



Prescribing Profile

Florida

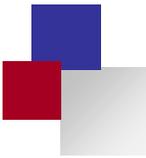


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Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II prescriptions may only be dispensing on the written prescription of a practitioner

- May be dispensed on the oral prescription of a practitioner in an emergency
 - Must be limited to a 72 hour supply
- May be dispensed on the faxed prescription of a practitioner as allowed by federal law

Schedule II prescriptions may not be refilled

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

Schedule III – IV prescriptions may be dispensed upon the written, faxed, or oral prescription of a practitioner

- Oral prescriptions must be promptly reduced to writing
- May not dispense more than a 30-day supply of a Schedule III substance on an oral prescription

Pharmacist may dispense a one-time emergency refill of a prescription for a Schedule III – V substance if:

- The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition
- In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause the patient physical or mental discomfort
- The dispensing pharmacist creates a written order containing all the prescription information required by law
- The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing
- It is limited to a 72-hour supply

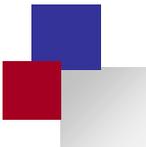
Schedule III – V prescriptions may not be filled or refilled more than five times within a period of six months after originally written unless renewed by the practitioner

- No prescription may be refilled more than one year from the date originally written

Miscellaneous Prescribing/Dispensing Requirements

Practitioners may not dispense Schedule II or III controlled substances, except that this does not apply to:

- The dispensing of samples or complimentary drugs for which the practitioner receives no remuneration
- Dispensing of controlled substances in the health care system of the Department of Corrections
- Dispensing of a Schedule II or III substance in connection with a surgical procedure
 - May not exceed a 14-day supply
 - Does not allow the dispensing more than 14 days after the surgical procedure
- Dispensing of a Schedule II or III substance in connection with a clinical trial
- Dispensing of methadone in an approved medication-assisted treatment for opiate addiction facility
- Dispensing of Schedule II or III substances in a licensed hospice facility



Miscellaneous Prescribing/Dispensing Requirements, cont'd.

Practitioners who dispense medicinal drugs for human consumption for fee or remuneration of any kind must:

- Register with his or her professional licensing board
- Comply with all laws and rules applicable to pharmacists and pharmacies
- Before dispensing any drug, give the patient a written prescription and advise orally or in writing that the patient may have the prescription filled in the practitioner's office or at any pharmacy

Prescriptions must contain the following information:

- Date and signature of prescriber
- Full name and address of patient
- Full name and address of prescriber and prescriber's federal registry number
- Name of the controlled substance, strength, quantity, and directions for use
- The number of the prescription
- The initials of the pharmacist filling the prescription and date filled

Prescribing/Dispensing Limitations for Dentists

No separate statutes or regulations related to prescribing and dispensing limitations for dentists.

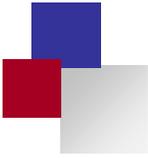
Prescribing/Dispensing Limitations for Optometrists

Certified optometrists may administer and prescribe ocular pharmaceutical agents for the diagnosis and treatment of ocular conditions of the human eye and its appendages

Certified optometrists may not prescribe or administer a controlled substance in Schedules III – V, except for an oral analgesic placed on the formulary pursuant to this section for the relief of pain due to ocular conditions of the eye and its appendages

Certified optometrists may not administer or prescribe a controlled substance in Schedule I or II

Certified optometrists may not prescribe a controlled substance for the treatment of chronic, non-malignant pain



Pain Clinic/Pain Management Regulations

A physician may prescribe or administer any controlled substance under Schedules II – V to a person for the treatment of intractable pain

Any physician who prescribes any Schedule II – IV controlled substance for the treatment of chronic, non-malignant pain must designate him or herself as a controlled substance prescribing practitioner on the physician's practitioner profile and comply with the pain management guidelines

Physicians must complete a complete medical history and physical examination

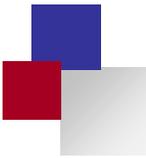
- Components of the physical examination shall be left to the discretion of the treating physician but should be proportionate to the diagnosis that justifies the treatment
- Medical record must document:
 - The nature and intensity of the pain
 - Current and past treatments
 - Underlying or coexisting diseases or conditions
 - Effect of the pain on physical and psychological function
 - Review of previous medical records
 - Previous diagnostic studies
 - History of alcohol and substance abuse
 - One or more recognized medical indications for the use of controlled substances

Physicians must develop a written treatment plan for each patient

- Plan must state the objectives to be reached to determine treatment success
 - Pain relief and improved physical and psychosocial function
- Must indicate whether any further diagnostic evaluations or other treatments are planned
- Physician shall adjust therapy after treatment begins to meet the needs of the patient
- Physician shall consider other treatment modalities, including rehabilitation programs, depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment

Physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences and shall have a written controlled substance agreement with the patient outlining the patient's responsibilities, including, but not limited to:

- Number and frequency of controlled substance prescriptions and refills
- Patient compliance and reasons for which drug therapy may be discontinued
- An agreement that controlled substances for the treatment of chronic, non-malignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record



Pain Clinic/Pain Management Regulations, cont'd.

