Federal and State Laws Relating to Prescribing of Controlled Substances

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FOMA MID-YEAR SEMINAR
AUGUST 20, 2015
GRAND HYATT TAMPA BAY
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.

- I am not here representing the BOOM
Purpose

– Knowledgeable about the controlled substance prescriber registration and standards of practice
– Familiarity with Florida Statutes regulating new dispensing laws
– Inform you about the new requirements for pain management clinics
– Overview of federal laws
MQA-Florida Dept. of Health

- **MISSION:** To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

- **VISION:** To be the **Healthiest State** in the Nation

- **PURPOSE:** To protect the public and make Florida the healthiest state in the nation through health care licensure, enforcement, and information.

- **FOCUS:** To be the nation's leader in quality health care regulation.

- **VALUES:** I CARE (Innovation, Collaboration, Accountability, Responsiveness, Excellence)
BOARD Functions

• Chapter 459 F.S. governs the appointment & responsibilities of BOOM
• Credentialing new applications-
• Disciplinary matters-consider what the action is necessary to **protect** the public and then only secondarily what action if any will serve to rehabilitate the licensee being disciplined
Board functions

• Operate under the sunshine law
• Operate under the code of ethics for public officers and employees
• All cases filed are public record after a probable cause panel determines there is a potential violation.
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.

Board of Osteopathic Medicine  8/ 2014  Meeting Minutes
Prepared by Betty Bates and Christy Robinson
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
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)
Definition - prescription - statute 893.02(21) FS

• 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.
Enforcement process

• Complaint goes to the DOH
• Analysis is done
  – Citation is issued- “get out of jail card-like a traffic ticket” non patient safety issues
  – Closure
  – Mediation
  – Investigation—prosecution service unit
  – Probable cause –mediation
    • No probable cause –dismissal
Enforcement process

• If probable cause is found
  – Administrative complain filed DOH
  – Election of Rights by licensee
    • Formal hearing before DOAH
    • Informal hearing before board-no dispute
    • Hearing waived before board-no dispute
    • Settlement by licensee to board for approval
Enforcement

• Final board action and disposition
• Final order imposing discipline filed with DOH
• Compliance monitoring
• Appeal procedures to district courts of appeal
Disciplinary guidelines 64B15-6.0111

- The BOOM have violations set forth
- Recommended penalties
- First offense and for subsequent offenses.
- The BOOM-by statute-the penalties are predetermined range. The BOOM may wish to administer a more lenient penalty $ vs. a stiffer penalty $ depending on the nature of the violation and previous offenses.
Discipline

• Each patient case against the doctor will count as a strike. In the past there could have been multiple patient cases impacted. It was all included in one administrative complaint.

• If this occurs the three strikes you are out of a license can occur.
Effective January 1, 2012 in accordance with s. 456.44(2), Florida Statutes, an allopathic physician licensed under chapter 458, an osteopathic physician licensed under chapter 459, a podiatric physician licensed under chapter 461 or a dentist licensed under chapter 466 who prescribes any controlled substance as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must designate himself or herself as a controlled substance prescribing practitioner on the practitioner profile.
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:
64B15-14.005

• 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.
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.
64B15-14.005

• (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.
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.
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
E-forcse- PDMP

- The Electronic - Florida Online Reporting of Controlled Substances Evaluation program (E-FORCSE)
- Safer prescribing of controlled substances
- Reduce drug abuse and diversion within the state of Florida
- Guide doctors in their decision making
- Recent updates- one can check their DEA prescribing history for accuracy
- 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.
Florida’s Prescription Drug Monitoring Program [http://www.e-forcse.com]

- Practitioners registered – 25,000
- Queries – 2.8M
- Since E-forcse implemented oxycodone deaths reduced by 41%

Doh.late news/pdmp 11/14/2014
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 than 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 Xanax, 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
Rule 64B16-27.81

- Florida Board of Pharmacy rule on controlled substances dispensing will be updated to reflect the recommendations on the consensus statement

- Educational programs on safer prescribing and dispensing CS
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
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. 4847  out of state active  1191
- Active M.D. 47069  out of state active  15688

Since 2009 84 actions vs MD  .17%
Since 2009 26 actions vs DO  .53%

http://mqawebteam.com/annualreports/1314/#12
# of disciplinary actions cnmp

- 7/1/2011  6
- 7/1/2012  20
- 2014-2015 13

- HB 7095 Toolbox report card 2/16/2015
2014-2015 of emergency actions

Emergency Actions vs MD 1
Emergency Actions vs DO 2
Disciplinary actions 13

- HB 7095 toolbox report card 2/16/2015
2013-2014 ESO/ERO

- Osteopathic Physicians: 0 ESO/ERO
- MD: 3 ESO/7 ERO

MQA 2013-2014 annual report
Pain management clinics

- 66 complaints
- 25 legally sufficient
- 4 voluntary surrendered license
- 2 probable cause
- 0 administrative complaints filed

- MQA FY 2013/2014 annual report
Impact

• # of patients discharged due to abuse of Rx since 7/1/2010 36093

• # of patients discharged due to diversion since 7/1/2010 12578
# registered prescribers for controlled substances for cnmp

- 7/1/2011 20175
- 7/1/2012 24754
- 7/2/2013 24895
- 2/16/2015 25089

- HB 7095 toolbox report card BOOM 2/16/2015
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
The CDC issued a Vital Signs report Tuesday that compares heroin trends from 2002 through 2013.

