

SUMMARY

Overview: On March 19, Governor Rick Scott signed into law HB 21, signifying Florida's first major response to the opioid crisis killing at least 16 Floridians every day. Those statistics led Scott in May 2017 to declare a state of emergency. The bill, sponsored by Representative Jim Boyd (R-Bradenton) and Senator Lizbeth Benacquisto (R-Fort Myers), passed both chambers unanimously on March 9, the last scheduled day of Session. It will become effective on July 1, 2018.

The bill also addresses opioid abuse by expanding the use of the Prescription Drug Monitoring Program (PDMP), increasing regulation of prescribers and dispensers, amending criminal laws, and making appropriations.

- Requires persons registered with the U.S. Drug Enforcement Administration, authorized to prescribe controlled substances, to complete a board-approved 2 hour continuing education course; must be completed by January 1, 2019; **must be offered by a statewide professional association of physicians in this state that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category I Credit or the American Osteopathic Category 1-A continuing medical education requirement. The following organizations will be offering in person and online board approved continuing education courses. Other organizations may be added in the near future.**
 - **The Florida Medical Association**
 - **The Florida Osteopathic Medical Association**
 - **The Florida College of Emergency Physicians**
- Defines "acute pain" and the standards of practice for the treatment of acute pain. Limits the supply for prescribing opioids to 3 days with certain exceptions for a 7-day supply.
- By January 1, 2019, pain management clinics claiming exemption must obtain a certificate of exemption.
- Requires prescribers and pharmacists to use the Florida Prescription Drug Monitoring Program, a statewide database of controlled substance prescriptions, and ramps up penalties for doctors that give out drugs without proper medical justification.
- Authorizes \$53 million on treatment and prevention.

DETAILS

456.0301 Requirement for instruction on controlled substance prescribing.

- Requires persons registered with the U.S. Drug Enforcement Administration and authorized to prescribe controlled substances to complete a board-approved 2 hour continuing education course. Does not apply to a licensee who is required by his/her applicable practice act to complete 2-hour CE on the safe and effective prescribing of controlled substances.
 - Must complete by January 1, 2019.
 - At each biennial renewal practitioner must show proof of completing course.
 - Each board may adopt rules for this requirement.

456.44 Controlled substance prescribing.

- Defines "acute pain" as the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness (excluding: cancer, terminal conditions, palliative care, and traumatic injury 9 or greater).
- Standard of practice for treatment of acute pain
 - Applicable board shall adopt rules establishing guidelines.

- Treatment of acute pain with an opioid listed as a Schedule II may not exceed a **3-day supply**.
- Certain exceptions for a 7-day supply:
 - Medically necessary
 - Prescriber indicates “acute pain exception” on the prescription
 - Prescriber dictates in the medical record the acute medical condition and lack of alternative treatment options to justify supply limit
 - If treatment is “nonacute pain” it must be indicated on the prescription

458.3265/ 459.0137 Pain-Management Clinics.

- Must be registered with the DOH or hold a valid certificate of exemption.
- Apply for certificate of exemption on form adopted by rule by the department.
- Department may approve or deny within 30 days of receipt of completed application.
- Certificate must be renewed every two years.
- Certificate must be displayed and made available to the department or board upon request.

465.0155 Standards of practice

- A person not known to the pharmacist must present valid/proper identification when purchasing, receiving, or acquiring controlled substances.
- Defines “proper identification” as identification issued by the state or Federal Government with the persons photograph, printed name, and signature.
- Does not apply to an institutional setting where a patient is admitted (e.g. long-term care facility or hospital).

465.0276 Dispensing practitioner

- Treatment of acute pain may not exceed a 3-day supply or a 7-day supply with certain exceptions.
- Practitioner must indicate “NONACUTE PAIN” on a prescription for treatment of pain other than acute pain.
- Treatment of pain related to a traumatic injury (Injury Severity Score of 9 or greater) a practitioner must concurrently prescribe an emergency opioid antagonist defined in s. 381.887.
- A person not known to the dispensing practitioner must present valid/proper identification when purchasing, receiving, or acquiring controlled substances.

893.055 Prescription drug monitoring program.

- Department will maintain an electronic system to obtain controlled substance dispensing information.
- Authorized to share information with other states.
- Under current law, when controlled substances listed in Schedule II, III, and IV are dispensed, it must be reported to the PDMP. The bill expands the reporting requirement to include controlled substances listed in Schedule V, but exempts any which are non-opioids. The bill also requires the dispenser to report the following additional information that is not currently collected:
 - The name of the prescribing practitioner, the practitioner’s federal Drug Enforcement Administration registration number, the practitioner’s National Provider Identification or other appropriate identifier, and the date of the prescription.
 - The date the prescription was filled and the method of payment.
 - The full name, address, telephone number, and date of birth of the person for whom the prescription was written.
 - The name, national drug code, quantity, and strength of the controlled substance dispensed.
 - The full name, federal Drug Enforcement Administration registration number, State of Florida Department of Health issued pharmacy permit number, and address of the pharmacy or other location from which the controlled substance was dispensed.
 - Whether the drug was dispensed as an initial prescription or a refill, and the number of refills ordered.
 - The name of the individual picking up the controlled substance prescription and type and issuer of the identification provided.
 - Other appropriate identifying information as determined by department rule.
- Exempt from reporting:
 - All acts of administration of a controlled substance.

- The dispensing in the health care system of the Department of Corrections.
- Dispensing a controlled substance to a person under the age of 16.
- The program manager and designated program and support staff must complete a level II background screening.

CONTROLLED SUBSTANCE REGULATION

Controlled Substances added to the existing Schedules.

Substances added to Schedule II:

- Dihydroetorphine
- Hydrocodone combination products
- Oripavine
- Remifentanil
- Tapentadol
- Thiafentanil
- Lisdexamfetamine
- Dronabinol (synthetic THC) in oral solution in a drug approved by the United States Food and Drug Administration

Substances added to Schedule III:

- Buprenorphine (which is being rescheduled from Schedule V)
- Embutramide
- Perampanel

Substances added to Schedule IV:

- Alfaxalone
- Dexfenfluramine
- Dichloralphenazone
- Eluxadoline
- Eszopiclone
- Fospropofol
- Lorcaserin
- Modafinil
- Petrichloral
- Sibutramine
- Suvorexant
- Zaleplon
- Zolpidem
- Zopiclone

Substances added to Schedule V:

- Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine per dosage unit; and
- Unless a specific exception exists or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of:
 - Brivaracetam
 - Ezogabine
 - Lacosamide
 - Pregabalin

ACTION ITEMS

The Department of Health shall adopt rules for the following:

- Guidelines for prescribing controlled substances for acute pain.
- Continuing education requirement to complete 2-hour course for prescribing controlled substances.
- Pain management certificate of exemption form.

CONTACT

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