New RULES and REGULATIONS for Pain Management and Opioid Use
Effective March 16, 2015, as promulgated by the Rhode Island Department of Health

FREQUENTLY ASKED QUESTIONS
A quick reference guide prepared by the Rhode Island Medical Society
for physicians and other prescribers

Background: A 14-month collaborative effort among many parties concerned with opioid use and misuse has resulted in new state regulations that set minimum requirements for pain management and opioid prescribing. They are in effect starting March 16, 2015. This document is intended to orient physicians to the new regulations. The complete regulations are published at: http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/8003.pdf

Who is subject to the new regulations?
Any health care professional who maintains a State of Rhode Island Controlled Substances Registration (CSR), aka Drug Enforcement Agency (DEA) number, and prescribes opioids. You must be a registered user with the state’s Prescription Drug Monitoring Program, PDMP or PMP. Some physicians have been automatically registered in the PMP when they renewed their CSR. You may check your registration status or register by going to www.ripmp.com.
Under legislation introduced by RIMS and enacted by the General Assembly in 2014, you may designate a staff member to query the PMP once you yourself have registered.

Is the treatment of all medical conditions subject to the new regulations?
No. The new regulations focus on chronic pain management and opioids. However, all professionals with a CSR must query the state’s Prescription Drug Monitoring Program before initiating any opioid treatment. If you are treating acute pain (as distinct from chronic pain) or the opioid is for palliative care, you are exempt from the remainder of the new regulations.

“Acute pain” means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical injury and typically is associated with invasive procedures, trauma, and disease. Acute pain generally results from nociceptor activation in damaged tissues. Acute pain typically resolves once the tissue damage is repaired. The duration of acute pain varies.

What is “chronic care” under the new regulations?
“Chronic pain” is considered to be pain lasting longer than ninety (90) days, excluding pain requiring palliative care.

What is the process for prescribing an opioid under the new regulations?
Section 3.0 Pain Management and Prescribing
3.1 Patient Evaluation. The practitioner shall obtain, evaluate and document the patient’s health history and physical examination in the health record prior to treating for chronic pain.
3.2 **Documentation of Treatment Plan.** Documentation in the medical record for chronic pain shall state the objectives that will be used to determine treatment success and shall include, at a minimum:

(a) Any change in pain relief;
(b) Any change in physical and psychosocial function; and
(c) Additional diagnostic evaluations or other planned treatments.

3.3 **Duration of Prescription.** Prescribing opioids for an acute injury shall be for a reasonable duration consistent with community standards for the pain that is being treated.

3.4 **Patient Education/Consent.** If prescribing opioids, the practitioner will advise patients specifically about adverse risks of taking alcohol or other psychoactive medications (e.g., sedatives and benzodiazepines), tolerance, dependence, addiction overdose or death if acute or long term use. For those patients in recovery from substance dependence, education shall be focused on relapse risk factors. This education will be communicated orally or in writing depending on patient preference and shall include as a minimum:

(a) Acknowledgment that it is the patient’s responsibility to safeguard all medications and keep them in a secure location; and
(b) Educate patient regarding safe disposal options for unused portion of a controlled substance.

**What if my patient needs “chronic care” as defined in the regulations as pain lasting more than 90 days?**

Chronic pain patients being treated with opioids for more than 90 days shall have a signed written patient treatment agreement that is a part of their medical record. The written agreement may be started at any point, at the practitioner’s discretion, no later than after ninety (90) days of treatment with an opioid medication.

The content of the written patient agreement for treatment is at the practitioner’s discretion.

Sample pain treatment agreements may be downloaded from [www.health.ri.gov/saferx](http://www.health.ri.gov/saferx)

**Is there a periodic review requirement for chronic pain patients in the new regulations?**

Yes. Periodic reviews, including an in-patient visit and PMP check, shall take place at least every 12 months, at which time the practitioner shall determine:

(1) Patient's adherence with any medication treatment plan;
(2) If pain, function, or quality of life have improved or diminished using objective evidence; and
(3) If continuation or modification of medications for pain management treatment is necessary based on the practitioner's evaluation of progress towards treatment objectives.

The practitioner shall consider tapering, changing, or discontinuing treatment when:

(1) Function or pain does not improve after a trial period; or
(2) There is reason to believe there has been misuse, addiction, or diversion.

**What about alternatives to opioids for treating chronic pain patients?**

Chronic pain often requires a multidisciplinary approach. Patients will often benefit from appropriate consultation not only with pain management specialists, but also with other professionals. Chiropractors, acupuncturists, behavioral health specialists and physical therapists are examples of clinicians who may be able to help alleviate patients’ chronic pain through other than medication.
Indications for referral to other professionals may include:

- patients self-escalating their doses
- early refills
- inadequate pain relief
- co-existing morbidities such as a need for dialysis, chronic liver disease, prior history of a substance disorder, or prior over-dose.

The threshold for adults for consideration, and documentation of consideration, of consultation is one hundred twenty (120) milligrams morphine equivalent dose per day (MED) (oral). In the event a practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty (120) milligrams MED (orally) per day, a consideration of consultation with a Pain Medicine Physician is required, and must be documented in the medical record.

If consultation is not obtained, the practitioner shall document in the patient’s medical record that a consultation was considered and the rationale for not obtaining such consultation

**Can I refer or require a chronic pain patient to see another practitioner?**

Yes, a practitioner may refer or require a patient to seek care from another practitioner for ongoing treatment. The referring practitioner shall facilitate a safe transition of care for any patient being referred to another practitioner. Safe transition shall include documented practitioner-to-practitioner contact regarding the patient and appropriate steps to prevent a disruption in the patient’s continuity of care for pain management.