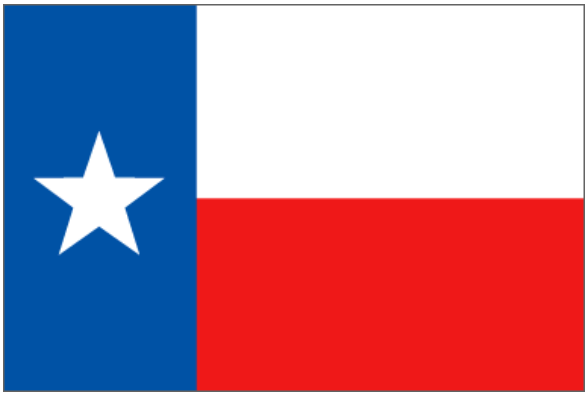
Prescribing and Dispensing Profile

Texas



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II prescriptions may only be dispensed on the written order of a practitioner

- May dispense on the oral prescription of a practitioner in an emergency
  - Pharmacist must maintain the written record created and note the emergency nature of the prescription
  - Prescriber must deliver a written prescription to the pharmacy within seven days
- May dispense on the faxed prescription of a practitioner in the following circumstances:
  - A Schedule II narcotic or nonnarcotic substance for a patient in a LTCF
  - A Schedule II narcotic to be compounded for the direct administration to a patient by certain methods
  - A Schedule II narcotic for a person with a documented terminal illness or a patient enrolled in a hospice program

Practitioner may issue multiple prescriptions for a Schedule II substance for up to a 90-day supply provided:

- Each prescription is issued for a legitimate medical purpose
- The practitioner issues written instructions on each prescription, other than the first which is to be filled within 21 days of issuance, indicating the earliest date on which a pharmacy may fill each prescription
- The practitioner concludes that providing multiple prescriptions to the patient does not create an undue risk of diversion or abuse

Schedule II prescriptions must be maintained in a separate file from all other prescriptions

Schedule II prescriptions may not be refilled

Schedule III, IV and V Prescribing Limitations (not related to pain clinics)

Schedule III – V substances may only be dispensed on the written, oral, electronic, or telephonic prescription of a prescriber

- A pharmacy that dispenses a Schedule III – V controlled substance pursuant to an oral or telephone prescription must inform the prescriber in the event of an emergency refill of the prescription

Pharmacist may dispense a Schedule III – V prescription refill without the authorization of the prescriber if:

- Failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering
- The quantity of the drug dispensed does not exceed a 72-hour supply
- The pharmacist must notify the patient that the prescription is being refilled without prescriber authorization and that authorization of the prescriber is required for any future refills
- The pharmacist must notify the prescriber at the earliest reasonable time

Schedule III – V prescriptions must be maintained in a separate file or in a readily retrievable format from all other records

Schedule III – V prescriptions may not filled or refilled more than six months after originally issued or refilled more than five times, unless renewed by the practitioner

Miscellaneous Prescribing/Dispensing Requirements

A physician who practices in an area located in a county with a population of 5,000 or less, or in a municipality or an unincorporated town with a population of less than 2,500, that is within a 15-mile radius of the physician's office and in which a pharmacy is not located may:

- Maintain a supply of dangerous drugs in the physician's office to be dispensed in the course of treating the physician's patients
- Be reimbursed for the cost of supplying those drugs without obtaining a license as a retail pharmacy
- Physician must notify the Board of Pharmacy and board that the physician practices in an area above described

Prescriptions must contain the following information:

- Quantity
- Date of issue
- Name, address, date of birth of patient
- Name and strength of controlled substance prescribed
- Directions for use
- Intended use of the substance, unless the practitioner determines that furnishing this information is not in the best interest of the patient
- Name, address, telephone number, and DEA registration number of prescriber
- Signature of prescriber

Prescribing/Dispensing Limitations for Dentists

Dentist may not prescribe, provide, obtain, order, administer, possess, dispense, give, or deliver to or for any person a narcotic drug, dangerous drug, or controlled substance that is not necessary or required or the use or possession of which would promote addiction to the drug or substance

Prescribing/Dispensing Limitations for Optometrists

An optometric glaucoma specialist may administer and prescribe any drug authorized by the Texas Optometry Act, in addition to those drugs that may be prescribed and administered by a therapeutic optometrist

- Includes appropriate oral pharmaceutical agents used for diagnosing and treating visual defects, abnormal conditions, and diseases of the human vision system, which are included in the following classifications:
  - One 10-day supply of oral antibiotics
  - One 72-hour supply of oral antihistamines
  - One 7-day supply of oral NASAIDs
  - One 3-day supply of any analgesic identified in Schedules III – V

Prescribing/Dispensing Limitations for Optometrists, cont'd.

