2017 -- H 5469 SUBSTITUTE A

LC001228/SUB A _____

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2017

AN ACT

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:

- 1 SECTION 1. Sections 21-28-1.2 and 21-28-3.32 of the General Laws in Chapter 21-28 2 entitled "Uniform Controlled Substances Act" are hereby amended to read as follows: 3 21-28-1.02. Definitions.
- 4 Unless the context otherwise requires, the words and phrases as defined in this section are 5 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 6 7 patient or research subject by:
- 8

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

- 9 (ii) The patient or research subject at the direction and in the presence of the practitioner 10 whether the application is by injection, inhalation, ingestion, or any other means.
- 11

(2) "Agent" means an authorized person who acts on behalf of or at the direction of a 12 manufacturer, wholesaler, distributor, or dispenser; except that these terms do not include a 13 common or contract carrier or warehouse operator, when acting in the usual and lawful course of 14 the carrier's or warehouse operator's business.

15 (3) "Apothecary" means a registered pharmacist as defined by the laws of this state and, 16 where the context requires, the owner of a licensed pharmacy or other place of business where 17 controlled substances are compounded or dispensed by a registered pharmacist; and includes 18 registered assistant pharmacists as defined by existing law, but nothing in this chapter shall be 19 construed as conferring on a person who is not registered as a pharmacist any authority, right, or

- 1 privilege that is not granted to him or her by the pharmacy laws of the state.
- 2 (4) "Automated data processing system" means a system utilizing computer software and
 3 hardware for the purposes of record keeping.
- 4 (5) "Certified law enforcement prescription drug diversion investigator" means a certified
- 5 law enforcement officer assigned by their qualified law enforcement agency to investigate

6 prescription drug diversion.

7 (5)(6) "Computer" means programmable electronic device capable of multi-functions,
8 including, but not limited to, storage, retrieval, and processing of information.

9 (6)(7) "Control" means to add a drug or other substance or immediate precursor to a
 10 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.

14 (8)(9) "Counterfeit substance" means a controlled substance which, or the container or 15 labeling of which, without authorization bears the trademark, trade name, or other identifying 16 mark, imprint, number, or device, or any likeness of them, of a manufacturer, distributor, or 17 dispenser, other than the person or persons who in fact manufactured, distributed, or dispensed 18 the substance and which thereby falsely purports or is represented to be the product of, or to have 19 been distributed by, the other manufacturer, distributor, or dispenser, or which substance is 20 falsely purported to be or represented to be one of the controlled substances by a manufacturer, 21 distributor, or dispenser.

22 (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.

- 26 (11)(12) "Department" means the department of health of this state.
- 27 (12)(13) "Depressant or stimulant drug" means:
- 28 (i) A drug which contains any quantity of:

29 (A) Barbituric acid or derivatives, compounds, mixtures, or preparations of barbituric30 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.

34 (ii) A drug which contains any quantity of:

1 (A) Amphetamine or any of its optical isomers;

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

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

8 (iv) Any other drug or substance which contains any quantity of a substance which the 9 attorney general of the United States, or the director of health, after investigation, has found to 10 have, or by regulation designates as having, a potential for abuse because of its depressant or 11 stimulant effect on the central nervous system.

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

13 (14)(15) "Dispense" means to deliver, distribute, leave with, give away, or dispose of a 14 controlled substance to the ultimate user or human research subject by or pursuant to the lawful 15 order of a practitioner, including the packaging, labeling, or compounding necessary to prepare 16 the substance for that delivery.

17 (15)(16) "Dispenser" is a practitioner who delivers a controlled substance to the ultimate
 18 user or human research subject.

19 (16)(17) "Distribute" means to deliver (other than by administering or dispensing) a 20 controlled substance or an imitation controlled substance and includes actual constructive, or 21 attempted transfer. "Distributor" means a person who so delivers a controlled substance or an 22 imitation controlled substance.

23 (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.

27 (19)(20) "Drug Enforcement Administration" means the Drug Enforcement
 28 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.

33 (22)(23) "Hospital" means an institution as defined in chapter 17 of title 23.

