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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2017

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A N A C T

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Representative Joseph M. McNamara

Date Introduced: February 15, 2017

Referred To: House Health, Education & Welfare

(Attorney General)

It is enacted by the General Assembly as follows:

SECTION 1. Sections 21-28-1.2 and 21-28-3.32 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" are hereby amended to read as follows:

21-28-1.02. Definitions.

Unless the context otherwise requires, the words and phrases as defined in this section are used in this chapter in the sense given them in the following definitions:

(1) "Administer" refers to the direct application of controlled substances to the body of a patient or research subject by:

(i) A practitioner, or, in his or her presence by his or her authorized agent; or

(ii) The patient or research subject at the direction and in the presence of the practitioner whether the application is by injection, inhalation, ingestion, or any other means.

(2) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, wholesaler, distributor, or dispenser; except that these terms do not include a common or contract carrier or warehouse operator, when acting in the usual and lawful course of the carrier's or warehouse operator's business.

(3) "Apothecary" means a registered pharmacist as defined by the laws of this state and, where the context requires, the owner of a licensed pharmacy or other place of business where controlled substances are compounded or dispensed by a registered pharmacist; and includes registered assistant pharmacists as defined by existing law, but nothing in this chapter shall be construed as conferring on a person who is not registered as a pharmacist any authority, right, or

privilege that is not granted to him or her by the pharmacy laws of the state.

(4) "Automated data processing system" means a system utilizing computer software and hardware for the purposes of record keeping.

(5) "Certified law enforcement prescription drug diversion investigator" means a certified law enforcement officer assigned by their qualified law enforcement agency to investigate prescription drug diversion and who has completed a certification course in prescription drug diversion approved by the director and certified by the police officers commission on standards and training.

~~(5)~~(6) "Computer" means programmable electronic device capable of multi-functions, including, but not limited to, storage, retrieval, and processing of information.

~~(6)~~(7) "Control" means to add a drug or other substance or immediate precursor to a schedule under this chapter, whether by transfer from another schedule or otherwise.

~~(7)~~(8) "Controlled substance" means a drug, substance, immediate precursor, or synthetic drug in schedules I -- V of this chapter. 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.

~~(8)~~(9) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness of them, of a manufacturer, distributor, or dispenser, other than the person or persons who in fact manufactured, distributed, or dispensed the substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, the other manufacturer, distributor, or dispenser, or which substance is falsely purported to be or represented to be one of the controlled substances by a manufacturer, distributor, or dispenser.

~~(9)~~(10) "CRT" means cathode ray tube used to impose visual information on a screen.

~~(10)~~(11) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled substance or imitation controlled substance, whether or not there exists an agency relationship.

~~(11)~~(12) "Department" means the department of health of this state.

~~(12)~~(13) "Depressant or stimulant drug" means:

(i) A drug which contains any quantity of:

(A) Barbituric acid or derivatives, compounds, mixtures, or preparations of barbituric acid; and

(B) "Barbiturate" or "barbiturates" includes all hypnotic and/or somnifacient drugs, whether or not derivatives of barbituric acid, except that this definition shall not include bromides

and narcotics.

(ii) A drug which contains any quantity of:

(A) Amphetamine or any of its optical isomers;

(B) Any salt of amphetamine and/or desoxyephedrine or any salt of an optical isomer of amphetamine and/or desoxyephedrine, or any compound, mixture, or preparation of them.

(iii) A drug which contains any quantity of coca leaves. "Coca leaves" includes cocaine, or any compound, manufacture, salt, derivative, mixture, or preparation of coca leaves, except derivatives of coca leaves, which do not contain cocaine, ecgonine, or substance from which cocaine or ecgonine may be synthesized or made.

(iv) Any other drug or substance which contains any quantity of a substance which the attorney general of the United States, or the director of health, after investigation, has found to have, or by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system.

~~(13)~~(14) "Director" means the director of health.

~~(14)~~(15) "Dispense" means to deliver, distribute, leave with, give away, or dispose of a controlled substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

~~(15)~~(16) "Dispenser" is a practitioner who delivers a controlled substance to the ultimate user or human research subject.

