# Florida's New Law on Controlled Substance Prescribing

## Provisions go into effect on July 1, 2018. Here is what you need to know.

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HB 21, signed into law by Gov. Rick Scott on March 19, 2018, imposes a number of legal requirements on healthcare practitioners who prescribe controlled substances, particularly opioids. This new law encompasses 205 pages and imposes new obligations on practitioners that carry penalties for noncompliance. The purpose of this article is to provide a summary of the provisions of HB 21, and provide practitioners with the information they need to comply with the new law. Unless otherwise noted, the provisions of this law will go into effect on July 1, 2018.

### Select Florida Law on Controlled Substance Prescribing Prior to HB 21

There are numerous state and federal statutes and regulations that govern the prescribing of controlled substances. HB 21 amended several of the state statutes on controlled substance prescribing. These statutes are briefly discussed below.

In 2009, the Florida Legislature responded to the pill mill epidemic by creating the "prescription drug monitoring program (PDMP). This law requires pharmacists and dispensing practitioners to report certain information to the database each time they dispense a controlled substance. As passed in 2009, the law required dispensers of controlled substances to report to the database within seven days. The law did not require physicians to check the database prior to prescribing a controlled substance.

In 2011, the Florida Legislature passed legislation that regulates the prescribing of controlled substances for chronic nonmalignant pain. Section 456.44, Florida Statutes provides that allopathic physicians, osteopathic physicians, podiatrists, dentists, physician assistants, and advanced registered nurse practitioners who prescribe any controlled substance in Schedules II-IV for the treatment of chronic nonmalignant pain must designate themselves as a controlled substance prescribing practitioner on their practitioner profiles, and must comply with the statutorily established standards of practice.

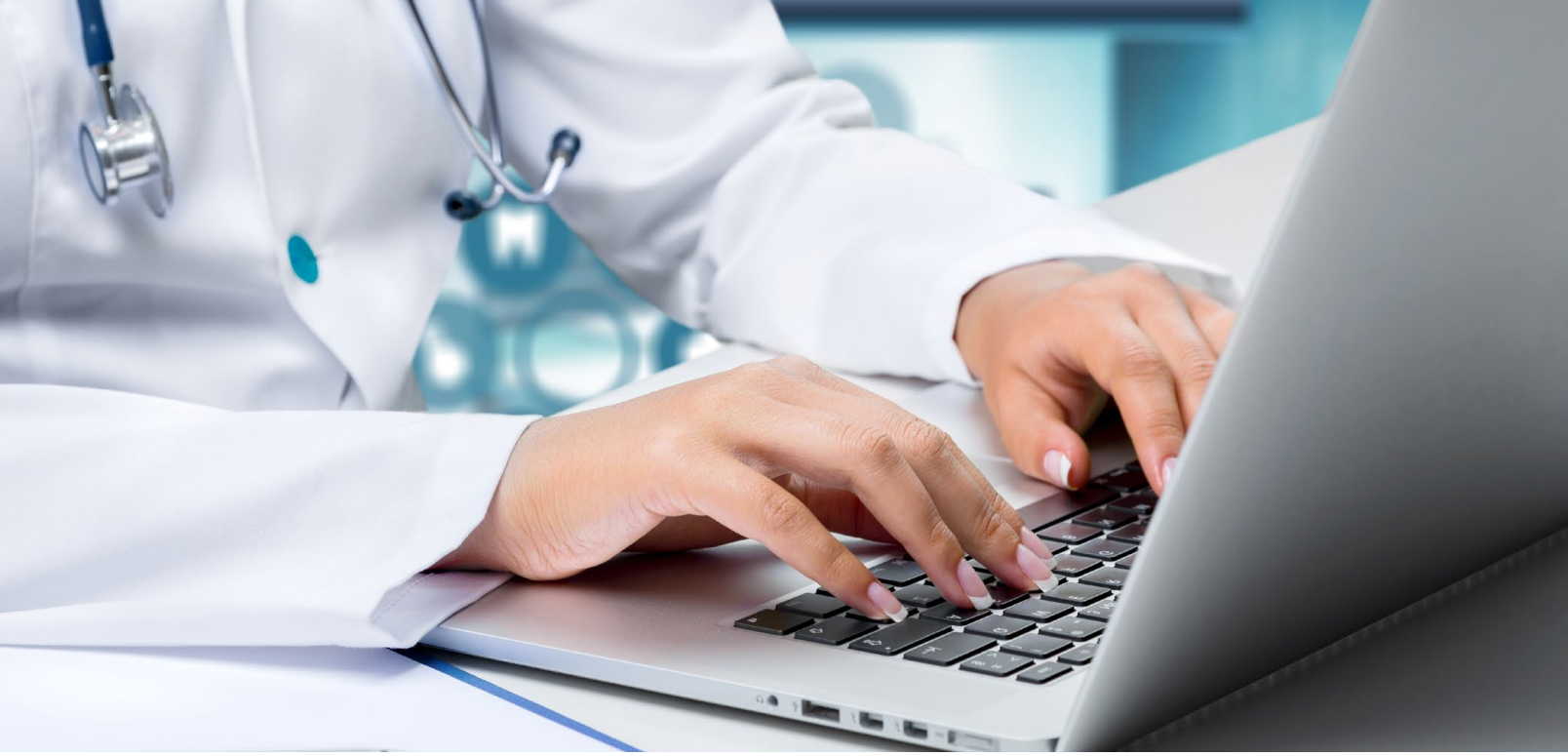
The pill mill epidemic also spawned legislation governing the operation of pain-management clinics. Section 458.3265 and section 459.0137 require "pain clinics" to register with the Department of Health and adhere to a number of regulations established by statute.

