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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. 2025

A N A C T

RELATING TO FOOD AND DRUGS -- UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Representative Matthew S. Dawson

Date Introduced: February 26, 2025

Referred To: House Health & Human Services

(Dept. of Health)

It is enacted by the General Assembly as follows:

SECTION 1. Sections 21-28-1.02, 21-28-3.20 and 21-28-3.20.1 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. [Effective January 1, 2023; see Sunset Provision note.]

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) “Acute pain” means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain is generally pain of less than thirty (30) days duration.

~~(1)~~(2) “Administer” refers to the direct application of controlled substances to the body of a patient or research subject by:

(i) ~~A practitioner~~ Practitioners, or, in ~~his or her~~ their presence by ~~his or her~~ their 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)~~(3) “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)~~(4) “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)~~(5) “Automated data processing system” means a system utilizing computer software and hardware for the purposes of record keeping.

(6) “Chronic intractable pain” means pain that is: excruciating; constant; incurable, and of such severity that it dominates virtually every conscious moment; and/or produces mental and physical debilitation. A diagnosis and written documentation of chronic intractable pain made by a physician licensed in the State of Rhode Island specializing in pain management, oncology, or similar specialty defined in regulations shall constitute proof that the patient suffers from chronic intractable pain.

(7) “Chronic pain” means pain of greater than ninety (90) days duration, excluding chronic intractable pain.

~~(5)~~(8) “Computer” means programmable electronic device capable of multi-functions, including, but not limited to: storage, retrieval, and processing of information.

~~(6)~~(9) “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)(10) “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)~~(11) “Co-prescribing” means issuing a prescription for an opioid antagonist along with a prescription for an opioid analgesic.

~~(9)~~(12) “Counterfeit substance” means a controlled substance that, 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 that 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.

~~(10)~~(13) “CRT” means cathode ray tube used to impose visual information on a screen.

~~(11)~~(14) “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.

~~(12)~~(15) "Department" means the department of health of this state.

~~(13)~~(16) "Depressant or stimulant drug" means:

(i) A drug that 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 that 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 that 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, that do not contain cocaine, ecgonine, or substance from which cocaine or ecgonine may be synthesized or made.

(iv) Any other drug or substance that contains any quantity of a substance that 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.

~~(14)~~(17) "Director" means the director of health.

~~(15)~~(18) "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.

~~(16)~~(19) "Dispenser" is a practitioner who delivers a controlled substance to the ultimate user or human research subject.

~~(17)~~(20) "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.

~~(18)~~(21) "Downtime" means that period of time when a computer is not operable.

~~(19)~~(22) “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.

~~(20)~~(23) “Drug Enforcement Administration” means the Drug Enforcement Administration, United States Department of Justice or its successor.

~~(21)~~(24) “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.

~~(22)~~(25) “Hardware” means the fixed component parts of a computer.

~~(23)~~(26) “Hospital” means an institution as defined in chapter 17 of title 23.

~~(24)~~(27) “Imitation controlled substance” means a substance that is not a controlled substance, that 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 that 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.

~~(25)~~(28) “Immediate precursor” means a substance:

(i) That 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) That 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.

~~(26)~~(29) "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.

~~(27)~~(30) "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)~~(31) "Manufacturer" means a person who manufactures but does not include an apothecary who compounds controlled substances to be sold or dispensed on prescriptions.

~~(29)~~(32) "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. Marijuana shall not include "industrial hemp" or "industrial hemp products" which satisfy the requirements of chapter 26 of title 2, nor shall it include products that have been approved for marketing as a prescription medication by the U.S. Food and Drug Administration and legally prescribed.

~~(30)~~(33) "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) that is chemically identical with any of the substances referred to in subsections (30)(i) and (30)(ii).

(iv) Any other substance that 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.

~~(31)~~(34) "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.

~~(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.~~

~~(33)~~(35) "Opioid ~~analgesics~~" means and includes, but is not limited to, the ~~medicines buprenophine,~~ medications butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, pentazocine, propoxyphene as well as their brand names, isomers, and combinations, or other medications approved by the department.

