

216-RICR-20-20-4

## TITLE 216 – DEPARTMENT OF HEALTH

### CHAPTER 20 – COMMUNITY HEALTH

#### SUBCHAPTER 20 – DRUGS

PART 4 – Pain Management, Opioid Use, and the Registration of Distributors of Controlled Substances in Rhode Island

#### 4.1 Authority

These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws § [21-28-3.01](#), for the purpose of establishing minimum requirements for pain management and opioid prescribing by a practitioner, and requiring registration of every person who manufactures, distributes, prescribes, administers or dispenses any controlled substance within Rhode Island.

#### 4.2 Incorporated Materials

These regulations hereby adopt and incorporate [21 C.F.R. § 1311](#) (Requirements for Electronic Orders and Prescriptions) (2018) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

#### 4.3 Definitions

A. Wherever used in these regulations, the following terms shall be construed as follows:

1. "Act" means the R.I. Gen. Laws Chapter 21-28 entitled, "Uniform Controlled Substances Act."
2. "Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain generally results from nociceptor activation due to damage to tissues. Acute pain typically resolves once the tissue damage is repaired. The duration of acute pain varies. For the purpose of this Part, acute pain shall not include chronic pain management, pain associated with a current cancer diagnosis, palliative care or nursing home care.

3. "Addiction medicine physician" means a physician who is specifically trained in a wide range of prevention, evaluation and treatment modalities addressing substance use disorder in ambulatory care settings, acute care and long-term care facilities, psychiatric settings, and residential facilities.
4. "Recovery from a substance use disorder" means a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential in areas of health, home, purpose and community, making informed, healthy choices that support physical and emotional wellbeing.
5. "Chronic pain" means pain of greater than ninety (90) days duration, excluding pain requiring palliative care.
6. "Common carrier" means any person who or which undertakes, whether directly or by any other arrangement, to transport property, or any class or classes of property, by motor vehicle between points within this state; for the general public for compensation, over the publicly used highways of this state, whether over regular or irregular routes, pursuant to [R.I. Gen. Laws § 39-12-2](#).
7. "Contract carrier" means any person who or which engages in transportation of property by motor vehicle, in intrastate commerce for compensation, under continuing contract with one (1) person, or an unlimited number of persons, for the furnishing of transportation services of a special and individual nature required by the shipper, and not generally provided by common carriers, pursuant to [R.I. Gen. Laws § 39-12-2](#).
8. "Controlled substance" means a drug, substance, or immediate precursor in Schedules I-V of [R.I. Gen. Laws Chapter 21-28](#). The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in [R.I. Gen. Laws Chapter 3-1](#), nor tobacco.
9. "Department" means the Rhode Island Department of Health.
10. "Director" means the Director of the Rhode Island Department of Health.
11. "Distribute" means to deliver (other than by administering or dispensing) a controlled substance or an imitation controlled substance, and includes actual, constructive, or attempted transfer.
12. "Distributor" means a person who so delivers a controlled substance, or an imitation controlled substance, pursuant to [R.I. Gen. Laws § 21-28-1.02\(18\)](#).

13. "Electronic prescription" means a secure (encrypted and encoded) technology system that allows practitioners to create, sign, transmit, and file prescriptions from a computer or smart device to a pharmacy computer directly and electronically. Electronic prescriptions do not include handwritten, emailed, or faxed prescriptions or calling in prescriptions.
14. "Hospice" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six (6) months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life, and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.
15. "Initial prescription" means first prescription given to someone who is new to the prescription of opioids from your institution or office, and has not used opioids in the most recent thirty (30) calendar days.
16. "Interstate carrier" means any person who or which operates motor vehicles for the transportation of property of others for compensation, over the publicly used highways of this state in interstate commerce, authorized or certified by the Interstate Commerce Commission, pursuant to [R.I. Gen. Laws § 39-12-2](#).
17. "Long acting and extended release opioids" – opioids intended for long acting or extended use have a half-life long enough that they are generally prescribed less than three (3) times a day. Examples of long acting and extended release opioids include, but are not limited to: Avinza (morphine sulfate) Extended-Release Capsules, Dolophine (methadone hydrochloride) Tablets, Duragesic (fentanyl transdermal system), Embeda (morphine sulfate and naltrexone hydrochloride) Extended-Release Capsules, Exalgo (hydromorphone HCl) Extended-Release Tablets, Kadian (morphine sulfate) Extended-Release Capsules, MS Contin (morphine sulfate) Extended-Release Tablets, Nucynta ER (tapentadol) extended-release tablets, Opana ER (oxymorphone hydrochloride) Extended-Release Tablets, Oxycontin (oxycodone hydrochloride) Extended-Release Tablets, Palladone (hydromorphone hydrochloride) Extended-Release Capsules) as well as other similar and future U.S. FDA-approved medications in this classification as defined by the U.S. FDA.
18. "Medical record" means a record of a patient's medical information and treatment history maintained by physicians and other medical personnel, which includes, but is not limited to, information related to medical

