

NAMSDL



National Alliance for Model State Drug Laws

**State Statutes and Regulations Relative to Chronic Pain and Pain Management
Emphasis on Pain Management Clinics
Brief Summary of Federal Provisions
June 2012**

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The first portion of this document outlines the common components of state statutes and regulations relative to privately and publically owned and operated pain clinics. As of June 2012, there are eight states that have laws or regulations that specifically address the operation of pain management clinics. Provisions cited include existing statutes and regulations from Florida, Kentucky, Ohio, Louisiana, Mississippi, Tennessee, Texas and West Virginia. States have a wide variety of additional statutes and regulations relative to pain management and the prescribing of controlled substances to manage pain - that information is summarized in the second portion of this document. Please note that the statutory examples noted in each section represent only a sample of relevant language from each state's respective pain clinic laws and regulations. Additionally, sections such as the "Exemptions" section may include bullet points that do not necessarily apply to every state with a pain clinic law or regulation.

Citations

FLA. STAT. ANN. §§ 456.037, 456.057, 458.3265, 458.327, 458.331, 459.013, 459.0137, 459.015 and 893.138 (West 2012)

FLA. ADMIN. CODE ANN. r. 64B-4.005, 64B-4.006, 64B-7.001, 64B-7.002, 64B8-9.0131, 64B8-9.0132, 64B15-14.0051 and 64B15-14.0052 (2012)

H.B. 1, 1st Extr. Sess. (Ky. 2012)

LA. REV. STAT. ANN. §§ 40:971.2, 40:2006, 40:2198.11, 40:2198.12 and 40:2198.13 (2012)

LA. ADMIN. CODE tit. 48, §§ 7801 through 7861 (2012)

30-17-1 MISS. CODE R. § 25 (2012)

OHIO REV. CODE ANN. §§ 4729.51, 4729.54, 4929.541, 4729.552, 4731.054 (West 2012)

OHIO ADMIN. CODE 4729:9-26, 4731:29-01 (2012)

TENN. CODE ANN. §§ 63-1-301 through 63-1-311 (West 2012)

TENN. COMP. R. & REGS. §§ 1200-34-01.01 to .10 (2012)

TEX. OCC. CODE ANN. §§ 168.001, 168.002, 168.051, 168.052, 167.053, 168.101, 168.102, 168.151, 168.152, 168.201, 168.202 (Vernon 2012)

22 TEX. ADMIN CODE §§ 195.1 through 195.4 (2012)

W. VA. CODE ANN. §§ 16-5H-1 through 10 (West 2012)

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Common Components of Pain Clinic Provisions

Defining the Term “Pain Management Clinic”

- Florida law defines a pain management clinic as *...any publicly or privately owned facility: (I) that advertises in any medium for any type of pain management services; or (II) where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain...*
- Newly enacted legislation in Kentucky defines a pain management facility as *...a facility where the majority of patients of practitioners at the facility are provided treatment for pain that includes the use of controlled substances and: 1. The facility’s primary practice component is the treatment of pain; or 2. The facility advertises in any medium for any type of pain management services...*
- Louisiana law defines a pain management clinic as *...a publically or privately owned facility which primarily engages in the treatment of pain by prescribing narcotic medications...*
- Mississippi regulations define a pain management clinic as a *...public or privately owned facility for which the majority (50% or more) of the patients are issued, on a monthly basis, a prescription for opioids, barbiturates, benzodiazepines, carisoprodol, butabital compounds, or tramadol...*
- Ohio law defines a pain management clinic as *...a facility to which all of the following apply: (i) the primary component of practice is treatment of pain or chronic pain; (ii) the majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol, or other drugs specified in rules adopted under this section; (iii) the facility meets any other identifying criteria established in rules under this section...*
- Tennessee law defines a pain management clinic as *...a privately-owned facility in which a majority of the facility’s patients, seen by any or all of its medical doctors, osteopathic physicians, advanced practice nurses with certificates of fitness to prescribe, or physician assistants, are provided pain management services by being prescribed or dispensed, opioids, benzodiazepines, barbiturates, or carisoprodol, but not suboxone, for more than ninety (90) days in a twelve (12) month period...*
- Texas law defines a pain management clinic as *...a publicly or privately owned facility for which a majority of patients are issued on a monthly basis a prescription for opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone...*
- West Virginia law defines a pain management clinic as *all privately owned facilities or offices where ...in any month more than fifty percent of patients of the prescribers or dispensers are prescribed or dispensed opioids or other controlled substances...for chronic pain resulting from non-malignant conditions...*