### HB 21

HB 21 kept the provisions above intact for the most part but made a number of significant changes in each area.

### Florida Prescription Drug Monitoring Program (PDMP)

HB 21 retains the requirement that the Department of Health maintain an electronic system to collect and store controlled substance dispensing information (the PDMP, known as



E-FORCSE — Electronic-Florida Online Reporting of Controlled Substances Evaluation Program — but referred to throughout this document as the "database"), but makes a number of changes regarding database reporting, checking and access to information. For practitioners, the most important change is the new requirement that a prescriber or dispenser (or the designee of a prescriber or dispenser) must consult the database to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance for a patient who is 16 years of age or older.

*Note that this requirement applies to all controlled substances, not just opioids. The one concession the Legislature made was to exempt a nonopioid controlled substance listed in Schedule V from the mandatory checking requirement. If a medication listed in Schedule V, however, contains any amount of a substance listed as an opioid in s. 893.03 or 21 U.S.C. 812, then the prescriber or dispenser has to consult the database prior to prescribing or dispensing.*

If the database is not operational or cannot be accessed by the prescriber or dispenser, the practitioner can go ahead and prescribe or dispense the controlled substance, but must document the reason why the database was not consulted and cannot prescribe or dispense more than a three-day supply of the controlled substance.

This is of course a significant change from the prior law regarding the operation of the PDMP. Questions naturally arise as to the scope of this change:

- Do practitioners have to check the database every time they prescribe a controlled substance for the same patient – even on a prescription that in essence is a refill for a three-day supply?
- Same question for an existing patient they are calling in a prescription for: Do they have to check the database before calling in the prescription?

Unfortunately, until the DOH or the respective boards provide guidance, all we have to go by is the text of the statute itself. As the law provides that the "prescriber or dispenser must consult the system to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance for a patient age 16 or older," it appears that practitioners must check the database each time they prescribe or dispense, regardless of whether the patient is an existing patient or not. If the boards interpret this provision differently, the FMA will put out a notice and will update this article accordingly.