34 (23)(24) "Imitation controlled substance" means a substance that is not a controlled

1 substance, which by dosage unit, appearance (including color, shape, size, and markings), or by 2 representations made, would lead a reasonable person to believe that the substance is a controlled 3 substance and, which imitation controlled substances contain substances which if ingested, could 4 be injurious to the health of a person. In those cases when the appearance of the dosage unit is not 5 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 6 7 addition to all other logically relevant factors, the following factors as related to "representations 8 made" in determining whether the substance is an "imitation controlled substance":

9 (i) Statement made by an owner, possessor, transferor, recipient, or by anyone else in
10 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 thesubstance may be resold for substantial profit.

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

15 (iv) Whether the distribution or attempted distribution included an exchange of or 16 demand for money or other property as consideration, and whether the amount of the 17 consideration was substantially greater than the reasonable value of the non-controlled substance.

18 (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 themanufacture of those controlled substances; and

24 (iii) The control of which is necessary to prevent, curtail, or limit the manufacture of that25 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.

29 (26)(27) "Marijuana" means all parts of the plant cannabis sativa L., whether growing or 30 not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, 31 manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not 32 include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the 33 seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of 34 mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the 1 plant which is incapable of germination.

2 (27)(28) "Manufacture" means the production, preparation, propagation, cultivation, 3 compounding, or processing of a drug or other substance, including an imitation controlled 4 substance, either directly or indirectly or by extraction from substances of natural origin, or 5 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 6 7 its container in conformity with the general laws of this state except by a practitioner as an 8 incident to his or her administration or dispensing of the drug or substance in the course of his or 9 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:

15 (i) Opium and opiates.

16 (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.

23 (30)(31) "Official written order" means an order written on a form provided for that 24 purpose by the Drug Enforcement Administration under any laws of the United States making 25 provision for an official form, if order forms are authorized and required by federal law, and if no 26 order form is provided then on an official form provided for that purpose by the director of health. 27 (31)(32) "Opiate" means any substance having an addiction-forming or addiction-28 sustaining liability similar to morphine or being capable of conversion into a drug having 29 addiction-forming or addiction-sustaining liability.

30 (32)(33) "Opium poppy" means the plant of the species papaver somniferum L., except
 31 the seeds of the plant.

32 (33)(34) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a
 fluid ounce as applied to liquids.

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

1 individuals.

2 (35)(36) "Physical dependence" means a state of adaptation that is manifested by a drug
3 class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose
4 reduction, decreasing blood level of the drug, and/or administration of an antagonist.

5 (36)(37) "Poppy straw" means all parts, except the seeds, of the opium poppy, after
6 mowing.

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(37)(38) "Practitioner" means:

8 (i) A physician, osteopath, dentist, chiropodist, veterinarian, scientific investigator, or 9 other person licensed, registered or permitted to distribute, dispense, conduct research with 10 respect to or to administer a controlled substance in the course of professional practice or research 11 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.

17 (39)(40) "Production" includes the manufacture, planting, cultivation, growing, or
 18 harvesting of a controlled substance.

(41) "Qualified law enforcement agency" means the U.S. Food and Drug Administration,
 Drug Enforcement Administration, Federal Bureau of Investigation, Office of Inspector General

20 Drug Enforcement Administration, Federal Bureau of Investigation, Office of Inspector General

21 of the U.S. Department of Health & Human Services, or the Medicaid Fraud and Patient Abuse

22 <u>Unit in the Office of the Attorney General.</u>

23 (40)(42) "Researcher" means a person authorized by the director of health to conduct a
 24 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.

27 (42)(44) "Software" means programs, procedures and storage of required information
 28 data.

29 (43)(45) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any
 30 synthetic cathinones as provided for in schedule I.

31 (44)(46) "Ultimate user" means a person who lawfully possesses a controlled substance
32 for his or her own use or for the use of a member of his or her household, or for administering to
33 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

1 a jobber, broker agent, or distributor, or for resale in any manner in this state any controlled

2 substance.

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21-28-3.32. Electronic prescription database.