diagnosis, immunizations, allergies, x-rays, copies of laboratory reports, records of prescriptions, and other technical information used in assessing the patient's health condition, whether such information is maintained in a paper or electronic format.

19. "Morphine milligram equivalents" or "MMEs" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables. [A copy of this tool may be downloaded from: <http://www.health.ri.gov/healthcare/medicine/about/safeopioidprescribing/>]
20. "Multidisciplinary pain clinic" means a clinic or office that provides comprehensive pain management provided by different health care disciplines including at least two (2) medical specialties and non-physician professionals. It shall include care provided by multiple available disciplines and treatment modalities in an integrated fashion.
21. "Opioid induced hyperalgesia" means increased perception of pain out of proportion to what is expected, that results from the effects of opioids on the central nervous system (CNS).
22. "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.
23. "Pain medicine physician" means a physician whose usual course of practice is to treat patients who have acute and/or chronic pain as a condition.
24. "Palliative care" means patient and family centered medical care that optimizes quality of life by anticipating, preventing, and treating suffering caused by advanced serious illness. Palliative care throughout the continuum of illness involves addressing physical, emotional, social and spiritual needs and facilitating patient autonomy, access to information, and choice. Palliative care includes, but is not limited to, discussions of the patient's goals for treatment; discussion of treatment options appropriate to the patient, including, where appropriate, hospice care; and comprehensive pain and symptom management.
25. "Person" means any corporation, association, partnership, or one or more individuals.
26. "Physical dependence" means a state of adaptation that is manifested by a drug-class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing the level of the drug in the blood.

27. "Practitioner" means, for the purpose of this Part, a physician licensed pursuant to R.I. Gen. Laws Chapter 5-37, a physician assistant licensed pursuant to R.I. Gen. Laws Chapter 5-54; an Advanced Practice Registered Nurse (APRN) licensed pursuant to R.I. Gen. Laws Chapter 5-34; dentist; podiatrist; veterinarian; scientific investigator; or other person licensed, registered or permitted to prescribe, distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in Rhode Island.
28. "Private carrier" means any person, other than a common carrier, or a contract carrier, or an interstate carrier, who or which transports in intrastate or interstate commerce by motor vehicle, property of which such person is the owner, lessee, or bailee, when such transportation is for the purpose of sales, lease, rent, or bailment, or in the furtherance of any commercial enterprise, pursuant to [R.I. Gen. Laws § 39-12-2](#).
29. "Substance use disorder" means a diagnosis provided by a licensed practitioner meeting the diagnostic criteria of the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM-5), or the coding of the International Statistical Classification of Diseases and Related Health Problems (ICD-10).
30. "Tolerance" means a state of adaptation in which exposure to a substance induces changes that result in a diminution of one or more of the substance's effects over time.

#### **4.4 Pain Management and Prescribing**

- A. 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.
- B. 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:
  1. Any change in pain relief;
  2. Any change in physical and psychosocial function; and
  3. Additional diagnostic evaluations or other planned treatments.
- C. Opioid Use in Acute Pain Management: For the purpose of this Part, acute pain shall not include chronic pain management, any chronic illness with recurrent acute pain that is a known expression of the chronic disease, pain associated

with sickle cell disease, pain associated with a current cancer diagnosis, palliative care or nursing home care.