There were 8,257 heroin overdose deaths in 2013, nearly four times the rate in 2006.

www.modernhealthcare.com/article/20150707/NEWS/150709943
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

[www.sunsentinel](http://www.sunsentinel) 2/15/13 Nicole Brochu “Heroin Taking Oxy’s Place for more Addicts”
Unintended consequences

- **Heroin taking oxy's place for more addicts**
- By [Nicole Brochu](#), Staff writer  Sun Sentinel  
  *February 15, 2013  |  9:06 AM*
- Surge in the number of people now hooked on **heroin**. With crackdowns focusing on siphoning off supplies rather then treating addiction, people are finding that **heroin**, which yields a high similar to the oxycodone.
Unintended consequences

• **Heroin taking oxy's place for more addicts**

• By Nicole Brochu, Staff writer  Sun Sentinel

  *February 15, 2013 | 9:06 AM*

• Surge in the number of people now hooked on heroin. With crackdowns focusing on siphoning off supplies rather then treating addiction, people are finding that heroin, which yields a high similar to the oxycodone.
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 >$50Million
- 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
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
- 2/16/2015  330
### Closed Pain Clinics continued

<table>
<thead>
<tr>
<th>Pain Management Clinic</th>
<th>Address</th>
<th>Code</th>
<th>Date</th>
<th>Reason</th>
<th>DOH-Code</th>
<th>Violation</th>
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<tbody>
<tr>
<td>CASSELBERRY RELIEF CENTER INC</td>
<td>1229</td>
<td>201109 296</td>
<td>16-Jun-2011</td>
<td>Voluntary Surrender</td>
<td>DOH-11-1342-S</td>
<td>Violate Statute/Rule of Board</td>
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<td>TOTAL MEDICAL EXPRESS, LLC</td>
<td>850</td>
<td>201110 774</td>
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<td>DOH-11-1688-S</td>
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<td>TOTAL MEDICAL EXPRESS OF ORLANDO</td>
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<td>201107 651</td>
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<td>DOH-11-1687-S</td>
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<td>REHABILITATION CONSULTANTS, PA</td>
<td>140</td>
<td>201023 870</td>
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<td>Violate Statute/Rule of Board</td>
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<td>201110 785</td>
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<td>License Nbr</td>
<td>Case No</td>
<td>Action Date</td>
<td>Action Taken</td>
<td>Final Order No</td>
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<td>------------</td>
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<tr>
<td>Pain Management Clinic</td>
<td>POMPANO PAIN MANAGEMENT</td>
<td>434</td>
<td>2010091 58</td>
<td>20-Jul-2010</td>
<td>Fine Paid</td>
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<td>Pain Management Clinic</td>
<td>SOCIAL MEDICAL CENTER USA</td>
<td>185</td>
<td>2010161 39</td>
<td>28-Oct-2010</td>
<td>Voluntary Surrender</td>
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<td>262</td>
<td>2010075 46</td>
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<td>PAIN RELIEF ORLANDO</td>
<td>1173</td>
<td>2011089 58</td>
<td>16-Jun-2011</td>
<td>Voluntary Surrender</td>
<td>DOH-11-1343-S</td>
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HB 7095- 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 3\textsuperscript{rd} degree felony

• Created a standard of care for all physicians prescribing controlled substances to treat chronic pain
**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
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.
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
Dr. John Smith
1234 Main Street
Anytown, Florida

Date: February 11, 2013
Patient Name: Jane Doe                        DOB: 05/29/1986
Address: 1111 Center Lane, Anytown, Florida 33312
Percocet (2.5/325)
Disp. # 60 Sixty
Sig: Take one tab every 6 hours PRN pain
No Refills
DEA #

Signature Line
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.

• CII 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.
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
New standards of care

- Medical history & physical exam prior to beginning treatment
- **Detailed medical records** must be kept
- Written treatment plan for assessing and monitoring risk
- Controlled substance agreement
- Regular follow up as least every three months
- Referral as necessary
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.
Http://www.scope of pain.com

• 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.
Federal

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

Federal addiction

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

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

Scheduling of CS is done by the Florida Legislature.
Tramadol rescheduled

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

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  Tallahassee, Fl 32399-3256
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

• https://www.nabp.net/system/rich/rich_files/rich_files/000/000/209/original/consensus-document.pdf
COMMON SIDE EFFECTS OF OPIOIDS

Pain agreement example

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