Physician shall see the patient at regular intervals, not to exceed three months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain

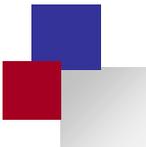
- Continuation or modification of therapy shall depend upon the evaluation of the patient's progress
- If treatment goals aren't being met despite medication adjustments, physician shall reevaluate the appropriateness of continued treatment
- Physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of three month intervals
- Physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives
 - Monitoring of patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist

Physician must maintain accurate, current, and complete records and include, but are not limited to:

- Complete medical history and physical examination, including history of drug dependence or abuse
- Diagnostic, therapeutic, and laboratory results
- Evaluations and consultations
- Treatment objectives
- Discussion of risks and benefits
- Treatments
- Medications, including type, dosage, and quantity prescribed
- Instructions and agreements
- Periodic reviews
- Results of any drug testing
- Photocopy of patient's government-issued identification
- If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription
- Physician's full name presented in a legible manner

Patients with signs or symptoms of substance abuse shall immediately be referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management

- Throughout the period before receiving a consultant's report, the physician shall clearly and completely document medical justification for continuing treatment with controlled substances
- Upon receipt of consultant's report, the physician shall incorporate the consultant's recommendation for continuing, modifying, or discontinuing controlled substance therapy
 - Any changes to therapy shall be documented in the patient's record
- Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy and the patient shall be discharged and all results and actions taken by the physician shall be documented in the patient's medical record
- This section doesn't apply to certain board-eligible or board-certified professionals



Pain Clinic/Pain Management Regulations, cont'd.

Pain management clinic means any publicly or privately owned facility that advertises in any medium for pain management services or where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic, non-malignant pain

Pain clinics must register with the department unless:

- It is licensed as a hospital
- The majority of physicians who provide services in the clinic primarily provide surgical services
- The clinic is owned by a publicly held corporation whose shares are traded on the national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceed \$50 million
- The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows
- The clinic does not prescribe controlled substances for the treatment of pain
- The clinic is owned by a 501(c)(3) corporate entity
- The clinic is wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists
- The clinic is wholly owned and operated by a physician multi-specialty practice where one or more board-eligible or board-certified medical specialists who have also completed approved fellowships in pain medicine, or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes

Each pain clinic must be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic

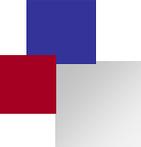
Clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic

- Physician must practice at the location for which s/he has been designated as the responsible party

Registration shall be denied for any clinic that is not fully owned by a physician, a group of physicians, or that is not licensed as a health care clinic

Registration shall also be denied for any clinic owned by or with any contractual or employment relationship with a physician:

- Whose DEA number has been revoked
- Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction
- Who has been convicted of or pleaded nolo contendere to an offense that constitutes a felony for receipt of illicit or diverted drugs, including controlled substances listed in Schedules I – V



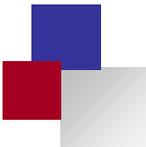
Pain Clinic/Pain Management Regulations, cont'd.

If a pain management clinic registration is revoked or suspended:

- All operations shall cease as of the effective date of the suspension or revocation
- All signs and symbols identifying the clinic as a pain management clinic shall be removed
- Upon the effective date of the suspension or revocation, the designated physician shall notify the department as to the disposition of medicinal drugs located on the premises
- If the registration is revoked, any person named in the registration documents of the clinic, including persons owning or operating the clinic, may not, as an individual or as part of a group, apply to operate a pain management clinic for five years after the date the registration is revoked
- Period of suspension may not exceed one year

Physician responsibilities with regard to any physicians who provide professional services in a pain management clinic:

- May not provide services if the clinic is not registered as required
- No person may dispense any medication on the premises of a pain management clinic unless s/he is a physician
- A physician, physician assistant, or advanced practice nurse must perform a physical examination of the patient on the same day the physician prescribes a controlled substance
 - If the physician prescribes more than a 72-hour dose of a controlled substance, the physician shall document in the record the reason for prescribing that quantity
- Physician is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication
- Physicians must ensure compliance with the following facility and physical operations requirements:
 - Pain management clinic shall be located and operated at a publicly accessible fixed location and must:
 - Display a sign that can be viewed by the public that contains the clinic name, hours of operation, and street address
 - Have a publicly listed telephone number and fax machine
 - Have emergency lighting and communications
 - Have a reception and waiting area
 - Provide a restroom
 - Have an administrative area, including room for storage of medical records, supplies, and equipment
 - Have private patient examination rooms
 - Have treatment rooms, if treatment is being provided to the patients
 - Display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the clinic's designated physician and the names of all physicians practicing at the clinic
- Physicians are also required to ensure compliance with infection control standards and health and safety requirements
- The designated physician is required to ensure compliance with quality assurance requirements, data collection and reporting requirements, and shall make reports to the Board of Medicine on a quarterly basis



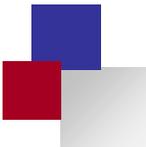
Pain Clinic/Pain Management Regulations, cont'd.