1. If a patient is given opioids in an inpatient setting and then discharged from an inpatient setting, and prescribed an opioid on discharge, this is considered an initial prescription if they have not otherwise used opioids in the past thirty (30) days.
  2. The initial prescription for an opioid for acute pain for an individual who has not received opioids in the last 30 days shall not exceed thirty (30) MMEs total dose per day for a maximum of twenty (20) doses.
  3. Long-acting and extended-release opioids, including methadone, shall not be prescribed for acute pain.
  4. Pursuant to § 4.4(E) of this Part, a practitioner must review the Prescription Data Monitoring Program (PDMP) prior to initiating an opioid, including prescriptions prescribed in an inpatient setting.
  5. Initial prescription of opioids for a patient under the age of eighteen (18) will not exceed twenty (20) doses. There is no limit on daily MME, however prescribers must document in the medical record their rationale for prescribing greater than thirty (30) MME per day for a minor. For the purpose of this Part, acute pain for patients under the age of eighteen (18) does not include chronic pain management, any chronic illness with recurrent acute pain that is a known expression of the chronic disease, pain associated with sickle cell disease, pain associated with a current cancer diagnosis, palliative care, or nursing home care.
- D. Patient Education/ Informed 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, overdose or death if acute or long-term use. For those patients in recovery from substance use disorder, education shall be focused on relapse risk factors. This education, which must be documented in the medical record, will be communicated orally or in writing depending on patient preference and shall include as a minimum:
1. Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and
  2. Educate patient regarding safe disposal options for unused portion of a controlled substance.

3. Requirement for Conversation: Prior to initiating a prescription for an opioid drug and, upon the second refill and/or upon the third prescription, specifically discuss with the patient who is eighteen (18) years of age or older, or the patient's parent or guardian if the patient is under eighteen (18) years of age:
    - a. The risks of developing a dependence or substance use disorder to the prescription opioid drug and potential of overdose or death;
    - b. The adverse risks of concurrent use of alcohol or other psychoactive medications;
    - c. The risk the medication(s) or underlying medical condition may impair an individual's ability to safely operate any motor vehicle;
    - d. The responsibility to safeguard all medications;
    - e. If the prescriber deems it appropriate, discuss such alternative treatments (including non-opioid medications, as well as non-pharmacologic treatments) as may be available; and
    - f. For patients in recovery from substance use disorder, education shall be focused on relapse risk factors. This discussion shall be noted in the patient's medical record at each applicable visit.
  4. Prescribers may find resources for patient education on the Department website at [www.health.ri.gov/saferx](http://www.health.ri.gov/saferx).
- E. Mandatory PDMP Review. Prior to initially prescribing any opioid, including prescriptions prescribed in an inpatient setting, and regardless how the prescription is issued, prescribers must review the PDMP, and must recheck the PDMP at least every three (3) months for patients under active treatment or who are receiving an ongoing opioid prescription.
- F. Written Patient Treatment Agreement.
1. Chronic pain patients who receive opioid medication(s) shall have a written patient treatment agreement which shall become part of their medical record. This written agreement may be started at any point, at the practitioner's discretion, based on individual patient history and risk; however, no later than after ninety (90) days of treatment with an opioid medication. The written agreement shall be signed between, at a minimum, the practitioner and the patient (or their proxy). This written patient agreement for treatment may include, at the practitioner's discretion:

