Frequently Asked Questions: Updated Regulations on Acute Pain Management

In March 2017, the Rhode Island Department of Health (RIDOH) amended regulatory changes for opioid use and the management of acute pain in the *Rules and Regulations for Pain Management, Opioid Use, and the Registration of Distributors of Controlled Substances in Rhode Island [216-RICR-20-20-4]*. These Frequently Asked Questions (FAQs) provide answers to common inquiries regarding the updated regulations.

The intent of the regulations is to: (1) prevent the incidence of accidental overdose of patients not yet tolerant to opioids; and, (2) prevent chronic opioid use for non-cancer pain by limiting the initial supply of opioid dosages.

1. **How is an "initial prescription" defined?**

   The updated regulations on acute pain management define an initial prescription as the first prescription given to an individual who is new to the prescription of opioids, and who has not taken opioids in the last 30 days.

2. **Are all initial opioid prescriptions limited to a quantity of 20 doses and no more than 30 morphine milligram equivalents (MME) per day?**

   No. Patients receiving palliative care, cancer treatment, or chronic pain treatment may receive initial prescriptions for opioids outside of these limitations.

3. **How is an "initiate" defined?**

   The updated regulations on acute pain management define initiates as individuals who have not taken an opioid within the last 30 days, or longer. These patients are considered "new starts."

   A prescription falls within the initial acute prescribing regulations under these circumstances:

   - The patient has not had a fill of an opioid medication, as confirmed by the Prescription Drug Monitoring Program (PDMP) for 30 days or more; and,
   - The patient has not taken opioid medications for 30 days or more.

Acute Pain: Hypothetical Examples for Prescribing Opioids				
	Last RX Fill Date for an Opioid	**Current Date**	**RX from Prescriber**	**Can Pharmacist Fill RX?**
Patient A ***Acute Pain*** **New to the prescription of opioids**	None	May 1, 2017	Short-acting opioid 20 doses < 30 MME	Yes, conforms to acute pain regulation.
Patient B ***Acute Pain*** **New to the prescription of opioids**	None	May 1, 2017	Short-acting opioid; 60 doses; < 30 MME	No, must call prescriber to conform to regulation and correct quantity.*
Patient C ***Acute Pain*** **New to the prescription of opioids**	None	May 1, 2017	Short-acting opioid; 20 doses; > 30 MME	No, must call prescriber to conform to regulation and correct MME to 30 or less.*
Patient D ***Acute Pain*** **Prior RX for opioids within last 30 days**	April 1, 2017	May 1, 2017	Short-acting opioid; 10-day supply; > 30 MME	Yes, patient is not new to the prescription of opioids.

*Please refer to page 6 regarding legally authorized changes to a controlled substance prescription; Drug Enforcement Administration guidance letter, October 15, 2008.

4. **How is acute pain defined?**

Acute pain is the body's normal response to damage caused by a procedure or serious injury. This type of pain is characterized by a sudden, well-defined onset and typically resolves once the tissue damage is repaired. Duration of acute pain varies depending upon the procedure or injury, and generally lasts less than 90 days. Acute pain can become chronic when the cause is difficult to treat.

5. **How is chronic pain defined?**

Chronic pain can begin after an injury, or because of a health condition associated with a cancer diagnosis, palliative/nursing home care, or chronic pain management. This type of pain can range from mild to severe; it can continue day after day or come and go. Duration of chronic pain varies depending upon the patient's injury or health condition, and generally lasts more than 90 days. Chronic pain may reduce quality of life, well-being, and ability to function over the long term. Pain requiring palliative care is excluded from this definition.

The Centers for Disease Control recommends limiting opioid prescriptions for chronic pain. Non-opioid pharmacologic therapies (e.g., anti-inflammatory drugs) and non-pharmacologic therapies (e.g., exercise, physical therapy, and cognitive behavioral therapy) are also effective in mitigating chronic pain. Combining non-opioid pharmacologic therapies and non-pharmacologic therapies with opioids can provide the greatest relief from chronic pain.

6. **For an initial prescription, do the quantity limits of 20 doses and no more than 30 morphine milligram equivalents (MME) per day apply to patients suffering from chronic pain?**

   No. The limits apply to patients who have not taken a prescription for opioids in the last 30 days or more, making them new to the prescription of opioids. These limits are in place to prevent "initiates" from becoming addicted to or physically dependent on opioids.

