

Florida Laws and Rules



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The Controlled Substances Bill – House Bill 21



- Passed March 2018
 - Increases regulation, training, and reporting required when controlled substances are prescribed and dispensed.
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- Prescription Drug Monitoring Program (PDMP)
 - Increases regulation of prescribers and dispensers
 - Amends criminal laws
 - Makes appropriations to fund these programs

Prescription Drug Monitoring Program PDMP



Requires that every *physician, podiatrist, or dentist* who prescribes controlled substances in the state of Florida to treat **chronic non-malignant pain**, must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in the statutes and rules.

Prescriber Responsibilities



Before prescribing controlled substances to treat chronic non-malignant pain

1. Complete a medical history and physical examination of the patient which must be documented in the patient's medical record and include:
 - a. The nature and intensity of the pain
 - b. Current and past treatments for pain
 - c. Underlying or coexisting diseases or conditions
 - d. The effect of the pain on physical and psychological function
 - e. A review of previous medical records and diagnostic studies
 - f. A history of alcohol and substance abuse.

Prescriber Responsibilities



2. Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment.
3. Develop a written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success.
4. Enter into a controlled substance agreement with each patient that must be signed by the patient or the legal representative and by the prescribing practitioner including:
 - a. The number and frequency of prescriptions and refills.
 - b. A statement outlining expectations for patient's compliance and reasons for which the drug therapy may be discontinued.
 - c. An agreement that the patient's chronic non-malignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.

Prescriber Responsibilities



For chronic non-malignant pain patients under your care, you must:

- See the patient at least once every three months.
- Maintain detailed medical records relating to such treatment.

****Risk Assessment & Prevention ****

Patients at **special risk for drug abuse or diversion** may require a consultation with, or referral to, an addiction medicine physician or a psychiatrist.

Prescription Drug Monitoring Program (PDMP)



- State-run
- Electronic databases
- Prescribing and dispensing
- Controlled prescription drugs



Florida Comprehensive Drug Abuse Prevention and Control Act



PDMP no later than the close of the next business day:

- Name of the prescribing practitioner
- Practitioner's federal Drug Enforcement Administration (DEA) registration number
- Practitioner's National Provider Identification (NPI) or other appropriate identifier
- Date of the prescription
- Date the prescription was filled and the method of payment
- Full name, address, and date of birth of the person for whom the prescription was written
- Name, national drug code, quantity, and strength of the controlled substance dispensed
- Full name, federal DEA registration number, and address of the pharmacy, other location, or other practitioner from which the controlled substance was dispensed
- Name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's NPI
- Other appropriate identifying information as determined by DOH rule.

Prescription Drug Monitoring Program (PDMP)



- **Tracks** the dispensing of prescribed controlled substances
- **Provides information** to subsequent prescribing physicians
- **Prevents** over-prescribing and diversion of such substances



Low Risk Exemptions



- Adequate to treat the patient during that particular treatment session Patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state
- Healthcare system of the Department of Corrections
- Emergency room of a licensed hospital
- A person under the age of 16
- A pharmacist or a dispensing practitioner dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient
- Rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient while the patient is present and receiving care as ordered by the patient's treating physician.

Mandatory Consultation Requirement



- **Prior to prescribing a controlled substance, you must consult the PDMP to review a patient's (age 16 and older) controlled substance dispensing history.**

A healthcare practitioner who fails to consult the system as required is subject to a nondisciplinary citation for the initial offense.

Any subsequent offense for failure to consult the PDMP will result in disciplinary action against the healthcare practitioner's license.

Consulting the PDMP is not mandatory when:



- Prescribing or dispensing a non-opioid Schedule V drug
- System is not operational or cannot be accessed by the healthcare practitioner due to a temporary technological or electrical failure.
 - Document in the patient's record the reason the PDMP was not consulted
 - May prescribe or dispense no more than a 3-day supply of a controlled substance.

Prescribing Controlled Substances

Acute Pain



- **Three-day supply**
 - U.S. Centers for Disease Control and Prevention
 - Guidelines for the treatment of acute pain
- Up to a **seven-day supply**
 - Medically necessary
 - Indicate **acute pain exception on the prescription.**



****DOCUMENTATION****

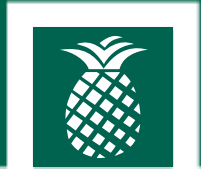
- Justification for deviating from the three-day supply limit.

Acute Pain Definition



- Normal, predicted, psychological, and time limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma or acute illness.

Prescribing Controlled Substances Non-Acute Pain



Non-Acute pain in the following cases is exempt from the statute:

- Cancer
- A terminal condition
 - Defined as a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by the treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course*
- Pain treated with palliative care
 - Defined as the provision of relief for symptoms related to an incurable, progressive illness or injury*
- A traumatic injury with an injury severity score of nine or higher.

Prescribing Controlled Substances Non-Acute Pain



Limits do not apply if:

- **Non-acute pain** is written on the prescription
- The prescription is for chronic pain
- The condition is excluded from the definition of acute pain
- There is a traumatic injury, in which case an emergency opioid antagonist should also be prescribed



Regulatory Boards

Department of Health (DOH)



The DOH requires:

- Evaluation of the patient
- Creation and maintenance of a treatment plan
- Obtaining informed consent and agreement for treatment
- Periodic review of the treatment plan
- Consultation
- Medical record review
- Compliance with controlled substance laws and regulations.

A healthcare practitioner who fails to follow the guidelines established by DOH is subject to disciplinary action against his or her license.

Dispensing Practitioners

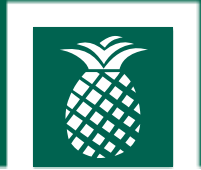


- Limits dispensing a supply of a Schedule II opioid
- Three days or seven days if the practitioner determines it is **medically necessary**.

Medically Assisted Treatment - Opiate Addiction

- Dispense Schedule II and Schedule III drugs for such purposes
- Telephone number of the person
- Demographic information the prescriber currently inputs
- Initial prescription or a refill, and the number of refills prescribed
- Name of the individual picking up the controlled substance prescription
- Type and issuer of the identification provided
- For a dispensing practitioner, other than a pharmacist, the practitioner's DOH-issued license number.

Criminal Penalties Related to Controlled Substance Prescribing



- **Intentionally** provides or prescribes a medically unnecessary controlled substance or a controlled substance
- Amount that is **not medically necessary** to a patient by **fraud, misrepresentation, or other deception**
- **Second-degree felony**

Violation is punishable by up to **15 years in prison** and a fine up to **\$10,000**.