



Frequently Asked Questions

***Rules and Regulations for Pain Management, Opioid Use, and the
Registration of Distributors of Controlled Substances in Rhode Island***

[216-RICR-20-20-4]

Updated September 10, 2018

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**Frequently Asked Questions About July 2018
Updated Pain Management Regulations**

September 20, 2018



Frequently Asked Questions About July 2018 Updated Pain Management Regulations

On July 2, 2018, the Rhode Island Department of Health (RIDOH) made regulatory changes to 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 regulations require prescribers to:

1. Have a conversation with patients about the risks and benefits of taking an opioid prescription;
2. Indicate the diagnosis code(s) on a patient's opioid prescription; and
3. Co-prescribe naloxone to patients who are at a higher risk for opioid overdose.

These Frequently Asked Questions (FAQs) provide detailed answers to common inquiries regarding the recently updated pain management regulations.

Patient Education and Conversation

1. What is expected in terms of the required conversation with patients about taking opioid prescription pain medications?

Before prescribing an opioid, healthcare providers must talk to patients about the risks of taking opioid pain medications as prescribed. This conversation is an opportunity to thoughtfully consider risks, potential benefits, and must include the following topics:

- Risks of developing physical and psychological dependence which may lead to harmful use, addiction, overdose, and/or death;
- Risks of concurrent use of alcohol or other sedating medications, such as benzodiazepines;
- Impaired ability to safely operate any motor vehicle;
- Patient's responsibility to safeguard all opioid medications in a secure location;
- Patient's ability to safely dispose of unnecessary or unused opioids;
- Alternative treatments for managing pain (non-opioid medications and/or non-pharmacologic treatments); and
- Risks of relapse for those who are in recovery from substance dependence.

2. Does RIDOH offer patient education materials to fulfill this requirement for conversation?

Yes. Before prescribing an opioid pain medication, clinicians can print and share RIDOH's ***Knowing the Risks of Opioid Prescription Pain Medications***, that is available in both [English](#) and [Spanish](#). It is designed to help start conversations about the risks of taking opioids, proper dosage, safe storage/disposal, and co-prescribing naloxone.

RIDOH has also drafted recommended [Conversation Starters for Use When Prescribing Opioids](#) that healthcare providers may find helpful to initiate discussions.

3. Does the requirement for conversation apply beyond the patient's first opioid prescription?

Yes. Prescribers are required to have a conversation with the patient about the risks of taking opioids before the second and third consecutive prescriptions. Consecutive opioid prescriptions increase a patient's risk of becoming a persistent opioid user (someone who takes an opioid for longer than 90 days) and at higher risk of misuse and overdose. The conversations before the second and third consecutive prescription should focus on the patient's individual needs and risks such as withdrawal and tolerance.

4. Can a healthcare provider delegate the responsibility of the required conversation with the patient to a trained health professional in their office?

Yes. The required conversation can be delegated to a nurse or a pharmacist; however, the prescriber is ultimately responsible for fulfilling the requirement of conducting the conversation with patients about the risks of taking opioids. The supplemental guides provide a solid background and consistent messaging for these conversations, no matter which acceptable healthcare provider conducts them.

5. Are there any additional requirements to fulfill the *Patient Education/Informed Consent – Requirement for Conversation* portion of the updated pain management regulations?

Yes, the prescriber is also required to document in the patient's medical record that a conversation occurred with the patient (or guardian) about the risks of the opioid medication. This documentation is required for the second and third prescriptions as well.

6. What are some considerations prescribers must be aware of when caring for patients with a cancer-associated pain diagnosis, on palliative/nursing home care, or other patients on chronic pain management?

Patients with a cancer-associated pain diagnosis, on palliative/nursing home care, or other patients on chronic pain management should continue to have access to treatment according to their specific chronic pain needs. Prescribers should be cognizant of not abruptly reducing or removing a patient from chronic pain medication, as this poses serious dangers to the patient. Chronic pain management regulations are addressed separately in other sections of [\[216-RICR-20-20-4\]](#).

7. Is there any suggested language regarding the safe storage and disposal of opioids that healthcare providers can share with their patients?

It is important to emphasize to patients that opioid medications should never be shared. If patients have leftover or expired opioid medications, RIDOH recommends mixing the medicines with cat litter or coffee grounds and then throwing them in the garbage. Patients can also flush the opioid medication down the toilet or bring it to a local [drug take-back location](#).

Documenting International Classification of Diseases (ICD) 10 Diagnosis Code(s) on Controlled Substance Prescriptions

1. Why is the documentation of ICD-10 diagnosis codes on all controlled substances prescriptions required?

The requirement for prescribers to provide a diagnosis code on a patient's prescription allows pharmacists to understand why the controlled substance is being dispensed. Pharmacists are able to use this information to have follow-up conversations with prescribers and patients to ensure that patients are being treated with the appropriate medication. This is a requirement for all clinicians with a Controlled Substance Registrations (CSR), including dentists, physicians, physician assistants (PAs), Advanced Practice Registered Nurses (APRNs), optometrists, midwives, podiatrists, and veterinarians. The ICD-10 code(s) must be entered in a visible location on the prescription.

