Department of Health

Three Capitol Hill
Providence, RI 02908-5097

TTY: 711
www.health.ri.gov

In accordance with the Administrative Procedures Act, R.I. Gen. Laws Section 42-35-3(a)(1), the following is the Rhode Island Department of Health's ("RIDOH") concise statement regarding this rulemaking for Pain Management, Opioid Use, and the Registration of Distributors of Controlled Substances in Rhode Island (216-RICR-20-20-4).

This amendment to the regulations creates requirements for electronic prescriptions, implements grammatical corrections and revise the use of several terms including MME and PDMP, eliminates definitions that are not utilized in the regulations or that are being replaced with updated terms, creates definitions for electronic prescription, standing order, and substance use disorder, clarifies mandatory PDMP review, clarifies requirements for documentation of patient education regarding opioids, clarifies requirements for ICD10 code equivalents as determined by RIDOH, revises/removes section titles, and corrects references to other RIDOH regulations.

In response to public comment, § 4.3(A)(15) has been revised to include "*or office*" in order to clarify the applicability to physician offices.

In response to public comment, the proposed § 4.3(A)(29), which included proposed language regarding the definition of the term "*standing order*," has been removed in order to allow for further discussion on this term with community stakeholders. Additionally, the provision referencing this definition in the proposed § 4.4(K)(3)(e) has also been removed.

In response to public comment, § 4.4(C) has been revised to account for chronic illnesses with recurrent acute pain and pain associated with sickle cell disease, and implement prescribing limits for minors.

In response to public comment, § 4.4(C)(4) has been revised to clarify the applicability to prescriptions prescribed in an inpatient setting.

In response to public comment, § 4.4(E) has been revised to clarify applicability to prescriptions prescribed in an inpatient setting, and to clarify the requirement for rechecking of the Prescription Drug Monitoring Program ("PDMP") for patients under active treatment or who are receiving an ongoing opioid prescription.

In response to public comment, § 4.4(I)(1) has been revised to include "*occupational therapists*" among the list of providers who can use their skills to alleviate patients' chronic pain.

In response to public comment, the proposed §§ 4.4(K)(7)(a) and (b), regarding actions not prohibited to be undertaken by unlicensed staff members, have been removed in order to allow for further discussion with community stakeholders.

In response to public comment, a new § 4.4(K)(8) has been created, which allows for applications for waivers from electronic prescription requirements of § 4.4(K) of the regulations by providing acceptable evidence to RIDOH that the applying practitioner will experience undue economic hardship from the implementation of such requirements.

In response to public comment, § 4.4(Q)(2) has been revised to provide for recording of voluntary non-opiate directive forms (or the revocation thereof) in paper health records if the practitioner does not use electronic health records.

During public comment, it was suggested that § 4.4(K)(7), regarding practitioner authorization for unlicensed staff members to telephonically or otherwise transmit controlled substance prescriptions to pharmacies, be revised to include "*unless and until the practitioner has reviewed and signed it*." RIDOH has determined that this suggested revision will not be implemented because of the clarification implemented in this provision via the removal of the proposed §§ 4.4(K)(7)(a) and (b) (see note above regarding those revisions).

During public comment, it was suggested that § 4.4(Q)(2) be revised to remove reference to the filing of non-opiate directive forms in the PDMP. RIDOH has determined that this suggested revision cannot be implemented because R.I. Gen. Laws § 21-28-3.33(b)(1) explicitly requires procedures to record voluntary non-opiate directive forms in the PDMP, and RIDOH does not have the authority to override this statutory mandate.

In the development of this rule, consideration was given to: 1) alternative approaches; 2) overlap or duplication with other statutory and regulatory provisions; and 3) significant economic impact on small business. No alternative approach, duplication, or overlap was identified based on available information. RIDOH has determined that the benefits of this rule justify its costs.