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

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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 to, a current patient to whom the practitioner is prescribing or considering prescribing a controlled substance;

9 (2) To a pharmacist who certifies that the requested information is for a current client to 10 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:

14 (i) The designee so authorized is employed by the same professional practice or15 pharmacy;

(ii) The practitioner or pharmacist takes reasonable steps to ensure that such designee issufficiently 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;

32 (5) By a department employee to a certified law enforcement prescription drug diversion
 33 investigator of a qualified law enforcement agency for use in an investigation.

34 (i) A certified law enforcement prescription drug diversion investigator shall provide to

1	the department the following information in order to receive information from the database:
2	(A) The identification credentials assigned by the department; and
3	(B) The case number of the investigation.
4	(ii) A qualified law enforcement agency shall submit to the department quarterly reports
5	of the data received by all certified law enforcement prescription drug diversion investigators in
6	the qualified law enforcement agency, including, without limitation:
7	(A) Written verification that the inquiries were part of a lawful prescription drug
8	diversion investigation as provided to the department through the case number of the
9	investigation; and
10	(B) A brief description of each case closed during that quarter for which the qualified law
11	enforcement agency used information from the database; and
12	(C) The disposition of the investigation.
13	(iii) The department shall:
14	(A) Create a verification form for use under subsection (5)(ii)(A) of this section; and
15	(B) Make the verification form available annually to the qualified law enforcement
16	agency.
17	(iv) The verification form under subsection (5)(ii)(A) of this section shall be submitted to
18	the department within thirty (30) days of receipt of the form by the qualified law enforcement
19	agency.
20	(v) Failure to submit a verification form under subsection (5)(iv) of this section shall
21	result in the immediate suspension of disclosure of information from the database by the
22	department to the qualified law enforcement agency and its certified law enforcement prescription
23	drug diversion investigators until a determination is made by the department to allow continued
24	disclosure.
25	(vi) The director shall, beginning January 1, 2018 and annually thereafter, review
26	disclosure of information pursuant to subsection (a)(5) of this section. Thereafter, the disclosure
27	of information pursuant to subsection (a)(5) of this section shall automatically renew for
28	successive one year terms unless the director provides written notice to:
29	(A) The qualified law enforcement agencies; and
30	(B) The speaker of the house and the president of the senate, at least sixty (60) days in
31	advance of the then existing term's end, that the department wishes to discontinue providing
32	information from the database pursuant to this subsection, the director may reinstitute disclosure
33	by providing written notice to the same parties.
34	(5)(6) To a patient who requests his or her own prescription information, or the parent or

1 legal guardian of a minor child who requests the minor child's prescription information;

2 (6)(7) To a health professional regulatory board that documents, in writing, that the 3 requested information is necessary for an investigation related to licensure, renewal, or 4 disciplinary action involving the applicant, licensee, or registrant to whom the requested 5 information pertains;

6 (7)(8) To any vendor or contractor with whom the department has contracted, pursuant to
7 state purchasing law and regulations in the contracting of vendors, to establish or maintain the
8 electronic system of the prescription-drug-monitoring database;

9 (8)(9) To public or private entities for statistical, research, or educational purposes, after
10 removing the patient and prescriber information that could be used to identify individual patients.
11 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 thefollowing:

(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;

20 (2) Prescribing practitioner's name and Drug Enforcement Administration prescriber 21 information number;

22 (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 theprescription.

(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

1 investigation that has been confirmed by the department, the disclosure to the patient that 2 information has been obtained pursuant to subdivision subsections (a)(4) and (a)(5) of this 3 section.

4 (d) A patient may request, from the dispensing pharmacy, correction of any inaccurate 5 information contained within the prescription-drug-monitoring database in accordance with the procedure specified by § 5-37.3-5(c). 6

7 (e) The department shall, for the period of time that prescription information is 8 maintained, maintain records of the information disclosed through the prescription-drug-9 monitoring database, including, but not limited to:

10 (1) The identity of each person who requests or receives information from the 11 prescription-drug-monitoring database and the organization, if any, the person represents;

12 (2) The information released to each person or organization and the basis for its release 13 under subsection (a); and

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

15 (f) Prescription information contained within the prescription-drug-monitoring database 16 shall be removed no later than five (5) years from the date the information is entered into the 17 database. Records in existence prior to the enactment of this section shall be removed no later 18 than ten (10) years from the date the information is entered into the database.

