

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

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- Past President, FOMA, 1996-1997.
- Past President, FOMA District XI, 2008-2010.
- Medical Director, ICP&R, Cape Coral, Fl.
- Risk Management/Continuing Medical Education
Florida Society of ACOFP.

Saturday 1:15 PM, July 29, 2017.

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, The Florida Board of Osteopathic Medicine.
2. JCAHO Standards 1999.
3. Federation of State Medical Boards Joint Consensus
4. Federal Controlled Substances Act 1970.
5. DEA Statements.
6. Florida House/Senate Bills 7095, 0462, and 2272, Florida Statute Chapter 893, 456.44, 459.0137, 64B-15-14.005. 2017 Update.
7. Risk Evaluation and Mitigation Strategy.
8. E-Force-PDMP.
9. Lee County Coalition for a Drug-Free South West Florida.
10. Responsible Opioid Prescribing- A Clinician's Guide, Second Edition.

Guidelines- Continued

- 11. Amendment 2.
- 12. House Bills 7097, 5203, and 557.

Addressing Prescription Pain Medicine Abuse & Misuse: *A Framework For Safe Prescribing*

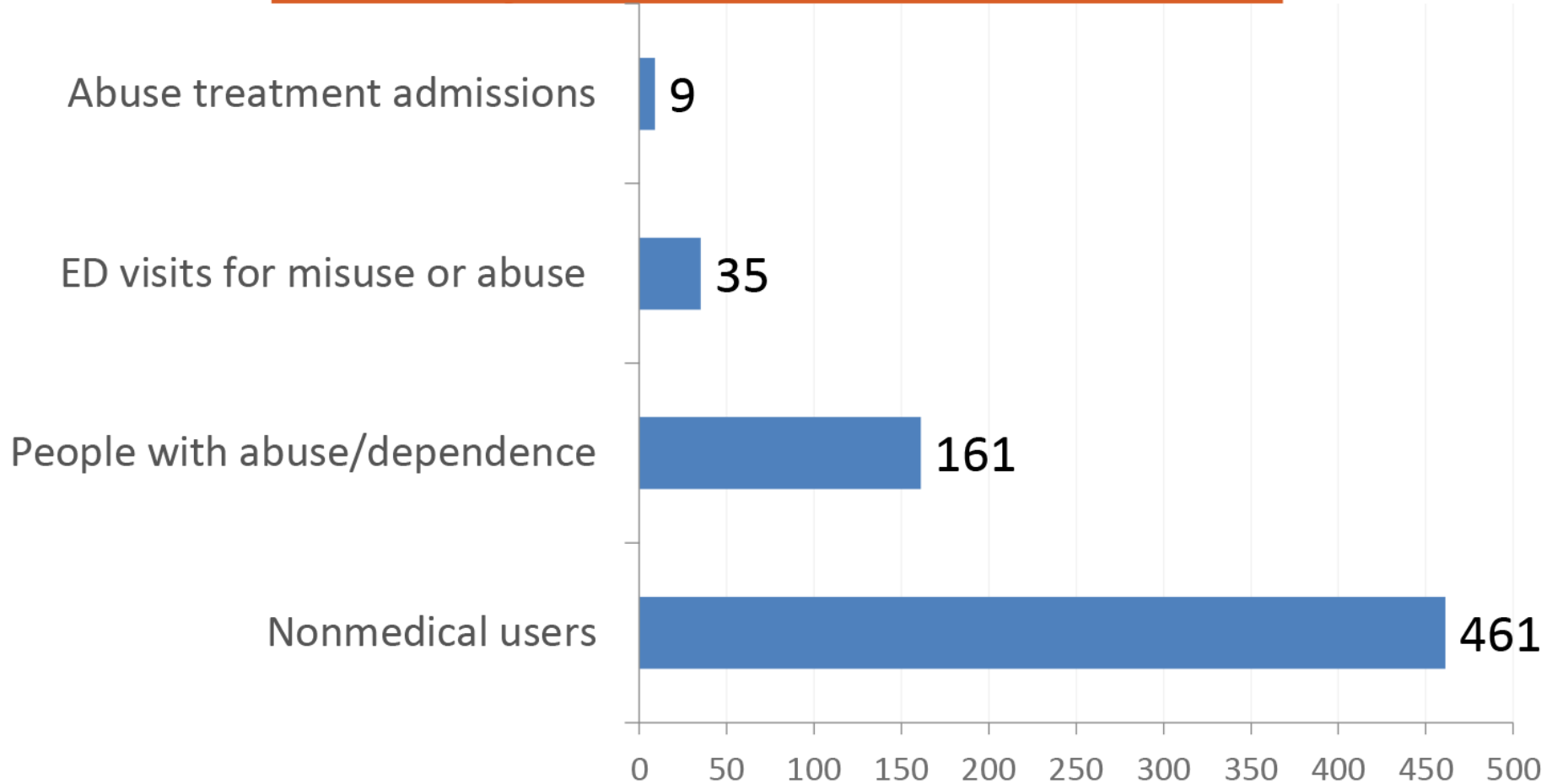


Florida Statistics

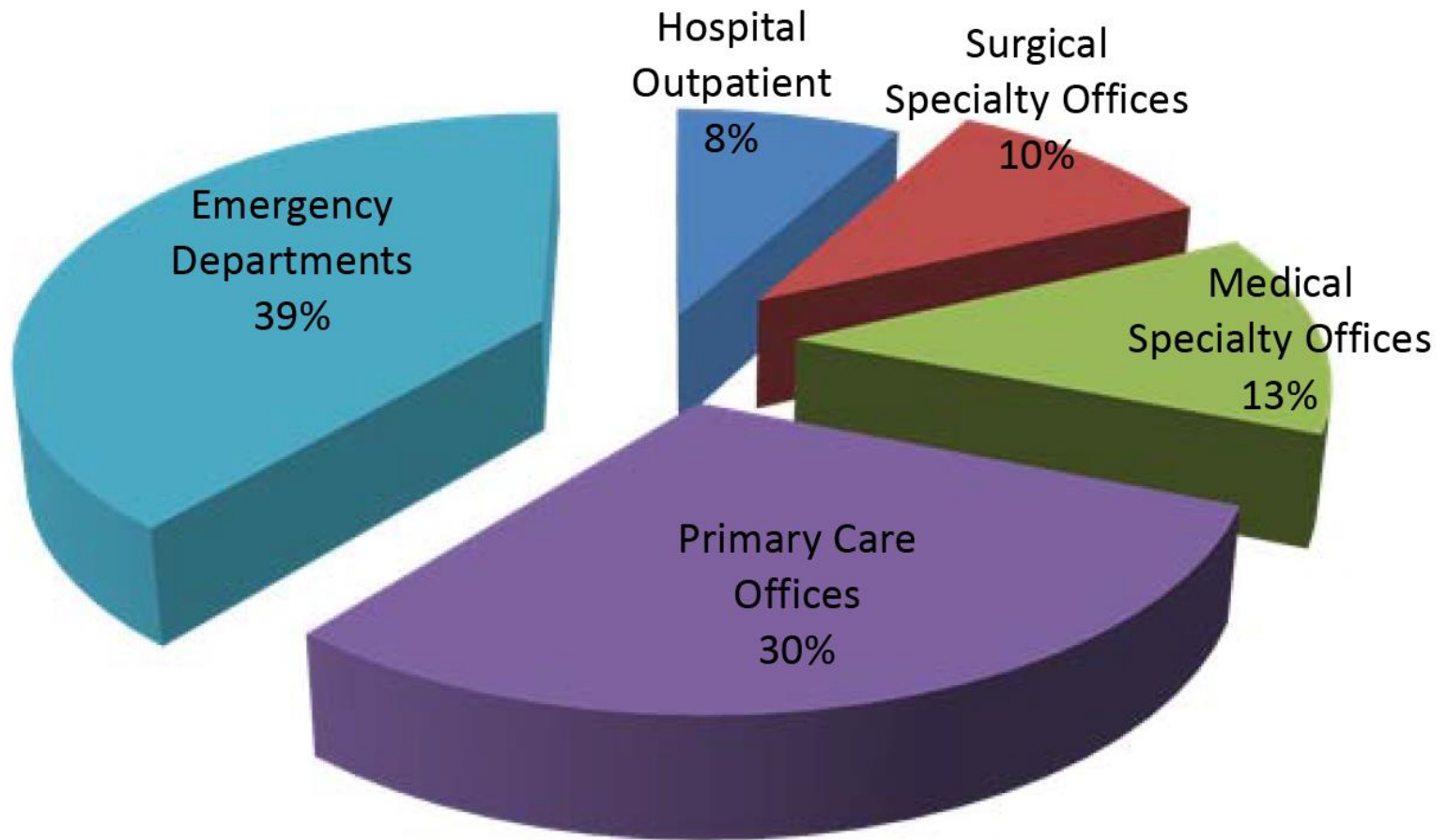
- 7 Floridians die daily from lethal overdoses. Additional 7 persons die daily with at least one prescription drug detected in combination with alcohol or other drugs. Florida 2014: Heroin detected in 447 fatalities, more than double in 2013. Fentanyl detected in 538 deaths, Oxycodone blamed in 978 deaths, down 7% from 2013. Alprazolam in 1,316 deaths. Alcohol in 3,675 deaths. Of 8,538 deaths in Florida on 2014, vast majority had more than 1 drug in their system. Deaths from most prescription drugs have slightly decreased, deaths from Heroin and Fentanyl have increased.

