

Frequently Asked Questions:

Who is a prescribing practitioner?

Physician, Dentist, Podiatrist, Certified Optometrist, Advanced Registered Nurse Practitioner, and Physician Assistant.

Does a prescribing practitioner have to be designated as a “Controlled Substance Prescriber” on the Department of Health’s website to write prescriptions for Schedule II opioids?

No. The “Controlled Substance Prescriber” designation found on the Department of Health’s website (www.flhealthsource.gov), is only an indicator by the prescribing practitioner that he/she prescribes controlled substances for the treatment of chronic non-malignant pain. It is for patient information only and does not affect the authority of a physician to write prescriptions for Schedule II opioids.

Are regular urine tests required under the new controlled substance law that became effective July 1, 2018?

No. The new law does not require urine testing. Your treating physician may choose to follow guidelines or recommendations from other sources, such as the CDC or DEA, but the controlled substance law does not include a requirement for regular urine tests.

Does the new controlled substance law require monthly visits if a patient’s condition is treated with a controlled substance?

No. The new law does not require monthly visits if a patient’s condition is treated with a controlled substance. Your treating physician may choose to follow guidelines or recommendations from other sources, such as the CDC or DEA, but the controlled substance law does not include a requirement for monthly visits.

If a prescribing practitioner forgets to write “ACUTE PAIN EXCEPTION” or “NONACUTE PAIN” on a prescription for a Schedule II opioid, may the pharmacist confirm with the prescriber and annotate the prescription?

Yes. If a prescription for a Schedule II opioid does not meet the requirements as specified in Section 456.44, F.S., the pharmacist should follow their current standard policy and procedures by contacting the prescribing practitioner to verify written information contained within the prescription. Any deviation or change in the prescription should be promptly reduced to writing and properly annotated based on your current pharmacy practice.

Does a prescribing practitioner need to write the words “Acute Pain” or “Acute Pain – 3 Days” on a prescription for a patient experiencing acute pain?

No. The law does not require the words “Acute Pain” to be written on a prescription, but rather the words “ACUTE PAIN EXCEPTION” for prescriptions greater than a 3-day and up to a 7-day supply. Please see Section 456.44(5)(a)(2), F.S.

When can up to a 7-day supply be prescribed for acute pain?

A prescribing practitioner may prescribe up to a 7-day supply if the prescriber:

- (1) determines it is medically necessary;
- (2) indicates "acute pain exception" on the prescription; AND
- (3) documents the justification for deviating from the 3-day supply limit in the patient's medical record.

Does a prescription for 3 days or less of a Schedule II opioid require "Acute Pain Exception" to be written on the prescription?

No. The law only requires the words "ACUTE PAIN EXCEPTION" to be written for prescriptions greater than a 3-day and up to a 7-day supply. Please see Section 456.44(5)(a)(2), F.S.

Do the 3-day or up to 7-day supply limits in the law mean that the prescription expires 3 days or 7 days after it is written?

No. The law provides that for the treatment of acute pain, a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812 may not exceed a 3-day supply, except that up to a 7-day supply may be prescribed if certain conditions are met. The "3-day" and "7-day" applies to the supply of the opioid drug listed as a Schedule II controlled substance, not the number of days after the prescription is written for which it is still valid.

Do prescribers need to write the words "Non-acute Pain" on a prescription for an opioid drug listed as a schedule II controlled substance?

Yes. If the prescription is for a greater than a 7-day supply, the prescriber must indicate "Non-Acute Pain."

What are the exceptions to the prescribing limits for the treatment of acute pain?

Exceptions to acute pain limits:

- (1) **cancer**,
- (2) **a terminal condition** (a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by the 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) **pain treated with palliative care** (the provision of relief for symptoms related to an incurable, progressive illness or injury), and
- (4) **a traumatic injury with an Injury Severity Score of 9 or higher**. See Trauma.org (<http://www.trauma.org>) for more information.

**The law did not change prescribing of controlled substances for treatment of nonacute pain or chronic nonmalignant pain.

What is the definition of acute pain?

"Acute pain" is the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. It does not include pain related to cancer, terminal conditions, pain treated with palliative care, or traumatic injuries with an Injury Severity Score of 9 or greater.

What must a prescriber do when prescribing a Schedule II opioid for a traumatic injury?

When prescribing opioids to a patient with an Injury Severity Score of 9 or higher, the prescriber must:

- (1) Prescribe an emergency opioid antagonist AND
- (2) Indicate "nonacute pain" on the prescription

When must an emergency opioid antagonist be prescribed?

