retrievable”
- Physical or chemical condition/state thru irreversible means and renders the CS unavailable and unusable for all practical purposes
- EPA may not like dumping in water supply
DEA disposal

- Final rule 9/8/2014 CSA amended by the Secure and Responsible Drug Disposal Act 21c.f.r. 1317.05(a)
- Mail back programs and collection receptacles registered
Universal Precautions

• Utilize PDMP prior to writing a prescription
• Obtain old records from previous provider
• Initial UDT on all patients and periodically
• Patient Prescriber Agreement - benefits and risks of opioids. Serves to educate, form a plan of care, counsel. Risk of harm from misuse, addiction, overdose, hyper analgesia and adverse effects discussed.
• FDA has mandated manufacturers of extended release/long acting opioid analgesics as part of a comprehensive risk evaluation and mitigation strategy (REMS) to make available comprehensive prescriber education in the safe use of these meds.

• Very informative, links to everything related to pain including pain contracts.
standards of care

• The first prescription, think carefully smallest amt shortest duration
• Medical history & physical exam prior to beginning treatment
• **Detailed medical records** must be kept, udt, PDMP check, old records
• Written treatment plan for assessing and monitoring risk
• Controlled substance agreement
• Regular follow up as least every three months
• Referral as necessary if patient not at treatment goal
Addendum – Are you an Expert?
10 questions PSU uses

• Do you know the subject of the case being referred for your opinion?
• Do you currently perform the examination/test/procedure/etc. or prescribe the medications that are at issue in this case within the last year?
Are you an Expert?

- Did the subject meet the applicable standards of care outlined in the FL statues in their examination/diagnosis, and treatment of the patient?
- Please identify in detail each instance in which the subject failed to meet a standard of care and describe the particular examination/test/procedure/etc. being performed by the subject on the patient at the time.
Are you an Expert?

• Did the subject adequately assess the patient complaints and symptoms?

• Was a complete assessment of the patient’s condition completed to include appropriate lab testing, x-rays and examinations?

• Was a complete and proper H&P documented by the subject?
Are you an Expert?

- Was the subject’s diagnosis of the patient’s condition appropriate, adequate, accurate, and timely?
- Did the patient’s complaints/condition call for the use of specialized consultations for the diagnosis and treatment?
Are you an Expert?

• Was the appropriate plan or treatment for the patient's condition identified and pursued by the subject?
• Did the subject prescribe, dispense, inject, or administer legend drugs or any substance to the patient that was inappropriate, in an inappropriate manner, or in excessive or inappropriate quantitative?
Are you an expert?

• Do the medical records maintained by the subject accurately and completely document and justify the course of treatment utilized in the care of the patient?

• Is the patient’s H&P complete? Are all test results, records of drugs prescribed, dispensed or administered, and reports of consultations and/or hospital included in the patient’s MR? Are there identifiable deficiencies or problems with the MR? Legibility?
Are you an expert?

- Do the billing records for services provided reflect appropriate tests/testing?
- Are fees within acceptable range?
- Is there any indication of fraud in the practice of medicine?
Post test questions

What is the most common missed diagnosis in the preceding biennium seen at the Board of Osteopathic Medicine case files?

– 1. Inappropriate opioid prescribing to patients of undiagnosed psychiatric condition and/or diversion.
– 2. Failure / delay in diagnosing cancer.
– 3. retained foreign objects & wrong site/patient surgery
– 4. surgical complications/errors/pre op evaluations
– 5. prescribing, dispensing, administering or using non FDA approved medications and devices.
Post test questions

• Who are not exempt from registering when practicing in a pain management clinic?
  • 1. anesthesiologists
  • 2. physiatrists
  • 3. neurologists
  • 4. rheumatologists
  • 5. family medicine physicians
  • 6. surgeons who perform surgical interventions
post test questions?

• A board certified FP/GP/internist are working part-time in a pain clinic. Who is responsible to register the pain clinic?
  – A. The pain clinic owner
  – B. The lawyer for the pain clinic
  – C. You as an employee must verify that the clinic is registered.
  – D. You should not worry because the lawyer/medical director for the pain clinic will take care of it.
Post test questions

• What is the minimum amount of time must a doctor see a chronic pain management patient for periodic review and refills?
  • 1. 30 days
  • 2. 60 days
  • 3. 90 days
  • 4. 120 days
Post test questions

• If working in a pain management clinic how many days do you have to notify the board in writing of your termination with the pain management clinic?
  – 1. 7 days
  – 2. 10 days
  – 3. 14 days
  – 4. 30 days
Post test

• What is the best way to protect your medical license – property asset?

1. Maintain your medical records
2. Good communication with patients- be their friend-give patient your cell phone
3. Utilize universal precautions
4. None of the above
Osteopathic pledge of commitment

• Provide compassionate, quality care to my patients;
• Partner with them to promote health;
• Display integrity and professionalism throughout my career;
• Advance the philosophy, practice and science of osteopathic medicine;
• Continue life-long learning;
• Support my profession with loyalty in action, word and deed; and
• Live each day as an example of what an osteopathic physician should be
Contact information

- **Kama.Monroe@flhealth.gov** BOOM ED
  - 850-245-4162
- **Carol.Taylor@flhealth.gov** administrator
  - 850-245-4588
- All telephone and correspondence are public records
- [https://www.fsmb.org/policy/education-meetings/educational-modules](https://www.fsmb.org/policy/education-meetings/educational-modules)
conclusion

• Familiar with Florida statues regulating pain clinics
• Knowledgeable about the controlled substance prescriber registration and standards of practice
• Maintain your medical records
• Take care of your patient’s pain safely
references

COMMON SIDE EFFECTS OF OPIOIDS

Pain agreement example

- http://quantiamd.com/player/yeaeihfny?cid=10000142