Public Health Impact of Opioid Analgesic Use:

For every 1 overdose death there are



Distribution of Prescription Opioid Analgesics by Health Care Setting



Stakeholders

- We are all stakeholders

- Physicians
- Nurses
- Pharmacists
- Dentists
- Law Enforcement Officials
- Hospitals
- EDs, Clinics
- Insert your name here _____

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's Attorney, 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 have slowed new unregulated Pain Clinics. REMS.

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 often stops once the pain is relieved.

Substance Abuse:

- use of any substance for non-therapeutic purposes (opioids for depressed mood).

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.
- Sub acute 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; comorbidities.
- 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/ADL's

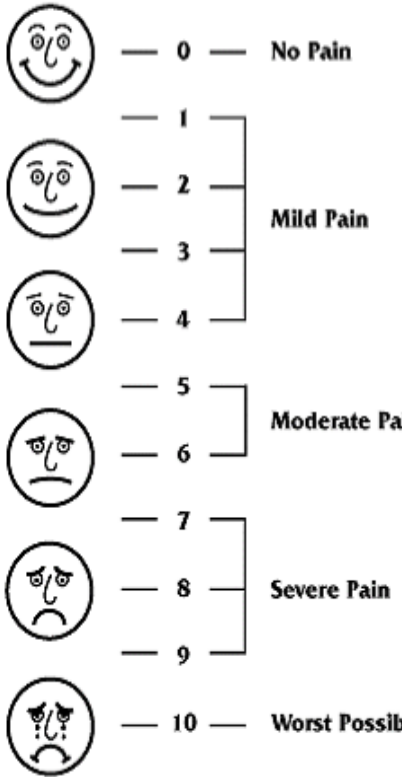
Initial Pain Assessment: Psychosocial Examination

- 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, always check central source
 - Adjacent sites (for referred pain)
 - Sites of known disease/ tumor invasion
 - Musculoskeletal and neurologic systems
- Diagnostic Evaluation:
 - Laboratory studies
 - Radiologic studies: X Ray ,CT, MRI.
 - Neurophysiologic testing
 - Urine drug screening

Pain Assessment Tools: Intensity



Opioid Risk

- *Old definition*
 - The potential for opioid analgesia adverse effects
 - Constipation
 - Nausea/Vomiting
 - Dry mouth
 - Itching
 - Sweating
- Respiratory Depression

Opioid Risk

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

SCREENER and OPIOID ASSESSMENT for PATIENTS with PAIN (SOAPP), PAIN ASSESSMENT and DOCUMENTATION TOOL (PADT). OPIOID RISK TOOL.

- 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?
PADT- Useful tool for clinicians evaluating care and outcomes during opioid therapy. Also Opioid Risk Tool.

Opioid Risk Assessment Tools

- **Screener and Opioid Assessment for Patients with Pain (SOAPP)^{®1}**
 - 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

1. Butler SF, Budman SH, Fernandez K, Jamison RN. *Validation of a screener and opioid assessment measure for patients with chronic pain*. Pain. 2004 Nov;112(1-2):65-75.

