“Federal and State Laws Relating to the Prescribing of Controlled Substances”.

- Walter B. Flesner III, D.O.
- Past President, FOMA District XI, 2008-2010.
- Medical Director, ICP&R, Cape Coral, Fl.
- Risk Management/Continuing Medical Education American Osteopathic College of Occupational and Preventive Medicine Midyear Seminar.
- Sunday, Sunday March 15th, Ft. Lauderdale, Fl.

**Guidelines and Recommendations**

1. Standards For The Use Of Controlled Substances For Treatment Of Pain; AHCA in consultation with The Florida Pain Commission, The Florida Board of Medicine, and The Florida Board of Osteopathic Medicine, Revised 12-21-99.  
2. JCAHO Standards 1999  
3. Federation of State Medical Boards Joint Concensus 
5. DEA Statements.  

**Florida Statistics**

- 7 Floridians die daily from lethal overdoses.  
- Additional 7 persons die daily with at least one prescription drug detected in combination with alcohol or other drugs. Florida led nation in sale of Oxycodone with over 400,000,000 pills sold annually! However down 20% in past year. 

How Prescription Drugs get to Floridians:

1. Physicians and Pharmacists- for profit, naïve, impaired.
2. Individuals- illegally obtain to satisfy addiction, traffic or divert for profit or to family or friend.
3. Internet pharmacies- major difficult threat.
Solutions
Be part of the solution, not part of the problem. You are here! Learn new guidelines, talk to your colleagues, consult specialists when indicated. Florida BOM, FBM, DEA, FDLA, State, County, Local law enforcement, State Attorney’s Off., FOMA, FMA, Specialty Societies- we all need to work together so legitimate acute, chronic, and terminal pain patients can have appropriate access to compassionate and multidisciplinary care. Urine drug testing, the Prescription Drug Monitoring Program (PDMP)-E-FORCSE.com, and patient-doctor opioid agreements have started to help. New Zoning Laws are coming for new Pain Clinics.

Definition of Pain

IASP definition:*
Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue injury or described in terms of such damage.”

Importance of the patient’s self-report:
"Pain is whatever the experiencing person says it is, existing whenever he/she says it does.”**

Definitions

• Tolerance
  Pseudotolerance
  Physical Dependence
  Addiction
  Pseudoaddiction
  Substance Abuse
  Acute Pain
  Chronic Pain

Tolerance:

• the need for increased dosage of medication to produce same level of analgesia that existed previously. Tolerance occurs also when a reduced effect is observed with constant doses. Analgesic tolerance is not always seen during opioid treatment and is not addiction.

Pseudotolerance:

• need to increase dosage is not due to tolerance, but due to other factors such as disease progression, increased activity, drug interaction, new disease, other medication changes, or deviant behavior.
Physical dependence:

- Occurrence of withdrawal symptom/syndromes after opioid use is stopped abruptly or decreased without titration. It can also occur if an antagonist is administered. Physical dependence is NOT addiction! It does not always occur with opioid usage, but is a common phenomenon with opioid treatment.

Addiction:

- Psychological dependence on the use of substances and their psychic effects and/or compulsive use of drugs over which patients no longer have control, and continue to use despite harm to themselves or others. Addiction is a disease.

Terminology (cont’d)

- **Addiction** - A primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations
  - Behavioral characteristics include one or more of the following:
    - Impaired control over drug use
    - Compulsive use
    - Continued use despite harm
    - Craving

Pseudoaddiction:

- Drug-seeking behavior that may seem similar to addiction, but is due to unrelieved or incompletely relieved pain. Often after a dosage increase, the behavior stops once the pain is relieved.

Substance Abuse:

- Use of any substance for non-therapeutic purposes.

Acute Pain:

- Normal predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with trauma, surgery, or acute illness. It usually resolves within 3 months.
  - Subacute Pain: 3-6 months.
  - Chronic pain: > 3-6 months.
Chronic Pain:

- state in which pain is persistent and cannot be removed or otherwise cured. It usually has occurred for more than 6 months.

