216-RICR-20-20-3

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 20 – COMMUNITY HEALTH

SUBCHAPTER 20 – DRUGS

PART 3 – Prescription Drug Monitoring Program

3.1 Authority

These regulations are promulgated pursuant to the authority set forth in R.I. Gen. Laws §§ 21-28-3.18(d)(2) and 21-28-3.32, 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, IV, and V controlled substances, and opioid antagonists.

3.2 Exemption

Pharmacies that do not have a Rhode Island Controlled Substance Registration (CSR) pursuant to R.I. Gen. Laws § 21-28-3.02(a) are not required to report the dispensing of schedules II, III, IV, V, and opioid antagonists to the prescription drug monitoring program.

3.3 Definitions

A. Wherever used in these regulations, the following terms shall be construed as follows:

1. "Controlled substance" means a drug, substance, or immediate precursor in Schedules I-V of R.I. Gen. Laws 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 R.I. Gen. Laws Chapter 3-1, nor tobacco.

2. “Department" means the Rhode Island Department of Health.

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.

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.

5. “Pharmacy” means that portion or part of a premise where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription or legend drugs.

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.

3.4 General Requirements

A. A pharmacy licensed as a retail pharmacy that dispenses schedule II, III, IV, or V controlled substances and opioid antagonists shall transmit prescription dispensing data for these substances to the Department in accordance with §§ 3.5(A) and (B) of this Part.

1. A pharmacy licensed as an institutional pharmacy that dispenses schedule II, III, IV, or V controlled substances and opioid antagonists shall transmit prescription dispensing data for these substances to the Department when dispensed to outpatients only and shall not be required to submit zero fill reports.

a. A pharmacy that possesses a Rhode Island Controlled Substance Registration (CSR) pursuant to R.I. Gen. Laws § 21-28-3.02(a) which does not dispense any controlled substances shall report “zero fills,” every twenty-four (24) hours.

b. Any pharmacy that does not possess a Rhode Island Controlled Substance Registration (CSR) is not required to submit “zero fills” reports.

2. A pharmacy licensed as a non-resident pharmacy shall be considered a pharmacy for the purpose of compliance with the reporting requirements of this Part.

3.5 Reporting and Management of Information

A. A pharmacy that dispenses schedule II, III, IV, or V controlled substances or opioid antagonists to a person, who is not an inpatient of a hospital, shall transmit electronically to the Department the following information:

1. Pharmacy Drug Enforcement Administration identification number;

2. Patient last name;

3. Patient first name;

4. Patient street address, including zip code;

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.

B. A pharmacy licensed as a retail pharmacy or a nonresident 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.

1. Pursuant to R.I. Gen. Laws § 21-28-3.18(n), A pharmacy shall transmit the information required pursuant to this Part one (1) business day following the date of dispensing.

2. A pharmacy shall transmit the information required pursuant to this Part 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).

3. Notification to the prescribing physician by the pharmacist for refusal to fill a prescription is pursuant to R.I. Gen. Laws § 21-28-3.32(k).

3.6 Management of Information.

A. The Department shall only disclose information obtained pursuant to this Part in accordance with R.I. Gen. Laws § 21-28-3.32(a).

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 R.I. Gen. Laws § 5-37.3-5(c).

C. Maintenance of records of information disclosed is pursuant to R.I. Gen. Laws § 21-28-3.32(e).

D. Removal of prescription information contained within the prescription drug monitoring database is pursuant to R.I. Gen. Laws § 21-28-3.32(f).

E. Notification of improper disclosure is pursuant to R.I. Gen. Laws § 21-28-3.32(g).

F. Notification to patients of the prescription drug monitoring program is pursuant to R.I. Gen. Laws § 21-28-3.32(h).

G. Department disclosure of information to patients is pursuant to R.I. Gen. Laws § 21-28-3.32(c).

3.7 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.

1. No person shall access information in the prescription monitoring database except to the extent and for the purposes authorized by § 3.6(A) of this Part.

3.8 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.

3.9 Delegation of Access to the Electronic Prescription Database

A. Notwithstanding the provisions of § 3.6(A) of this Part, 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 the requirements of R.I. Gen. Laws § 21-28-3.3.32(a)(3) are satisfied.

B. 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.

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