Therapeutic optometrist may administer and prescribe any drug authorized by law

- Therapeutic optometrist may prescribe oral medications only in the following classifications of oral pharmaceuticals:
  - One 10-day supply of oral antibiotics
  - One 72-hour supply of oral antihistamines
  - One 7-day supply of oral nonsteroidal anti-inflammatories
  - One 3-day supply of any analgesic in Schedules III – V
  - Any other oral pharmaceutical recommended by the advisory committee and approved by the board

Pain Clinic/Pain Management Regulations

Pain management clinic is 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

Pain management clinics are required to obtain a certificate from the board

- Physician owner or medical director, if there is more than one physician owner, shall submit an application to the board on the prescribed form
- Only the primary physician owner shall be required to register with the board

Pain management clinics may not be owned in whole or in part by a person who has been convicted of, pled nolo contendere to, or received deferred adjudication for:

- An offense that constitutes a felony
- An offense that constitutes a misdemeanor, the facts of which relate to the distribution of illegal prescription drugs or a controlled substance

As a condition of eligibility, a physician applying for pain management certification must meet the active practice of medicine definition

Pain management clinics do not include:

- A medical or dental school or outpatient clinic associated with a medical or dental school
- A hospital, including any outpatient facility or clinic of a hospital
- A hospice
- A facility owned or operated by the state
- A clinic maintained or operated by the United States
- A nonprofit health organization
- A clinic owned or operated by a physician who treats patients within the physician's area of specialty and who personally uses other forms of treatment, including surgery, with the issuance of a prescription for a majority of patients
- Clinic owned or operated by an advanced practice nurse in this state who treats patients in the nurse's area of specialty and who personally uses other forms of treatment with the issuance of a prescription for the majority of patients

Pain Clinic/Pain Management Regulations, cont'd.

Pain clinic must be owned and operated by a medical director who is a physician that practices in Texas and has an unrestricted medical license and holds a certificate issued by the board

Medical director must:

- On an annual basis, ensure that all personnel of the clinic are properly licensed and, if applicable, trained to include 10 hours of CME related to pain management
- Be on-site at the clinic at 33% of the clinic's total number of operating hours
- Review at least 33% of the total number of patient files of the clinic, including the patient files of a clinic employee or contractor to whom authority for patient care has been delegated by the clinic
- Establish protocols
- Establish quality assurance procedures to include, at a minimum, the following:
  - A practice quality plan that requires the medical director to complete at least 10 hours of CME in the area of pain management every 2 years
  - Documentation of the background, training, and certifications for all clinical staff
  - A written drug screening policy and compliance plan for patients receiving chronic opioids
  - Performance of periodic quality measures of medical and procedural outcomes and complications that may include questionnaires or surveys for activities of daily living scores, pain scores, and standardized scales

Board policy for the treatment of pain, the intent of which is to protect the public and give guidance to physicians

- The principles underlying this policy include:
  - Pain is a medical condition that every physician sees and is an integral part of the practice of medicine
    - The goal of pain management is to treat the patient's pain in relation to overall health, including physical function, psychological, social, and work-related factors
  - The regulatory atmosphere must support a physician's ability to treat pain, no matter how difficult the case, using whatever tools are most appropriate
  - Board is charged with the responsibility of ensuring that drugs are used in a therapeutic manner
    - Physician has a duty to use drugs to help not hurt patients and the public
  - Harm can result when a physician doesn't use sound clinical judgment in using drug therapy
    - Undertreatment can result in the patient suffering continued pain
    - Overtreatment can result in abuse, addiction, and/or diversion of drugs
  - Sound clinical judgment results from evidence-based medicine and/or the use of generally accepted standards
  - Physician can demonstrate sound clinical judgment by recording his/her rationale for the treatment plan and maintaining medical records that are legible, complete, accurate, and current for each patient
  - Treatment of chronic pain requires a reasonably detailed and documented plan to assure that treatment is monitored

Pain Clinic/Pain Management Regulations, cont'd.