2. [Link to tool on PainEDU.org](#)

Opioid Risk Assessment Tools

- **Pain Assessment and Documentation Tool (PADT™)¹**
 - Clinician-directed interview – progress note format
 - Covers the 4 “A”s
 - Not scientifically validated
 - Subjective assessment
 - No scoring
 - Overall impression of benefit
 - Includes a section for plan

Opioid Risk Assessment Tools

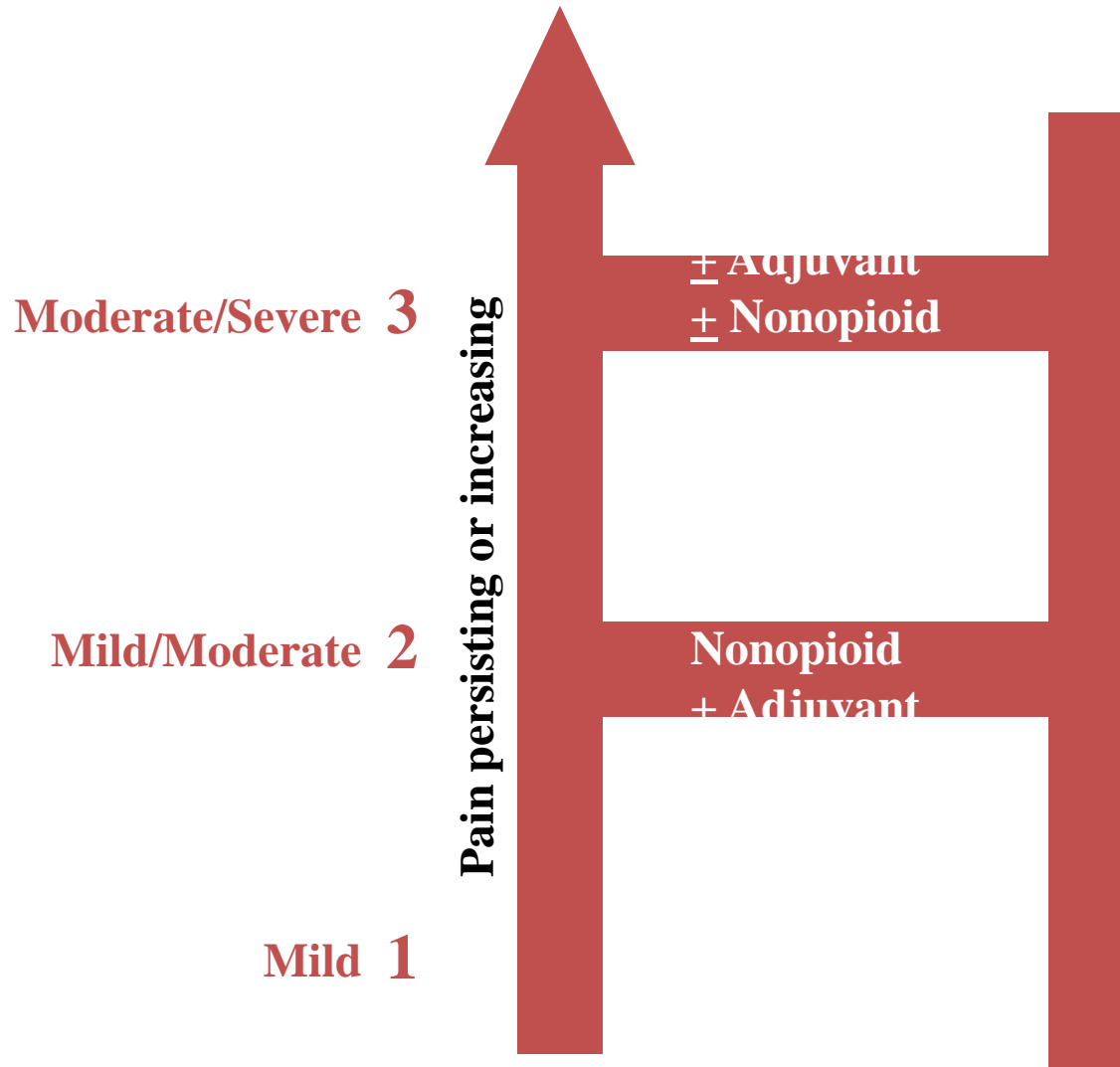
- **Opioid Risk Tool (ORT)¹**
 - Brief screening tool
 - Simple
 - Clinician administered
 - Not validated, but used frequently

1. Webster LR, Webster RM. *Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool*. Pain Med. 2005 Nov-Dec;6(6):432-42.

