

RULES AND REGULATIONS
GOVERNING THE DISPOSAL
OF LEGEND DRUGS
(R21-31-LEG)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH
March 1987 (E)

As amended:

April 1987

April 1991(E)

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July 1997 (E)

October 1997 (E)

October 1997

December 1997 (E)

March 1998

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accordance with the
provisions of section 42-35-
4.1 of the Rhode Island
General Laws, as amended)**

INTRODUCTION

These *Rules and Regulations Governing the Disposal of Legend Drugs (R21-31-LEG)* are promulgated pursuant to the authority conferred under Chapters 21-28-5.07 and 21-31 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting methods for the disposal of legend drugs in this state, and for the protection of the health, safety and welfare of the public.

Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following issues have been given consideration in arriving at the amended regulations: (a) alternative approaches to the regulations; (b) duplication or overlap with other state regulations; and (c) significant economic impact. No alternative approaches, or overlap was identified. The protection of the health and safety of the public necessitates the adoption of these amended regulations despite the economic impact which may ensue as a result of the regulations adopted in the best interest of the health, safety and welfare of the public.

These rules and regulations shall supersede any other regulations governing the disposal of legend drugs previously promulgated by the Department of Health and filed with the Secretary of State.

Section 1.0 *Definitions*

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

- 1.1 **"Controlled substance"** means a drug, substance or immediate precursor in Schedules I - V of Chapter 21-28 of the Rhode Island General Laws, as amended.
- 1.2 **"Health care facility"** means any health care institution as defined in section 23-17-2 of the Rhode Island General Laws, as amended, and licensed according to the provisions of Chapter 23-17 of the Rhode Island General Laws, as amended.
- 1.3 **"Legend drug"** shall mean any drug so designated pursuant to the provisions of section 21-32-15(k)(c)(3) of the General Laws of Rhode Island, as amended, and said drug shall be labeled: "Caution: Federal Law Prohibits Dispensing Without a Prescription."
- 1.4 **"Person"** means any individual, trust or estate, partnership, corporation (including associations, joint stock companies) state or political subdivision or instrumentality of the state.

Section 2.0 *Disposal of Controlled Substances*

- 2.1 Any health care facility or person licensed by the Rhode Island Department of Health that is lawfully in possession of excess or undesired controlled substances shall inventory and dispose of all such controlled substances in accordance with federal Drug Enforcement Administration (DEA) regulations of reference 1 and all other applicable federal, state, and local regulations.

Section 3.0 *Disposal of All Other Legend Drugs (i.e., Non-controlled Substances)*

All other legend drugs (i.e., those not classified as controlled substances) shall be the responsibility of the health care facility or person to dispose of as provided in one of the following ways:

- 3.1 Legend drugs may be disposed of as solid waste provided that all of the following conditions are met: (1) the legend drugs are rendered unrecognizable; (2) the legend drugs would not pose a threat to the public or to the environment; and (3) the legend drugs cannot be recycled. **OR**
- 3.2 The legend drugs may be disposed of as regulated medical waste (defined in reference 2), through the use of an entity holding a regulated medical waste transporter permit issued pursuant to the requirements of reference 2, and in compliance with the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste (DEM-DAH-MW-01-92)* of reference 2.
- 3.3 The Director of Health or her/his designee is authorized to: (1) enter any premises where legend drugs, including controlled substances, are maintained and/or held for disposal pursuant the requirements herein; (2) inspect any and all aspects of the disposal process and related records;

and (3) obtain and test samples of any and all controlled substances being processed for disposal for the purpose of determining compliance with state and federal laws.

Section 4.0 *Severability*

- 4.1 If any provision of these regulations or the application thereof to any facility or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

REFERENCES

1. “Procedure for Disposing of Controlled Substances,” Drug Enforcement Administration, Department of Justice. Title 21 *Code of Federal Regulations (CFR)* Part 1307.21, p. 81 (April 1, 1996 edition).
2. *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92)*, Rhode Island Department of Environmental Management, June 1994.
3. “Rhode Island Food, Drugs, and Cosmetics Act,” Chapter 21-31 of the Rhode Island General Laws, as amended.
4. “Disposition of Controlled Substances,” Chapter 21-28-5.07 of the Rhode Island General Laws, as amended.
5. “Uniform Controlled Substances Act,” Chapter 21-28 of the Rhode Island General Laws, as amended.