# RULES AND REGULATIONS GOVERNING ELECTRONIC DATA TRANSFER OF CONTROLLED SUBSTANCES IN SCHEDULES II, III AND IV

[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)

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

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

**June 2014**

# INTRODUCTION

These amended *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II, III and IV* [*R21-28-EDT*] are promulgated[1] pursuant to the authority set forth in §21-28-3.18 of the General Laws of Rhode Island, as amended, and are established for the purpose of defining minimum standards for the transfer of electronic data between the Department of Health and pharmacies for schedules II, III and IV controlled substances.

Pursuant to the provisions of §42-35-3(a)(3) and §42-35.1-4 of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at these amended regulations:

(a) Alternative approaches to the regulations;

(b) Duplication or overlap with other state regulations.; and

(c) Significant economic impact on small business.

Based on the available information, no known alternative approach, duplication or overlap was identified.

Upon promulgation of these amendments, these amended regulations shall supersede all previous *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III* [*R21-28-EDT*] promulgated by the Rhode Island Department of Health and filed with the Secretary of State.

[1] Prior to April 2014, these Regulations were promulgated under the title *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III* [R21-28-EDT]. Beginning with the April 2014 edition, the title was changed to *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II, III and IV* [*R21-28-EDT*] to reflect the addition of a requirement to include Schedule IV controlled substances in the mandated reporting.

## *TABLE OF CONTENTS*

Section 1.0 ***Definitions***

Wherever used in these 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 RIGL Chapter 21-28 ("Uniform Controlled Substances Act"). The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in RIGL Chapter 3-1, nor tobacco.

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

1.3 ***"Nonresident pharmacy"*** means a pharmacy located outside Rhode Island in any state in the United States or any province or territory of Canada that ships, mails, or delivers prescription drugs and/or devices to a patient or person in Rhode Island.

1.4 "***Parent or legal guardian***" means the custodial parent for a person under eighteen (18) years of age or the legal guardian with responsibility for health care decisions for a person of any age.

1.5 "***Pharmacy***" means that portion or part of a premises where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription or legend drugs.

1.6 "***Practitioner***" means a physician, physician assistant, dentist, veterinarian, nurse or other person duly authorized by law in the state in which they practice to prescribe drugs.

1.7 ***"RIGL"*** means the General Laws of Rhode Island, as amended.

1.8 "***These Regulations***" mean all parts of the Rhode Island *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II, III and IV.*

Section 2.0 ***General Requirements***

2.1 (a) A pharmacy that dispenses schedule II, III or IV controlled substances shall transmit the prescription information for these controlled substances to the Department in accordance with §§3.1 and 3.2 of these Regulations.

(b) A hospital pharmacy, long term care facility pharmacy or correctional facility pharmacy shall transmit controlled substance prescription information for outpatients only.

(1) A pharmacy, required to submit data pursuant to §2.1(b) of these Regulations, who does not dispense any outpatient controlled substance prescription during a calendar year shall submit a "zero fill affidavit" to the Department no later than January 31st of the following calendar year[2].

(c) A nonresident pharmacy shall be considered a pharmacy for the purpose of compliance with the reporting requirements of these Regulations.

2.2 through 2.4 **[DELETED]**

[2] For example, a hospital pharmacy that did not dispense any outpatient controlled substance prescriptions during calendar 2014 would be required to submit a "zero fill affidavit " no later than 31 January 2015.

Section 3.0 ***Reporting and Management of Information***

3.1 (a) A pharmacy that dispenses a schedule II, III or IV controlled substance to a person, who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit electronically to the Department the information set forth in the edition of the *Electronic Reporting Standard for Prescription Monitoring Programs*[3], established by the American Society for Automation in Pharmacy, that is currently approved by the Department.

(b) The information transmitted electronically by the pharmacy shall include the following:

(1) Pharmacy Drug Enforcement Administration identification number;

(2) Patient last name[4];

(3) Patient first name;

(4) Patient street address;

(5) City;

(6) State;

(7) Date of birth;

(8) Gender code;

(9) Prescription species code;

(10) Prescription number;

(11) Date prescription written;

(12) Number of refills authorized;

(13) Date prescription filled;

(14) Refill number;

(15) National Drug Code number;

(16) Quantity dispensed;

(17) Days supply;

(18) Payment code for either cash or third-party provider; and

(19) Prescriber Drug Enforcement Administration identification number.

3.2 (a) A pharmacy shall transmit the required prescription information by means of a secure web-based data system, or other approved electronic methods, designated by the Department.