456.44: Chronic nonmalignant pain means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

Keys to Appropriate Pain Assessment

- Complete initial assessment
- Use appropriate tools
  - patient self-report
  - easily administered rating scales
  - documentation forms available to all clinicians: Pain Assessment and Documentation Tool/ PADT, Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain/ SOAPP.
- Assess pain at regular intervals
- Be aware of common pain syndromes
- Risk Identification and Stratification

Initial Pain Assessment: Medical History

- Extent of disease
- Previous therapies: effective & failures
- Treatment-related signs and symptoms
- Other medical conditions
- Efficacy of previous chronic/acute/palliative therapy

Initial or Ongoing Pain Assessment: Characterization of Pain

- Location
- Description
- Intensity
- Temporal nature
  - onset
  - duration
  - relationship to scheduled analgesic dose
- Aggravating/alleviating factors
- Efficacy of previous analgesic treatments
- Effects on function

Initial Pain Assessment: Psychosocial Examination

- Disease state: effects and understanding
- Reactions to pain
  - meaning of pain
  - coping strategies and support system
  - effects on function
  - effects on mood
- Perceptions regarding analgesic therapy
  - expectations, knowledge, and preferences
  - concerns regarding controlled substances
- Financial concerns regarding therapy
  *Assess whether low, medium, or high risk for abuse for chronic opioid therapy (COT).

Initial Pain Assessment: Physical Examination and Diagnostic Studies

- Physical Examination:
  - Site of pain
  - Adjacent sites (for referred pain)
  - Sites of known disease/ tumor invasion
  - Musculoskeletal and neurologic systems
- Diagnostic Evaluation:
  - Laboratory studies/tumor markers
  - Radiologic studies
  - Neuropsychologic testing
  - Urine drug screening
Pain Assessment Tools: Intensity

- Simple Descriptive Pain Intensity Scale
- Visual Analog Scale (VAS)

Opioid Risk

- New definition
  - Adverse effects
  - Aberrant drug-related behavior
  - Abuse
  - Misuse
  - Diversion
  - Addiction
- Unintended Deaths

Opioid Risk Assessment Tools

- Screener and Opioid Assessment for Patients with Pain (SOAPP) •
  - 5, 14, and 24 – item
  - Intended for use at the time the decision is made to utilize chronic opioid therapy
  - Self-report
  - Scientifically validated
  - Includes instructions and monitoring recommendations

- Pain Assessment and Documentation Tool (PADT) •
  - Clinician-directed interview – progress note format
  - Covers the 4 “A”
  - Not scientifically validated
  - Subjective assessment
  - No scoring
  - Overall impression of benefit
  - Includes a section for plan

SOAPP version 1.0 is an easy and relatively quick questionnaire to help physicians and providers evaluate patients’ risk for higher problems if long-term opioid therapy is to be considered.

SOAPP is not a lie detector test. It is not intended for all patients. It is likely to predict which patients will need less or more close monitoring on long-term opioid therapy. Version 1.0 has 24 questions. Version 1.0 SF has 5 questions. 2 most important questions: Smoke and drink? PAIN ASSESSMENT and DOCUMENTATION TOOL (PADT). OPIOID RISK TOOL.
Pharmacologic Management of Pain
• Select the appropriate Drug.
• Prescribe the appropriate Dose- do under or over treat.
• Administer by the appropriate Route.
• Schedule the appropriate dosing Interval- consider long acting for ATC, short acting for rescue/breakthrough.
• Prevent Persistent pain/relieve Breakthrough pain.
• Titrate doses aggressively.
• Anticipate, prevent, and manage the Side Effects.
• Use appropriate Adjuvant drugs when indicated.
• Assess treatment response at regular intervals.

Choice of Agent:
Three-Step Analgesic Ladder

Opioid Risk Assessment Tools
- Opioid Risk Tool (ORT)
- Brief screening tool
- Simple
- Clinician administered
- Not validated, but used frequently

- Choice of Agent:

• Naturally occurring Opioids
• Semisynthetic Opioids
• Synthetic Opioids

Opioid Classification

The word opioid is a general term that refers to all compounds related to opium. The term narcotic (causing narcosis) once used to refer to any drug that induced sleep, is currently used in a legal context to refer to a variety of substances not restricted to opioids with abuse or addictive potential. DO NOT use these terms interchangeably.

Naturally Occurring Opioids
• Morphine
• Codeine
• Thebaine
Semisynthetic Opioids

- Hydrocodone
- Hydromorphone
- Oxycodone
- Oxymorphone
- Heroin
- Buprenorphine

Synthetic opioids

- Meperidine
- Methadone
- Fentanyl
- Pentazocine
- Tramadol - Atypical; Thought to be synthetic but in bark of S. African tree.

