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
Email: takecontrol@flhealth.gov

Updated as of: July 24, 2018

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
Section 1

Continuing Education

With questions email: takecontrol@flhealth.gov

Required Continuing Education

• Must complete a 2 hour continuing education course

• Required by January 31, 2019 and at each subsequent licensure renewal
Content of the Course

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

Where will the course be offered?

• Please refer to CE Broker at CEBroker.com
Failure to take the Course

• The DOH may not renew the Prescriber’s license at the time of renewal

• flhealthsource.gov/floridatakecontrol

Section 2

Acute Pain

With questions email: takecontrol@flhealth.gov
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

Prescription Limits for Acute Pain Treatment

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

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
Identification requirement for dispensing of controlled substances

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

Section 3
Nonacute Pain

With questions email: takecontrol@flhealth.gov
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

Nonacute Pain Prescription Requirements

• Must write “Nonacute Pain” on the prescription
• Applies to:
  • Prescriptions for chronic pain
  • Nonacute conditions
Prescribing requirements for a Traumatic Injury

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

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
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

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
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

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
Section 4

Pain Management Clinics

With questions email: takecontrol@flhealth.gov

Requirements under the new law

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

Certificate of Exemption Requirements

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

- Each certificate must be renewed biennially

Requirements for Pain Management Clinics

- Prominently display the certificate of exemption
- Available upon request
Certificate Holder Requirements:

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

Becoming Aware of Ineligibility

• Must notify the DOH within 3 days
• Register as a Pain Management Clinic
• OR Cease Operation
Section 5

Prescription Drug Monitoring Program (PDMP)

With questions email: takecontrol@flhealth.gov

PDMP Registration

• Go to florida.pmpaware.net to register
What if you do no 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.

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
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.

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
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

PDMP Consultation

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

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.
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.

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
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

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
Retention of PDMP Records

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

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
QUESTIONS?

Contact Information:

Email: takecontrol@flhealth.gov