

**RULES AND REGULATIONS FOR PAIN MANAGEMENT,
OPIOID USE AND THE REGISTRATION OF DISTRIBUTORS
OF CONTROLLED SUBSTANCES IN RHODE ISLAND**

[R21-28-CSD]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

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INTRODUCTION

These amended *Rules and Regulations for Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island [R21-28-CSD]* are amended pursuant to the authority set forth in Chapter 21-28-3.01 of the General Laws of Rhode Island, as amended, and are established for the purpose of updating minimum requirements for pain management, opioid use and registration of every person who manufactures, distributes, prescribes, administers or dispenses any controlled substance within Rhode Island.

These Regulations govern the use of opioids in the treatment of patients for chronic pain. It is recognized that principles of quality medical practice dictate that the people of the State of Rhode Island have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

Practitioners are encouraged to view pain management as part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All practitioners shall become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances.

It is recognized that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery. Use for chronic pain carries significant risk and the risks of chronic opioid use need to be weighed against limited benefits. Practitioners should always consider the many facets of pain and strongly consider an interdisciplinary or multidisciplinary approach to management of pain, (acute, episodic or chronic). Practitioners shall recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

Pursuant to the provisions of § 42-35-3(a)(3) and § 42-35.1-4 of the General Laws of Rhode Island, as amended, consideration was given to:

- (1) Alternative approaches to the regulations;
- (2) Duplication or overlap with other state regulations; and
- (3) Significant economic impact on small business.

Based upon available information, no known alternative approach, duplication or overlap was identified.

Upon promulgation of these amendments, these amended Regulations shall supersede all previous *Rules and Regulations for Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island [R21-28-CSD]* and *Rules and Regulations Pertaining to the Registration of Distributors of Controlled Substances in Rhode Island*¹ promulgated by the Department of Health and filed with the Secretary of State.

¹ Prior to March 2015, these Regulations were promulgated under the title *Rules and Regulations for the Registration of Distributors of Controlled Substances in Rhode Island*. Beginning with the March 2015 edition, the title was changed to *Rules and Regulations for Pain Management, Controlled Substance Prescribing and the Registration of Distributors of Controlled Substances in Rhode Island* to reflect the expansion of the Regulation's scope to include pain management and controlled substances prescribing.

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Section 1.0 *Definitions*

Wherever used in these Regulations, the following terms shall be construed as follows:

- 1.1 "**Act**" refers to RIGL Chapter 21-28 entitled, "Uniform Controlled Substances Act."
- 1.2 "**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 is resulting 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 these Regulations, acute pain shall not include chronic pain management, pain associated with a current cancer diagnosis, palliative or nursing home care.
- 1.3 "**Addiction**" means a chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Addiction is a chronic disease and often relapses. It is characterized by behaviors that include:
 - (a) Impaired control over drug use;
 - (b) Craving
 - (c) Compulsive use or ~~continue~~ use despite harm.
- 1.4 "**Addiction Medicine Physician**" means a physician who is specifically trained in a wide range of prevention, evaluation and treatment modalities addressing substance use and addiction in ambulatory care settings, acute care and long-term care facilities, psychiatric settings, and residential facilities.
- 1.5 "**Addiction Recovery**" 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.
- 1.6 "**Chronic pain**" means pain of greater than ninety (90) days duration, excluding pain requiring palliative care.
- 1.7 "**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 RIGL § 39-12-2.
- 1.8 "**Comorbidity**" means a preexisting or coexisting physical or psychiatric disease or condition.
- 1.9 "**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 RIGL § 39-12-2.
- 1.10 "**Controlled substance**" means a drug, substance, or immediate precursor in Schedules I - V of RIGL Chapter 21-28. The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in RIGL Chapter 3-1, nor tobacco.
- 1.11 "**Department**" means the Rhode Island Department of Health.
- 1.12 "**Director**" means the Director of the Rhode Island Department of Health.