(b) A pharmacy shall transmit the information required pursuant to these Regulations not later than Monday of the following week for the weekly reporting period ending on Saturday.

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[3] A copy of the *Electronic Reporting Standard for Prescription Monitoring Programs* may be obtained from the American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160, Blue Bell, Pennsylvania 19422. Telephone: (610) 825-7783. Website: www.asapnet.org.

[4] A patient identification number may be included in place of the patient's last name provided that the identification number not include the patient's social security number in whole or in part.

(c) If the reporting date falls on a holiday, a pharmacy shall transmit the required information by the next state of Rhode Island workday.

(d) A pharmacy shall transmit the information required pursuant to these Regulations to the Department in such a manner as to insure the confidentiality of the information in compliance with all applicable federal and state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

(e) Any pharmacist who, in his or her professional judgment, refuses to fill a prescription based on information contained within the prescription drug monitoring database shall inform the prescribing physician within twenty-four (24) hours.

3.3 **Management of Information.**

(a) The Department shall only disclose information obtained pursuant to these Regulations:

(1) To a practitioner who certifies that the requested information is for the purpose of evaluating the need for or providing medical treatment for a current patient to whom the practitioner is prescribing or considering prescribing a controlled substance;

(2) To a pharmacist who certifies that the requested information is for a current client to whom the pharmacist is dispensing or considering dispensing a controlled substance;

(3) Pursuant to a valid search warrant based on probable cause to believe a violation of federal or state criminal law has occurred and that specified information contained in the database would assist in the investigation of the crime;

(4) To a patient who requests his or her own prescription information, or the parent or legal guardian of a minor child who requests the minor child's prescription information;

(5) To a health professional regulatory board that documents, in writing, that the requested information is necessary for an investigation related to licensure, renewal or disciplinary action involving the applicant, licensee or registrant to whom the requested information pertains;

(6) To any vendor or contractor with whom the Department has contracted to establish or maintain the electronic system of the prescription drug monitoring database; or

(7) To public or private entities for statistical, research or educational purposes, after removing the patient and prescriber information that could be used to identify individual patients. This shall not include entities receiving a waiver from the Institutional Review Board.

(b) A patient may request from the dispensing pharmacy correction of any inaccurate information contained within the prescription drug monitoring database in accordance with the procedure specified by RIGL §5-37.3-5(c).

(c) The Department shall, for the period of time that prescription information is maintained, maintain records of the information disclosed through the prescription drug monitoring database, including, but not limited to:

(1) The identity of each person who requests or receives information from the prescription drug monitoring database and the organization, if any, the person represents;

(2) The information released to each person or organization and the basis for its release under §3.3(a) of these Regulations; and

(3) The dates the information was requested and provided.

(d) Prescription information contained within the prescription drug monitoring database shall be removed no later than five (5) years from the date the information is entered into the database.

(1) Records in existence prior to 24 June 2013 shall be removed no later than ten (10) years from the date the information is entered into the prescription drug monitoring database.

(e) The Department shall promptly notify any affected individual of an improper disclosure of information from the prescription drug monitoring database or a breach in the security of the prescription drug monitoring database that poses a significant risk of disclosure of patient information to an unauthorized individual.

(f) At the time of signing a prescription which is required by the Department to be entered into the prescription drug monitoring database, the prescribing physician shall inform the patient in writing of the existence of the prescription drug monitoring database, the patient's right to access their own prescription information, and the name and contact information for the Department.

(g) The Department will disclose any information relating to a patient maintained in the prescription drug monitoring database to that patient, at no cost to the patient, within thirty (30) business days after the Department receives a written request from the patient for the information. This information will include the records maintained by the Department pursuant to §3.1 of these Regulations.

(1) Notwithstanding the provisions of §3.3(g) of these Regulations, the Department may, at the request of the law enforcement agency, withhold for up to sixty (60) days following the conclusion of a law enforcement investigation, the disclosure to the patient that information has been obtained pursuant to §3.3(a)(3) of these Regulations.

Section 4.0 ***Storage of Information***.

(a) The Department shall ensure the privacy of patients and confidentiality of patient information transmitted or obtained is maintained in accordance with applicable state and federal laws, rules and regulations.

(b) No person shall access information in the prescription monitoring database except to the extent and for the purposes authorized by §3.3(a) of these Regulations.

Section 5.0 ***Evaluation***.

The Department may evaluate the prescription information received from pharmacies for the purposes of preventing controlled substance diversion, public health initiatives and statistical reporting.

Section 6.0 ***Severability***

6.1 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.

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