- a. The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
  - b. Reasons for which medication therapy may be discontinued, including but not limited to, violation of the written treatment agreement or lack of effectiveness;
  - c. The requirement that all chronic pain management prescriptions are provided by a single practitioner or a limited agreed upon group of practitioners;
  - d. The patient's agreement to not abuse alcohol or use other medically unauthorized substances or medications;
  - e. Acknowledgment that a violation of the agreement may result in action as deemed appropriate by the prescribing practitioner such as a change in the treatment plan or referral to a substance use disorder treatment program; and
  - f. A request that toxicology screens be performed at random intervals at the practitioner's discretion.
2. At their discretion, practitioners may have a written patient treatment agreement with any patient who receives opioid medication for any duration, based on individual patient history and risk.
- G. Periodic Review. Periodic reviews, including an in-person visit, shall take place at intervals not to exceed six (6) months.
1. During the periodic review, the practitioner shall determine:
    - a. Patient's adherence with any medication treatment plan;
    - b. If pain, function, or quality of life have improved or diminished using objective evidence; and
    - c. If continuation or modification of medications for pain management treatment is necessary based on the practitioner's evaluation of progress towards treatment objectives.
  2. The practitioner shall consider tapering, changing, or discontinuing treatment when:
    - a. Function or pain does not improve after a trial period; or



other professionals who offer treatment for pain. Other professionals such as chiropractors, acupuncturists, behavioral health providers, occupational therapists, and physical therapists are examples of providers who can use their skills to help alleviate patient's chronic pain.

2. Practitioners shall consider referral to other professionals as clinically indicated, some indications would include, patients self-escalating their doses, early refills, inadequate pain relief, co-existing morbidities such as requirement for dialysis, chronic liver disease, prior history of a substance disorder or prior over-dose.
  3. The consideration, and documentation of consideration, for consultation threshold for adults is ninety (90) MMEs per day (orally). In the event a practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of ninety (90) MME per day (orally), a consideration of consultation with a pain medicine physician is required, and must be documented in the medical record.
    - a. 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;
    - b. Consultation may include:
      - (1) An office visit with the patient and the pain medicine physician;
      - (2) A telephone consultation between the pain medicine physician and the practitioner;
      - (3) An electronic consultation between the pain medicine physician and the practitioner; or
      - (4) An audio-visual evaluation conducted by the pain medicine physician remotely, where the patient is present with either the practitioner or a licensed health care practitioner designated by the practitioner or the pain medicine physician.
  4. Nothing in this Part shall limit any practitioner's ability to contractually require a consultation with a pain medicine physician at any time.
- J. Transition of Care for Patients on Long-term Opioid Therapy. Periodically, a practitioner will require a patient to seek care from another practitioner for ongoing treatment. 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.

K. Transmission of Controlled Substance Prescriptions.

1. Effective January 2, 2020, a practitioner must review, sign, transmit, and file (confirmation of successful transmittal) prescriptions electronically for controlled substances in Schedules II, III, IV, and V.
  - a. The software utilized by a practitioner to sign, transmit, and file electronic prescriptions must meet all federal security requirements for electronic prescribing of controlled substances (EPCS) including, but not limited to, 21 C.F.R. § 1311, incorporated by reference at § 4.2 of this Part.
  - b. A practitioner is prohibited from using any software application to process electronic prescriptions if the software does not meet federal and state confidentiality and security requirements.
2. The practitioner must:
  - a. Print out the electronic prescription in hardcopy; or
  - b. Store the electronic record so that it is readily retrievable in the patient's medical record.
3. A practitioner is not required to process prescriptions electronically when:
  - a. Electronic prescribing is not available due to temporary technological or electronic failure. For the purposes of this Part, temporary technological or electrical failure means:
    - (1) The failure of a computer system, application, or device; or
    - (2) The loss of electrical power to such system, application, or device; or
    - (3) Any other service interruption to such system, application, or device that prevents the practitioner from utilizing his or her system to electronically transmit a prescription.
    - (4) The practitioner must document in the patient's medical record that a written prescription was issued or given by

verbal order to a pharmacist over the telephone along with the reason for failure of the electronic prescription.