Controlled Substances Act of 1970
Congress - Legislation

Schedule I Opioids

- Marijuana-Federal
- Heroin (In 1898 Bayer Chemical Co. of Germany introduces diacetylmorphine, naming it “Heroin”)
- LSD

Schedule II Opioids

- Morphine
- Codeine
- Hydromorphone
- Oxymorphone
- Oxycodone, Oxycodone/acetaminophen, Oxycodone/ aspirin
- Fentanyl
- Meperidine
- Methadone
- Hydrocodone without APAP-new. *Hydrocodone - all versions: DEA just announced Hydrocodone with is Schedule II as of 10-1-14.

Schedule I
NO PRESCRIBING ALLOWED!
Even in California!!
Current acceptable medical uses?
not in current form.
Very high potential for abuse and addiction.
Medical marijuana is controversial.
Methadone

Methadone is prescribed for chronic pain states including neuropathic pain, somatic pain, visceral pain, cancer pain, and sickle cell pain. Most common dose is three times daily. Methadone lacks active metabolites, has high level of bioavailability, is inexpensive, and exhibits antagonistic activity at N-Methyl-D-Aspartate receptors. Be careful of lethargy and hypersomnolence. Do not use for rescue or breakthrough pain. Do not use unless you have a lot of experience.

Schedule II - Prescribing

- Fentanyl- Actiq and Duragesic
- Demerol (Meperidine)- Avoid! Toxic metabolite after 3 days.
- Dilaudid (Hydromorphone).
- Morphine (Astromorph, Duramorph, Infumorph, Kadian, MS Contin, MS-IR, Oramorph, Roxanol).
- Oxycodone (Oxyfast, OX-IR, Roxicodone, Oxycontin, Percocet, Percodan, Tylox).
- Levo-Dromorphan (levorphanol).
- Numorphan (Oxymorphone).
- Methadone.
- Opana/Opana-ER (Oxymorphone).
- Hydrocodone/Hydrocodone long acting without APAP/Zohydro-ER, Hydrocodone combinations.
- *Long acting for around the clock/chronic pain; rapid acting for rescue/breakthrough pain.

Schedule III Opioids/Combinations

- Codeine with acetaminophen
  Hydrocodone with acetaminophen-Now II.
  Hydrocodone with ibuprofen- Now II.
  Hydrocodone-containing elixirs-Now II.
  Buprenorphine film, tablets, and patch(used to be Class V)

Schedule III Prescribing

- Written, oral (promptly reduced to writing by pharmacist), partial filling permitted (may be transmitted by fax).
- Must be filled/refilled within 6 months of issuance and can be refilled no more than 5 times within those 6 months.
- Moderate abuse potential.
**DEA Controls Tramadol as schedule IV effective August 18, 2014.**

- Tramadol now schedule IV.
- Central acting atypical opioid analgesic.
- Serotonin-norepinephrine reuptake inhibitor.
- Once thought synthetic opioid however found in bark of tree.

**Schedule IV- Not just opioids**

- Stadol Nasal Spray
- Phenobarbital
- Benzodiazepines
- Sedative hypnotics
- Phentermine
- Tramadol-as of 8-18-2014 per DEA.
- Talwin: Pentazocine/Naloxone
- Pregabalin/ Lyrica: Schedule V.

**Schedule IV Prescribing**

- Written, oral (promptly reduced to writing by pharmacist), partial filling permitted (may be transmitted by fax).
- Must be filled/refilled within 6 months of issuance and can be refilled no more than 5 times within those 6 months.
- Lower abuse potential.

**Model Policy for the Use of Controlled Substances for the Treatment of Pain**

- Federation of State Medical Boards of the United States, Inc., approved May 2004.

**Federation of State Medical Boards’ Model Policy**

- Introduction
- Section I: Preamble
- Section II: Guidelines
- Evaluation of the Patient, Treatment Plan, Informed Consent and Agreement for Treatment
- Periodic Review
- Consultation
- Medical Records
- Compliance with Controlled Substances Laws and Regulations
- Section III: Definitions- Acute Pain, Addiction, Chronic Pain, Pain, Physical Dependence, Pseudoaddiction, Substance Abuse, Tolerance.