19 (g) The department shall promptly notify any affected individual of an improper 20 disclosure of information from the prescription-drug-monitoring database or a breach in the 21 security of the prescription-drug-monitoring database that poses a significant risk of disclosure of 22 patient information to an unauthorized individual.

23 (h) At the time of signing a prescription that is required by the department to be entered 24 into the prescription-drug-monitoring database, the prescribing practitioner shall inform the 25 patient in writing of the existence of the prescription-drug-monitoring database; the patient's right 26 to access his or her own prescription information; and the name and contact information of the 27 agency operating the program.

28 (i) No person shall access information in the prescription-monitoring-database except to 29 the extent and for the purposes authorized by subsection (a).

30 (j) In any civil action allowing a violation of this chapter, the court may award damages, 31 including punitive damages, and reasonable attorneys' fees and costs to a prevailing plaintiff, and 32 injunctive and any other appropriate relief.

33 (k) Any pharmacist who, in his or her professional judgment, refuses to fill a prescription 34 based on information contained within the prescription-drug-monitoring database shall inform the 1 prescribing physician within twenty-four (24) hours.

2 (1) All practitioners shall, as a condition of the initial registration or renewal of the
3 practitioner's authority to prescribe controlled substances, register with the prescription-drug4 monitoring database maintained by the department of health.

5 (m) The prescription-monitoring program shall be reviewed prior to starting any opioid. 6 A prescribing practitioner, or designee as authorized by subsection (a)(3) of this section, shall 7 review the prescription-monitoring program prior to refilling or initiating opioid therapy with an 8 intrathecal pump. For patients the prescribing practitioner is maintaining on continuous opioid 9 therapy for pain for three (3) months or longer, the prescribing practitioner shall review 10 information from the prescription-monitoring program at least every three (3) months. 11 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;

17 (2) Analyzing information submitted to the prescription-drug-monitoring database to 18 ensure that prescription data collected from dispensing pharmacists is readily accessible for a 19 given patient; to identify unusual or aberrant patterns of prescribing, dispensing, or receiving 20 controlled substances; and to generate an automatic alert when such patterns arise to automate 21 standard reports and to provide ad hoc reports on a real-time basis on this data as well as other 22 data feeds. These reports shall comply with the patient confidentiality requirements of federal and 23 state law;

24 (3) Developing regulations to ensure that prescription-drug-monitoring analyses are 25 updated and disseminated regularly to appropriate officials and that summary reports are provided 26 to the general assembly on or before February 1st of each year. Given the intent to decrease the 27 number of Rhode Island citizens affected by opioid use, the department shall provide an interim 28 report on the status of the directives included herein and any progress made as of October 1, 29 2016. In the development of said regulations, the department may include any of the following 30 analytical functions, within the boundaries of patient confidentiality rights under state and federal 31 law:

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

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(ii) Identify unusual or aberrant patterns of prescribing controlled substances, by relevant

1 prescriber attributes, and generate an automatic alert when such patterns arise;

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

- 5 (iv) Identify unusual or aberrant patterns of dispensing controlled substances, by relevant
- 6 dispenser attributes, and generate an automatic alert when such patterns arise;
- 7 (v) Identify and visually display linkages among prescribers, patients, and dispensers that
- 8 can be used to detect any collusive behaviors; and
- 9 (vi) The department shall apply for federal funding in support of the goals and objectives
- 10 contained in this subsection.
- 11 SECTION 2. This act shall take effect on January 1, 2018 and the amendments hereto
- 12 <u>shall expire on January 1, 2023</u>.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

AN ACT

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

1 This act would allow information contained in the prescription drug monitoring database 2 to be disclosed to a certified law enforcement drug diversion investigator of a qualified law 3 enforcement agency who has completed a certification course approved by director of the 4 department of health and certified by the police officers commission on standards and training. 5 This act would take effect on January 1, 2018 and the amendments hereto would expire

6 on January 1, 2023.

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