- b. The practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner and that the delay would have a negative impact on the patient's health. The prescription duration shall not exceed a five (5) day supply. The practitioner must document in the patient's medical record the reason(s) electronic prescription would be impractical for the patient.
- c. The practitioner determines that electronic prescription would have a negative impact on or delay patient care, such as:
  - (1) A prescription containing two (2) or more substances to be compounded by a pharmacist;
  - (2) A prescription for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion;
  - (3) A prescription with long and complicated directions; or
  - (4) An oral prescription communicated to the pharmacist by a practitioner in a licensed chronic and convalescent nursing home, hospice facility, or emergency department.
  - (5) The practitioner must document in the patient's medical record the reason electronic prescription would have a negative impact on or delay patient care.
- d. A prescription is issued for a drug for which the U.S. FDA requires the prescription to include certain elements that are not able to be accomplished with electronic prescription including, but not limited to, a drug with risk evaluation and mitigation strategies that include elements to assure safe use. The practitioner must document the reason in the patient's medical record.
- e. The prescription cannot be transmitted electronically due to the constraints of the National Council for Prescription Drug Programs (SCRIPT) Standard.
- f. The prescription will be dispensed at a pharmacy outside of the state without access to electronic transmission of controlled substances.



the Department that the practitioner will experience undue economic hardship from the implementation of the requirements of § 4.4(K).

- L. Documentation of ICD-10 Code on Controlled Substance Prescriptions. Prescribers are required to enter an ICD-10 code, or equivalent thereto as determined by the Department (such as the diagnosis of the condition requiring the prescription), on all controlled substance prescriptions.
- M. Co-prescribing of Naloxone. A prescriber must co-prescribe naloxone when:
  - 1. Prescribing an opioid which individually or in aggregate with other medications is more than or equal to fifty (50) MMEs per day, or document in the medical record why this is not appropriate for the patient.
  - 2. Prescribing any dose of an opioid when a benzodiazepine has been prescribed in the past thirty (30) days, or will be prescribed at the visit. Prescribers shall note medical necessity of the co-prescription of the opioid and the benzodiazepine and explain why the benefit outweighs the risk given the U.S. FDA black box warning.
  - 3. Prescribing any dose of an opioid to a patient with a prior history of opioid use disorder or overdose. Prescribers must note medical necessity of prescribing of the opioid and explain why the benefit outweighs the risk given the patient's previous history.
- N. Long-Acting and Extended-Release Opioids.
  - 1. All practitioners prescribing long-acting and extended-release opioids shall have completed an educational program compliant with the Extended Release/Long Acting Opioid Analgesic Risk Evaluation and Mitigation Strategy Educational requirements issued by the U.S. FDA. This may be from a continuing education program or from an accredited professional preparation education program including approved residency training programs.
  - 2. For patients on long-acting and extended-release opioids, including methadone, practitioners shall monitor use closely, especially upon initiation and following any dose increases. Practitioners shall also document in the medical record that the following education has been given to the patient and the patient has had the opportunity to ask questions and understands the following risks:
    - a. Serious life-threatening or even fatal respiratory depression may occur;

- b. Methadone treatment may initially not provide immediate pain relief, and patient needs to be aware of overdose potential if taken in excess of dose, as prescribed;
  - c. Accidental consumption of long-acting and extended-release opioids especially in children, can result in fatal overdose;
  - d. Long-term opioid use can result in physical dependence on opiates and abrupt stopping of medication may cause withdrawal symptoms including, but not limited to: runny eyes, runny nose, insomnia, diarrhea, vomiting, restlessness, nausea, weakness, muscle aches, leg cramps and hot flushes; and
  - e. Substance use disorder.
3. Patients who receive long-acting and extended-release opioid medication(s) on a long-term basis (ninety (90) days or greater) shall have a written patient treatment agreement, which shall become part of their medical record. This written agreement may be started at any point at the practitioner's discretion, based on individual patient history and risk; however; no later than after ninety (90) days of treatment with an opioid medication. The written agreement shall be signed between, at a minimum, the practitioner and the patient (or their proxy). This written patient agreement for treatment may include, at the practitioner's discretion:
- a. The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
  - b. Reasons for which medication therapy may be discontinued, including but not limited to, violation of the written treatment agreement or lack of effectiveness;
  - c. The requirement that all chronic pain management prescriptions are provided by a single practitioner, or a limited agreed upon group of practitioners;
  - d. The patient's agreement to not abuse alcohol, misuse other prescribed medications or use other medically unauthorized substances or medications;
  - e. Acknowledgment that a violation of the agreement may result in action as deemed appropriate by the prescribing practitioner such

as a change in the treatment plan or referral to a substance use disorder treatment program; and

- f. A request that toxicology screens be performed at random intervals at the practitioner's discretion.