- 1.13 **"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.
- 1.14 **"Distributor"** means a person who so delivers a controlled substance, or an imitation controlled substance, pursuant to § 21-28-1.02(14) of the Act.
- 1.15 **"Episodic care"** means medical care provided by a practitioner other than the designated primary care practitioner in the acute care setting, for example, urgent care or emergency department.
- 1.16 **"Episodic/Procedural pain"** means pain that varies depending on procedure, generally less than thirty (30) days.
- 1.17 **"Functional Assessment"** means a method of assessing pain by evaluating patient individually in the context of effects of physical and psychosocial functioning, such as activities of daily living, ability to exercise, sleep.
- 1.18 **"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.
- 1.19 **"Initial Prescription"** means first prescription given to someone who is *new to the prescription of opioids* from your institution, and has not used opioids in the most recent thirty (30) calendar days.
- 1.20 **"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 RIGL § 39-12-2.
- 1.21 *Long Acting and Extended Release opioids*²– *opioids intended for long acting or extended use have a half-life long enough that they are generally prescribed less than 3 times a day. Examples of long acting and extended release opioids includes, but is 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 (oxycodone hydrochloride) Extended-Release Tablets, Oxycontin (oxycodone hydrochloride) Extended-Release Tablets, Palladone (hydromorphone hydrochloride) Extended-Release Capsules) as well as other similar and future FDA approved medications in this classification as defined by the FDA.*
- 1.22 **"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

² Long acting and Extended release opioids: <http://www.fda.gov/safety/medwatch/safetyinformation/ucm396503.htm>

health condition, whether such information is maintained in a paper or electronic format.

- 1.23 **"Morphine equivalent dose"** 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 www.health.ri.gov/healthcare/medicine/about/safeopioidprescribing/.]
- 1.24 **"Multidisciplinary and Interdisciplinary 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.
- 1.25 **"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).
- 1.26 **"Pain"** means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.
- 1.27 **"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.
- 1.28 **"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.
- 1.29 **"Person"** means any corporation, association, partnership, or one or more individuals.
- 1.30 **"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.
- 1.31 **"Practitioner"** means, for the purpose of these Regulations, a physician licensed pursuant to RIGL Chapter 5-37, a physician assistant licensed pursuant to RIGL Chapter 5-54; an Advanced Practice Registered Nurse (APRN) licensed pursuant to RIGL 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.
- 1.32 **"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 RIGL § 39-12-2.
- 1.33 **"RIGL"** means the General Laws of Rhode Island, as amended.
- 1.34 **"These Regulations"** mean all parts of Rhode Island *Rules and Regulations for Pain Management, Opioid Use and the Registration of Distributors of Controlled Substances in Rhode Island* [R21-28-CSD].
- 1.35 **"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.

Section 2.0 *Scope and Applicability*

2.1 These Regulations establish minimum requirements for pain management and opioid prescribing by a practitioner. These Regulations also require registration of every person who manufactures, distributes, prescribes, administers or dispenses any controlled substance within Rhode Island.

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 **Opioid Use in Acute Pain Management**³.

- (a) 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.
- (b) The initial prescription for an opioid for acute pain for an individual who has not received opioids in the last thirty (30) days shall not exceed thirty (30) morphine milligram equivalents (MMEs) total daily dose per day for a maximum of twenty (20) doses.
- (c) Long acting or extended release opioids including methadone shall not be prescribed for acute pain.
- (d) Pursuant to § 3.5 of these Regulations, a practitioner must review the Prescription Data Monitoring Program (PDMP), prior to initiating an opioid.

3.4 **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, 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

³ Practitioners treat acute pain from a variety of clinical settings for a variety of clinical indications, stemming from injuries, procedures, disease. It is important that the initial prescription for an opioid be created thoughtfully and tailored to the individual patient's pain requirements.

them in a secure location; and

(b) Educate patient regarding safe disposal options for unused portion of a controlled substance.

3.5 The Prescription Drug Monitoring Program (PDMP) shall be reviewed prior to starting any opioid.

3.6 **Written Patient Treatment Agreement.**⁴

(a) 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:

- (1) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
- (2) Reasons for which medication therapy may be discontinued, including but not limited to, violation of the written treatment agreement or lack of effectiveness;
- (3) The requirement that all chronic pain management prescriptions are provided by a single practitioner or a limited agreed upon group of practitioners;
- (4) The patient's agreement to not abuse alcohol or use other medically unauthorized substances or medications;
- (5) 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 an addiction treatment program; and
- (6) A request that toxicology screens be performed at random intervals at the practitioner's discretion.

(b) 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.

3.7 **Periodic Review.** Periodic reviews, including an in-person visit, shall take place at intervals not to exceed six (6) months.

