



# *Rhode Island Department of Health*

## **PUBLIC NOTICE**

The Director of the Rhode Island Department of Health has determined to amend the rules and regulations listed below to remove the specific dollar value of all fees for licensing, laboratory and administrative services provided by the Department of Health from the individual regulations and reference all such fees to a new consolidated fee regulation (to be promulgated separately). These amendments are proposed pursuant to the authority contained in Public Law 2012-241, enacted by the General Assembly on 15 June 2012, and the relevant sections of the respective professional practice and licensure acts.

### **The following seventy-five (75) regulations are proposed to be amended:**

1. Food Code
2. Rules and Regulations Establishing Educational and Experience Requirements for Registration as a Sanitarian
3. Rules and Regulations for Asbestos Control
4. Rules and Regulations for Bottled Water
5. Rules and Regulations for Certifying Analytical Laboratories
6. Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services
7. Rules and Regulations for Lead Poisoning Prevention
8. Rules and Regulations for Licensing Assisted Living Residences
9. Rules and Regulations for Licensing Athletic Trainers
10. Rules and Regulations for Licensing Birth Centers
11. Rules and Regulations for Licensing Chemical Dependency Professionals
12. Rules and Regulations for Licensing Clinical Laboratories and Stations
13. Rules and Regulations for Licensing Clinical Social Workers and Independent Clinical Social Workers
14. Rules and Regulations for Licensing Doctors of Acupuncture and Acupuncture Assistants
15. Rules and Regulations for Licensing Home Nursing Care Providers and Home Care Providers
16. Rules and Regulations for Licensing Hospice Care
17. Rules and Regulations for Licensing Interpreters for the Deaf
18. Rules and Regulations for Licensing Kidney Disease Treatment Centers
19. Rules and Regulations for Licensing Massage Therapists
20. Rules and Regulations for Licensing Mental Health Counselors and Marriage and Family Therapists
21. Rules and Regulations for Licensing Occupational Therapists and Occupational Therapy Assistants
22. Rules and Regulations for Licensing of Hospitals
23. Rules and Regulations for Licensing of Midwives
24. Rules and Regulations for Licensing of Nursing Facilities
25. Rules and Regulations for Licensing of Nursing Home Administrators
26. Rules and Regulations for Licensing Physical Therapists and Physical Therapist Assistants
27. Rules and Regulations for Licensing Psychologists
28. Rules and Regulations for Licensing Rehabilitation Hospital Centers

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29. Rules and Regulations for Licensing Respiratory Care Practitioners
30. Rules and Regulations for Licensing Speech Pathologists and Audiologists
31. Rules and Regulations for Licensing Swimming and Wading Pools, Hot Tubs, and Spas
32. Rules and Regulations for Licensure and Discipline of Chiropractic Physicians
33. Rules and Regulations for Limited Medical Registration
34. Rules and Regulations for Radon Control
35. Rules and Regulations for the Certification of Administrators of Assisted Living Residences
36. Rules and Regulations for the Certification of Health Plans
37. Rules and Regulations for the Control of Radiation
38. Rules and Regulations for the Licensing of Freestanding Ambulatory Surgical Centers
39. Rules and Regulations for the Licensing of Freestanding Emergency Care Facilities
40. Rules and Regulations for the Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs
41. Rules and Regulations for the Licensing of Nursing Service Agencies
42. Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities
43. Rules and Regulations for the Licensing of Podiatrists
44. Rules and Regulations for the Licensing of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants
45. Rules and Regulations for the Licensure and Discipline of Physicians
46. Rules and Regulations for the Licensure of Barbers, Hairdressers/Cosmeticians, Manicurists, Estheticians, and Instructors
47. Rules and Regulations for the Licensure of Clinical Laboratory Science Practitioners
48. Rules and Regulations for the Licensure of Physician Ambulatory Surgery Centers and Podiatry Ambulatory Surgery Centers
49. Rules and Regulations for the Licensure of Physician Assistants
50. Rules and Regulations for the Licensure of Veterinarians
51. Rules and Regulations for the Registration of Body Piercing Technicians and Body Piercing Establishments
52. Rules and Regulations for the Registration of Distributors of Controlled Substances in Rhode Island
53. Rules and Regulations for the Registration of Tanning Facilities
54. Rules and Regulations for the Registration of Tattoo Artists and Tattoo Parlors
55. Rules and Regulations for the Utilization Review of Health Care Services
56. Rules and Regulations Governing Vital Statistics
57. Rules and Regulations Pertaining to Certification of Managers in Food Safety
58. Rules and Regulations Pertaining to Dentists, Dental Hygienists, and Dental Assistants
59. Rules and Regulations Pertaining to Embalmers, Funeral Directors, and Funeral Service Establishments
60. Rules and Regulations Pertaining to Opticians
61. Rules and Regulations Pertaining to Optometrists
62. Rules and Regulations Pertaining to Permits for Screening Programs
63. Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors
64. Rules and Regulations Pertaining to Public Drinking Water
65. Rules and Regulations Pertaining to Rhode Island Certificates of Registration for Nursing Assistants, Medication Aides, and the Approval of Nursing Assistant and Medication Aide Training Programs
66. Rules and Regulations Pertaining to the Certification of Public Drinking Water Supply Treatment and Public Water Supply Transmission and Distribution Operators

