HOUSE BILL 21 – Frequently Asked Questions (updated 7.6.2018)

PRESCRIPTION QUESTIONS

1. Does a prescriber need to write the words "Acute Pain" or "Acute Pain – 3 Days" on a prescription for a patient experiencing acute pain?

No. The legislation does not require the words "Acute Pain" to be written on a prescription, but rather the words "ACUTE PAIN EXCEPTION". Please see Section 456.44(5)(a)(2), F.S. -

5) PRESCRIPTION SUPPLY—

(a) 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:

1. The prescriber, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition;

2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and

3. The prescriber adequately documents 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 established in this subsection.

2. Section 456.44(5)(a), F.S. limits Schedule II drugs to a 3-day supply and in certain cases a 7-day supply (Acute Pain Exception); however, the law does not provide guidance on quantity limits. In an effort to be compliant and understand quantity limits, can you please provide guidance on what are the quantity limits (in pills based off of MME) for Schedule II drugs?

The current law found in Section 456.44(5)(a), F.S. does not limit the days' supply of a scheduled II opioid for the treatment of acute pain based on morphine milligram equivalents (MME). According to the Centers for Disease Control the MME conversion factor is intended only for analytic purposes where prescription data is used to calculate daily MME. It is to be used in the formula:

Strength per Unit x (Number of Units / Days Supply) X MME conversion factor = MME/Day.

The links to the attached documents may be helpful:

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016
https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

NYC has created a MME calculator and made available at the following link:
https://www1.nyc.gov/site/doh/providers/health-topics/mme-calculator.page

3. Does the new law affect all prescriptions written after July 1st?

No. The legislation only relates to prescriptions for treatment of "acute pain" for opioid drugs listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812. Prescriptions for non-opioid or non-Schedule II drugs are not affected by this legislation for prescribing practitioner.

Please see Section 456.44(5)(a), F.S. -

5) PRESCRIPTION SUPPLY—

(a) 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:

4. If a prescriber writes a 7-day acute pain Scheduled II prescription, but forgets to write "ACUTE PAIN EXCEPTION " may the pharmacist confirm with the prescriber and annotate the prescription?

Section 456.44(5), F.S. provides as follows:

5) PRESCRIPTION SUPPLY—

(a) 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:

1. The prescriber, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition;

2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and

3. The prescriber adequately documents 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 established in this subsection.

If a prescription for a Schedule II prescription does not meet the requirements as specified in the legislation, 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.

5. If after July 1, if a prescription exceeds the correct number of days for medicinal supply, and/or and if there is nothing on the prescription indicating "acute" vs. non-acute, is the pharmacist able to limit the prescription to a 3-day supply or must we refuse the prescription?

Section 456.44(5), F.S. 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:

1. The prescriber, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition;

2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and

3. The prescriber adequately documents 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 established in the law.

Additionally, for the treatment of pain other than acute pain, a prescriber must indicate "NONACUTE PAIN" on a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

If a prescription for a Schedule II prescription does not meet the requirements as specified in the legislation, 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.

6. If a prescriber has written a Schedule II prescription for more than a 3-day supply, is it able to be filled for only a 3-day supply or is it void?

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:

1. The prescriber, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition;

2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and

3. The prescriber adequately documents in the patient's medical record the acute medical condition and lack of alternative treatment options that justify deviation from the 3-day supply limit.

If a prescription for a Schedule II prescription does not meet the requirements as specified in the legislation, 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.

7. If a prescriber writes a prescription for 30 days but fails to document "NONACUTE PAIN" on the hard copy, is that something we are able to verbally authorize or would the patient need to bring the prescription back for proper documentation?

For the treatment of pain other than acute pain, a prescriber must indicate "NONACUTE PAIN" on a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

If a prescription for a Schedule II prescription does not meet the requirements as specified in the legislation, 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.

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8. If a prescriber notates "Acute Pain Exception", they can prescribe a 7-day supply of a Schedule II drug, but that justification must be documented in the medical record. Does this information need to be documented on the prescription as well?

