RULES AND REGULATIONS

GOVERNING

HYPODERMIC NEEDLES, SYRINGES,

AND OTHER SUCH INSTRUMENTS

(R21-28-CS-4)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health
August 1979

As Amended:
March 1982
September 1985
March 1987(E)
April 1987
November 1992
June 1997
October 1997
December 1997 (E)
March 1998
August 2000 (E)
December 2000 (E)
February 2001
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
INTRODUCTION

These amended *Rules and Regulations Governing Hypodermic Needles, Syringes, and Other Such Instruments* (*R21-28-CS-4*) are promulgated pursuant to the authority set forth in section 21-28-3.01 of the General Laws of Rhode Island, as amended, and are established for the purpose of promoting public health by permitting the sale of hypodermic needles and syringes in licensed pharmacies and adopting provisions governing hypodermic needles, syringes, and other such instruments without the need for a prescription.

Furthermore, pursuant to the provisions of section 32-35-3(c) of the General laws of Rhode Island, the following issues were given consideration: (1) alternative approaches; (2) duplication or overlap with other state regulations; and (3) significant economic impact which would be placed on small business as defined in Chapter 42-35 of the General Laws, through these amended regulations. No known alternative approach, duplication or overlap with other regulations, or significant economic impact, were identified. Consequently, the amended regulations are adopted in the best interest of the public health, safety, and welfare.

These amended regulations shall supersede all previous *Rules and Regulations Governing Hypodermic Needles, Syringes, and Other Such Instruments* 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 “**Authorized pharmacy personnel**” means a person who is licensed, registered, or enrolled by the Department pursuant to Chapter 5-19 of the Rhode Island General Laws, as amended, and the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors (R5-19-PHAR)*.

1.2 "**Department**" means the Rhode Island Department of Health.

1.3 “**Director**” means the Director of the Rhode Island Department of Health.

1.4 “**Pharmacy**” means that portion or part of a premises where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription drugs or legend drugs, and which is licensed pursuant to Chapter 5-19 of the Rhode Island General Laws, as amended, and the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors (R5-19-PHAR)*.

Section 2.0  *Sale of Hypodermic Needles and Syringes in Licensed Pharmacies*

*General Requirements*

2.1 As of September 1, 2000, a prescription shall no longer be required for each sale of a hypodermic syringe(s), needle(s), or any instrument adapted for the administration of drugs by injection.

2.2 Hypodermic needles and syringes shall be sold only in licensed pharmacies.

2.2.1 Hypodermic needles and syringes shall be stored in the pharmacy. Access to hypodermic needles and syringes shall be by authorized pharmacy personnel only.

2.3 Upon each sale of a hypodermic needle(s) and syringe(s), the pharmacist shall make available to the purchaser, information on the safe disposal of hypodermic syringes or needles that shall include:

2.3.1 Information on the safe disposal of home-generated medical waste, and

2.3.2 A list of local disposal locations, and/or

2.3.3 A telephone number to call for information on local disposal sites and methods of disposal.
2.4 Pharmacists may also provide purchasers with information on drug addiction treatment, including a local telephone number to get assistance.

Section 3.0 Pharmacy Certification

3.1 The registrant of each licensed pharmacy in the state shall certify to the Director, on a form provided by the Department, his/her participation in an appropriate activity for the safe disposal of hypodermic needles and syringes. Activities shall include:

3.1.1 Pharmacy is registered as a regulated medical waste generator with the Department; or

3.1.2 Pharmacy is an established site for the collection for home-generated medical waste in a medical waste program certified by the Director, or provides information to purchasers that lists the locations of the local collection sites for home-generated medical waste; or

3.1.3 Pharmacy provides written information relating to the safe disposal of hypodermic needles and syringes.

3.2 When there is a change in registrant, the incoming registrant shall certify participation in activities as outlined in section 3.1.

Section 4.0 Destruction of Excess, Undesired, and Contaminated Hypodermic Needles, Syringes, or Other Such Instruments

4.1 The legal destruction of hypodermic needles, syringes or other such instruments is the responsibility of the last entitled or authorized possessor.

4.2 Methods of Disposal: In accordance with the requirements of reference 3 herein, the following methods of disposal are intended to accomplish the purpose of adequate final destruction without danger of contamination of or injury to waste disposal personnel and to prevent diversion of the instruments or transmission of communicable diseases to the general population.

4.2.1 The requirements cited below shall apply to all health care facilities and individuals licensed by the Department of Health and authorized to handle needles, syringes, and other such instruments.

a) Pursuant to section 21-29.1-1 of the General Laws of Rhode Island, as amended, all facilities or persons legally entitled to use disposable syringes and needles including but not limited to hospitals, physicians, skilled nursing and intermediate care facilities,
shall destroy them after one (1) use. Any violation of this provision shall constitute a misdemeanor.

b) Excess and undesired needles, syringes and other such instruments shall be stored in impervious, rigid, puncture-resistant containers for disposal. Intact needles must be placed directly into the collection containers (i.e., without recapping, clipping, breaking or compacting) unless the person can demonstrate that an alternative is feasible and the alternatives are approved by the Department of Health, or that such action is required by a specific medical procedure.

c) Personnel handling disposal waste materials such as needles, syringes, and other such instruments may treat and destroy such waste on-site in a Department of Environmental Management (DEM)-permitted incinerator or by a DEM-approved alternative treatment/destruction technology or prepare the regulated medical waste for off-site transport by a DEM-permitted medical waste transporter.

d) Containers with used or unused needles, syringes, and other sharps may be treated and destroyed on-site in a DEM-permitted incinerator or by a DEM-approved alternative medical waste treatment/destruction technology, or at an off-site treatment and destruction facility.

Section 5.0  Severability

5.1 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 provision of the regulations are declared to be severable.
REFERENCES

