Federal & State Laws Related to Prescribing Controlled Substances


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OVERVIEW

- Introduction
- Background
- Controlled Substances Act & the DEA
- Prescription Drug Monitoring Programs (PDMPs)
- Florida’s PDMP
- Controlled Substance Prescribing in FLORIDA \(\rightarrow\) § 456.44 (amendment effective 7-1-12)
- Summary & Conclusions
BACKGROUND
“Prescription drug abuse is a growing concern among public and state legislators alike. With the increasing number of pain killers and other medically necessary products on the market, the likelihood of a person, particularly youth or seniors, to accidentally overdose or abuse products has been rising. [For example], 30% of prescription pain killer deaths involve methadone, even though only 2% of painkiller prescriptions are for this drug.”
THE DATA

- Prescription opioid use quadrupled between 1997 & 2007\(^1\)
- Risk of opioid overdose is correlated with quantity of these drugs prescribed\(^2\)

THE REASONS

• Reasons for liberalization of opioid prescribing:
  ▪ Heightened focus on pain management
  ▪ Joint Commission mandate: assess pain as “vital sign”
  ▪ Use of pain scores to measure patient satisfaction
  ▪ New indication for long-term opioid use to treat non-cancer related pain
THE PARADOX

Simultaneous pressures to increase opioid prescribing for the benefit of individual patients and to reduce it for the sake of public health.
CONTROLLED SUBSTANCES ACT & DRUG ENFORCEMENT AGENCY
DEA & CSA

• Drug Enforcement Administration (DEA)
  ▪ Established in 1973
  ▪ Responsible for enforcing the CSA
  ▪ 2 Fold Responsibility
    ✓ Prevent diversion & abuse of controlled substances
    ✓ Ensure adequate & uninterrupted supply is available to meet legitimate medical, scientific & research needs

• Controlled Substance Act (CSA)
  ▪ 21 USC §§ 801-890 (2011)
  ▪ Sets forth federal law → illicit & licit controlled substances

• Controlled Substance
  ▪ Categorization of meds having higher-than-average potential for abuse or addiction by class
  ▪ Divided into 5 classes (Schedules I through V) based on abuse and/or addiction potential

• DEA publishes annual updated schedules
  ▪ 21 C.F.R. §§ 1308.11-1308.15
  ▪ Schedule I → illegal street drugs (heroin, LSD, cannabis...)
  ▪ Schedule II through V (most → least potential for abuse)
DEA & CSA

• **Schedule Examples:**
  - **I**  hero, cannabis, LSD, peyote, ecstasy, ...
  - **II**  morphine, codeine, opium, hydromorphone, methadone, meperidine, oxycodone, fentanyl
  - **III**  contain < 15 mg hydrocodone/dose (Vicodin®) & products containing < 90 mg codeine/dose (Tylenol w/codeine®) + non-narcotics: benzphetamine, dronabinol (Marinol®), ketamine, anabolic steroids
  - **IV**  propoxyphene, benzodiazepams, triazolam (Halcion®)
  - **V**  generally used for antitussive, antidiarrheal & analgesic purposes containing limited amounts of narcotics & stimulants

• **CSA Practitioner’s Manual**
Prescription Drug Monitoring Programs (PDMPs)
PDMPs

• Created in 1993 through federal legislation
• Support formation of state-based PDMPs
  ▪ **Goal:** track prescribing of controlled substances
• Programs had limited effect in pre-Internet era
  ▪ lag time of paper reporting, absence of off-hours access to programs, voluntary nature of reporting
• Renewed interest in PDMPs due to the government (White House Office of National Drug Policy/CDC/FDA) & increased funding

http://www.namsdl.org/presdrug.htm
PDMPs

• As of April 2012
  ▪ 42 states have operational PDMPs
  ▪ 6 states have enacted legislation to develop programs
• Florida’s provisions were amended & became effective July 1, 2012
  ▪ www.fl senate.gov/Session/Bill/2012/0787
PDMPs

Status of Prescription Drug Monitoring Programs (PDMPs)

http://www.namsdl.org/presdrug.htm
PDMPs

What are they???
PDMPs

- PDMPs are tools used by government officials to reduce prescription drug abuse & diversion
- PDMPs collect, monitor & analyze electronically transmitted prescribing & dispensing data
- PDMPs get data submitted by pharmacies & dispensing practitioners
- Managed under auspices of a state, district, Commonwealth or U.S. territory

http://www.pmpalliance.org
PDMPs

### Characteristics of an Ideal Prescription-Drug Monitoring Program.*

- Ease of access
- Standardized content
- Real-time updates
- Mandatory pharmacy reporting
- Monitoring of prescribing of drugs in DEA Schedules 2–5 and “drugs of concern”
- Interstate accessibility
- Confidentiality and security
- Support for public health initiatives and research
- Capability for strictly monitored access by nonprescribers

* DEA denotes Drug Enforcement Administration.
PDMPs

Reasons That Prescribers Are Not Using a PDMP if Available.


- Time restraints: 73%
- Feeling it would not change practice for that patient: 39%
- Difficult navigation: 29%
- Forgetting the password: 28%
- Never having applied for access: 11%
- Lack of computer availability: 9%
Florida’s PDMP
E-FORCSE
FLORIDA’s PDMP

- E-FORCSE
  - Electronic-Florida Online Reporting of Controlled Substances Evaluation program
  - Created in 2009 to encourage safer prescribing of controlled substances and reduce drug abuse & diversion in the state of Florida
  - Selected Health Information Designs, Inc. to develop database
    - Will collect & store prescribing & dispensing data

- Monitors controlled substances in Schedules II, III & IV

www.doh.state.fl.us/mqa/pdmp/home.html
FLORIDA’s PDMP
E-FORCSE

• § 893.055 Florida Statutes
  ▪ Requires health care practitioners to report to PDMP each time a controlled substance is dispensed
  ▪ Reported through electronic system ASAP but not > 7 days after dispensing

• E-FORCSE is HIPAA compliant

http://flsenate.gov/laws/statutes/2010/893.055
Controlled Substance Prescribing

Florida Statute
Title XXXII § 456.44

http://www.flsenate.gov/Laws/Statutes/2011/Chapter456/All
Controlled Substance Prescribing

§ 456.44

• Amendment effective 7/1/12: a licensed physician under chapter...459 (osteopathic),...who prescribes any controlled substance, as defined in § 893.03, for the treatment of chronic nonmalignant pain must:
  ▪ Designate himself or herself as a controlled substance prescribing practitioner on the physician’s practitioner profile
  ▪ Comply with the requirements of [the] section and applicable state boards

• Defines the STANDARDS OF PRACTICE

http://www.fl senate.gov/Laws/Statutes/2011/Chapter456/All
Controlled Substance Prescribing
§ 456.44

STANDARDS of PRACTICE

• Complete H & P
  ▪ Documentation Requirements re: PAIN
  ▪ Pain
    ➢ Nature, intensity, current & past treatment, underlying or coexisting conditions, effect on physical & psychological function, review of past records, previous diagnostic studies, & h/o EtOH & substance abuse

• Recognized medical indications for use of a controlled substance

• Written plan for assessing risk of aberrant drug-related behavior (may include drug testing)

• Assess risk & monitor ongoing use for aberrant drug-related behavior

Controlled Substance Prescribing
§ 456.44

STANDARDS of PRACTICE

• **Documentation** in medical record
  - Written individualized treatment plan for each patient
  - Discussion of risks & benefits of controlled substances
  - Written agreement between physician & patient outlining patient’s responsibilities

STANDARDS of PRACTICE

• **Documentation** in medical record
  - Seen @ regular intervals not > 3 months
    - Requirements outlined for each office visit

• **Referral Requirement**
  - Refer patient as necessary for additional evaluation & treatment to achieve treatment objectives
  - Consult or refer to “Addictionologist” any patient with h/o substance abuse or comorbid psychiatric problem
Controlled Substance Prescribing

§ 456.44

STANDARDS of PRACTICE

• Referral Requirement
  ▪ Patients with S/S of substance abuse shall be immediately referred to board-certified pain management physician, addiction medicine specialist, or mental health addiction facility dealing with drug abuse or addiction **UNLESS** the physician is board certified/eligible in pain management

Controlled Substance Prescribing

§ 456.44

EXCLUSIONS

- Board certified anesthesiologist, physiatrist or neurologist
- Board certified physician who has surgical privileges @ a hospital or ASC & primarily provides surgical services
- Board certified medical specialist who has completed a fellowship in pain medicine approved by the ACCGME or AOA, or who is board approved by the American Board of Medical Specialties or AOA & performs interventional pain procedures of the type routinely billed using surgical codes

http://www.fl senate.gov/laws/statutes/2011/456.44
Summary & Conclusions
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