As of Jan. 1, 2018, the dispensing of a controlled substance must be reported to the database no later than the close of the next business day. If a dispenser usually dispenses controlled substances in Florida but has no dispensing transactions to report for the preceding seven (7)-day period, the dispenser must report this information to E-FORCSE by filing a zero report, as described in the Dispenser's Implementation Guide, which can be found at: **https://flmd.us/dig**.

As many practitioners will be required under the new law to check the database for the first time, the following link will take you to the Department of Health's website on accessing the E-FORCSE database: **E-FORCSE Dispener Guide**

You will need to establish an E-FORCSE account to log into

the system. Access is granted to practitioners authorized to prescribe or dispense controlled substances so that they may look up, view and print controlled substance dispensing information on their specific patients.

It should be noted that the DOH is required to issue a non-disciplinary citation to any prescriber or dispenser who fails to consult the database prior to prescribing or dispensing a controlled substance. For each subsequent offense, a practitioner is subject to discipline from their respective board. A practitioner who willfully and knowingly fails to report the dispensing of a controlled substance commits a misdemeanor of the first degree.

MANDATORY REPORTING UNDER THIS SECTION GOES INTO EFFECT ON JULY 1, 2018.

## Section 456.44 – Controlled Substance Prescribing

This statute, enacted in 2011 as noted above, governs the prescribing of controlled substances in Florida for the treatment of "chronic nonmalignant pain." HB 21 amends this statute to add a new section governing the prescribing of controlled substances for the treatment of "acute pain."

Acute pain is defined as "the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. After intense lobbying by the FMA and other groups, the Legislature exempted from this definition pain related to:

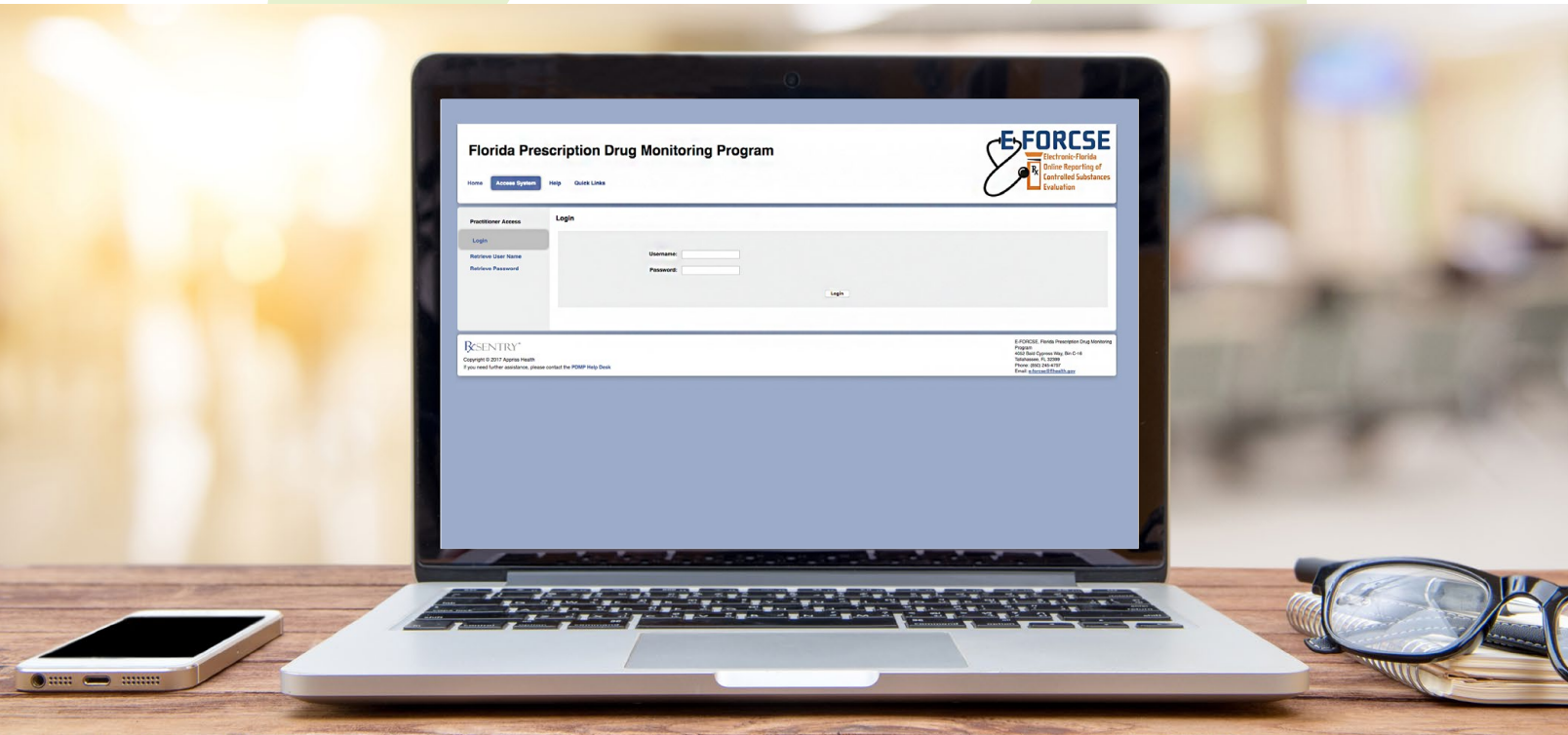
- Cancer
- A terminal condition (defined as a "progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within one year after diagnosis if the condition runs its normal course")
- Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury; or
- A traumatic injury with an Injury Severity Score of 9 or greater