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 listed in s. 893.03 or 21 U.S.C. s. 812 must concurrently prescribe an emergency opioid antagonist, as defined in s. 381.887(1).

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

No. For example, the day supply limits do not apply to Hycodan® Cough Syrup for a patient who is being treated for an unrelenting cough or to Ritalin® for a patient being treated for ADHD. The 3-day and up to 7-day limits apply to Schedule II opioids prescribed for the treatment of acute pain.

Do the 3 and up to 7-day supply limits apply to the dispensing of controlled substances listed in Schedule II or Schedule III, which have been approved by the United States Food and Drug Administration for the purpose of treating opiate addictions, including, but not limited to, buprenorphine and buprenorphine combination products?

No. The days supply limits apply to Schedule II opioids prescribed for the treatment of acute pain.

If a prescription for an opioid drug listed as a Schedule II controlled substance exceeds the 3-day limit and no indication "Acute Pain Exception" (for a 4-7 day supply) or "Non-Acute Pain" (for a greater than 7 day supply) should the pharmacist limit the amount dispensed or refuse to fill the prescription?

If a prescription for a Schedule II opioid does not meet the requirements as specified in the law, the pharmacist should follow their current standard policy and procedures by contacting the prescribing practitioner to verify written information contained within the prescription. Any change in the prescription should be promptly reduced to writing and properly annotated based on your current pharmacy practice.

When using eRX (Electronic Prescribing) if a note is included / transmitted to the pharmacist that indicates “Acute Pain Exception” or “Non-Acute Pain” will that meet the requirement of the law?

Yes. If the “note” is transmitted with or considered to be part of the actual electronic prescription to be transmitted to the pharmacist, then the annotation of “Acute Pain Exception” or “Non-Acute Pain” would be acceptable.

Can the pharmacy fill a controlled substance prescription from an out of state prescriber?

The law is silent and does not reference the filling of out-of-state prescriptions (which may or may not comply with Florida’s new requirements). The law does not set forth a prohibition on filling them.

Are prescribers in registered pain management clinics who prescribe Schedule II opioid controlled substances for the treatment of acute pain exempt in any way from the requirements of the new controlled substance law?

No. The legislature did not carve out an exemption for prescribers in pain management clinics who prescribe Schedule II opioid controlled substances for the treatment of acute pain. They are subject to the 3 and up to 7-day supply limits and to the labeling requirements for “ACUTE PAIN EXCEPTION” (for 4-7 day supply) and “NONACUTE PAIN” (for greater than 7-day supply).

Must a prescriber see a patient for whom they prescribe controlled substances every 30 days?

No. This is not a requirement of the new controlled substances law. After the passing of CS/CS/HB 21, only the section numbering and title for Section 456.44, Controlled Substance Prescribing, changed to: Section 456.44(3) Standards of Practice for Treatment of Chronic Nonmalignant Pain.

The language did not change and reads:

S. 456.44(3)(d) states, in part, “The patient shall be seen by the registrant at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient’s progress toward treatment objectives, consider adverse drug effects, and to review the etiology of the pain....”

Prescription Drug Monitoring Program FAQs:

General Questions

I am a prescriber with a Drug Enforcement Administration (DEA) registration, however I do not prescribe controlled substances. Am I required to register for E-FORCSE?

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

You are still authorized to register. You can view your patient’s-controlled substance dispensing histories.

Updated as of: 9/27/2018

How do I register with the PDMP?

Prescribers, dispensers and their designees may register for access at <https://florida.pmpaware.net>.

Is there penalty for failing to consult the PDMP?

Yes.

What is the penalty for the initial offense?

The DOH will issue a non-disciplinary citation for the initial offense.

What is the penalty for any subsequent offense?

Any subsequent offense will result in disciplinary action against the prescribing/dispensing practitioner's license. Disciplinary guidelines are individually established by the appropriate licensing board.

Does the PDMP purge information from its database?

Yes. Information that is more than 4 years old.

Data Requestors

Prescriber Consultation

When must a prescriber or his or her designee consult the PDMP?

A prescriber or his or her designee must consult the PDMP to review their patient's controlled substance dispensing history prior to prescribing a controlled substance in Schedules II-V, as defined in section 893.03, F.S., for patients age 16 and older.

When is a prescriber not required to consult the PDMP?

- If the PDMP system is not operational as determined by DOH, or
- The PDMP cannot be accessed by the prescriber practitioner due to a temporary technological or electrical failure or
- When prescribing a nonopioid Schedule V drug or
- The patient is less than 16 years of age

What must the prescriber do if they are unable to consult the PDMP due to operational, (determined by the PDMP program), or temporary technology/electrical failure?

