

RULES AND REGULATIONS
GOVERNING
ELECTRONIC DATA TRANSFER OF
CONTROLLED SUBSTANCES IN
SCHEDULES II AND III
(R21-28-EDT)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

June 1997

As Amended:

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 *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III (R21-28-EDT)* are promulgated pursuant to the authority set forth in sections 42-35 and 21-28-3.18 of the General Laws of Rhode Island, as amended. These regulations are established for the purpose of defining minimum standards for the establishment of an electronic data transfer system between the Department of Health and pharmacies in this state for schedules II and III controlled substances.

Pursuant to the provisions of section 42-35-3(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.

These amended regulations shall supersede all previous *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III and Hypodermic Needles and Syringes (R21-28-EDT)* 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 ("Uniform Controlled Substances Act") of the Rhode Island General Laws, as amended. The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in Chapter 1 of Title 3, nor tobacco.
- 1.2 **"Department"** means the Rhode Island Department of Health, which is the designated agency responsible for the functions listed in section 2.0 herein.
- 1.3 **"Dispenser"** means a person who distributes to the ultimate user, a schedule II or III controlled substance, as defined in section 21-28 of the General Laws of Rhode Island, as amended, to the ultimate user. For the purposes of these rules and regulations, "dispenser" shall not include:
 - 1.3.1 a licensed institutional pharmacy that distributes such substances for the purposes of inpatient hospital care;
 - 1.3.2 a practitioner, or other authorized person, who administers such a substance; or
 - 1.3.3 a wholesale distributor of a schedule II or III controlled substance.
- 1.4 **"Electronic Data Transfer (EDT)"** means the method for reporting the dispensing by pharmacies of controlled substances in schedules II and III, as defined in Section 21-28 of the Rhode Island General Laws, as amended ("Uniform Controlled Substances Act").

Section 2.0 *General Requirements*

- 2.1 There shall be established within the Department a system for the monitoring of the prescribing and dispensing of schedules II and III controlled substances, by all professionals licensed to prescribe or dispense such substances for any resident of this state.
- 2.2 The prescription system that is established shall be an electronic monitoring system, that shall be maintained under the direction of the Department.
 - 2.2.1 Said system shall collect and maintain prescription and dispensing information for schedules II and III controlled substances.
- 2.3 All retail and institutional pharmacies dispensing twenty-five (25) or more prescriptions per month for schedules II and III controlled substances in this state shall electronically transmit to

the Department, by the fifth (5th) day of each month following the date of dispensing, the record of each prescription dispensed.

2.3.1 This requirement shall not apply to an inpatient of a hospital or correctional institution.

2.4 Any pharmacy dispensing fewer than twenty-five (25) prescriptions per month for schedules II and III controlled substances may submit the data on a form provided by the Department and mailed by the fifth (5th) day of the month following dispensing to:

Rhode Island Department of Health, Pharmacy Unit
3 Capitol Hill, Room 205
Providence, RI 02908-5097

Section 3.0 *Data Collection*

3.1 The electronic system shall provide for the method of data collection; transmission from all dispensers to the Department; maintenance and use of data; and shall be as set forth in the latest edition of the *ASAP Telecommunications Format for Controlled Substances* of reference 1 herein.

3.2 Required data shall be transmitted by direct computer link, double sided/high density micro floppy disk, or microcassette. All computerized pharmacies shall submit the required data no later than 1 July 1997.

3.3 The Department shall:

3.3.1 be authorized to provide data in the electronic prescription system to other regulatory, investigative or law enforcement agencies for disciplinary, civil, or criminal purposes, and for the purposes of educating practitioners in lieu of disciplinary, civil or criminal action.

3.3.2 be authorized to provide data to appropriate public or private entities for statistical, research, or educational purposes provided that the privacy and confidentiality of patients and patient information is not compromised.

3.3.3 in using the information for investigative or prosecutorial purposes, consider the nature of the prescriber's or dispenser's practice and the condition(s) for which the patient is being treated.

3.3.4 ensure the privacy and confidentiality of patients and shall ensure that patient information collected, recorded, transmitted, and stored in the prescription system is maintained in accordance with applicable state and federal laws, rules and regulations.

3.3.5 ensure that the EDT program does not infringe on the legal use of any schedule II or III controlled substance.

Section 4.0 *Severability*

- 4.1 If any provision of these regulations or the application thereof to any facility or circumstance shall be held invalid, such invalidity shall not affect the provisions or the 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. *ASAP Telecommunications Format for Controlled Substances*, American Society for Automation in Pharmacy, May 1995, and subsequent revisions thereto, 482 Norristown Road, Suite 112, Blue Bell, PA 19422 [610-825-7783 (telephone) 610-825-7641 (facsimile)].
2. Chapter 21-28 of the Rhode Island General Laws, as amended, "Uniform Controlled Substances Act."
3. *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors (R5-19-PHAR)*, Rhode Island Department of Health, July 2000 (E) and subsequent amendments thereto.