The FMA expended a tremendous amount of effort attempting to add to this list pain related to major surgery. The governor's office refused to accept this change and thus the exceptions to the definition of acute pain are limited to the four set forth above. This is important because of the limitation on controlled substance prescribing for acute pain contained in HB 21.

The Florida Legislature, following the lead of the governor, set an arbitrary limit on the amount of opioids that could be prescribed for the treatment of acute pain. HB 21 provides that a prescription for a Schedule II opioid for the treatment of acute pain may not exceed a three-day supply. The legislation does allow a seven-day supply to be prescribed if:

- More than a three-day supply is needed based on the professional judgment of the prescriber;
- The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and
- The prescriber documents in the medical records the acute medical condition and lack of alternative treatment options that justify deviation from the three-day supply limit.

If a prescriber writes a prescription for a Schedule II opioid for the treatment of pain other than acute pain (i.e. for chronic



nonmalignant pain, or for pain that is excluded from the definition of acute pain), the prescriber must indicate "NONACUTE PAIN" on the prescription.

In addition, if the practitioner prescribes a Schedule II controlled substance for the treatment of pain related to a traumatic injury with a severity score of 9 or greater, the practitioner must concurrently prescribe an emergency opioid antagonist. Of note is the fact that the statute says a "Schedule II controlled substance" and not an "opioid drug listed as a Schedule II controlled substance." While it would not make any sense to concurrently prescribe an emergency opioid antagonist with a non-opioid Schedule II controlled substance, the Legislature did not limit this requirement. Hopefully, the boards will interpret this requirement in a reasonable manner. The FMA will seek guidance from the boards and will provide an update as information becomes available.

In addition to the 3-7 day limitation on the prescribing of Schedule II opioids, HB 21 requires each board to adopt rules establishing guidelines for prescribing controlled substances for acute pain. The guidelines are to include 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, and compliance with controlled substance laws and regulations.

It is hoped that the guidelines will provide answers to the inevitable questions that will be raised based on the 3-7 day prescribing limitation. For example, does a physician have to physically see the patient after the 3-7 day prescription expires before the physician can issue another prescription? Can the physician consult with the patient over the phone after the initial 3-7 day prescription period and e-prescribe a Schedule II opioid that the patient can pick up without having to go the physician's office? Can the physician hand the patient three staggered 3-7-day prescriptions for a Schedule II opioid?