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Entities that States Typically Exempt from Pain Management Clinic Statutes and Regulations

- ambulatory surgical facilities
- clinics that do not prescribe controlled substances for the treatment of pain
- clinics that provides surgical services and thus prescribe narcotics for post-operative pain
- hospice providers
- hospitals and clinics maintained or operated by the federal government
- hospitals and outpatient facilities associated therewith
- medical or dental schools and outpatient clinics associated therewith
- nursing homes
- nursing schools and outpatient clinics associated therewith
- osteopathic schools and outpatient clinics associated therewith
- long-term care facilities
- state-operated facilities

Specific Procedures and Requirements for Certifying (a.k.a. Licensing or Registering) a Pain Management Clinic - Note that some states exempt pain clinics from registration under certain circumstances, for example, (1) if the clinic was in existence prior to the state's adoption of relevant laws and regulations or (2) the clinic is owned and operated by individuals who meet a specific set of enumerated criteria.

- A clinic's certificate must be posted in a conspicuous location that is clearly visible to both patients and inspectors
- A change in a clinic's ownership requires the submission of a new certification application
- Depending on the state, certification is generally valid for a period of one or two years after which time the owner will need to renew the clinic's certification
- Each certification is valid only at the physical address for which it was issued – if a clinic has multiple locations, the owner must obtain a certification for each physical location
- Any changes in a clinic's name, address, ownership, etc. must be reported to the relevant regulatory body within a certain timeframe – the timeframe and types of changes that must be reported vary by state
- A clinic's certification can be denied or revoked for reasons including but not limited to:
 - failure to comply with certification requirements
 - failure to employ qualified personnel
 - failure to provide a proper duty of care to patients
 - conviction of a felony for a clinic's owner or another principal staff member
 - revocation of an owner's Drug Enforcement Administration number
 - making false/misleading statements or providing false/misleading materials to state inspectors, regulatory bodies or the certifying authority

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- committing any misdemeanor or felony related to the prescribing, distribution or provision of controlled substances
- failure to file any required reports
- failure to maintain proper patient and prescription records

Regulation of Ownership of a Pain Management Clinic - Designation and Qualifications of an Operational Physician – Education Requirements

- Florida laws and regulations stipulate the following:
 - the direct or indirect owner of a pain management clinic must never have been subject to Drug Enforcement Administration number revocation, must never have has his license to prescribe, dispense, or administer a controlled substance denied by any jurisdiction and must never have been convicted of a felony for receipt of illicit and diverted drugs; and
 - though not specific to owners, Florida regulations stipulate that physicians who prescribe or dispense controlled substances in a pain clinic must meet one of seven enumerated qualifications ranging from board certification in pain medicine by the American Board of Pain Medicine to three years of documented full-time practice (defined as an average of twenty hours per week) in pain management.
- Kentucky law stipulates that at least one of a clinic’s owners or an owner’s designee (who is a physician employed by and under the supervision of that owner) must meet one of the following criteria: hold a current subspecialty certification in hospice and palliative care, hold a current board certification by the American Board of Pain Medicine, hold a current board certification by the American Board of Interventional Pain Physicians or have completed an accredited residency or fellowship in pain medicine.
- Louisiana laws and regulations stipulate the following:
 - A pain management clinic shall not be owned by a physician who has been denied the privilege of prescribing, dispensing, administering, supplying, or selling controlled dangerous substance;
 - pain management clinics must be owned by a medical director who is a physician;
 - pain management clinics may not be owned by a person who has been convicted of a felony offense or of a misdemeanor offense related to the distribution or illegal prescription of any narcotic; and
 - pain management clinics in existence since June 15, 2005 must be 100 percent owned and operated by a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