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

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.

Opioid Classification

- Naturally occurring Opioids
- Semisynthetic Opioids
- Synthetic Opioids

Naturally Occurring Opioids

- Morphine
Codeine
Thebaine

Semisynthetic Opioids

- Hydrocodone
Hydromorphone
Oxycodone
Oxymorphone
Heroin
Buprenorphine

Synthetic opioids

- Meperidine/Demerol
Methadone
Fentanyl
Pentazocine/Talwin
- 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 I

Federally still Schedule I.

Medical marijuana is controversial; It has passed and the Legislature finally agreed on a bill. We need more studies. Long term effects may be worse than benefit.

Charlotte's Web legislation went through Florida Legislature and by July 3rd new DOH guidelines will be implemented, and has until Oct. 3rd to put rules into effect. Medical directors, growth farm regions, and retail outlets have been selected. Continue to monitor FOMA newswire and DOH updates.

Florida Governor Rick Scott

- On 6-23-17 he signed legislation to implement the medical marijuana amendment voters approved last year. The legislation paves the way for 10 more medical marijuana treatment centers by Oct. 3, in addition to the seven already operating. 5 that applied in 2015 will be licensed in Aug. The other 5 include one set aside for a group of black farmers. The law allows for either low-THC cannabis or full strength medical marijuana but still bans smoking marijuana. John Morgan has sued to try to having smoking available.

Schedule II Opioids

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

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 two to 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.

Fentanyl- Actiq and Duragesic

Demerol (Meperidine)-Avoid! Toxic metabolite after 3 days.

Dilaudid (Hydromorphone, *Hydromorphone-ER).

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. Marinol.

Opana/*Opana-ER (Oxymorphone)

Nucynta,*Nucynta-ER

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 II- Prescribing

- Written only, partial filling permitted in certain circumstances (may be transmitted via fax in certain circumstances).

No refills permitted.

High potential for abuse

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- III.
(used to be Class V)

Schedule III.

- No longer III: Hydrocodone-acetaminophen combinations- (Hydrocet, Lorcet, Lortabs, Vicodin/-ES/-HP, Norco)-all Schedule II.
Tylenol with Codeine 3 & 4- III.
No longer III: Hydrocodone/Ibuprophen
Vicoprofen)-now II.
- Suboxone/ Buprenorphine- III.

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.

- Federal Registry- 79 Fed Reg 37,623. July 2, 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 told patient to fill prescriptions at different pharmacies.
5. Physician issued prescriptions knowing that patient was delivering drugs to others.
6. Physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
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! Marijuana may replace opioids for pain in some patients but taken together can significantly decrease respiratory drive and alertness.

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 in moderate/high risk patients.
- 4. Reasons for discontinuation of treatment (dismissal from practice/care).
- 5. Patient responsibilities. Doctor responsibilities.
- 6. REMS.

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. Exit strategy.
- 5. Risk/Benefit discussion.
- 6. Informed Consent/Patient-Physician Agreement.
- 7. Treatments-Psychotherapy, PT, Interventional, Specialty Referrals.
- 8. Medications.
- 9. Instructions and directions.
- 10. Periodic/ Regular reviews. At least every 3 Months- low risk, more often-moderate risk, co manage or refer- high risk.

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

- Standards for the Use of Controlled Substances for the Treatment of Pain- Joint Consensus of AHCA, The Florida Pain Commission, The Florida Board of Medicine, and the Florida Board of Osteopathic Medicine. Initially Adopted 12-21-99, Amended 11-10-02, and 10-19-03, New Statutes 2011-2012.

Guidelines/Standards....

- 1. Pain management principles- documentation is essential!
- 2. Definitions.
- 3. Standards-very similar to “Federation...”
Guidelines.

State of Florida Dept. of Health
Board of Osteopathic Medicine
Florida Statute 459, 458 Florida
Board of Medicine, and Rule
Chapter 64-B15

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, CT scan or MRI 1 yearly.