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67. Rules and Regulations Pertaining to the Licensing of Dietitians/Nutritionists
  68. Rules and Regulations Pertaining to the Medical Examiner System
  69. Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program
  70. Rules and Regulations Pertaining to the Processing and Distribution of Shellfish
  71. Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products
  72. Rules and Regulations Related to the Licensure of Hearing Aid Dealers and Fitters
  73. Rules and Regulations Related to the Medical Marijuana Program
  74. Rules and Regulations Related to the Practice of Electrolysis
  75. Rules and Regulations Relating to Emergency Medical Services
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Notice is hereby given in accordance with the provisions of §42-35-3(a)(2) of the Rhode Island General Laws, as amended, that the Director is affording all interested persons the opportunity to submit data, views, or arguments in writing on this matter. Opportunity for public hearing shall be granted if requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members. *Otherwise, no hearing shall be convened.* Should a hearing be requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members, *a hearing shall be scheduled only for the regulation(s) for which the request for hearing was received.* All regulations for which a public hearing is not requested will be filed with the Rhode Island Secretary of State pursuant to Chapter 42-35 of the Rhode Island General Laws, as amended, shortly after the **10 September 2012** deadline (as below).

Such input or requests for public hearing must be received in writing **no later than Monday, 10 September 2012**. Such input or requests should be addressed to: Michael Fine, M.D., Director, Rhode Island Department of Health, Three Capitol Hill, Room #401, Providence, Rhode Island 02908-5097.

In the development of these amendments, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach, duplication, or overlap was identified based upon available information.

Copies of all regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, Three Capitol Hill, Providence, Rhode Island 02908-5097, on the Secretary of State's website: <http://www.sos.ri.gov/rules/>, by calling 401-222-7767, or by e-mail to [Bill.Dundulis@health.ri.gov](mailto:Bill.Dundulis@health.ri.gov).

Signed this 3<sup>rd</sup> day of August 2012

*Original signed by Michael Fine, MD*

Michael Fine, M.D., Director of Health

**RULES AND REGULATIONS  
FOR THE REGISTRATION OF  
DISTRIBUTORS OF  
CONTROLLED SUBSTANCES  
IN RHODE ISLAND  
(R21-28-CSD)**



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

August 1982

***As Amended:***

April 1990

May 2000

January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

September 2007

January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

**August 2012 (Proposed)**

**COMPILER'S NOTES:**

**Proposed Additions: Underlined**

**Proposed Deletions: ~~Strikeouts~~**



## ***INTRODUCTION***

These *Rules and Regulations for 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 amending the fee for the registration of every person who manufactures, distributes, prescribes, administers or dispenses any controlled substance within this state, or who proposes to engage in the manufacture, distribution, prescribing, administering, or dispensing of any controlled substance within this state.

In accordance with the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, consideration was given to: (1) alternative approaches to the regulations; and (2) duplication or overlap with other state regulations. Based upon available information, no known alternative approach, duplication or overlap was identified. The protection of the health, safety and welfare of the public necessitates the adoption of these regulations.

These rules and regulations shall supersede all previous rules and regulations pertaining to the registration of distributors of controlled substances in Rhode Island promulgated by the Department of Health and filed with the Secretary of State.

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## Section 1.0 *Definitions*

Wherever used in these rules and regulations, the following terms shall be construed as follows:

- 1.1 **"Act"** shall refer to Chapter 21-28 of the General Laws of Rhode Island, as amended, entitled, "Uniform Controlled Substances Act."
- 1.2 **"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 section 39-12-2 of the General Laws of Rhode Island, as amended.
- 1.3 **"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 section 39-12-2 of the General Laws of Rhode Island, as amended.
- 1.4 **"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.  
  