**DEA Policy Statement on Dispensing Controlled Substances for the Treatment of Pain**

- It recognizes the importance of pain management with controlled substances.
- It does not have a campaign to target physicians who prescribe controlled substances for pain for legitimate medical reasons.
- Physicians should not curb legitimate prescribing to avoid legal liability or under-prescribing might occur. Diversion is a serious problem and physicians have an obligation to take reasonable measures to prevent diversion, misuse, and abuse. ER visits associated with misuse/abuse and nonmedical use have alarmingly escalated.
DEA Continued..

Proposed “90 Day supply rule for stable low-risk patients. The DEA’s authority under the CSA is not equivalent to that of State Medical Boards.

DEA does not regulate the general practice of medicine, nor is responsible for educating and training physicians so that they make sound medical decisions in treating pain. This responsibility lies with medical schools, post graduate programs, state accrediting bodies, specialty societies, and state and national medical associations with medical expertise. DEA has neither legal authority nor the expertise to provide medical training to physicians or issue guidelines that constitute medical advice.

The majority of cases in which physicians lose their DEA registrations result from cases referred by State Medical Boards to revoke or suspend the physicians’ state medical license. Most licenses are not well defended due to lack of or poor quality medical records.

DEA Concluded.

- DEA continues to have legal obligation to investigate the extremely low percentage of physicians who use their DEA registration to commit criminal acts or otherwise violate the CSA. Recurring patterns indicative of diversion, misuse, and abuse.

  1. An inordinately large quantity of controlled substances prescribed.
  2. Large numbers of prescriptions issued.
  3. No physical exam was given (medical necessity not established).
  4. Physician failed to fill prescriptions at different pharmacies.
  5. Physician issued prescriptions knowing that patient was delivering drugs to others.
  7. Physician uses “street slang” rather than medical terms for medication prescribed.
  8. No logical relationship between the drugs prescribed and treatment of condition allegedly existing.
  9. Physician wrote more than one prescription on multiple occasions in order to spread them out.

Most cases demonstrate blatant criminal conduct. Most common ways controlled substances are diverted: Family and friends, ease of access via internet, improper prescribing.

If patient has urine drug screen with THC- do not prescribe opioid treatment per DEA agent!

Informed Consent/ Patient-Physician Agreement

- 1. Risks and Benefits of use of controlled substances.
- 2. Obtain Opioids/Controlled Substances from one physician and fill Rx’s at preferably one or at the most two pharmacies.
- 3. Urine/Serum Drug tests when requested, unannounced at least twice yearly, more often if moderate/high risk.
- 4. Reasons for discontinuation of treatment (dismissal from practice/care).

Medical Records

- 1. Medical history and physical exam-initially complete
- 2. Diagnostic, therapeutic, and lab tests.
- 3. Evaluations and Consultations.
- 4. Treatment goals-decrease pain, increase activity, improve quality of life.
- 5. Risk/Benefit discussion
- 6. Informed Consent/Patient-Physician Agreement.
- 7. Treatments-Psychotherapy, PT, Interventional
- 9. Instructions and directions.
- 10. Periodic/Regular reviews. At least every 3 Months-low risk, more often-moderate risk, comanage/refer-high risk.

Medical Practice Guidelines for practitioners licensed under Florida Statutes Chapters 458 or 459.


Guidelines/Standards....

- 1. Pain management principles-documentation is essential!
- 2. Definitions.
Similar recommendations.

Florida Rule 64 b 15-14.005 Dec. 2005
- Patients maintained on controlled substances, Class II & III, should comply with the following guidelines:
  - Medical records: Physician’s medical record must indicate accurate diagnosis, need for long duration of pain management medication. History, Physical exam, and Plan of care and Goals in each evaluation.
  - Diagnostic and/or radiologic test results indicate accurate diagnosis and need for long duration of pain management.
  - X-Rays Annually, Ct scan or MRI within 1 year.
  - Comprehensive metabolic profile (CMP) and CBC every 12 months. ESR, Rheumatoid and Hepatitis profiles in appropriate patients annually.

Medical Records Compliance
- Treatment/Medication is prescribed after:
  - Documented history and physical.
  - Assessment of physical and psychological impact of pain.
  - History of/or potential substance abuse, Coexisting disease/comorbidities.
  - Recognized medical indication for controlled substance.
  - Written treatment plan, individualized for patient.
  - Treatment progress and success evaluated objectively: Pain relief, improved physical and psychosocial functioning.
  - Review and update every 3 months. List goals.
  - Treat patient, consult and co-manage, or refer.