The prescriber must document in the patient's record the reason the PDMP was not consulted and may prescribe no more than a 3-day supply of a controlled substance.

If a prescription has refills, must the prescriber consult the PDMP before each refill?

The prescriber is not required to consult the PDMP before each refill, however, the prescriber must consult the PDMP prior to writing a new prescription for a controlled substance listed in Schedule II through V. A prescription for a controlled substance listed in Schedule II may not be refilled.

How far in advance can I consult the PDMP? (i.e. 1 day? 1 week?)

Updated as of: 9/27/2018

The statute does not provide any guidance on how far in advance the PDMP may be consulted. Please refer to your Board's website for further guidance.

Do I have to consult the PDMP each time I write a prescription, or only at the initial appointment?

The PDMP must be consulted each time a prescription for a controlled substance is written.

Dispenser Consultation

Does a dispenser always have to consult the PDMP?

A dispenser or a designee of a dispenser must consult the PDMP to review a patient's-controlled substance dispensing history prior to dispensing a controlled substance in schedules II-V, as defined in section 893.03, F.S., for patients age 16 or older for each new and refill prescription.

When may a dispenser not consult the PDMP?

A dispenser or a designee of a dispenser does not have to consult the PDMP when dispensing a nonopioid controlled substance listed in Schedule V of s. 893.03, F.S. or 21 U.S.C. 812.

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 dispenser or a designee of the dispenser because of a temporary technological or electrical failure

What should a dispenser do if he or she cannot consult the system?

A dispenser or designee of a dispenser who does not consult the PDMP shall document the reason he or she did not consult the system in the patient's medical record or prescription record and shall not dispense greater than a 3-day supply of a controlled substance to the patient.

Is a dispenser required to consult the PDMP on refills for schedules III, IV, and V controlled substances?

A dispenser must consult the PDMP on the new prescription and on each subsequent refill.

Data Submitters

What is a dispenser?

A dispenser is a dispensing health care practitioner, pharmacy, or pharmacist licensed to dispense controlled substances to the ultimate consumer or his or her agent in or into this state.

What is a dispensing practitioner?

A dispensing practitioner is a practitioner authorized by law to prescribe drugs who may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with s. 465.0276,

F.S. Dispensing practitioners may include: physicians, dentists, certified optometrists, podiatrists, advanced registered nurse practitioners and physician assistants.

Is a dispenser required to report controlled substances dispensed to a patient?

Dispensers are required to report to the PDMP each time a controlled substance is dispensed to a patient, as soon thereafter as possible, but no later than close of business the day after the prescription is dispensed unless an extension or exemption is approved by the Department of Health.

Which controlled substances must be reported to the PDMP?

All controlled substances in schedules II through V must be reported to the system by the close of the next business day. If the dispenser does not dispense any controlled substances for that day, then a zero report must be submitted.

Are there exemptions to reporting to the PDMP?

Yes, there are two exemptions from reporting:

- Controlled substances administered to patients;
- Controlled substances dispensed in the health care system of the Department of Corrections; and
- Controlled substances dispensed to patients under the age of 16 are exempt from reporting to E-FORCSE.

What new reporting requirements must the dispenser submit to the PDMP?

- The telephone number of the person for whom the prescription was written, in addition to the name, address, and date of birth the prescriber currently inputs;
- Whether the prescription is an initial prescription or a refill, and the number of refills prescribed;
- The name of the individual picking up the controlled substance prescription and the type and issuer of the identification provided; and
- The pharmacy's DOH-issued permit number or the dispensing practitioner's DOH-issued license number

When will dispensers be required to submit controlled substance data using the new ASAP 2009 version 4.2a format?

The Department has published a notice of rule development and will be amending Rule 64K-1.002, FAC . The PDMP will continue to accept submissions in the ASAP 2009 version 4.2 and the new 4.2a standard for one year from the effective date of the rule.

What are the new fields that are required to be reported in ASAP 2009 version 4.2a?

- The pharmacy permit number or the dispensing health care practitioner's license number.
- The name of the individual picking up the controlled substance prescription and type and issuer of the identification provided.

What will happen if a dispenser fails to report the dispensing of a controlled substance?

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, punishable as provided in s. 775.082 or s. 775.083, F.S. Further, the department shall issue a non-disciplinary citation to any prescriber or dispenser who fails to consult the system as required by this subsection for an initial offense. Each subsequent offense is subject to disciplinary action pursuant to s. 456.073, F.S.