Comprehensive metabolic profile (CMP) and CBC every 12 months. ESR, Rheumatoid and Hepatitis profiles in appropriate patients annually; more often when clinically indicated.

Medical Records Compliance

Treatment/Medication is prescribed after:

Documented history and physical.

Assessment of physical and psychological impact of pain. * Assess Low-Medium-High risk patient .

History of/or potential substance abuse,* low-med-hi!

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.

US CONGRESS Approves Office of National Drug Control Policy Reauthorization Act of 2006

- 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
- Dextroamphetamines, 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 -hypothermy
- 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 OMM/OMT in conjunction with any other treatment modalities. OMM/OMT alternative to opioids.
Use proper CPT/ICDM codes for reimbursement.
Take OMT refresher courses!

Vitamin/Nutraceutical Antiinflammatories

- Glucosamine/Chondroitin sulfates
- Boswella
- Omega 3 Fish Oil-EPA/DHA/GLA (Borage seed oil),
Perilla oil , Krill oil- not with gout!
- Cod liver oil, Flaxseed oil, Evening Primrose oil
- Udo' s Choice oil
- Methylsulfonylmethane (MSM)
- Shark cartilage
- Serrazyme
- “Arthropro”
- “Chondrox” *Turmeric !!
- Osteo-Bi Flex: Gluc.+Chondr.+MSM. Triple Strength

Management of Common Opioid Side Effects

- Constipation
 - prophylactic use of laxatives and stool softeners
- Nausea and vomiting
 - neuroleptics, metaclopramide, 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