- Contains provision that increases buprenorphine prescribing limit from 30 to 100 patients per waived physician. Increases access to opioid addiction treatment. If patients are taking opioids for nonmedical purposes or are physically dependent or abusing opioids, Suboxone may be an option.
- Suboxone is now approved for both induction and maintenance treatment of opioid dependence. REMS is necessary to ensure the benefits outweigh the risks. Counseling is important. Here To Help.COM

Non-opioid pain medications
- Acetaminophen
- Aspirin
- Aspirin/Acetaminophen/Caffeine
- NSAID’s
- COX II’s

Analgesic Adjuvant Agents
- Antihistamines
- Benzodiazepines
- Muscle relaxants; Central/Spinal-peripheral
- Caffeine
- Dextroamphetamine, Modafinil/Provigil,
- Armodafinil/Nuvigil
- Corticosteroids
- Tricyclic antidepressants, SSRI’s, SNRI’s
- Anticonvulsants
- NMDA receptor antagonists
- GABA agonist, alpha 2-adrenergic agonist
- Topical agents- Lidocaine, Combinations, Compounded combinations.
Anesthetics/Pain transmission-blocking

- Nerve blocks
- Neurolytic blocks
- Trigger point injections
- Paravertebral injections, Epidural injections
- Prolotherapy/ Sclerotherapy/ Regenerative injection therapy (RIT).

Counter-irritants: overrides noxious input, prevents full pain recognition.

- 1. Hot packs/ hyperthermy
- 2. Ice/cold
- 3. Ethyl Chloride spray
- 4. Vibration
- 5. Transcutaneous nerve stimulation (TENS) or Electrical muscle stimulation (EMS).

Osteopathic/Chiropractic Manipulative Treatment

- May relieve or reduce pain.
- May restore or improve range of motion and function.
- Use HVLA, Muscle energy, Myofascial release (MFR), Strain- Counterstrain, et al.
- If one type does not help, use another method or may need to use combinations- muscle energy + HVLA.
- Use OMT in conjunction with any other treatment modalities.
- Use proper CPT/ICDM codes for reimbursement.
- Take OMT refresher courses!

Vitamin/Nutraceutical Antiinflammatories

- Glucosamine/Chondroitin sulphates
- Boswella
- Omega 3 Fish Oil-EPA/DHA/GLA (Borage seed oil), Perilla oil , Krill oil
- Cod liver oil, Flaxseed oil, Evening Primrose oil
- Udo’s Choice oil
- Methylsulfonylmethane (MSM)
- Shark cartilage
- Serraflazyme
- “Arthropro”
- “Chondrox” *Turmeric !
- Osteo-Bi Flex: Gluc.+Chondr.+MSM. Triple Strength

Opioids Commonly Prescribed for Moderate-to-Severe Pain

Step 2 opioids (combination*)

- Codeine
- Dihydrocodeine
- Hydrocodone
- Oxycodone

Step 3 opioids (single agent)

- Morphine
- Fentanyl
- Oxycodone
- Hydromorphone
- Oxymorphone

Not recommended for use

- Meperidine
- Buprenorphine -Patch?
- Pentazocine?
- Butorphanol
- Dezocine
- Nalbuphine

Management of Common Opioid Side Effects

- Constipation
  - prophylactic use of laxatives and stool softeners
- Nausea and vomiting
  - neuroleptics, metadlopramide, cisapride, antivertigenous drugs
- Sedation
  - discontinue other CNS depressants
  - add psychostimulants
- Respiratory depression
  - monitor if not severe; carefully administer naloxone if severe
Management of Common Opioid Side Effects

- Orient patient to report side effects
- Routinely assess side effects
- Manage with specific agents/antinauseants
- Manage by switching opioid agent or changing dosing regimen

Dose Titration and Timing

- Start low to minimize side effects, enhance compliance
- Dose to analgesic effect
- No ceiling effect to analgesia with opioids - watch for pulmonary central depression
- No maximum dose of opioids
- Titrate both ATC and breakthrough medications
- Analgesic effects must be balanced with side effects

Characteristics of Breakthrough Pain

- Moderate to severe intensity
- Rapid onset (< 3 minutes in 43% of patients)
- Relatively short duration
- Frequency: 1-4 episodes per day

Treating Pain–Ideal

- Rapid onset
- Short duration of effect
- Minimal side effects
- Noninvasive, easy to use
- Cost-effective

Post Herpetic Neuralgia
DPN and PHN

- Lidocaine patches and NMDA-receptor antagonists
- Severity often requires opioids for breakthrough pain.