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- Mississippi regulations stipulate the following:
 - pain management clinics must be owned and operated by a hospital or medical director who (i) practices full time in Mississippi, with full time defined as at least 20 hours per week of direct patient care (ii) holds an unrestricted medical license and (iii) holds a certificate of registration from the state's Board of Medical Licensure;
 - owner/operators of pain management clinics, clinic employees and persons with whom the clinic contracts for services may not (i) have been denied a DEA license by any jurisdiction (ii) have held a restricted DEA license and (iii) have been subject to a disciplinary action involving controlled substances;
 - a pain management clinic may not be wholly or partly owned by a person who has been convicted of a misdemeanor related to the illegal sale of controlled substances or any offense constituting a felony.
- Ohio laws and regulations stipulate the following:
 - each pain management clinic must be owned and operated by one or more physicians;
 - every physician owner must complete at least twenty hours of category I CME courses in pain management every two years, including one or more courses addressing the potential for addiction;
 - every physician owner must meet one of five listed qualifications ranging from board certification by the American Board of Pain medicine to holding a subspecialty certification in hospice and palliative medicine; and
 - no physician owner has been the subject of a disciplinary action by any licensing entity that was *...based in whole or in part, on the prescriber's inappropriate prescribing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug...*
- Tennessee laws and regulations stipulate the following:
 - *... a pain management clinic...must have a medical director who is a physician that practices in this state under an unrestricted and unencumbered license...;*
 - a medical director must meet at least one of six qualifications enumerated in state regulations – these qualifications range from board certification in pain medicine by the American Board of Pain Medicine to completion of forty hours of in-person, live-participatory American Medical Association Category I CME courses in pain management; and
 - a pain management clinic may not be owned by a person who has been convicted of a felony offense or a misdemeanor, *...the facts of which relate to the distribution of illegal prescription drugs or a controlled substance or controlled substance analog...*
- Texas laws and regulations stipulate the following:
 - *... a pain management clinic must be owned and operated by a medical director who is a physician who practices in this state under an unrestricted license...;*

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- a pain management clinic cannot be wholly or partly owned by a person who's been convicted of a (1) felony offense or (2) a misdemeanor offense related to the distribution of illegal prescription drugs or controlled substances;
- owners of pain management clinics may not have previously been denied or had a restricted Drug Enforcement Administration license in any jurisdiction; and
- *...a pain management clinic may not operate in Texas unless the clinic is owned and operated by a medical director who is a physician who practices in Texas and has an unrestricted medical license...A clinic may be owned by more than one physician licensed in Texas, but a non-physician may not hold any ownership interest...*
- West Virginia law stipulates the following:
 - at least one owner of each clinic must be a physician actively licensed to practice medicine, surgery or osteopathic medicine in West Virginia;
 - each pain management clinic must designate a physician owner who bears responsibility for the clinic's operation;
 - the designated responsible physician must:
 - have a full, unencumbered license to practice
 - meet either of two training requirements (completing an accredited pain medicine fellowship or holding a current board certification from the American Board of Pain Medicine, the American Board of Anesthesiology or another approved board)
 - practice at the licensed location for which the physician has assumed responsibility
 - be responsible for complying with all requirements related to licensing and operation of the clinic
 - supervise, control and direct the activities of each individual working or operating at the facility;
 - a clinic may not be owned, nor may it employ any prescriber or physician, whose DEA number has been revoked, whose application for a license to prescribe or administer controlled substances has been denied or who has been convicted of a felony offense related to the receipt of illicit and diverted drugs.

Operating a Pain Management Clinic - Responsibilities of an Operational Physician

- Restrictions on the amount of any controlled substance that can be prescribed
 - Louisiana regulations limit prescriptions to a non-refillable thirty-day supply
 - Florida law requires physicians who prescribe more than a seventy-two hour dose of controlled substances, for treatment of chronic pain, to document the patient's record with the reason for prescribing that quantity
 - West Virginia law limits direct dispensations of controlled substances to 72-hour supply