After July 1, 2012, physicians who have not met the below listed qualifications must have successfully completed an approved pain medicine fellowship or accredited pain management residency:

- Board certification in a specialty recognized by the American Board of Medical Specialties with a subspecialty in pain medicine or a Certificate of Added Qualification in Pain Management
- Board certification in pain medicine by the American Board of Pain Medicine
- Successful completion of an accredited pain medicine fellowship or accredited pain medicine residency
- Successful completion of an approved residency program in physical medicine or rehabilitation, anesthesiology, neurology, neurosurgery, psychiatry, family practice, internal medicine, orthopedics, or a current Certificate of Added Qualification in hospice, palliative medicine, or geriatric medicine
- Current staff privileges at a Florida-licensed hospital to practice pain medicine or perform pain medicine procedures
- Three years of documented full-time practice, which is defined as an average of 20 hours per week each year, in pain management and attendance and successful completion of 40 hours of in-person AMA Category I or IA CME courses in pain management that address all of the following:
 - Goals of treating both short term and ongoing pain treatment
 - Controlled substance prescribing rules, including controlled substance agreements
 - Drug screens or testing, including usefulness and limitations
 - Use of controlled substances in treating short-term and ongoing pain syndromes, including usefulness and limitations
 - Evidence-based non-controlled pharmacological pain treatments
 - Complete pain medicine history and a physical examination
 - Appropriate progress note keeping
 - Comorbidities with pain disorders, including psychiatric and addictive disorders
 - Drug abuse and diversion and prevention of same
 - Risk management
 - Medical ethics
- In addition to all of the above, practitioners must be able to document hospital privileges at a Florida-licensed hospital, practice under a physician who is qualified in one of the specialties listed above, or have the practice reviewed by a Florida-licensed risk manager and document compliance with all of the recommendations of the risk management review
- Upon completion of the 40 hours of CME set forth above, physicians qualifying under this section must also document completion of 15 hours of in-person AMA Category I or IA CME for every year the physician is practicing pain management

Standards for the use of controlled substances for the treatment of pain

- Encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic
- All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances
- Inadequate pain control may result from physicians' lack of knowledge about pain management or inadequate understanding of addiction as well as fears of investigation or sanction by regulatory agencies
- Medical management of intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities



Pain Clinic/Pain Management Regulations, cont'd.

Standards for the use of controlled substances for the treatment of pain, cont'd.

- Standards for the use of controlled substances:
 - Evaluation of the patient
 - Written treatment plan
 - Informed consent and agreement for treatment
 - Periodic review
 - Outside consultation
 - Complete and accurate medical records

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

Practitioners are required to have one hour of continuing education regarding the uses and abuses of controlled substances and one hour of continuing education on the federal and state laws related to the prescribing of controlled substances every two years

Practitioners must also take a two hour prevention of medical errors course every two years which includes information on the five most misdiagnosed conditions, including the following:

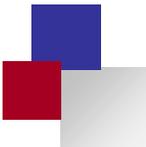
- Inappropriate prescribing of opioids in patients in whom there have been misdiagnosis or failure to diagnose addiction, psychiatric conditions, and diversion
- Prescribing, dispensing, administering, or using non-FDA approved medications and devices

Physicians prescribing or dispensing controlled substances for pain management who qualify by successful completion of 40 hours of in-person, live-participatory AMA Category I or Category IA CME courses in pain management must also document completion of 15 hours of in-person, live-participatory CME in pain management for every year the physician is practicing pain management

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

This section deals only with the conditions that qualify a patient for the use of medical marijuana or a therapeutic research program and the attendant physician responsibilities. For complete information on state medical marijuana and therapeutic research programs, please visit the NAMSDL website at www.namsdl.org.

Qualifying conditions for the use of low-THC cannabis include cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms



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

Physician may order low-THC cannabis for a qualifying patient if:

- No other satisfactory alternative treatment options exist
- The patient is a permanent resident of Florida
- The physician determines that the risks are reasonable in light of the potential benefit for the patient
- The physician registers as the orderer of low-THC cannabis for the named patient for the compassionate use registry maintained by the department and updates the registry to reflect the contents of the order
 - Shall deactivate patient's registration when treatment is discontinued
- Physician maintains a patient treatment plan that includes dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to treatment
- The physician submits the patient treatment plan quarterly to the University of Florida's College of Pharmacy for research on the safety and efficacy of low-THC cannabis on patients
- The physician obtains the voluntary informed consent of the patient

Physician commits a misdemeanor if the physician orders low-THC cannabis for a patient without a reasonable belief that the patient meets the qualifications

Physicians must successfully complete an 8-hour course and subsequent examination that encompasses the clinical indications for the appropriate use of low-THC cannabis, the appropriate delivery mechanisms, the contraindications for such use, as well as the relevant state and federal laws governing the ordering, dispensing, and possessing of this substance

The medical director of a dispensing organization must complete a 2-hour course and subsequent examination the encompasses the appropriate safety procedures and knowledge of low-THC cannabis

PMP Requirements for Mandatory Registration and Access

None.

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

None.