O. Intrathecal Pump and the Use of Chronic Opioids.

1. A practitioner shall review the PDMP prior to refilling or initiating opioid therapy with an intrathecal pump.
2. A practitioner is responsible to educate the patient and document in the medical record about risks and benefits of an intrathecal pump as well as risk of withdrawal if the pump goes dry, or the pump malfunctions causing interruption of delivery of medication.
3. An intrathecal pump can only be refilled by licensed professional, who has documented competency in performing this task.
4. An intrathecal pump shall only be used if there is a pain agreement, highlighting risks of using alcohol and/or taking other controlled substances.

P. Prescriber Training Requirement for Best Practices Regarding Opioid Prescribing. This specific training requirement is required only once and must be completed before renewal of controlled substance registration or two (2) years, whichever is longer.

1. Any practitioner who prescribes a Schedule II opioid is required to successfully complete eight (8) hours of Category 1 Continuing Medical Education (or equivalent in Continuing Education Units/Continuing Education) in any or all of the following topics:
  - a. Appropriate prescribing of opioids for pain;
  - b. Pharmacology;
  - c. Adverse events;
  - d. Potential for dependence;
  - e. Tolerance;
  - f. Substance use disorder; and
  - g. Alternatives to opioids for pain management.

2. Although no one specific course is required, the Drug Addiction Treatment Act of 2000 (DATA 2000) waiver training course qualifies for the above requirement. (Practitioners who have completed the DATA 2000 waiver training course and have an active Drug Enforcement Certificate with an “X” designation are exempt from this additional training.)

Q. Voluntary Non-Opiate Directive. Pursuant to R.I. Gen. Laws § [21-28-3.33](#), patients may file a voluntary non-opiate directive form, which indicates to all practitioners that the individual must not be administered or offered a prescription or medication order for an opiate.

1. The patient may revoke the voluntary non-opiate directive for any reason and may do so in writing or orally.
2. The voluntary non-opiate directive form, or the revocation of such form, must be filed in both the patient's electronic health record (or in the paper health record if the practitioner does not use electronic health records), and in the PDMP.
3. Patients may appoint a duly authorized guardian or health care proxy to override a previously recorded voluntary non-opiate directive form.
4. Protections for pharmacists, health care providers acting in good faith, and agents/health care proxies are stated in R.I. Gen. Laws § [21-28-3.33\(c\) through \(e\)](#).
5. For those patients who are able to consent, pre-hospital emergency medical services practitioners must obtain verbal consent before administering an opioid. For patients who are unable to consent, pre-hospital emergency medical services practitioners who administer opioids in good faith and pursuant to the Rhode Island Statewide Emergency Medical Services Protocols and Standing Orders shall not be subject to penalties pursuant to non-compliance with § 4.4(Q) of this Part.

## 4.5 Registration Requirements

A. Pursuant to R.I. Gen. Laws § [21-28-3.02\(a\)](#), every person who manufactures, distributes, prescribes, administers, or dispenses any controlled substance within Rhode Island, or who proposes to engage in the manufacture, distribution, prescribing, administering, or dispensing of any controlled substance within Rhode Island, must obtain a registration, issued by the Director, at intervals not to exceed two (2) years, unless exempt in accordance with [R.I. Gen. Laws § 21-28-3.30](#).