~~(16)~~(17) "Distribute" means to deliver (other than by administering or dispensing) a controlled substance or an imitation controlled substance and includes actual constructive, or attempted transfer. "Distributor" means a person who so delivers a controlled substance or an imitation controlled substance.

~~(17)~~(18) "Downtime" means that period of time when a computer is not operable.

~~(18)~~(19) "Drug addicted person" means a person who exhibits a maladaptive pattern of behavior resulting from drug use, including one or more of the following: impaired control over drug use; compulsive use; and/or continued use despite harm, and craving.

~~(19)~~(20) "Drug Enforcement Administration" means the Drug Enforcement Administration United States Department of Justice or its successor.

~~(20)~~(21) "Federal law" means the Comprehensive Drug Abuse Prevention and Control Act of 1970, (84 stat. 1236) (see generally 21 U.S.C. § 801 et seq.), and all regulations pertaining to that federal act.

~~(21)~~(22) "Hardware" means the fixed component parts of a computer.

~~(22)~~(23) "Hospital" means an institution as defined in chapter 17 of title 23.

~~(23)~~(24) "Imitation controlled substance" means a substance that is not a controlled substance, which by dosage unit, appearance (including color, shape, size, and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance and, which imitation controlled substances contain substances which if ingested, could be injurious to the health of a person. In those cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

(i) Statement made by an owner, possessor, transferor, recipient, or by anyone else in control of the substance concerning the nature of the substance, or its use or effect.

(ii) Statements made by the owner, possessor, or transferor, to the recipient that the substance may be resold for substantial profit.

(iii) Whether the substance is packaged in a manner reasonably similar to packaging of illicit controlled substances.

(iv) Whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable value of the non-controlled substance.

~~(24)~~(25) "Immediate precursor" means a substance:

(i) Which the director of health has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(ii) Which is an immediate chemical intermediary used or likely to be used in the manufacture of those controlled substances; and

(iii) The control of which is necessary to prevent, curtail, or limit the manufacture of that controlled substance.

~~(25)~~(26) "Laboratory" means a laboratory approved by the department of health as proper to be entrusted with controlled substances and the use of controlled substances for scientific and medical purposes and for the purposes of instruction.

~~(26)~~(27) "Marijuana" means all parts of the plant cannabis sativa L., whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the

seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the plant which is incapable of germination.

~~(27)~~(28) "Manufacture" means the production, preparation, propagation, cultivation, compounding, or processing of a drug or other substance, including an imitation controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substance or labeling or relabeling of its container in conformity with the general laws of this state except by a practitioner as an incident to his or her administration or dispensing of the drug or substance in the course of his or her professional practice.

~~(28)~~(29) "Manufacturer" means a person who manufactures but does not include an apothecary who compounds controlled substances to be sold or dispensed on prescriptions.

~~(29)~~(30) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) Opium and opiates.

(ii) A compound, manufacture, salt, derivative, or preparation of opium or opiates.

(iii) A substance (and any compound, manufacture, salt, derivative, or preparation of it) which is chemically identical with any of the substances referred to in paragraphs (i) and (ii) of this subdivision.

(iv) Any other substance which the attorney general of the United States, or his or her successor, or the director of health, after investigation, has found to have, and by regulation designates as having, a potential for abuse similar to opium and opiates.

~~(30)~~(31) "Official written order" means an order written on a form provided for that purpose by the Drug Enforcement Administration under any laws of the United States making provision for an official form, if order forms are authorized and required by federal law, and if no order form is provided then on an official form provided for that purpose by the director of health.

~~(31)~~(32) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

~~(32)~~(33) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.

~~(33)~~(34) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a

fluid ounce as applied to liquids.

~~(34)~~(35) "Person" means any corporation, association, partnership, or one or more individuals.

~~(35)~~(36) "Physical dependence" means a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

~~(36)~~(37) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

~~(37)~~(38) "Practitioner" means:

(i) A physician, osteopath, dentist, chiropodist, veterinarian, scientific investigator, or other person licensed, registered or permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(ii) A pharmacy, hospital, or other institution licensed, registered or permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

~~(38)~~(39) "Printout" means a hard copy produced by computer that is readable without the aid of any special device.