2. Where can dentists and other clinicians who typically do not work with ICD-10 codes find the appropriate diagnosis code?

The most common dental ICD-10 codes are:

- K01: impacted teeth
- K04: pulpal and periapical diseases
- K05: periodontal diseases
- K08: loss of teeth (This code could be used for implant placement or another pre-prosthetic surgery.)

For dentists, it is sufficient to document the three-character code—the category code—when documenting a diagnosis on a prescription. For example, the three-character code of **K01** supplies sufficient information to indicate a diagnosis of **Embedded and Impacted Teeth**. To find a more specific diagnosis code, prescribers can visit the World Health Organization's (WHO) [comprehensive list of ICD-10 codes](#).

3. If the prescriber cannot find an appropriate ICD-10 code or if the prescriber's profession does not typically use ICD-10 codes, how should the patient's diagnosis be indicated on the prescription?

In these specific cases, the patient's diagnosis should be written legibly in a visible location on the face of the prescription.

4. **Does the ICD-10 code have to be documented in the medical record, too?**
RIDOH does not require a prescriber to record an ICD-10 code in the patient's medical record.
5. **If a prescriber omits the ICD-10 code, can pharmacists take verbal orders from the prescriber for the code, or does a new prescription need to be issued?**
A verbal order from the prescriber can be obtained to fulfill the requirement for the ICD-10 code.

Co-Prescribing Naloxone

1. **Does a healthcare provider need to co-prescribe naloxone each time an opioid is prescribed?**

No. It is a requirement to co-prescribe naloxone in three clinical scenarios:

1. When prescribing an opioid individually or in aggregate with other medications that is **more than or equal to 50 oral Morphine Milligram Equivalents (MMEs) per day**.
2. When prescribing any dose of an opioid when a **benzodiazepine has been prescribed in the past 30 days or will be prescribed at the current visit**, prescribers must note in a patient's medical record the medical necessity of the co-prescription of opioid and benzodiazepine and why the benefit outweighs the risk given the Food and Drug Administration's (FDA) black-box warning.
3. **When prescribing any dose of an opioid to a patient with a prior history of opioid use disorder or overdose**. Prescribers must also document in the patient's medical record the medical necessity of prescribing an opioid to this high-risk individual and explain why the benefit outweighs the risk given the patient's previous history.

If the patient does not meet one of these three clinical scenarios and does not need to be co-prescribed naloxone, then the healthcare provider must document this information in the patient's medical record.

2. **What if my patient does not meet the criteria of one of the three clinical scenarios?**

If the patient does not meet the criteria in one or more of the three clinical scenarios and it is not appropriate to co-prescribe naloxone, the prescriber must document the reason(s) in the patient's medical record. Since the Surgeon General, Dr. Jerome Adams, has advocated that everyone carries naloxone during the opioid overdose epidemic, a universal approach to prescribing naloxone could be considered.

3. **For patients meeting one or more of the three clinical scenarios, what is the required frequency for co-prescribing naloxone?**

There is no frequency requirement for co-prescribing naloxone to a patient that meets one or more of the three clinical scenarios. If a patient declines the naloxone prescription, it must be documented in the patient's medical record (e.g., "Patient already has naloxone."). The [American Medical Association's \(AMA\) Task Force](#) encourages healthcare providers to co-prescribe naloxone when it is clinically appropriate. The following chart highlights clinical scenarios that are deemed appropriate by the AMA and the State of Rhode Island for co-prescribing naloxone.

Prescribing Naloxone when Clinically Appropriate

Question	July 2018 Updated Pain Management Regulations	Indications
<i>Does the patient's medical history or the Prescription Drug Monitoring Program (PDMP) show that my patient is on a high dose of opioids?</i>	50 oral Morphine Milligram Equivalents (MMEs) or more	<ul style="list-style-type: none"> • High-dose • Extended release • Long-acting opioids
<i>Is my patient also on a concomitant benzodiazepine prescription?</i>	Past 30 days and/or during current visit	Uses opioids with: <ul style="list-style-type: none"> • Antidepressants • Benzodiazepines • Alcohol • Other drugs
<i>Does my patient have a history of a substance use disorder?</i>	Opioid Use Disorder or a history of overdose	<ul style="list-style-type: none"> • Known history of intravenous drug use or misuse of prescription opioids • Documented history of an alcohol or substance use disorder • Received emergency medical care or been hospitalized for an opioid overdose
<i>Does my patient have an underlying mental health condition that might make him or her more susceptible to overdose?</i>	N/A	<ul style="list-style-type: none"> • Documented history of a mental health condition.
<i>Does my patient have a medical condition, such as a respiratory disease, sleep apnea, or other co-morbidities, which might make him or her susceptible to opioid toxicity, respiratory distress, or overdose?</i>	N/A	<ul style="list-style-type: none"> • Patient has a respiratory ailment or other co-morbidity that may be exacerbated by the use of opioid medications.