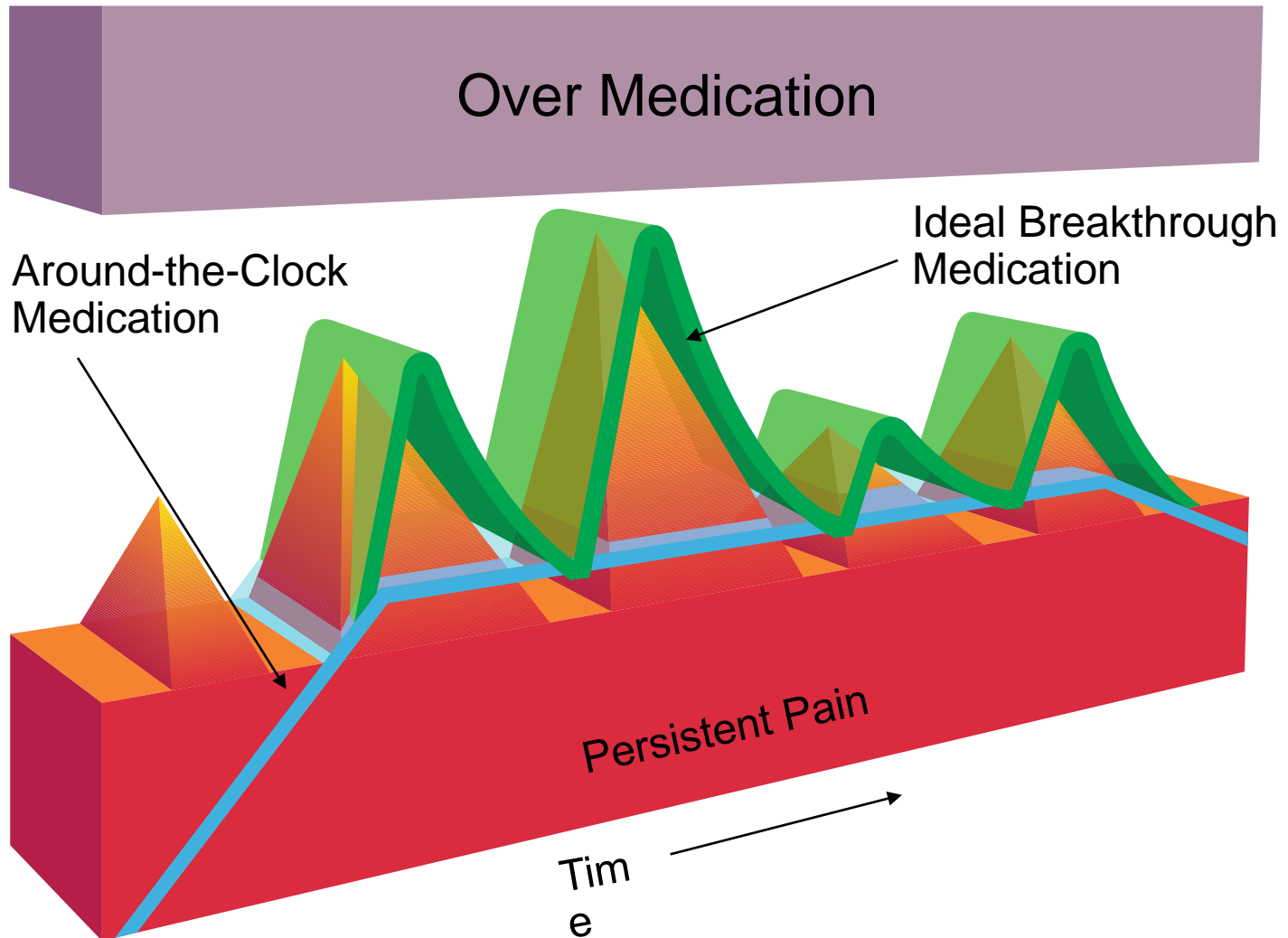
Dose Titration and Timing

- 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



Ideal Breakthrough Pain Medication

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



Post Herpetic Neuralgia

DPN and PHN

- New choices and options: Pregabalin/Lyrica. Add antiviral.
- 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 chemical mediators and CNS substance P and glutamate findings.
- Functional MRI and PET scan findings different from normal patients are definitive.

Pharmacotherapy for Arthritis

OA

- Analgesics
- NSAIDs
 - nonselective
 - COX-2 selective inhibitors
- Intra-articular glucocorticoids
- Intra-articular hyaluronic acid
- Opioids for severe.

RA

- DMARDs
- NSAIDs
 - nonselective
 - COX-2 selective inhibitors
- Local or low-dose systemic steroids
- Opioids for severe.

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, Opioids for severe only- mixed results.

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.
ER/LA Opioid manufacturers are encouraging/promoting REMS.
- 2 hour course offered by FOMA/AOA, and by FOMA District XI at our last 2 October Captiva Seminars.
- FDA Advisory Committee has voted to modify the Risk Evaluation and Mitigation Strategy For ER/LA

Senate Bill 0462

- 1. Established electronic monitoring system for scheduled II-IV Rx's. PDMP. It is here now! Sign up!
- 2. Avoid drug duplication and interactions.
- 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. Exceptions-Complimentary or sample controlled substances, Dept. of Corrections, Acute Post –Op limits, Clinical trials approved, Methadone licensed treatment programs, Hospice.

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.

HB- 7095/ 456.44/ F.S.

- 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./

HB- 7095/ 456.44/ F.S.

- The standards of practice for a controlled substance prescribing practitioner are spelled out in the law.
- A complete medical history and physical exam.

HB- 7095/456.44, F.S.

- 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

- Effective Jan. 1 2012. Complete Hx and Px before any treatment. Some specialists exempt.
- Individual treatment plan for each patient.
- Risks , benefits of controlled substances as well as Hx. of 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.

Legislation 64B15-14.005- continued

- 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.

On June 26, 2017, Governor Scott signed 3 bills relating the PDMP.

- HB 7094 extends the the scheduled repeal of the law authorizing the PDMP direct-support organization (DSO) to October 1, 2027.
- HB 5203 is the budget conforming bill of the PDMP, which authorizes the DOH to use state funds to administer the PDMP to reflect budget recommendations for fiscal year 2017-2018.
- HB 557 reduces the amount of time a dispenser has to report the dispensing of a controlled substance to the database to the close of the next business day after the controlled substance is dispensed.

Board/AHCA-Guidelines

- A) Evaluation-complete H&P, document nature/intensity of pain, current and past Tx, coexisting conditions,& presence of 1 or more recognized medical conditions for use of controlled substances or off-label medication uses.
- B) Tx 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 defensible documentation. Include all discussed in A through E. Records must be current, maintained in accessible manner and readily available for review, EHR helps .
- 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
-

Universal Precautions Approach

- Regularly Assess the Four “A”s¹ of Pain Management
 - Analgesia
 - Activity
 - Adverse effects
 - Aberrant drug-related behavior

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!