Fibromyalgia

- Pregabalin (Lyrica), Milnacipran (Savella), Duloxetine (Cymbalta)
- Central sensitization, painful fascia, nonrestorative sleep, improving evidence based medicine: fibrous tissue inflammatory and CNS substance P and glutamate findings.
- Functional MRI and PET scan findings different from normal patients are definitive.

Pharmacotherapy for Arthritis

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Primary Dysmenorrhea

- Cramping, lower abdominal pain at the onset of menstruation; no underlying pathology
- Most common gynecologic problem in menstruating women
  - experienced by up to 90% of women
  - a reason for missed workdays
- Treatment includes oral/IM contraceptives and anti-inflammatory agents

Why Use Cox II Inhibitors?

- 1. Approx. 200 deaths attributed to Oxycontin use/abuse in 2002.
- 2. Approx. 16,000 deaths in 2002 related to NSAID side effects.
- 3. It makes common sense to more safely utilize Cox II’s vs. traditional NSAIDs.

When can you utilize Cox-II’s?

- 1. Any acute or chronic pain syndromes if not contraindicated.
  a. somatic pain
  b. visceral pain (dysmenorrhea)
  c. neuropathic pain-as adjunctive treatment
- 2. OA-RA-Rheumatoid variants
- 3. As safe or safer than NSAID’s for longer term usage?
What to do if your patient cannot tolerate COX-II meds?
- Tylenol/Acetaminophen if no liver disorders nor elevated liver enzymes.
- Tramadol-Acetaminophen (Ultracet) if Acetaminophen alone is not effective.
- Tramadol alone in patients with liver disorders or with elevated liver enzymes.
- Start going up Analgesic ladder if appropriate and medically necessary.

Other New Choices
- Fosphenytoin (Cerebyx)- inactive pro-drug of phenytoin.
- Tapentadol Hcl (Nucynta)- dual mode centrally acting opioid with Mu agonism and norepinephrine reuptake inhibition.
- Oxycodone-Naltrexone (Oxytrel)- analgesic equivalent to oxycodone, lower risk for physical dependence.
- Opana-ER- extended release oxymorphine.
- Hydromorphone extended release (Exalgo)- extended release for chronic pain patients.
- Nucynta-ER.
- Buprenorphine patch- moderate pain patients.

Risk Evaluation and Mitigation Strategy (REMS).
- Goal 1: Inform patients and healthcare professionals about potential for abuse, misuse, overdose, and addiction to opioids.
- Goal 2: Inform patients and healthcare professionals about safe use of opioids.
- Opana-ER, Suboxone, Exalgo, Nucynta-ER, and Oxycontin manufacturers are encouraging/promoting REMS.
- 2 hour course offered by FOMA/OOA.

Senate Bill 0462
- 1. Establish electronic monitoring system for scheduled II-IV Rx’s. PDMP. It is here now! Sign up!
- 3. Enhance capacity for law enforcement agencies to collect and analyze data in order to reduce drug diversion.
- 4. Regulate “Pain Clinics”.
- If over 50% of patients you see are prescribed opioids for chronic pain, you must register with the AHCA.
- Department of Health received federal grant for prescription drug program for $400,000.
- Prescription Drug Monitoring Program/PDMP is up and running!
- www.E-FORCSE.com- It works! It can save your license and protect your practice.

Senate Bill 2272 Pain Clinic Law
You must be registered with AHCA by October 1, 2010 if you advertise pain management services or if you prescribe opioids to more than 50% of your patients.
- Additional exemptions to pain management clinic registration.
- Limitations on ownership of a pain management clinic as of July 1, 2012.
- Only MD/DO may dispense any medication at a pain management clinic; the MD/DO must perform a physical on same day that he/she subscribes or dispenses controlled substance to patient at pain management clinic; prohibits dispensing more than 72 hr. supply of controlled substances to a patient at a pain management clinic for cash, check, or credit card.; requires use of counterfeit-resistant prescription blanks at pain management clinics.
- Prohibits promoting, advertising by any physician in any communications media the use, sale, or dispensing of any controlled substances.
- Requirements/limitations on designated physicians, including requiring unencumbered license.
- Limitations on who may practice in a pain management clinic after July 1, 2012.
- Criminal and disciplinary penalties for violations.
- Do you use “pain” in any of your advertising?