**"Distributor"** means a person who so delivers a controlled substance, or an imitation controlled substance, pursuant to section 21-28-1.02(14) of the Act.
- 1.5 **"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 section 39-12-2 of the General Laws of Rhode Island, as amended.
- 1.6 **"Person"** means any corporation, association, partnership, or one or more individuals.
- 1.7 **"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 section 39-12-2 of the General Laws of Rhode Island, as amended.

## Section 2.0 *Registration Requirements*

- 2.1 Pursuant to section 21-28-3.02(a) of the Act, every person who manufactures, distributes, prescribes, administers, or dispenses any controlled substance within this state, or who proposes to engage in the manufacture, distribution, prescribing, administering, or dispensing of any controlled substance within this state, must obtain annually, a registration issued by the Director of Health, unless exempt in accordance with section 21-28-3.30 of this Act.

### 2.1.1 *Application for Registration and Fee*

Application for registration may be obtained at:

Rhode Island Department of Health  
Board of Pharmacy  
Three Capitol Hill, Room 205  
Providence, RI 02908

A filing fee of ~~seventy dollars (\$70.00)~~ 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.

- 2.2 Pursuant to section 21-28-3.28 of the Act, security requirements for controlled substances shall be the same as those enumerated in federal law, in addition to these rules and regulations, and such further regulations as the Director of Health may, from time to time, promulgate in order to prevent diversion of controlled substances.
- 2.3 The ability of the registrant to maintain effective controls against diversion, will be considered by the Director of Health in determining whether issuance of a registration is consistent with the public interest (see section 21-28-3.03(a)(1) of the Act and section 3.0 herein).

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

### 2.4 *Distributors*

2.4.1 In addition, all distributors must:

- a) 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 statutory and regulatory provisions of Chapter 5-19 of the General Laws of Rhode Island, as amended, as a prerequisite for registration;
- b) comply with the federal registration requirements set forth by the federal Drug Enforcement Administration, Department of Justice (or successor agency), documented on DEA Form 225 (or a successor form), limiting distribution only to those controlled substances identified on the registration;
- c) demonstrate ability to maintain effective security controls against diversion.

### Section 3.0 *General Security Requirements*

In determining whether an applicant has demonstrated maintenance of effective security controls, the Director of Health will consider, but not be limited to, the following:

- 3.1 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);

- 3.2 recordkeeping requirements of the Act;
- 3.3 drug destruction requirements of the Act;
- 3.4 past experience of the Department of Health;
- 3.5 federal standards as to the type of activity conducted, the type and form of controlled substances handled, the quantity of controlled substances handled;
- 3.6 the location of the premises, and the relationship such location bears on security needs, the type of construction comprising the facility;
- 3.7 the type of vaults, safes, secured enclosures, or other storage systems, the type of closures on vaults, safes, and secured enclosures, the adequacy of key control systems, and/or combination lock control systems, the adequacy of electric detection and alarm systems, and the ability to use supervised transmittal lines for standby power sources;
- 3.8 the extent of unsupervised public access to controlled substances storage, including the presence and characteristics of perimeter security, if any, the adequacy of supervision of employees having access to storage areas, the procedures for handling business guests, visitors, maintenance personnel, non-employee service personnel;
- 3.9 the availability of local police protection, or the applicant's security personnel;
- 3.10 the adequacy of the applicant's system for monitoring the receipt, manufacture, distribution, and distribution of controlled substances;
- 3.11 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
- 3.12 any other factor which would assist the Director of Health to conclude that the registration for each distributor is not inconsistent with the public interest.

#### Section 4.0 *Limitation on Registration*

- 4.1 The registration issued by the Department of Health limits distribution to controlled substances permitted by federal registration from DEA Form 225 (or a successor form).
- 4.2 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.

Nothing in this rule 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 5.0 *Violations and Hearings*

- 5.1 Any person who violates any provision of the Act, or of the rules and regulations herein, shall be subject to the penalty provisions as specified in the Act.
- 5.2 All hearings and reviews required hereunder, shall be held in accordance with the provisions of Chapter 42-35 of the General Laws of Rhode Island, as amended, and the *Rules and Regulations of the Rhode Island Department of Health Regarding Practice and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*.

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*Monday, 30 July 2012*