Guidelines to assess a physician's treatment of pain:

- Physician is responsible for obtaining a medical history and physical examination that includes a problem-focused exam specific to the chief presenting complaint
- Medical record shall document the medical history and physical examination as well as:
  - The nature and intensity of the pain
  - Current and past treatments for pain
  - Underlying or coexisting diseases and conditions
  - The effect of the pain on physical and psychological function
  - Any history and potential for substance abuse
  - The presence of one or more recognized indicators for the use of a dangerous or scheduled drug
- The physician is responsible for a written treatment plan that includes:
  - How the medication relates to the chief presenting complaint
  - Dosage and frequency of any drugs prescribed
  - Further testing and diagnostic evaluations to be ordered
  - Other treatments that are planned or considered
  - Periodic reviews planned
  - Objectives that will be used to determine treatment success, such as pain relief and improved physical and psychological function
- The physician must discuss the risks and benefits of the use of controlled substances with the patient
  - Discussion should be documented in the record
  - Discussion should include an explanation of:
    - The diagnosis
    - Treatment plan
    - Anticipated therapeutic results, including the realistic expectations for sustained pain relief and improved functioning and possibilities for lack of pain relief
    - Therapies in addition to or instead of drug therapy
    - Potential side effects
    - Adverse effects, including the potential for tolerance, dependence, addiction, and withdrawal
    - Potential for impairment of judgment and motor skills
- Physician should consider the use of a written pain management agreement between the physician and patient that sets out patient responsibilities, including:
  - That the physician may require drug tests upon request
  - Physician may limit the number and frequency of refills
  - Only one physician will prescribe dangerous drugs
  - Only one pharmacy will be used for prescriptions
  - Reasons for which drug therapy may be discontinued
- Periodic review of the treatment of chronic pain
  - Physician should see the patient for periodic reviews at reasonable intervals in view of the individual circumstances of the patient
  - Review should assess the progress toward reaching treatment objectives, taking into consideration the history of the medication usage, as well as any new information about the etiology of the pain
  - Reviews shall be documented in the medical record
  - Physician should note any adjustment to the treatment plan

Pain Clinic/Pain Management Regulations, cont'd.

- Physician should continue or modify the use of drug therapy based on an evaluation of progress toward treatment objectives
    - Progress or lack thereof in relieving pain should be documented in the patient's record
    - Satisfactory response to the treatment may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life
    - Objective evidence of improved or diminished function should be documented
    - If the patient's progress is unsatisfactory, physician should reassess the current treatment plan and consider the use of other therapeutic modalities
- Physician should refer a patient for further evaluation and treatment as necessary
- Medical records shall document the physician's rationale for the treatment plan and the prescription drugs for the chief presenting complaint and show that the physician has followed these guidelines, and shall include:
    - The medical history and physical examination
    - Diagnostic, therapeutic, and laboratory results
    - Evaluations and consultations
    - Treatment objectives
    - Discussion of risks and benefits
    - Informed consent
    - Treatments
    - Medications
    - Instructions and agreements
    - Periodic reviews

Notwithstanding any other law, a physician may prescribe or administer a dangerous drug or controlled substance to a person in the course of the physician's treatment of the person for intractable pain

- Intractable pain means a state of pain for which:
    - The cause of the pain cannot be removed or otherwise treated
    - In the generally accepted course of medical practice, relief or cure of the cause of the pain is not possible or has not been found after reasonable efforts
- Physician shall monitor the patient to ensure that a prescribed dangerous drug or controlled substance is used only for the treatment of the patient's medical condition
- To ensure that the drug is not diverted to another use and to ensure appropriateness of the treatment of the patient's targeted symptoms, the physician shall:
    - Document:
        - The understanding between the physician and patient about the patient's prescribed treatment
        - The name of the drug or substance prescribed
        - The dosage and method of taking the drug
        - The number of dosage units prescribed
        - The frequency of prescribing and dispensing the drug
    - Consult with a psychologist, psychiatrist, expert in the treatment of addictions, or other health care professional as appropriate

Training or Education Requirements or Recommendations for Practitioners who Prescribe or Dispense Controlled Substances

No specific statutes or regulations identified.

