



Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration proposed amendments to the rules and regulations listed below:

1. *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II, III and IV [R21-28-EDT]*, promulgated pursuant to the authority conferred under §21-28-3.18 and Chapter 42-35 of the Rhode Island General Laws, as amended. The purpose of the proposed changes is to update 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 PL 2013-124 and PL 2013-132.
2. *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19.1-PHAR]*, promulgated pursuant to the authority conferred under Chapters 5-19.1 and 42-35 of the Rhode Island General Laws, as amended. The purpose of the proposed changes is to adopt administrative procedures and pharmaceutical practices for e-scripting of Schedule II Controlled Substances and for return of unused drugs pursuant to PL 2013-124, PL 2013-132 and PL 2013-331

Notice is hereby given in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws, as amended, that the Director will hold a public hearing on the above mentioned matter, in the **AUDITORIUM** of the Rhode Island Department of Health (on the lower level of the Cannon Building), Three Capitol Hill, Providence, Rhode Island on **TUESDAY, 21 JANUARY 2014 AT 1 P.M.** at which time and place all persons interested therein will be heard. The seating capacity of the room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

In the development of the rules and regulations, consideration was given to the following: (1) alternative approaches; (2) overlap or duplication with other statutory and regulatory provisions and (3) financial impact on small business. No alternative approach, duplication, or overlap was identified based upon available information.

For the sake of accuracy, it is requested that statements to be made relative to any aspect of the regulations, including alternative approaches or overlap, be submitted in writing at the time of the hearing or prior to the hearing date to: Edward D'Arezzo, Interim Associate Director of Health at edward.d'arezzo@health.ri.gov or by calling 401-222-1006.

Copies of the regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, on the Secretary of State's website: <http://www.sos.ri.gov/rules/>, by e-mail to Bill.Dundulis@health.ri.gov or by calling 401-222-7767

Rhode Island Department Of Health – Public Hearing Notice

The Department of Health is accessible to the handicapped. If communication assistance (readers/ interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-7767 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

Signed this 2nd day of December 2013

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

2nd PUBLIC HEARING DRAFT – REVISED 26 NOVEMBER 2013

**RULES AND REGULATIONS GOVERNING
ELECTRONIC DATA TRANSFER OF CONTROLLED
SUBSTANCES IN SCHEDULES II, ~~AND 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)

December 2013 (Proposed)

COMPILER'S NOTES:

Additions: Underlined

Proposed Deletions: ~~Strikeouts~~

INTRODUCTION

These amended Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II, ~~and III and IV~~ [R21-28-EDT] are promulgated¹ pursuant to the authority set forth in ~~sections 42-35 and §21-28-3.18~~ of the General Laws of Rhode Island, as amended, ~~and~~. These ~~regulations~~ are established for the purpose of defining minimum standards for the establishment of an transfer of electronic data transfer system between the Department of Health and pharmacies ~~in this state~~ for schedules II, ~~and III and IV~~ controlled substances.

Pursuant to the provisions of ~~section 42-35-3(e)~~ §42-35-3(a)(3) and §42-35.1-4 of the General laws of Rhode Island, ~~as amended~~, the following ~~issues~~ 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 ~~which would be placed~~ on small business as ~~defined in Chapter 42-35 of the General Laws~~, through these ~~amended regulations~~.

Based on the available information, no known alternative approach, duplication or overlap ~~with other regulations, or significant economic impact~~, were 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 December 2013, 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 December 2013 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.

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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 RIGL 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 RIGL Chapter 3-1 ~~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 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.~~
- 1.3 "***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 ~~"***Electronic Data Transfer (EDT)***" means the method for reporting the dispensing by pharmacies of controlled substances in schedules II or III, as defined in Section 21-28 of the Rhode Island General Laws, as amended ("Uniform Controlled Substances Act").~~
- 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 ~~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~~

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prescribe or dispense such substances for any resident of this state.

(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.

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

~~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~~

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

3.1 (a) ~~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. 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 most recent edition of the *Electronic Reporting Standard for Prescription Monitoring Programs*² established by the American Society for Automation in Pharmacy.~~

~~(b) The information transmitted electronically by the pharmacy shall include, as a minimum, the following:~~

~~(1) Drug Enforcement Administration Pharmacy number;~~

² 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.

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- (2) Birth date;
 - (3) Sex code;
 - (4) Date prescription filled;
 - (5) Prescription number;
 - (6) New-refill code;
 - (7) Quantity;
 - (8) Days supply;
 - (9) National Drug Code number;
 - (10) Drug Enforcement Administration Prescriber Identification Number;
 - (11) Date prescription written;
 - (12) Number of refills authorized;
 - (13) Prescription species code;
 - (14) Patient last name³;
 - (15) Patient first name;
 - (16) Patient street address;
 - (17) State;
 - (18) Payment code for either cash or third-party provider; and
 - (19) Prescription name.
- 3.2 (a) 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. A pharmacy shall transmit the required prescription information by means of a secure web-based data system 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.
- (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:

³ 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.

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- (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.

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- (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 § 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.

~~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 *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.

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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 4.0 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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Tuesday, 26 November 2013

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, January 2010 and subsequent amendments thereto.~~