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- Requirement that a clinic owner be physically present at the clinic for a certain number of hours
 - Kentucky law requires that at least one clinic owner or an owner's designee be physically present practicing medicine in the clinic at least 50% of the time that patients are in the facility.
 - Tennessee regulations require the medical director of a clinic to be onsite for at least twenty percent of the clinic's total number of operating hours
 - Texas law requires the owner or operator of the clinic to be on-site for at least 33 percent of the clinic's operating hours
- Patient log maintenance requirements
 - Ohio regulations require that a log of patients be maintained for each day the clinic is in operation – the logs must contain the month/day/year, the legible first and last name of each patient and the patient's signature at each visit – logs must be maintained for seven years
- Requiring that a clinic owner review a certain percentage of the clinic's patient files
 - Texas law requires that a clinic owner or operator review at least thirty-three percent of the total number of patient files
- Patient record maintenance to include patient identification information, medical history, a prescription monitoring report (if applicable), chief complaint and diagnosis, lab orders and results, pathology and radiology reports, substances prescribed or dispensed and a patient-signed treatment agreement
- Physical location specifications, such as a clean environment, clearly posted required signage and notifications, a reception area and waiting room, private examination rooms, adequate file storage, secure storage for controlled substances and restrooms
- Requirements specific to patient visits
 - Louisiana regulations require (1) clinics to verify patient identity for each patient who is seen and treated for chronic pain management and who is prescribed a controlled substance and (2) patients who are prescribed controlled dangerous substances on a particular visit to a clinic to be personally examined by a pain specialist
- Requirement to access the state's prescription monitoring program
 - Louisiana regulations require a clinic's medical director to apply for access to and query capability of the Louisiana Prescription Monitoring Program; information from the PMP is to be utilized by the medical director and pain specialist to help ensure adherence to the treatment agreement signed by a patient
 - Tennessee regulations require a pain clinic's medical director to establish quality assurance policies and procedures related to health care provider access to the state's controlled substance monitoring database as clinically indicated but at a minimum for each new patient admission and once every six months thereafter
 - West Virginia law requires a treating physician in a pain management clinic to access the state's Controlled Substance Monitoring Program to ensure that a patient is not obtaining controlled substances from multiple physicians

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Mandating the Adoption of Implementing Regulations that Address the Following:

- Billing procedures
- Inspection procedures
- Complaint procedures
- Certification application procedures
- Grounds for denial or revocation of certification
- Standards and procedures governing daily operation of the clinic
- Standards for patient care
- Clinic personnel requirements
- Training and education requirements
- Record-keeping
- Defining relevant terms (if definitions are not provided in the state's statute)
- Fee schedules

Inspections

- Louisiana regulations require the following on an annual basis:
 - annual fire marshal inspection;
 - annual inspection by the Office of Public Health;
 - quarterly fire alarm system test by facility staff; and
 - regular inspections of the clinic elevators
- Tennessee law provides that *...each board shall have the authority to inspect a pain management clinic which utilizes the services of a practitioner licensed by that board. During such inspections, the authorized representatives of the board may inspect all necessary documents and medical records to ensure compliance...*
- Texas regulations provide that the *...board may conduct inspections...including inspections of a pain management clinic and of documents of a physicians' practice...The board shall conduct inspections of pain management clinics if the board suspects that the ownership or physician supervision is not in compliance with board rules...*

Violations and Penalties

- Violations relative to operation of a pain management clinic can include the following:
 - The practice of medicine without a valid medical license issued by the state in which the clinic is located;
 - Knowingly operating, owning or managing an uncertified pain management clinic;
 - Failing to maintain required records;

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- Providing investigators and regulatory agencies with false or misleading information and/or interfering with an inspection;
- Failing to file required reports;
- Any felony or misdemeanor related to the prescription, distribution or provision of controlled substances
- False or misleading advertising of clinic services; and
- Committing medical malpractice in relation to operation of a pain management clinic.
- Florida law states that the *...department may impose an administrative fine on the clinic of up to \$5,000 per violation for violating the requirement of this section...In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:*
 - *The gravity of the violation...;*
 - *...What actions, if any, the owner or designated physician took to correct the violations;*
 - *Whether there were any previous violations at the pain management clinic;*
 - *The financial benefits that the pain management clinic derived from committing or continuing to commit the violation...*
- Kentucky law states that violating the state's pain management facility provision constitutes a Class A misdemeanor.
- Louisiana law states that *...Whoever violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years, and in addition may be sentenced to pay a fine of not more than fifty thousand dollars...*
- Mississippi regulations state that violation of the pain management clinic provision constitutes unprofessional, dishonorable or unethical conduct likely to deceive, defraud or harm the public; individual offenses, depending on their nature, are considered either felonies or misdemeanors and punished in accordance with relevant state law.
- Ohio law states that the *...board may impose a fine of not more than twenty thousand dollars on a physician who fails to comply with rules adopted under this section...*
- Tennessee law states that a *...practitioner who provides pain management services at an uncertified pain management clinic is subject to an administrative penalty of one thousand dollars (\$1,000) per day...*
- Texas law states that a *...violation of this chapter or a rule adopted under this chapter is grounds for disciplinary action against a pain management clinic...*
- West Virginia law stipulates that violators of the Chronic Pain Clinic Licensing Act will be assessed a civil penalty, with each violation considered and penalized separately.