   This regulation does not apply to chronic pain patients, and does not apply to patients receiving palliative care.

Chronic Pain: Hypothetical Examples for Prescribing Opioids

	Last RX Fill Date for an Opioid	Current Date	RX from Prescriber	Can Pharmacist Fill RX?
Patient A ***Chronic Pain*** **Chronic prescription opioid use**	March 15, 2017	April 14, 2017	Short-acting opioid; 30-day supply; >30 MME	Yes, chronic pain is an exclusion.
Patient B ***Intermittent Use of Prescription Opioids*** **(prior RX for 30 days was recent)**	March 15, 2017	May 1, 2017	Short-acting opioid; 30-day supply; >30 MME	Yes, chronic pain is an exclusion and the prescription is within 60 days.
Patient C ***Intermittent Use of Prescription Opioids*** **(prior RX for 30 days was not recent)**	January 10, 2017	May 1, 2017	Short-acting opioid; 30-day supply; >30 MME	No, needs to fall within acute pain regulation of 20 doses and not to exceed 30 MME.

7. **For an initial prescription, do the quantity limits of 20 doses and no more than 30 morphine milligram equivalents (MME) per day apply to patients suffering from chronic addiction or opioid use disorder?**

   No. The quantity limits apply to patients who have not had a prescription for opioids in the last 30 days or more, making them new to the prescription of opioids. These limits are in place to prevent "initiates" from becoming addicted or physically dependent on opioids.

8. **Can a prescriber write and a pharmacist fill an amount for a long-acting opioid, such as OxyContin, for an "initiate?"**

   No.

9. **Can a prescriber write an initial prescription and a pharmacist fill an initial prescription greater than 20 doses of an opioid for chronic pain?**

   Yes. Prescribers should follow Section 4.4: *Rules and Regulations for Pain Management, Opioid Use, and the Registration of Distributors of Controlled Substances in Rhode Island [216-RICR-20-20-4]*.

10. **How will a pharmacist know that the initial prescription for an opioid is not for the initial treatment of acute pain?**

    The pharmacist or a designee should check the PDMP.

11. **If an initial opioid prescription is written for a quantity greater than 20 doses, can it be filled for the appropriate quantity (20 doses or less) without getting a new prescription?**

    Yes. The practitioner who wrote the prescription must be contacted and any legally authorized changes must be documented on the prescription.

11a. **If an initial opioid prescription is written for a quantity greater than 20 doses, can this prescription be refilled for the remaining balance of doses?**

    No. The partial filling of a Schedule II drug is permissible under certain circumstances (i.e., pharmacy did not have the full amount in stock); however, it is not permitted to fill a remaining balance of pills for a Schedule II to patients considered initiates or opioid naïve.

12. **Can a prescriber write an initial prescription for an opioid that normally allows refills (e.g., Tylenol with codeine, tramadol) and authorize refills?**

    No. Prescribers are not authorized to refill an initial opioid prescription for a "new start" according to Rhode Island's acute pain management regulations and the U.S. federal government's Controlled Substances Act. It is recommended that the pharmacist document the reasons(s) for not refilling the prescription.

13. **Is a prescriber authorized to write an initial opioid prescription that a patient does not need in order to bypass Rhode Island's acute pain management regulations?**

    No. Prescriptions for an opioid should only be written with appropriate clinical judgement and only if needed, balancing management of patient's pain with risk of dependence or other unintended harm. Prescribers should evaluate if subsequent opioid prescriptions are needed based on patient's clinical response and functional improvement; and should strongly consider if non-opioid options are more appropriate. If prescribing an opioid is necessary, limiting to the lowest appropriate morphine milligram equivalent dose is strongly advised.

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

www.dea.gov

OCT 15 2008

Dear Colleague:

On November 19, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the Rule's preamble are in opposition to policy posted on the DEA Diversion website regarding changes a pharmacist may make to a schedule II prescription after oral consultation with the prescriber. In a Question and Answer section, the website instructed that a "pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner."

DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.

Questions regarding this correspondence may be directed to the Liaison and Policy Section, Office of Diversion Control, DEA at (202) 307-7297.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator/
Deputy Chief of Operations
Office of Diversion Control