House Bill 7095/456.44, F.S.
- As of July 1, 2011, Physicians will no longer be authorized to “dispense” controlled substances.
- Effective 1-1-2012 Each Physician who prescribes controlled substances for the treatment of chronic nonmalignant pain must designate with their appropriate Florida State Board on his or her practitioner profile that he or she is a controlled substance prescribing practitioner. Standards-same as state and federal. Some physicians are exempt.
Development of a written individualized treatment plan for each patient, with objectives for treatment success and other treatment modalities.

Discussion with patient concerning risks and benefits of use of controlled substances.

A written agreement between physician and patient that includes reasons for which drug therapy may be discontinued and that controlled substances shall be prescribed by a single treating physician, unless authorized and documented in the medical record.

The standards of practice for a controlled substance prescribing practitioner are spelled out in the law.

A complete medical history and physical exam.

Regular follow up appointments at least every 3 months to assess efficacy and appropriateness of treatment—low risk, moderate and high more often.

Referrals to specialists when indicated.

Maintenance of accurate and complete medical records for each patient—I recommend EHR/EMR.

Certain Certified specialists and surgeons are exempted from these standards of practice.

Counterfeit-proof prescription pads/blanks must be used by practitioners for prescribing of any controlled substance as of July 1, 2011. They must be Board approved. Numeric and word numbers

Legislation 64B15-14.005


Individual treatment plan for each patient.

Risks, benefits of controlled substances as well as abuse, addiction, physical dependence.

Written controlled substance agreement.

Patient will be seen at regular intervals not to exceed 3 months.

Maintain accurate, current, and complete records.

Medical records must include but are not limited to:

- Complete Hx and Px including Hx of drug abuse or dependence/Use PADT-ORT. Diagnostic, lab, therapeutic results. Evaluations and consultations. Treatment objectives. Discussion of risks and benefits. Treatments. Rxs-Medications including date, type, dose, and quantity prescribed.
- Instructions and agreements. Periodic reviews, at least every 3 months. Results of drug testing. Photo of patient’s government issued photo identification. If a written controlled substance is given to patient, a duplicate/copy of the prescription. The physician’s full name presented in a legible manner.

Board/AHCA-Guidelines

A) Evaluation-complete H&P, document nature/intensity of pain, current and past Txs, coexisting conditions, & presence of 1 or more recognized medical conditions for use of controlled substances or off-label medication uses.

B) Treatment plan-objectives, individualize, document response, amend plan each visit.

C) Informed Consent/Patient Agreement—Patient and Doctor obligations and duties, unannounced urine tests, compliance to plan, including proper medication schedule, pill counts.

D) Periodic Review—modify plan each visit, document changes in pain levels, levels of functioning, compliance to treatment plan 3 Month Review of plan standard.

E) Consultations-Orthopedics, Neurology, Psychiatry, Physical Medicine, Neurosurgery, Rheumatology: Co-manage vs. 2nd Opinion vs. Refer—Low risk, medium risk, high risk.
Board continued.
- F) Medical Records - document everything!
  Dictate or utilize electronic medical records for most accurate and defendable documentation. Include all discussed in A through E. Records must be current, maintained in accessible manner and readily available for review.
- G) Compliance with Controlled Substances Laws and Regulations, State Board and AHCA Guidelines - Remain current, keep up with CME, AOA, AMA, FOMA, FMA, Academy resources. Use E-FORCSE.com.

Universal Precautions Approach
- Reassessment of Pain Score and Function
  - At regular intervals
  - Supports the decision to continue or discontinue trial

Monitoring Patients on Chronic Opioid Therapy
- Key Components
  - Reassessment
    - Pain
    - Function
    - Progress towards mutually defined goals
    - Adverse events
    - The patient’s “experience”
- Tools
  - PADT, COMM
  - Pill, patch counts
  - Urine drug screens
  - Prescription monitoring programs

Identifying Aberrant Drug-related Behavior
- Differential diagnosis
  - Understand the terminology
- Know how you will approach the situation
  - Exit strategy
- Discuss concerns with the patient
  - Addiction
  - Long-term plan
  - Safe medicine practices (e.g., storage, disposal, sharing)

Questions?
Thank you!

References: