

TREATING PAIN: A DELICATE BALANCE

Presented by Sherry Green, CEO
National Alliance for Model State Drug Laws



National Association of State Controlled Substance Authorities
Annual Conference
October 18th through 21st, 2011

- **2010 Patient Protection and Affordable Care Act**
- **2011 Pill Mill Crackdown Act**
- **Federation of State Medical Boards:
Model Policy for the Use of Controlled
Substances for the Treatment of Pain
(May 2004)**

2010 PATIENT PROTECTION AND AFFORDABLE CARE ACT

Institute of Medicine (IOM) released report on Relieving Pain in America

Annual cost of common chronic pain conditions is \$560-635 billion in direct medical treatment and lost productivity

Diversion and abuse of opioids are serious problems

Safe and effective option – use as prescribed and monitor use appropriately

2011 PILL MILL CRACKDOWN ACT

Outlines penalties for operation of a pill mill

Prison for those who distribute Schedule II's and III's through a pill mill

FEDERATION OF STATE MEDICAL BOARDS: MODEL POLICY
FOR THE USE OF CONTROLLED SUBSTANCES FOR THE
TREATMENT OF PAIN (MAY 2004)

Diagnosis and treatment of pain is integral to the practice of medicine

Encourages physicians to view pain management as part of a quality medical practice

Use of approved analgesics for non-legitimate purposes can lead to diversion and abuse

Expects physicians to incorporate safeguards into their practices

- Physician-patient relationship must exist
- Prescribing of controlled substances for pain must be based on clear documentation of unrelieved pain

LOS ANGELES TIMES - SEPTEMBER 17TH, 2011

REPORTED BY LISA GIRION, SCOTT GLOVER AND DOUG SMITH

Drug deaths outnumber traffic fatalities for
the first time

Surge in deaths fueled by prescription pain
and anxiety drugs

MEDICAL NEWS TODAY – JULY 22ND, 2011

Geisinger Health System study of 705 patients undergoing long-term opioid therapy for non-cancer pain

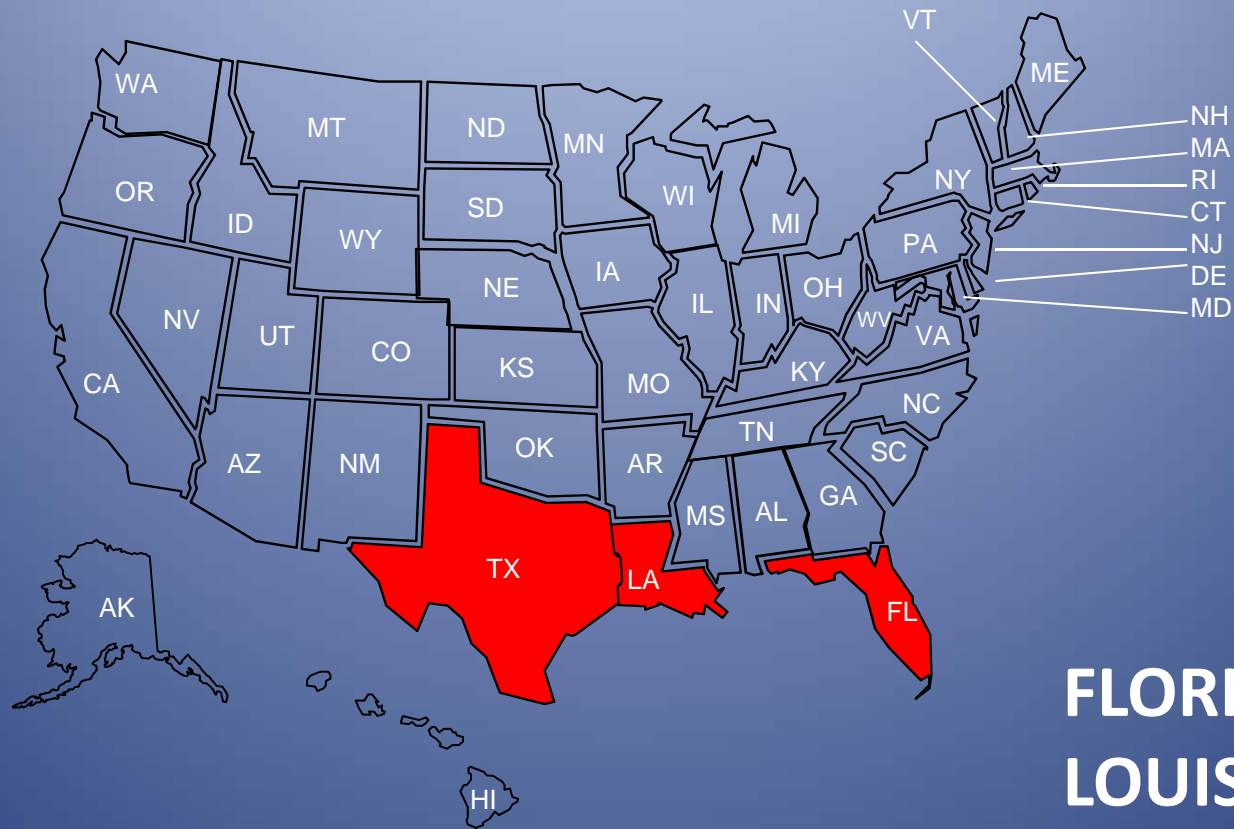
35% of patients met the American Psychiatric Association's (APA) new criteria for addiction

STATE REGULATION OF PAIN CLINICS

There are currently 5 states that regulate pain clinics or passed legislation to do so in 2011

More states are likely to introduce pain clinics legislation in their respective upcoming legislative sessions

STATES THAT REGULATED PAIN CLINICS PRIOR TO 2011



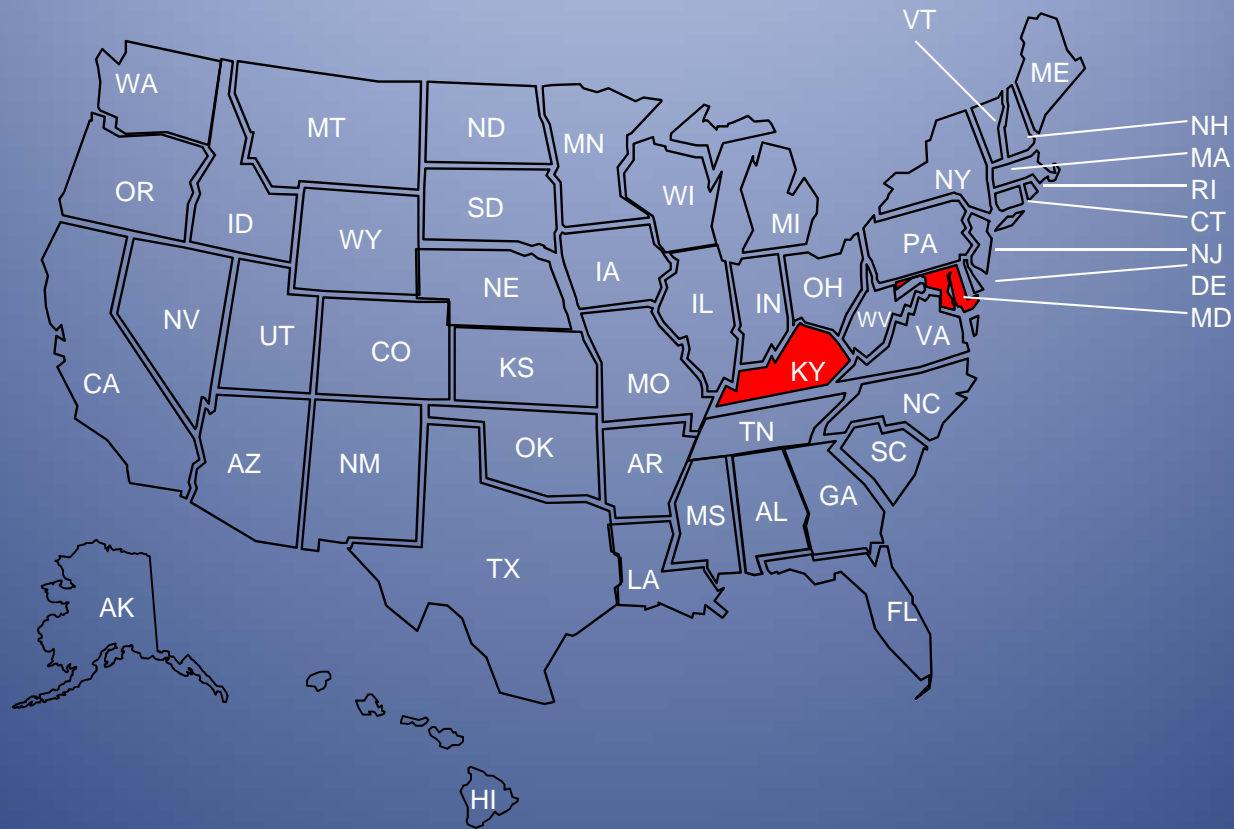
FLORIDA
LOUISIANA
TEXAS

STATES THAT PASSED LEGISLATION IN 2011 TO REGULATE PAIN CLINICS



OHIO
TENNESSEE

STATES THAT INTRODUCED LEGISLATION IN 2011 TO REGULATE PAIN CLINICS



KENTUCKY
MARYLAND

**NINE COMMON
COMPONENTS OF STATE
PAIN CLINIC LAWS AND
REGULATIONS**

1. DEFINITIONS

“Pain Management Clinic” – Defining the facilities to which the law will apply

Can be publically or privately owned

Generally a free-standing location

Clinic physicians and nurses are primarily engaged in the treatment of pain by prescribing narcotic medications

“Operating Physician” –

Responsibilities and qualifications for physician in charge of day-to-day operation

“Department” – State agency or department charged with clinic oversight

2. EXEMPTIONS

- Clinics that do not prescribe controlled substances for the treatment of pain
- State- or federally-operated facilities
- Hospice providers
- Hospitals and associated outpatient facilities
- Nursing homes

3. CERTIFICATION PROCEDURES

Clinics must register with designated agency or department

Qualified clinics are issued a license to operate

Annual or bi-annual review of certification

4. CLINIC OWNERSHIP QUALIFICATIONS

- Board certification by the American Board of Pain Medicine or American Board of Interventional Pain Physicians
- Subspecialty certification in pain management
- Required continuing medical education (CME) courses in pain medicine
- Required CME courses in prescribing controlled substances

Clinic ownership not permitted if person:

- Was convicted of any felony involving the prescribing, dispensing or administering of controlled substances
- Had their medical license suspended, restricted or revoked
- Was denied a drug enforcement registration number in any jurisdiction

5. OPERATING PROCEDURES

Owner must be on-site for a certain percentage of the clinic's operating hours

Maintenance of comprehensive patient records

Accessing a state's Prescription Monitoring Program, if applicable

Restricting the on-site dispensation of controlled substances

Operating physician must review a percentage of patient files

6. REGULATIONS

Law directs a designated agency to adopt regulations

Law can mandate adoption of specific regulations or that an agency must adopt any regulations necessary to implement the law

Topics addressed in existing regulations include:

- Standards for patient care
- Clinic personnel requirements
- Record-keeping procedures
- Training and education requirements

7. INSPECTION PROCEDURES

Pain clinics are subject to regular inspections to ensure compliance with state laws and regulations

Department of Health - Board of Pharmacy -
Department of Public Safety

Inspection and review of patient medical records

8. VIOLATIONS AND PENALTIES

Knowingly operating an uncertified pain clinic

Failing to maintain required records

Failing to file required reports

Crimes related to prescribing or dispensing of controlled substances

9. FEES & FINES

Inspection fees – typically paid annually or biannually

License application and renewal fees

Fines for regulatory infractions

STATE LEGISLATIVE TRENDS

Establishing “Pain Awareness Month”

Requiring pain management CME
courses

Establishing standards for treating
chronic pain

Medical Marijuana

CONTACT INFORMATION

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