(a) During the periodic review, 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

⁴ Sample pain agreement may be downloaded from www.health.ri.gov/saferx

objectives.

- (b) 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.
- (c) For patients the practitioner is maintaining on continuous opioid therapy for pain for six (6) months or longer, the practitioner shall review information from the prescription monitoring program (PMP) at least every twelve (12) months. Documentation of that review shall be noted in the patient's medical record.

3.8 **Pain Medicine/Addiction Medicine Physician.** To qualify as a Pain Medicine or Addiction Medicine Physician, a physician shall meet one or more of the following qualifications:

- (a) (1) Board certified or board eligible by an American Board of Medical Specialties (ABMS) approved board in physical medicine and rehabilitation, neurology, neurosurgery, rheumatology, addiction medicine, addiction psychiatry or anesthesiology; or by the American Board of Pain Medicine (ABPM); or
 - (2) Board certified or board eligible by an American Osteopathic Association (AOA) approved board in physical medicine and rehabilitation, neurology and psychiatry, anesthesiology, or neuromusculoskeletal medicine; or
- (b) Possess a subspecialty certificate in pain medicine by an ABMS-approved board; or
- (c) Possess a certification of added qualification in pain management or pain medicine or a certification of special qualification in rheumatology by the AOA; or
- (d) Completion of a minimum of three (3) years of clinical experience in a chronic pain management care setting; and
 - (1) Successful completion of at least eighteen (18) continuing education hours in pain management during the past two (2) years; and
 - (2) At least thirty percent (30%) of the physician's current practice is the direct provision of pain management care or is in a multi-disciplinary pain clinic.

3.9 **Multidisciplinary Approach to Treatment of Chronic Pain**

- (a) Medication is only one aspect of treating chronic pain. Chronic pain often requires a multidisciplinary approach and the patient will often benefit from appropriate consultation not just with pain management specialists, but other professionals who offer treatment for pain. Other professionals such as chiropractors, acupuncturists, behavioral health providers, physical therapists are examples of providers who can use their skills to help alleviate patient's chronic pain.
- (b) 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.
- (c) The consideration, and documentation of consideration, for consultation threshold for adults is ninety (90) milligrams morphine equivalent dose per day (MME) (oral). In the event a

practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of ninety (90) milligrams MME (orally) per day, a consideration of consultation with a Pain Medicine Physician is required, and must be documented in the medical record.

(1) 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;

(2) Consultation may include:

(i) An office visit with the patient and the Pain Medicine Physician;

(ii) A telephone consultation between the Pain Medicine Physician and the practitioner;

(iii) An electronic consultation between the Pain Medicine Physician and the practitioner; or

(iv) 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.

(d) Nothing in these Regulations shall limit any practitioner's ability to contractually require a consultation with a Pain Medicine Physician at any time.

3.10 **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.

3.11 **Transmission of Controlled Substance Prescriptions.** A practitioner shall not authorize or allow an unlicensed staff member (e.g., medical assistant) to telephone or otherwise transmit a prescription for a controlled substance to a pharmacy.

3.12 Long-acting Opioids, Including Methadone.

- (a) Effective 15 January 2017, all practitioners prescribing long-acting opioids shall have completed an educational program compliant with the ER/LA Opioid Analgesic REMS Educational requirements issued by the U.S. Food and Drug Administration (FDA). This may be from a continuing education program or from an accredited professional preparation education program including approved residency training programs.
- (b) For patients on long-acting 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:
 - (1) Serious life-threatening or even fatal respiratory depression may occur;
 - (2) 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;
 - (3) Accidental consumption of long-acting opioids especially in children, can result in fatal overdose;
 - (4) Long-term opioid use can result in physical addiction to 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.
 - (5) Substance use disorder
- (c) Patients who receive long-acting 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 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:
 - (1) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
 - (2) Reasons for which medication therapy may be discontinued, including but not limited to, violation of the written treatment agreement or lack of effectiveness;
 - (3) The requirement that all chronic pain management prescriptions are provided by a single practitioner, or a limited agreed upon group of practitioners;
 - (4) The patient's agreement to not abuse alcohol, misuse other prescribed medications or use other medically unauthorized substances or medications;
 - (5) 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 an addiction treatment program; and
 - (6) A request that toxicology screens be performed at random intervals at the practitioner's discretion.