~~(39)~~(40) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(41) "Qualified law enforcement agency" means a local, state, and federal law enforcement agency or the medical fraud unit in the office of the attorney general that has a certified law enforcement prescription drug diversion investigator and a chief or law enforcement chief executive officer who has successfully completed a certification course in prescription drug diversion approved by the director and certified by the police officers commission on standards and training.

~~(40)~~(42) "Researcher" means a person authorized by the director of health to conduct a laboratory as defined in this chapter.

~~(41)~~(43) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another, or to offer or agree to do the same.

~~(42)~~(44) "Software" means programs, procedures and storage of required information data.

~~(43)~~(45) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in schedule I.

~~(44)~~(46) "Ultimate user" means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household, or for administering to an animal owned by him or her or by a member of his or her household.

~~(45)~~(47) "Wholesaler" means a person who sells, vends, or distributes at wholesale, or as a jobber, broker agent, or distributor, or for resale in any manner in this state any controlled substance.

21-28-3.32. Electronic prescription database.

(a) The information contained in any prescription-drug-monitoring database maintained by the department of health pursuant to § 21-28-3.18 of this chapter shall be disclosed only:

(1) To a practitioner who certifies that the requested information is for the purpose of evaluating the need for, or providing medical treatment to, 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) To 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:

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

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

(iii) The practitioner or pharmacist remains responsible for ensuring that access to the database by the designee is limited to authorized purposes as provided for in subsections (a)(1) and (a)(2);

(iv) 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;

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

(vi) 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.

(4) 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;

(5) To a certified law enforcement prescription drug diversion investigator of a qualified law enforcement agency.

(i) A certified law enforcement prescription drug diversion investigator shall provide to the department the following information in order to be granted access:

(A) The identification credentials assigned by the department; and

(B) The case number of the investigation.

(ii) A qualified law enforcement agency shall submit to the department an annual report of the data accessed by all certified law enforcement prescription drug diversion investigators in the qualified law enforcement agency, including, without limitation:

(A) Written verification that the inquiries were part of a lawful prescription drug diversion investigation as provided to the department through the case number of the investigation; and

(B) The disposition of the investigation.

(iii) The department shall:

(A) Create a verification form for use under subsection (5)(ii)(A) of this section; and

(B) Make the verification form available annually to the qualified law enforcement agency.

(iv) The verification form under subsection (5)(ii)(A) of this section shall be submitted to the department within thirty (30) days of receipt of the form by the qualified law enforcement agency.

(v) Failure to submit a verification form under subsection (5)(iv) of this section shall result in the immediate suspension of the access to the database by the qualified law enforcement agency and its certified law enforcement prescription drug diversion investigators until a determination is made by the department to allow continued access.

~~(5)~~(6) 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;

~~(6)~~(7) 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;

~~(7)~~(8) To any vendor or contractor with whom the department has contracted, pursuant to state purchasing law and regulations in the contracting of vendors, to establish or maintain the electronic system of the prescription-drug-monitoring database;

~~(8)~~(9) 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; or

~~(9)~~(10) To any vendor, agent, contractor, or designee who operates an electronic health record or clinical-management system for the purpose of sharing data with practitioners, pharmacists, or licensed health care facilities or designees.

(b) Information stored in the prescription-drug-monitoring database shall include only the following:

(1) Patient's first and last name and/or patient identification number; provided, however, the patient's social security number shall not be recorded in whole or in part, patient sex, patient date of birth, and patient address;

(2) Prescribing practitioner's name and Drug Enforcement Administration prescriber-information number;

(3) Prescribing practitioner's office or hospital contact information;

(4) Prescription name, prescription number, prescription species code, national drug code number, prescription dosage, prescription quantity, days' supply, new-refill code, number of refills authorized, date the prescription was written, date the prescription was filled, payment type; provided, however, no credit card number shall be recorded in whole or in part; and

(5) The Drug Enforcement Administration pharmacy number of the pharmacy filling the prescription.