1. Application for registration may be obtained at:

Rhode Island Department of Health - Board of Pharmacy

Three Capitol Hill, Room 205

Providence, RI 02908

2. An applicant for registration shall comply with the federal registration requirements set forth by the federal Drug Enforcement Administration, Department of Justice (or successor agency).
  3. In addition to all other applicable requirements of this Part, an applicant for a distributor registration must hold a current Rhode Island state license for distribution of drugs, medicines and poisons, issued by the Rhode Island Board of Pharmacy, pursuant to the provisions of R.I. Gen. Laws Chapter 5-19.1 and the rules and regulations pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors (Part [40-15-1](#) of this Title).
  4. The ability of an applicant or registrant to maintain effective controls against diversion, as required pursuant to § 4.6 of this Part, will be considered by the Director in determining whether issuance of a registration is consistent with the public interest.
  5. A filing fee, as set forth in the Fee Structure for Licensing, Laboratory, and Administrative Services Provided by the Department of Health (Part [10-05-2](#) of this Title), is required for all classes of registration.
  6. All practitioners shall, as a condition of the initial registration or renewal of the practitioner's authority to prescribe controlled substances, register with the PDMP.
- B. Pursuant to [R.I. Gen. Laws § 21-28-3.03](#), the Director may refuse registration, where the issuance of said registration would be inconsistent with the public interest.

#### **4.6 Limitation on Registration**

- A. The registration issued by the Department shall limit distribution to controlled substances permitted by the applicant's federal registration.
- B. Distributors may not distribute controlled substances labeled "Physician's Sample", "Complimentary", "Physician's Sample - Not to be Sold", "Complimentary Package", "Patient Starter Package", "Professional Sample", or

any other designation indicating other than a trade package available for resale by, or to, a registrant in the public interest.

- C. Nothing in this Part shall prohibit a distributor from distributing controlled substances to a practitioner, upon required order forms, by means of common, contract, or interstate carrier, at the usual and customary cost, or as a gift.

#### **4.7 General Security Requirements**

- A. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.
- B. In determining whether an applicant or registrant has demonstrated maintenance of effective security controls pursuant to [R.I. Gen. Laws § 21-28-3.28](#), the Director may consider, but not be limited to, the following factors:
1. The type of activity conducted;
  2. The type and form of controlled substances handled;
  3. The quantity of controlled substances handled;
  4. The location of the premises and the relationship such location bears on security needs;
  5. The type of building construction comprising the facility and the general characteristics of the building or buildings;
  6. The type of vault, safe, and secure enclosures or other storage system used;
  7. The type of closures on vaults, safes, and secure enclosures;
  8. The adequacy of key control systems and/or combination lock control systems;
  9. The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
  10. Method sought to be used for transportation of said controlled substance being distributed (e.g., common carrier, contract carrier, interstate carrier, private carrier, or other);
  11. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

12. The adequacy of supervision over employees having access to manufacturing and storage areas;
13. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
14. The availability of local police protection or of the registrant's or applicant's security personnel;
15. Recordkeeping requirements of the Act;
16. Drug destruction requirements of the Act;
17. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations;
18. The applicability of the security requirements contained in all Federal and Rhode Island laws and regulations governing the management of waste;
19. Past experience of the Department;
20. Past patterns of abuse, arrest, and noncompliance by distributors in Rhode Island, drug destruction data, citizen and police complaints, detection of samples, outside of legitimate channels, seizure of misbranded drugs; and
21. Any other factor which would assist the Director to conclude that the registration for each distributor is not inconsistent with the public interest.

#### **4.8 Violations and Hearings**

- A. Any person who violates any provision of the Act, or this Part, shall be subject to the penalty provisions as specified in the Act.
- B. All hearings and reviews required by this Part shall be held in accordance with the provisions of [R.I. Gen. Laws Chapter 42-35](#) and the rules and regulations pertaining to Practices and Procedures Before the Rhode Island Department of Health (Part [10-05-4](#) of this Title).

**216-RICR-20-20-4**

**TITLE 216 - DEPARTMENT OF HEALTH**

**CHAPTER 20 - COMMUNITY HEALTH**

**SUBCHAPTER 20 - DRUGS**

PART 4 - PAIN MANAGEMENT, OPIOID USE AND THE REGISTRATION OF DISTRIBUTORS OF CONTROLLED SUBSTANCES IN RHODE ISLAND (216-RICR-20-20-4)

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**Agency Signature**

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Agency Head Signature

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Agency Signing Date

**Department of State**

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Regulation Effective Date

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Department of State Initials

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Department of State Date