3.13 Intrathecal Pump and the Use of Chronic Opioids.

- (a) A practitioner shall review the prescription monitoring program (PMP) prior to refilling or initiating opioid therapy with an intrathecal pump.
- (b) 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.
- (c) An intrathecal pump can only be refilled by licensed professional, who has documented competency in performing this task
- (d) An intrathecal pump shall only be used if there is a pain agreement, highlighting risks of using alcohol and/or taking other controlled substances.

3.14 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)

- (a) Any practitioner who prescribes a Schedule 2 opioid is required to successfully complete eight (8) hours of Category 1 CME (or equivalent in CEU/CE) in any or all of the following topics:
 - (1) Appropriate prescribing of opioids for pain;
 - (2) Pharmacology;
 - (3) Adverse events;
 - (4) Potential for dependence;
 - (5) Tolerance;
 - (6) Addiction;
 - (7) Alternatives to opioids for pain management.
 - (8) 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.)

Section 4.0 *Registration Requirements*

- 4.1 Pursuant to § 21-28-3.02(a) of the Act, 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 § 21-28-3.30 of the Act.

- (a) **Application for Registration.** Application for registration may be obtained at:
Rhode Island Department of Health - Board of Pharmacy
Three Capitol Hill, Room 205
Providence, RI 02908
- (b) 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).
- (c) In addition to all other applicable requirements of these Regulations, 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 RIGL Chapter 5-19 and the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19.1-PHAR]*.
- (d) The ability of an applicant or registrant to maintain effective controls against diversion, as required pursuant to § 5.0 of these Regulations, will be considered by the Director in determining whether issuance of a registration is consistent with the public interest.
- (e) **Registration Fee.** A filing fee, as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*, is required for all classes of registration.
- (f) All practitioners shall, as a condition of the initial registration or renewal of the practitioner's authority to prescribe controlled substances, register with the prescription drug monitoring (PMP) database maintained by the Department.

4.2 Pursuant to § 21-28-3.03 of the Act, the Director may refuse registration, where the issuance of said registration would be inconsistent with the public interest.

Section 5.0 *Limitation on Registration*

- 5.1 The registration issued by the Department shall limit distribution to controlled substances permitted by the applicant's federal registration.
- 5.2 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.
- 5.3 Nothing in these Regulations 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.

Section 6.0 *General Security Requirements*

- 6.1 All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.
- 6.2 In determining whether an applicant or registrant has demonstrated maintenance of effective

security controls pursuant to § 21-28-3.28 of the Act, the Director may consider, but not be limited to, the following factors:

- (a) The type of activity conducted⁵;
- (b) The type and form of controlled substances handled⁶;
- (c) The quantity of controlled substances handled;
- (d) The location of the premises and the relationship such location bears on security needs;
- (e) The type of building construction comprising the facility and the general characteristics of the building or buildings;
- (f) The type of vault, safe, and secure enclosures or other storage system⁷ used;
- (g) The type of closures on vaults, safes, and secure enclosures;
- (h) The adequacy of key control systems and/or combination lock control systems;
- (i) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
- (j) 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)
- (k) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- (l) The adequacy of supervision over employees having access to manufacturing and storage areas;
- (m) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- (n) The availability of local police protection or of the registrant's or applicant's security personnel;
- (o) Recordkeeping requirements of the Act;
- (p) Drug destruction requirements of the Act;
- (q) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations;
- (r) The applicability of the security requirements contained in all Federal and Rhode Island laws and regulations governing the management of waste;
- (s) Past experience of the Department;
- (t) 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

⁵ For example, processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.

⁶ For example, bulk liquids or dosage units, usable powders or nonusable powders.

⁷ For example, automatic storage and retrieval system.

- (u) Any other factor which would assist the Director to conclude that the registration for each distributor is not inconsistent with the public interest.

Section 7.0 *Violations and Hearings*

- 7.1 Any person who violates any provision of the Act, or these Regulations shall be subject to the penalty provisions as specified in the Act.
- 7.2 All hearings and reviews required by these Regulations shall be held in accordance with the provisions of RIGL Chapter 42-35 and the *Rules and Regulations Pertaining to Practices and Procedures before the Rhode Island Department of Health [R42-35-PP]*.

Section 8.0 *Severability*

- 8.1 If any provisions of these Regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.

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Monday, February 20, 2017