(c) The department shall 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 shall include the records maintained by the department pursuant to subsection (e). Notwithstanding the above, 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 that has been confirmed by the department, the disclosure to the patient that information has been obtained pursuant to ~~subdivision~~ subsections (a)(4) and (a)(5) of this section.

(d) 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 § 5-37.3-5(c).

(e) 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 subsection (a); and

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

(f) 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. Records in existence prior to the enactment of this section shall be removed no later than ten (10) years from the date the information is entered into the database.

(g) 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.

(h) At the time of signing a prescription that is required by the department to be entered into the prescription-drug-monitoring database, the prescribing practitioner shall inform the patient in writing of the existence of the prescription-drug-monitoring database; the patient's right to access his or her own prescription information; and the name and contact information of the agency operating the program.

(i) No person shall access information in the prescription-monitoring-database except to the extent and for the purposes authorized by subsection (a).

(j) In any civil action allowing a violation of this chapter, the court may award damages, including punitive damages, and reasonable attorneys' fees and costs to a prevailing plaintiff, and injunctive and any other appropriate relief.

(k) 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.

(l) All practitioners shall, as a condition of the initial registration or renewal of the practitioner's authority to prescribe controlled substances, register with the prescription-drug-monitoring database maintained by the department of health.

(m) The prescription-monitoring program shall be reviewed prior to starting any opioid. A prescribing practitioner, or designee as authorized by subsection (a)(3) of this section, shall review the prescription-monitoring program prior to refilling or initiating opioid therapy with an intrathecal pump. For patients the prescribing practitioner is maintaining on continuous opioid

therapy for pain for three (3) months or longer, the prescribing practitioner shall review information from the prescription-monitoring program at least every three (3) months. Documentation of that review shall be noted in the patient's medical record.

(n) The department shall improve the usefulness and value of the prescription-drug-monitoring database program by increasing its analytical functionality, timeliness, and scope, such as by:

(1) Utilizing data from additional data sources as permissible under state and federal statutes;

(2) Analyzing information submitted to the prescription-drug-monitoring database to ensure that prescription data collected from dispensing pharmacists is readily accessible for a given patient; to identify unusual or aberrant patterns of prescribing, dispensing, or receiving controlled substances; and to generate an automatic alert when such patterns arise to automate standard reports and to provide ad hoc reports on a real-time basis on this data as well as other data feeds. These reports shall comply with the patient confidentiality requirements of federal and state law;

(3) Developing regulations to ensure that prescription-drug-monitoring analyses are updated and disseminated regularly to appropriate officials and that summary reports are provided to the general assembly on or before February 1st of each year. Given the intent to decrease the number of Rhode Island citizens affected by opioid use, the department shall provide an interim report on the status of the directives included herein and any progress made as of October 1, 2016. In the development of said regulations, the department may include any of the following analytical functions, within the boundaries of patient confidentiality rights under state and federal law:

(i) Consolidate raw prescription data collected from dispensing pharmacists into a single view of all prescriptions filled for a given patient;

(ii) Identify unusual or aberrant patterns of prescribing controlled substances, by relevant prescriber attributes, and generate an automatic alert when such patterns arise;

(iii) Identify unusual or aberrant patterns of receiving prescriptions for controlled substances, by relevant patient attributes, and generate an automatic alert when such patterns arise;

(iv) Identify unusual or aberrant patterns of dispensing controlled substances, by relevant dispenser attributes, and generate an automatic alert when such patterns arise;

(v) Identify and visually display linkages among prescribers, patients, and dispensers that can be used to detect any collusive behaviors; and

(vi) The department shall apply for federal funding in support of the goals and objectives contained in this subsection.

SECTION 2. This act shall take effect on January 1, 2018.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

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This act would allow information contained in the prescription drug monitoring database to be disclosed to a certified law enforcement drug diversion investigator of a qualified law enforcement agency who has completed a certification course approved by director of the department of health and certified by the police officers commission on standards and training.

This act would take effect on January 1, 2018.

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