No. 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:

1. The prescriber, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition;

2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and

3. The prescriber adequately documents in the patient's medical record the acute medical condition and lack of alternative treatment options that justify deviation from the 3-day supply limit.

9. If a patient has a prescription written before July 1, 2018, is it still valid if written for more than a 3 -day supply?

The effective date of the legislation is July 1, 2018, and any requirements regarding prescriptions would be applicable starting July 1, 2018, and going forward. Prescriptions written before July 1, 2018, should still be valid and would be subject to the law at the time that prescription was written. The requirement to include the language "ACUTE PAIN EXCEPTION" or "NONACUTE PAIN" on the prescription would only be requirement after the effective date of the bill, July 1, 2018.

Please note that as of July 1, 2018, Section 893.055(3)(a), F.S. provides that for each controlled substance dispensed to a patient in this state, certain information must be reported by the dispenser to the system as soon thereafter as possible but no later than the close of the next business day after the day the controlled substance is dispensed unless an extension or exemption is approved by the department. Please click on the below link to see the complete list of required information:

http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0800-0899/0893/Sections/0893.055.html

10. When using eRX (Electronic Prescribing) if a note is included / transmitted to the retail pharmacist that says for "Acute Pain", "Acute Pain Exception" or "Non-Acute Pain" will that meet the requirement of the law?

If the "note" is transmitted with or considered to be part of the actual electronic prescription to be transmitted to the retail pharmacist, then the annotation of "Acute Pain Exception" or "Non-Acute Pain" would be acceptable. Section 456.44(5), F.S. 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:

1. The prescriber, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition;

2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and

3. The prescriber adequately documents 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 established in the law.

Section 456.44(5)(b), F.S. also provides that for the treatment of pain other than acute pain, a prescriber must indicate "NONACUTE PAIN" on a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

11. If a pharmacist receives a prescription for a traumatic injury with a severity score of 9 or above and does not receive the prescription for the emergency opioid antagonist, is the pharmacist allowed to dispense the opioid antagonist? (UPDATED)

The legislation provides that 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). If the pharmacist does not receive a prescription for the antagonist as specified in the legislation, the pharmacist should follow their current standard policy and procedures by contacting the prescribing practitioner. Any deviation or change in the prescription should be promptly reduced to writing and properly annotated based on your current pharmacy practice.

12. Do the 3-day or 7-day supply limits in the bill mean that the prescription expires 3 days or 7 days after it is written?

No. The legislation 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 elapsed after the prescription is written.

IDENTIFICATION QUESTIONS

13. Could you please tell me what forms of ID are acceptable, both on getting a prescription and the person picking up the prescription?

Before dispensing a controlled substance to a person not known to the pharmacist, the pharmacist 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. If the person does not have proper identification, the pharmacist may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system is considered to be proper identification.

"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). See the following hyperlink: https://www.law.cornell.edu/cfr/text/8/274a.2

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LONG TERM CARE FACILITIES and ADMINISTRATION

14. Are there any exceptions to the new regulations in the legislation as they pertain to Long Term Care Prescribers and Long-Term Care Pharmacies?

The legislation provides that the ID requirement for getting or picking up a prescription does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted.

15. Are long-term care facilities, including, but not limited to, an assisted living facility or a hospital required to consult the PDMP?

The Department will be addressing this issue via rulemaking and a notice of proposed rule will be published soon. The proposed rule will provide clarification and should answer your questions. Once the notice of proposed rulemaking is noticed, the public will have the opportunity to review and provide feedback.

16. What is the difference between "administration" or "dispensing" of medicinal drugs?

Section 465.003(1), Florida Statutes, defines "administration" as the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption, and Section 465.003(6), Florida Statutes defines "dispense" as the transfer of possession of one or more doses of a medicinal drug by a pharmacist [or a practitioner] to the ultimate consumer or her or his agent.