



TAKE CONTROL

OF CONTROLLED SUBSTANCES

Florida's New Regulations on Controlled Substances

This webinar is for informational purposes only and is not approved for continuing education credits.


Florida Department of Health
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What is House Bill 21?

- Establishes prescribing limits to combat opioid abuse
- Expands the use of the Prescription Drug Monitoring Program (PDMP)
- Increases the regulation of Pain Management Clinics



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Section 1

Continuing Education

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Required Continuing Education

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

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Content of the Course

- The prescribing of controlled substances
- Alternative therapies
- Information involving opioid addiction

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Where will the course be offered?

- Please refer to CE Broker at CEBroker.com

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Failure to take the Course

- The DOH may not renew the Prescriber's license at the time of renewal
- flhealthsource.gov/floridatakecontrol

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Section 2

Acute Pain

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What is 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

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Prescription Limits for Acute Pain Treatment

- 3-day limit
 - Brings Florida even with the CDC guideline for the treatment of acute pain

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Prescription Limits for Acute Pain Treatment

- 7-day limit if:
 - Based on the professional judgment of the prescriber
 - Indicates "acute pain exception" on the prescription
 - Justification is documented on the medical record

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Dispensing Limits on Practitioners

- The same 3 and 7-day limits as prescribers
- Dispensers approved to provide medically assisted treatment for opiate addiction are permitted

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Identification requirement for dispensing of controlled substances

- A Pharmacist MUST verify the identity of an individual prior to dispensing a controlled substance

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Section 3

Nonacute Pain

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Prescriptions for Opioids for Nonacute Pain

- Nonacute pain:
 - 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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Nonacute Pain Prescription Requirements

- Must write "Nonacute Pain" on the prescription
- Applies to:
 - Prescriptions for chronic pain
 - Nonacute conditions

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Prescribing requirements for a Traumatic Injury

- Prescribe an emergency opioid antagonist AND
- Indicate “nonacute pain” on the prescription

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What if a Pharmacist does not receive a prescription for the emergency opioid antagonist?

- The pharmacist should follow their current standard policy and procedures:
 - Contact the prescribing practitioner to verify written information
- Any change should be promptly reduced to writing and properly annotated

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May the Pharmacist fill the prescription if the patient cannot afford the opioid antagonist?

- The law does not have any express language that prohibits the dispensing
- The only requirement set forth in the law is that the prescriber must prescribe the emergency opioid antagonist

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Do the 3-day and up to 7-day supply limits apply to all opioid drugs listed as Schedule II controlled substances?

- No, the limits on Schedule II controlled substances only apply to acute pain

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Buprenorphine Products

- The 3 and up to 7 day supply limits do not apply to schedule II or III controlled substances approved by the US Food and Drug Administration for the purpose of treating opiate pain

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What if a Prescription Fails to meet requirements specified by law?

- The pharmacist should follow their current standard policy and procedures:
 - Contact the prescribing practitioner to verify written information
- Any change should be promptly reduced to writing and properly annotated

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Section 4

Pain Management Clinics

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Requirements under the new law

- Pain Clinics are subject to prescribing requirements under the new law



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New Requirements for Pain Management Clinics

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

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Certificate of Exemption Requirements

- Name or names under which the applicant does business
- Address
- Specific exemption
- Any other information necessary

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Certificate Renewal

- Each certificate must be renewed biennially

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Requirements for Pain Management Clinics

- Prominently display the certificate of exemption
- Available upon request

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Certificate Holder Requirements:

- Only valid for the applicant the certificate was issued
- Not transferable
- Notification to DOH

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Becoming Aware of Ineligibility

- Must notify the DOH within 3 days
- Register as a Pain Management Clinic
- OR Cease Operation

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Section 5

Prescription Drug Monitoring Program (PDMP)

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PDMP Registration

- Go to florida.pmpaware.net to register

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What if you do not prescribe controlled substances but you have a DEA registration?

- If you do not prescribe any controlled substances you are not required to register with or consult EFORCSE.

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New Requirements for PDMP

- Consultation to 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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PDMP Consultation

- The statute does not provide any guidance on how far in advance the PDMP may be consulted

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Refills and Consultation

- A prescriber is **not** required to consult the PDMP before each refill
- Before writing a new prescription for a controlled substance listed Schedule II-V the PDMP **must** be consulted
- A Schedule II controlled substance may **not** be refilled

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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

- **Effective as of July 1, 2018**
 - Pharmacies and dispensing practitioners must report controlled substance dispensing **no later than the next business day.**
 - Pharmacies and dispensing practitioners must report **zero dispensing** activity by the close of the next business day.
 - Failing to report the dispensing of a controlled substance is a first degree misdemeanor

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Dispensing Information Reported

- Patient
 - Name, Address, Date of Birth, Prescription Information, Payment Type, **Number of refills; Telephone Number, and Person's Identification**
- Prescriber
 - Name, Address, DEA Number
- Pharmacy
 - Name, Address, DEA Number and **Permit Number**

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Controlled Substance Information Not Reported to the Database

- All acts of **administration**
- If **dispensed** to a person under the age of 16
- If **dispensed** in the health care system of the Department of Corrections;
- If **dispensed** by a Department of Defense facility
- Medical marijuana

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Failure to Report the PDMP

- A person who **willfully and knowingly** fails to report the dispensing of a controlled substance as required by this law commits a misdemeanor of the first degree
- Subsequent offense is subject to discipline under s.456.073

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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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Conclusion

- New requirements for:
 - Continuing education
 - Prescribing acute and non-acute pain
 - Pain management clinics
 - PDMP use
- For more information please refer to:
 - flhealthsource.gov/floridatakecontrol

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QUESTIONS?

Contact Information:

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