

# TAKE CONTROL

OF CONTROLLED SUBSTANCES

## HOUSE BILL 21

### Understanding Florida's Regulatory Changes

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# FLORIDA'S NEW CONTROLLED SUBSTANCE LAW

- Requires continuing education on controlled substance prescribing
- Establishes prescribing limits to combat opioid abuse
- Increases the regulation of pain management clinics
- Expands the use of the Prescription Drug Monitoring Program (PDMP)

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# CONTINUING EDUCATION REQUIREMENTS

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# Required Continuing Education

All prescribing practitioners that are registered with the DEA and authorized to prescribe controlled substances must:

- Complete a 2-hour continuing education course by January 31, 2019 and at each subsequent licensure renewal

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# Content of the Course

- Current standards on prescribing of controlled substances, particularly opiates;
- Alternatives to the current standards on controlled substance prescribing;
- Nonpharmacological therapies;
- Prescribing emergency opioid antagonists; and
- Information on the risks of opioid addiction following all stages of treatment in the management of acute pain.

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# Where will the course be offered?

Practitioners can find the approved courses at [CEBroker.com](http://CEBroker.com)

- CEBroker is the vendor that provides renewal services to health care practitioners licensed and regulated by the Department

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# Failure to take the Course by January 31, 2019

The Department may not renew the Prescriber's license at the time of renewal

- [flhealthsource.gov/floridatakecontrol](http://flhealthsource.gov/floridatakecontrol)

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# ACUTE PAIN

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# Definition of Acute Pain

The normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness

- Reflects the current definition in the rule for physicians titled "Standards for the Use of Controlled Substances for the Treatment of Pain"

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# Prescription Limits for the Treatment of Acute Pain

## 3-day supply limit

- Aligns with the CDC guideline for the treatment of acute pain
- Standard—does not require prescription notation

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# Prescription Limits

## Exception to the 3-day Limit

More than 3 and up to a 7-day limit if the prescriber:

- Bases the need for the increased supply on their professional judgment
- Indicates "acute pain exception" on the prescription
- Documents justification in the patient's medical record

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# Dispensing Practitioners

- Dispensing practitioners are practitioners authorized by law to prescribe drugs
  - May dispense drugs to their patients in the regular course of their practice
  - Must comply with Section 465.0276, F.S. (Pharmacy Practice Act)
  - Dispensing practitioners may include allopathic physicians, osteopathic physicians, dentists, optometrists, podiatrists, ARNPs and PAs.

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# Dispensing Practitioners

Same 3-day and up to 7-day supply limits apply to dispensers

- Dispensing practitioners may dispense Schedule II and III controlled substances for medication-assisted treatment of opiate addiction to their own patients to treat opiate addictions

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# Identification requirement for dispensing controlled substances

Before dispensing to a person not known to the practitioner, they must require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity.

A pharmacist MUST verify the identity of an individual before dispensing a controlled substance by documenting the patient name, type, and issuer of photo identification.

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# NONACUTE PAIN

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# Exclusions from definition of acute pain

- Pain related to:
  - Cancer
  - A terminal condition
  - Pain treated with palliative care
  - A traumatic injury with an Injury Severity Score of 9 or higher

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# Prescribing requirements for a Traumatic Injury

A prescribing practitioner must also prescribe an emergency opioid antagonist

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# Nonacute Pain Prescription Requirements

- Prescriber must write “Nonacute Pain” on the prescription
- Applies to:
  - Prescriptions for chronic nonmalignant pain
  - Nonacute conditions

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# NEW REQUIREMENT FOR PAIN MANAGEMENT CLINICS

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# New Requirements for Pain Management Clinics

All pain management clinics must be registered with the Department of Health or hold a certificate of exemption by January 1, 2019

- No fee to file for a certificate of exemption

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# Certificate of Exemption Application Requirements

- Name or names under which the applicant does business
- Address
- Specific exemption and supporting documentation
- Any other information necessary for the department to determine eligibility

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# Certificate Renewal

Each certificate must be renewed biennially

- Initial certificate may be issued for up to 3 years to allow the Department to establish renewal cycles

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# Requirements for Pain Management Clinics

- Prominently display the certificate of exemption
- Have certificate available on request

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# Certificate Holder Requirements

- Only valid for the applicant who applied for and was issued the certificate
- Not transferable
- Notify department at least 60 days before a change of ownership, name change, or relocation
- Must apply for new certificate

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# Change in exemption eligibility status

The clinic must notify the DOH within 3 days if the clinic's exemption status changes and:

- Register with the department as a Pain Management Clinic

or

- Cease Operation

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# PDMP REQUIREMENTS

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# PDMP Updates

- Mandatory consultation of the PDMP
- Expands use to include Medical Examiners and employees of VA, DOD and IHS with prescriptive authority
- Electronic health recordkeeping systems
- Interstate data sharing
- Record retention schedule
- Identification requirement for dispensing of controlled substances

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# Required Consultation

- A prescriber or dispenser or his or her designee must consult the PDMP to review a patient's controlled substance dispensing history prior to prescribing or dispensing a controlled substance for patients age 16 or older

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# Statutory Exemptions

- If the patient is less than 16 years of age
- Drug being prescribed is a **nonopioid** schedule V
- System is not operational
- Requestor has technological or electrical failure

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# PDMP Consultation

- The health care practitioner must document in the patient's record the reason the PDMP was not consulted and may prescribe or dispense no more than a 3-day supply of a controlled substance

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# Penalty for failing to consult the PDMP

- Initial offense
  - Subject to a non-disciplinary citation for the initial offense
- Subsequent Offense
  - Results in disciplinary action against the health care practitioner's license

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# Reporting Requirements to the PDMP

- Schedule II, III, IV, and V must all be reported
- The dispenser now has four additional reporting requirements

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# Retention of PDMP Records

- The PDMP will purge information from its database that is more than 4 years old

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# PDMP Registration

- <https://florida.pmpaware.net>
- Training tools: [www.eforcse.com](http://www.eforcse.com)

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# Summary

New controlled substance law includes new requirements for:

- Continuing education
- Prescribing for acute and non-acute pain
- Pain management clinics
- PDMP use
- For more information please refer to:
  - [Flhealthsource.gov/floridatakecontrol](https://flhealthsource.gov/floridatakecontrol)

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# QUESTIONS?

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