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Fees Associated With Operation of a Pain Management Clinic

- Florida regulations stipulate that *...an inspection fee of \$1,500 shall be paid annually for each location required to be inspected...*
- Louisiana law provides that *...there shall be an annual license fee to be set by the department not to exceed one thousand dollars for any license issued in accordance with the provisions of this Part...*
- Tennessee regulations include a fee schedule for pain management clinics including a \$405.00 Initial Certificate Fee, a Renewal Fee of \$405.00, a Regulatory Fee of \$10.00 and a late renewal penalty fee of \$100.00 per month for each month or fraction of a month that renewal is late.

Payment for Clinic Services

- Kentucky law requires pain management facilities to accept private health insurance as an allowable form of payment for services rendered and goods provided.
- Tennessee law provides that a pain management clinic may only accept checks, credit cards or money orders as payment for services provided; cash payments are only permitted for co-pays, coinsurance or a deductible when the remainder of the payment due is submitted to the patient's insurance plan.

Other Types of State Statutes and Regulations Relative to Chronic Pain and Pain Management – Please Note that the States Cited Below are only a Representative Sample of Those With Statutes Relative to the Areas Listed

1. Chronic Intractable Pain Treatment Acts – Use of Controlled Substances to Treat Pain
 - a. Many states have enacted an Intractable Pain Treatment Act, which generally includes a statement of purpose, the defining of relevant terms, a patient's bill of rights, permissible and impermissible practices with regard to prescribing and administering controlled substances for treatment of pain, possible disciplinary actions and authority for the state to promulgate rules and regulations.
 - b. The Georgia Composite Medical Board approved a new rule outlining procedures for physicians to follow when prescribing controlled substances for the treatment of pain or chronic pain. GA. COMP. R. & REGS. 360-3-.06 (2012)
 - c. Missouri authorizes a physician to prescribe, administer or dispense controlled substances for a therapeutic purpose to a person diagnosed and treated for a condition resulting in intractable pain. MO. REV. STAT. ANN. § 334.106 (West 2012)

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- d. Oklahoma enacted a provision (1) stating that Schedule II, III, IV and V drugs have a legitimate medical purpose (2) encouraging physicians to view effective pain management as part of quality medical practice and (3) authorizing a doctor to administer a high dosage of controlled drugs if that doctor feels that dosage is part of appropriate pain management for that patient.
OKLA. STAT. ANN. tit. 63 § 2-551 (West 2012)
- e. Washington recently adopted new comprehensive rules on pain management covering numerous practice specialties and a range of topics from dosing criteria, patient evaluation requirements, treatment plans and pain management specialist qualifications. (Authorizing statutes are found in Title 18 of the statutory code Business and Occupations and Implementing Rules are found in Chapter 246 of the administrative code Department of Health, both current as of 2012)

2. Medical Marijuana

- a. The Arizona Medical Marijuana Act permits the use of an allowable amount of marijuana for an enumerated list of debilitating medical conditions, which includes severe and chronic pain. ARIZ. REV. STAT. ANN. §§ 36-2801 to 2819 (2012)
- b. The New Jersey Compassionate Use Medical Marijuana Act dictates that a distinction be made between medical and non-medical uses of marijuana and protects from arrest patients who use marijuana to alleviate suffering from debilitating medical conditions, including chronic pain. N.J. STAT. ANN. §§ 24:6I-1 to 16 (West 2012)