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

Executive commissioner may establish a controlled substance therapeutic research program for the supervised use of THC for medical and research purposes

There shall be created a review board

- Review board shall be composed of:
  - A licensed physician certified by the American Board of Ophthalmology
  - A licensed physician certified by the American Board of Internal Medicine and certified in the subspecialty of medical oncology
  - A licensed physician certified by the American Board of Psychiatry
  - A licensed physician certified by the American Board of Surgery
  - A licensed physician certified by the American Board of Radiology
  - A licensed attorney with experience in law pertaining to the practice of medicine
- Review board shall review research proposals and medical case histories of persons recommended for participation in a research program and determine which research programs and persons are most suitable for the therapy and research purposes of the program
- Review board shall approve the research programs, certify program participants, and conduct periodic reviews of the research and participants
- Review board may seek authorization to expand the types of diseases covered

Physician may not recommend a person for the research program unless the person:

- Has glaucoma or cancer
- Is not responding to traditional treatment for glaucoma or cancer or is experiencing severe side effects from treatment
- Has symptoms or side effects from treatment that may be alleviated by medical use of THC or its derivatives

Commissioner shall acquire THC and its derivatives from the National Institute on Drug Abuse and shall supervise the distribution of THC to program participants

- Physician is responsible for dispensing to patients

Texas Compassionate Use Act

- The department shall establish and maintain a secure online compassionate-use registry that contains the name of each physician who registers as a prescriber, the name and date of birth of the patient, the dosage prescribed, the means of administration ordered, and the total amount of low-THC cannabis required to fill the patient's prescription

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions, cont'd.

- The department shall ensure the registry:
  - Is designed to prevent more than one qualified physician from registering as a prescriber for the same patient
  - Allows a physician qualified to prescribe low-THC cannabis to input safety and efficacy data derived from the treatment of patients for whom low-THC cannabis is prescribed
- Medical use means ingestion by means of administration other than smoking of a prescribed amount of low -THC cannabis by a person for whom low-THC has been prescribed
- A physician is qualified to prescribe low-THC cannabis to a patient with intractable epilepsy if the physician:
  - Is licensed in Texas
  - Dedicates a significant portion of clinical practice to the evaluation and treatment of epilepsy
  - Is certified:
    - By the American Board of Psychiatry and Neurology in epilepsy or neurology or neurology with special qualification in child neurology and is otherwise qualified for the examination for certification in epilepsy
    - In neurophysiology by the American Board of Psychiatry and Neurology or the American Board of Clinical Neurophysiology
- A physician may prescribe low-THC cannabis to alleviate a patient's seizures if:
  - The patient is a permanent resident of this state
  - The physician complies with the registration requirements
  - The physician certifies to the department that:
    - The patient is diagnosed with intractable epilepsy
    - The physician determines the risk of low-THC cannabis by the patient is reasonable in light of the potential benefit to the patient
    - A second physician qualified to prescribe low-THC cannabis has concurred with the determination and the second physician's concurrence is recorded in the patient's medical record
- Before a physician qualified to prescribe low-THC cannabis may prescribe or renew a prescription for low-THC cannabis, the physician must register as the prescriber for that patient in the compassionate-use registry and must indicate:
  - The physician's name
  - The patient's name and date of birth
  - The dosage prescribed
  - The means of administration
  - The total amount of low-THC cannabis required to fill the patient's prescription
- A physician who prescribes low-THC cannabis for a patient's medical use must maintain a treatment plan that indicates:
  - The dosage, means of administration, and planned duration of treatment with low-THC cannabis
  - A plan for monitoring the patient's symptoms
  - A plan for monitoring indicators of tolerance or reaction to low-THC cannabis

PMP Requirements for Mandatory Registration and Access

The board may adopt rules providing for a person authorized to access PMP information to be enrolled in the program at the time the person obtains or renews the person's applicable professional or occupational license or registration

Prior to prescribing dangerous drugs or controlled substances for the treatment of chronic pain, a physician must consider reviewing the PMP data related to the patient

- If the physician determines it is not necessary to do so, s/he must document in the medical record his or her rationale for not doing so

Physician must periodically review the patient's compliance with the prescribed treatment plan for treatment of chronic pain

- In such a review, physician must consider reviewing the PMP data related to the patient
  - If the physician determines it is not necessary to do so, s/he must document in the medical record his or her rationale for not doing so

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

None.