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
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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; (2) duplication or overlap with other state regulations; and (3) any significant economic impact on small business, as defined in Chapter 42-35 of the General Laws. Based upon available information, no known alternative approach, duplication or overlap, or significant economic impact was identified. The protection of the health, safety and welfare of the public necessitates the adoption of these regulations, despite the economic impact which may be incurred as a result of the 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.

TABLE OF CONTENTS

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 fifty dollars ($50.00) 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 policy 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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