4. If minimal dosing of a benzodiazepine and an opioid is prescribed, what should the prescriber document in the patient's medical record if the provider feels naloxone is not needed?

Prescribers can document in the medical record why naloxone is not indicated. In the case of mild oral sedation in a dental office, a prescriber can document that the benzodiazepine is for a pre-procedural use only without overlapping opioid dosing to occur post-procedurally.

5. Does a healthcare provider need to prescribe naloxone if a patient is currently taking buprenorphine/naloxone (Suboxone®) for Opioid Use Disorder (OUD)?

The decision to prescribe naloxone to a patient who is taking buprenorphine/naloxone for OUD is at the prescriber's discretion; however, appropriate documentation in the patient's medical record is required. There may be benefits because the naloxone within the buprenorphine/naloxone combination only deters injection of the film or pill formulations; it does not prevent nor treat opioid overdose. Because people diagnosed with opioid use disorder are likely in contact with others at higher risk of overdose, have reversed overdoses, or experienced overdose themselves, co-prescribing naloxone to them may help protect the community against opioid overdose.

6. Will the pharmacy fill an opioid prescription if the PDMP indicates a concomitant benzodiazepine and there is not a co-prescription for naloxone?

If a pharmacist finds that a patient's opioid prescription is not compliant with the updated regulations, the pharmacist will contact the prescriber to correct the prescription.

7. Will health insurers cover the cost of naloxone?

Yes. All health insurers in Rhode Island cover at least one type of generic naloxone. Rhode Island Medicaid fully covers the cost of generic naloxone and Narcan® single-step intranasal spray. Clinicians are encouraged to download and print this [new naloxone prescription template](#) when co-prescribing naloxone. Providers can also visit FormularyLookup.com to review insurance eligibility and coverage details. Healthcare providers can learn more about the prescribing and dispensing of naloxone as well as other useful overdose prevention resources, by visiting PrescribetoPrevent.org. The site also offers a detailed [Naloxone Comparison Chart](#) for more information on specific naloxone products.

8. How can a prescriber best communicate with patients about the benefits of co-prescribing naloxone?

Opioid addiction, overdose, and death has affected Rhode Islanders, their families, and their friends. While we have made progress to reverse the overdose crisis, additional public health measures like co-prescribing naloxone in high-risk cases is essential. Healthcare providers can consider using phrases such as “accidental overdose,” “bad reaction,” or “opioid safety” when explaining why a patient is being co-prescribed naloxone. Additional messaging to consider:

- *Opioids can cause bad reactions that make your breathing slow down or stop. This can happen if your body can't handle the opioids you take that day or if you take opioids with alcohol or other drugs. Naloxone is a lifesaver, just like a seatbelt or a fire extinguisher.*
- *Naloxone is the antidote to opioids. It is [sprayed in the nose/injected] if there is a bad reaction and you can't be woken up.*
- *Naloxone is for opioid medications like an epinephrine pen is for someone with an allergy.*
- *These medications can be helpful but have a range of side effects, like slowing down or stopping breathing completely. Naloxone can help restore breathing if this happens.*
- *Opioid medications increase the risk of a breathing emergency for the person who takes the opioid and for anyone in their household. Naloxone is needed in case of emergency.*
- *Let's keep you and your family as healthy as possible while you have these medications in your house. Just in case, get naloxone.*

Additional inquiries:

- Margaret Clifton, MS, RN-BC, CLNC; State Director of the Rhode Island Board of Nurse Registration and Nursing Education, RIDOH Margaret.Clifton@health.ri.gov
- James McDonald, MD, MPH; Chief Administrative Officer of the Board of Medical Licensure and Discipline and Medical Director for the Prescription Drug Overdose Prevention Program, RIDOH James.McDonald@health.ri.gov
- Peter Ragosta, Chief Administrative Officer of the Rhode Island State Board of Pharmacy, RIDOH Peter.Ragosta@health.ri.gov
- Samuel Zwetchkenbaum, DDS, MPH; Dental Director, Oral Health Program, RIDOH Samuel.Zwetchkenbaum@health.ri.gov



**Frequently Asked Questions About March 2017 Updated
Acute Pain Management Regulations**

May 23, 2017



Frequently Asked Questions About March 2017 Updated Acute Pain Management Regulations

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?
<u>Patient A</u> 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.
<u>Patient B</u> 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.*
<u>Patient C</u> 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.*
<u>Patient D</u> 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 <u>not</u> new to the prescription of opioids.

* Please refer to page 15 regarding legally authorized changes to a controlled substance prescription; Drug Enforcement Administration (DEA) 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?
<i>Patient A</i> <i>Chronic Pain</i> Chronic prescription opioid use	March 15, 2017	April 14, 2017	Short-acting opioid; 30-day supply; >30 MME	Yes, chronic pain is an exclusion.
<i>Patient B</i> <i>Intermittent Use of Prescription Opioids</i> (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.
<i>Patient C</i> <i>Intermittent Use of Prescription Opioids</i> (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 updated acute pain management regulations](#) and the US 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
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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,

A handwritten signature in black ink, appearing to read "Joe Rannazzisi".

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