



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 Governing Electronic Data Transfer of Controlled Substances in Schedules II, III and IV [R21-28-EDT]* 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. These amendments modify the Prescription Monitoring Program (PMP) reporting period and allow for delegation of a prescriber's or pharmacist's access to the PMP database under certain conditions.

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 matters, 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 **MONDAY, 8 SEPTEMBER 2014 AT 11:00 AM** 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 in electronic format prior to the hearing date to: Peter J. Ragosta, RPh, Chief Administrative Officer, Board of Pharmacy: Peter.Ragosta@health.ri.gov or 401-222-2837.

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/ProposedRules/>, by calling 401-222-7767 or by e-mail to Bill.Dundulis@health.ri.gov.

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 21st day of July 2014

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

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**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

August 2014 (Pending)

COMPILER'S NOTES:

Proposed Additions: Double-Underlined

Proposed Deletions: ~~Strikeouts~~

INTRODUCTION

These amended *Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II, III and IV [R21-28-EDT]* are promulgated⁺ 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. These amendments modify the Prescription Monitoring Program (PMP) reporting period and allow for delegation of a prescriber's or pharmacist's access to the PMP database under certain conditions.

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.

⁺ ~~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.~~

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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 year².
 - (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.

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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 name⁴;
 - (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 within seventy-two (72) hours following the date of dispensing, not later than Monday of the following week for the weekly reporting period ending on Saturday.

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.

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- (c) ~~**DELETED** 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;

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- (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.*

- 4.1 (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.

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Section 6.0 Delegation of Access to the Electronic Prescription Database⁵

6.1 Notwithstanding the provisions of §3.3(a) of these Regulations, a pharmacist or prescriber is allowed to share access to the prescription drug monitoring database with an authorized designee of the practitioner and/or pharmacist, to consult the prescription drug monitoring database on the practitioner's and/or pharmacist's behalf, provided that:

(a) The designee so authorized is employed by the same professional practice or pharmacy;

(b) The practitioner or pharmacist takes reasonable steps to ensure that such designee is sufficiently competent in the use of the database;

(c) The practitioner or pharmacist remains responsible for ensuring that access to the database by the designee is limited to authorized purposes as provided in §3.3(a)(1) and §3.3(a)(2) of these Regulations.

(d) The practitioner or pharmacist remains responsible for ensuring access to the database by the designee occurs in a manner that protects the confidentiality of information obtained from the database, and remains responsible for any breach of confidentiality;

(e) The practitioner or pharmacist terminates the designee's access to the database at the termination of the designee's employment; and

(f) The ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the practitioner or pharmacist and is reasonably informed by the relevant controlled substance history information obtained from the database.

6.2 The actual user name and password that is used will be that of the pharmacist or prescriber and shared solely at the discretion of the professional.

Section 7.0 Severability

7.1 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.

*Pharmacy_PMP_PublicHearingDraft_Revised_August2014.doc
Monday, 04 August 2014*

⁵ Compiler's Note: New §6.0 has been added. Existing §6.0 has been redesignated as §7.0. (without annotation). Only actual text changes have been annotated.