FAQ re: Florida House Bill 21 (2018)

On March 19th, 2018, Gov. Rick Scott signed bill Florida's House Bill 21 into law, which includes a variety of measures related to pain management and opioids, including CME requirements, prescription limits, and more. This legislation will have an effect on how many prescribers provide care to their patients. To help you, our Florida members, to understand your obligations under this new legislation, AIPM's policy team has put together the following FAQ.

This FAQ contains information on:

- Limit on Opioids for the Treatment of Acute Pain
- Required Prescription of Emergency Opioid Antagonist
- Required Use of the Prescription Drug Monitoring Program
- Continuing Education
- Pain Management Clinics and Certificates of Exemption
- Identification Required Before Dispensing a Controlled Substance

The provisions of this legislation go into effect on July 1st, 2018. However, the initial requirement related to continuing education does not have to be fulfilled until January 31st, 2019.

Please contact Katie Duensing, J.D., Director of Legislative and Regulatory Affairs with any questions.

Limit on Opioids for the Treatment of Acute Pain

General Rule: For the treatment of acute pain, a prescription for an opioid drug listed as a Schedule II may not exceed a 3-day supply.

What does "acute pain" mean under this statute?

"Acute pain" means the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The term does not include pain related to:

1. Cancer.
2. A terminal condition, meaning 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 1 year after diagnosis if the condition runs its normal course.
3. Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury.
4. A traumatic injury with an Injury Severity Score of 9 or greater.

Can I prescribe more than a 3-day supply for acute pain if I believe it is necessary?

Yes. A prescriber may prescribe up to a 7-day supply for the treatment of acute pain if the prescriber believes, in his or her professional judgment, that more than a 3-day supply of a Schedule II opioid is medically necessary to treat the patient's pain.

What do I need to do if I need to prescribe more than a 3-day supply for acute pain?

To prescribe more than a 3-day supply of a Schedule II opioid for the treatment of acute pain, you must:

1. Write "ACUTE PAIN EXCEPTION" on the prescription; and
2. Adequately document in the patient's medical records the acute medical condition and lack of alternative treatment options that justify deviation from the 3-day supply limit.

Will this new limitation affect my patients being treated for chronic pain?

Yes and no. The new limitations do not apply to patients being treated for chronic pain. However, to ensure these patients are able to receive their prescriptions and to help pharmacists to know that these patients' prescriptions are not related to acute pain, you must write "NONACUTE PAIN" on a prescription for an opioid written to a patient being treated for chronic pain.

Required Prescription of Emergency Opioid Antagonist

General Rule: For the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, a prescriber who prescribes a Schedule II controlled substance must concurrently prescribe an emergency opioid antagonist (naloxone).

Does this mandate apply to any other types of patients?

No, this mandate is specific only to those patients receiving treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater.

Is there any exception to this mandate?

No, this mandate must be followed without exception.

What if my patient is unable to afford the opioid antagonist?

The requirement is that the prescriber must write the prescription, but the patient is under no obligation to fill the prescription if they are unable to afford it.

Required Use of the Prescription Drug Monitoring Program

General Rule: A prescriber or dispenser, or a designee of a 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.

What controlled substances are included within this mandate?

All controlled substances are included within this mandate—not just opioids. However, non-opioid controlled substances that are listed in Schedule V are not included within the mandate.

What do I do if the PDMP is not working?

The duty to consult the system does not apply when the system is determined by the department to be nonoperational or cannot be accessed by the prescriber or dispenser or a designee of the prescriber or dispenser because of a temporary technological or electrical failure.

However, a prescriber or dispenser or designee of a prescriber or dispenser who does not consult the system for whatever reason, including because the system was nonoperational, shall: (1) document the reason he or she did not consult the system in the patient's medical record or prescription record, and (2) not prescribe or dispense greater than a 3-day supply of a controlled substance to the patient.

What are the consequences for failing to check, or report to, the PDMP?

The department shall issue a non-disciplinary citation to any prescriber or dispenser who fails to consult the system as required for an initial offense. Each subsequent offense is subject to disciplinary action.

A person who willfully and knowingly fails to report the dispensing of a controlled substance as required commits a misdemeanor of the first degree.

Continuing Education

General Rule: Every person registered with the United States Drug Enforcement Administration and authorized to prescribe controlled substances must complete a board-approved 2-hour continuing education course on prescribing controlled substances.

What information must the CE contain?

The course must include information on the current standards for prescribing controlled substances, particularly opiates; alternatives to these standards; nonpharmacological therapies; prescribing emergency opioid antagonists; and the risks of opioid addiction following all stages of treatment in the management of acute pain.

May I obtain the CE online?

Yes, the course may be offered in a distance learning format.

What is the deadline for obtaining the CE?

The course must be completed by January 31, 2019, and at each subsequent renewal.

Where can I obtain this CE?

Because Florida intends for the required CE to include information specific to Florida that explains the requirements of Florida policies as they relate to controlled substances, the statute specifies that the CE must be "offered by a statewide professional association of physicians in [Florida] that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 Credit or the American Osteopathic Category 1-A continuing medical education credit."

The proposed rule from the Department of Health is not yet final, but the draft version of the rule would approve the controlled substance prescribing courses offered by the Florida Medical Association, the Florida Osteopathic Medical Association, the Florida Academy of Family Physicians, and the Florida College of Emergency Physicians.

What if I was already required to take pain-related CE by my licensing board?

The new requirements do not apply to a licensee who was already required by his or her applicable practice act to complete a minimum of 2 hours of continuing education on the safe and effective prescribing of controlled substances.

Specifically, this new requirement does not apply to physician assistants. This is because, as of January 1, 2017, all prescribing PAs were already required to take a three (3) hour CE course on Safe and Effective Prescribing of Controlled Substances prior to license renewal.

Pain Management Clinics and Certificates of Exemption

General Rule: Each pain management clinic must register with the Department of Health or hold a valid certificate of exemption.

Have the types of clinics that may receive a Certificate of Exemption changed?

No. Previously existing law that controlled which types of pain management clinics qualify for a Certificate of Exemption has remained the same with the exception of a few technical, non-substantive changes. Therefore, if you qualified for an exemption before, you should still qualify now.

Have the rules related to obtaining a Certificate of Exemption changed?

Yes. The legislature has adopted very specific requirements related to the application process for a Certificate of Exemption. See page 10 of the new legislation for more information.

Identification Required Before Dispensing a Controlled Substance

General Rule: Before dispensing a controlled substance to a person not known to the dispenser, the dispenser 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.

What constitutes "proper" identification?

The term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

Verification of health plan eligibility through a real-time inquiry or adjudication system is also considered to be proper identification

What if the person does not have proper identification?

If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent.

Unfortunately, the statute does not specify how a dispenser would go about these verifications, and the Department of Health has not yet issued any guidance.