The FMA expects the guidelines from the Board of Medicine and Board of Osteopathic Medicine to be adopted sometime after the July 1 effective date of the legislation. The FMA will work to ensure that the guidelines are reasonable, will make all drafts available to our members, and will issue a notification once the guidelines are adopted.

THE PRESCRIBING LIMITATIONS ON SCHEDULE II OPIOIDS GO INTO EFFECT ON JULY 1, 2018.

## Pain-management Clinic Registration

On Oct. 1, 2010, the Florida Statutes began to require "pain-management clinics" to register with the Florida Department of Health. In 2011, the Legislature amended the definition of a "pain-management clinic" to require registration for all publicly or privately owned facilities that (1) advertise in any medium for any type of pain management services, or (2) where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

The Legislature exempted the following entities from the registration requirement:

- A clinic licensed as a facility pursuant to chapter 395
- A clinic in which the majority of the physicians who provide services in the clinic primarily provide surgical services
- A clinic owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market, and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million
- A clinic affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows

- A clinic that does not prescribe controlled substances for the treatment of pain
- A clinic owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3)
- A clinic wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists
- The clinic is wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists, who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association, perform interventional pain procedures of the type routinely billed using surgical codes

Prior to the passage of HB 21, a facility that met the definition of a "pain-management clinic" but did not have to register as a pain-management clinic because it fit into one of the exemptions, did not have to take action to comply with the pain-clinic legislation. The facility could determine on its own whether it was required to register. If the facility erroneously chose not to register, any physician who practiced medicine therein would be in violation of section 458.3265 or section 459.0137, Florida Statutes, and would be subject to discipline by his or her medical board.

HB 21 changes this arrangement by requiring that the clinics exempt from having to register must apply to the DOH for a **certificate of exemption**.

Thus, if a facility advertises in any medium for any type of pain-management service or prescribes in any month the above mentioned medications to a majority of the facility's patients for the treatment of chronic nonmalignant pain, but fits within one of the eight exceptions, that facility has to apply for a certificate of exemption. The DOH will have to adopt a form for the application, and will have to approve or deny the certificate within 30 days after receipt of the application.

The FMA will notify members as soon as the application form is approved and available.

THE CERTIFICATE OF EXEMPTION REQUIREMENT GOES INTO EFFECT ON JAN. 1, 2019.

## Controlled Substance Prescribing Continuing Education Requirement

HB 21 requires each person registered with the DEA and authorized to prescribe controlled substances to take a board-approved two-hour continuing education course on prescribing controlled substances. The course must be taken from a "statewide professional association of physicians in this state that is accredited to provide educational activities designated for the AMA PRA Category 1 credit™ or the American Osteopathic Category 1-A continuing medical education credit as part of biennial license renewal."

The course must be taken by allopathic physicians, osteopathic physicians, podiatrists, dentists and optometrists who are registered with the DEA. Advanced registered nurse practitioners and physician assistants already have to take a three-hour course on controlled substance prescribing.

The Board of Medicine and the Board of Osteopathic Medicine have approved a joint FMA/FOMA course, which is available at **www.FLmedical.inreache.com**.

EACH PHYSICIAN REQUIRED TO TAKE THE COURSE MUST DO SO INITIALLY BY JAN. 31, 2019, AND THEN PRIOR TO EACH SUBSEQUENT LICENSURE RENEWAL.

## Summary

It should be noted that the standards of practice regarding the treatment of chronic, nonmalignant pain are unchanged. The 3-7 day limit on prescribing Schedule II opioids only applies to acute pain – not chronic nonmalignant pain.

The requirement for checking the PDMP database, however, applies for the prescription of almost any controlled substance, for any reason. It does not matter if the prescription is for acute pain or chronic nonmalignant pain.

If you are an FMA member who has questions about how HB 21 affects your practice, please contact FMA General Counsel Jeff Scott, Esq., at **jscott@flmedical.org**.

*The FMA will continue to provide updates and information about HB 21. To take the required new Controlled Substance Prescribing CME Course,* ***click here****.*