- 3. Insurance Coverage for Pain Treatment Services - Connecticut mandates that every individual and group health insurance policy must provide access to a pain management specialist and coverage for pain treatment ordered by such a specialist.
CONN. GEN. STAT. ANN. §§ 38a-492i, 518i (West 2012)

- 4. Patients Bills of Rights – Some states address pain management and access to treatment for pain in a Pain Patient’s Bill of Rights, noting that inadequate treatment of acute and chronic pain is a significant health problem and that patients who suffer from pain should have access to proper treatment for that pain

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5. Pain Treatment Medical Education

- a. California requires all physicians and surgeons to complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. CAL. BUS. & PROF. §§2190.5, 2191 and 2196.2 (West 2012)
- b. The Michigan department of consumer and industry services, together with the department of community health, is tasked with developing, publishing and distributing a booklet on pain. MICH. COMP. STAT. ANN. § 333.16204d (West 2012)
- c. New Jersey designated September of each year as “Pain Awareness Month.” N.J. STAT. ANN. §§ 36:2-157, 158 (West 2012)
- d. New Mexico law requires non-cancer pain management continuing education for health care providers who hold a federal drug enforcement administration registration and licensure to prescribe opioids. N.M. STAT. ANN. § 24-2D-5.1 (West 2012)
- e. Ohio requires the state medical board to approve one or more continuing medical education course of study included within the programs certified by the state medical association and the state osteopathic association. OHIO REV. CODE ANN. § 4731.283 (West 2012)
- f. The Texas Education Code stipulates that pain treatment medical education course work should include instruction in pain assessment, pain anatomy and physiology, the advantages and disadvantages of various methods of drug administration, the impacts of chronic pain on patients, the indications for outcomes of pain relieving techniques and the outcome of treatment of pain emanating from a damaged nervous system and neuropathic pain. TEX. EDUC. CODE ANN. § 51.309 (Vernon 2012)

6. Pain Management Commissions, Authorities and Proclamations

- a. Michigan created an advisory committee on pain and symptom management to help develop an integrated approach to understanding and applying pain management symptoms and techniques. MICH. COMP. LAWS ANN. § 333.16204a (West 2012)
- b. New Mexico created a pain management advisory council tasked with reviewing current pain management practices in the state as well as national pain management standards and educational efforts for both consumers and professionals. N.M. STAT. ANN. § 24-2D-5.2 (West 2012)

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- c. Oregon established a Pain Management Commission tasked with developing pain management recommendations, developing ways to improve pain management services and representing the pain management concerns of patients in Oregon to the Governor and the Legislative Assembly.
OR. REV. STAT. ANN §§ 413.570 to 599 (West 2012)

Federal Provisions

1. On March 14th, 2011 H.R. 1065 a.k.a. the Pill Mill Crackdown Act of 2011 was introduced in the House of Representatives – the measure was referred to the subcommittee on Crime, Terrorism and Homeland Security on March 21, 2011 and this was the last action taken on the bill. The Act enumerates penalties for operation of a pill mill, providing for imprisonment for those involved in distributing Schedule II and III controlled substances through a pill mill operation. The Senate version of this bill, S.1760, was introduced on October 20th, 2011 and after two readings was referred to the Judiciary Committee. These bills define a “pill mill” to include a doctor’s office, clinic or health care facility that routinely prescribes or dispenses controlled substances outside the scope of the prevailing standards of medical practice.
2. As part of the White House’s plan for addressing the epidemic of prescription drug abuse, the Food and Drug Administration is in the process of implementing new Opioid Drugs and Risk Evaluation and Mitigation Strategies (REMS). This program will require manufacturers of long-acting and extended-release opioids to provide educational programs to prescribers of those medications. The plan calls for drug makers to work together to develop a single system for implementing the REMS strategies. A core element of the Opioid REMS is educating prescribers (e.g., physicians, nurse practitioners, physician assistants, surgeons) so that long-acting and extended release opioid drugs can be prescribed and used safely. On November 4, 2011, the FDA announced the availability for public comment of a draft "Blueprint," developed by FDA in conjunction with other Federal agencies. The Blueprint provides a basic outline and the principals that FDA feels ought to be conveyed to prescribers and is intended to be used as a guide during the development of continuing education curricula.

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