~~(34)~~(36) "Opioid antagonist" means naloxone hydrochloride and any other drug approved by the United States Food and Drug Administration for the treatment of opioid overdose.

(37) "Opioid therapy" means to prescribe, administer, or dispense controlled substances not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition by any route of administration.

~~(35)~~(38) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.

~~(36)~~(39) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a fluid ounce as applied to liquids.

~~(37)~~(40) "Person" means any corporation, association, partnership, or one or more individuals.

~~(38)~~(41) "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.

~~(39)~~(42) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

~~(40)~~(43) "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.

~~(41)~~(44) "Printout" means a hard copy produced by computer that is readable without the aid of any special device.

~~(42)~~(45) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

~~(43)~~(46) "Researcher" means a person authorized by the director of health to conduct a laboratory as defined in this chapter.

~~(44)~~(47) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another, or to offer or agree to do the same.

~~(45)~~(48) "Software" means programs, procedures, and storage of required information data.

~~(46)~~(49) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in schedule I.

(50) "Therapeutic purpose" means the use of controlled substances for the treatment of pain in appropriate doses as indicated by the patient's medical record. Any other use is nontherapeutic.

~~(47)~~(51) "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.

~~(48)~~(52) "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.

21-28-3.20. Authority of practitioner to prescribe, administer, and dispense.

(a)(1) ~~A practitioner~~ Practitioners, in good faith and in the course of ~~his or her~~ their professional practice only, may prescribe, administer, and dispense controlled substances, or ~~he or she~~ may cause the controlled substances to be administered ~~by a nurse or intern~~ under ~~his or her~~ their direction ~~and supervision~~ after completing an assessment of pain experienced by a patient.

(2) Opioid therapy must only be initiated for acute pain unresponsive to non-opioid therapies or if, based on clinical assessment, benefits of opioid therapy for acute pain management outweigh risks.

~~(2)~~(3) When issuing ~~an initial~~ a prescription for an ~~opiate~~ opioid to an adult patient, a practitioner ~~shall not exceed the maximum daily dose requirements established by the department of health~~ must prescribe the lowest effective dosage of an immediate-release opioid in a quantity

sufficient to treat the expected duration of pain. A practitioner shall not write an initial prescription for an opioid in a quantity exceeding a seven (7)-day supply for treatment of acute pain.

~~(3)~~(4) Except as provided in subsection (a)(4) of this section, a practitioner shall not issue an opiate prescription to a minor for more than twenty (20) doses at any time. Prior to issuing an opiate prescription to a minor, a practitioner shall discuss with the parent or guardian of the minor the risks associated with opiate use and the reasons why the prescription is necessary. The practitioner shall document his or her discussion with the parent or guardian in the medical record.

~~(4)~~(5) ~~Notwithstanding the limitations referenced in subsection (a)(3) of this section, if, in the professional medical judgment of a practitioner, a greater dosage or supply of an opiate is required to treat the minor patient's acute medical condition or is necessary for the treatment of chronic pain management, sickle cell related pain, intractable pain treatment as defined in chapter 37.4 of title 5, pain associated with a cancer diagnosis, or for palliative care, then the practitioner may issue a prescription for the quantity needed to treat the acute medical condition, chronic pain, sickle cell related pain, intractable pain, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care, provided that this dosage shall not exceed the maximum daily dosage permitted for the treatment of this pain as set forth in the department of health regulations.~~ The medical condition triggering the prescription of an ~~opiate shall~~ opioid must be documented in the ~~minor~~ patient's medical record, and the practitioner ~~shall~~ must indicate that a ~~non-opiate~~ non-opioid alternative was not appropriate to address the medical condition.

~~(5) Notwithstanding subsections (a)(2) and (a)(3) of this section, this section shall not apply to medications designed for the treatment of substance abuse or opioid dependence.~~

(b) The prescription ~~monitoring~~ drug monitoring program ~~shall~~ must be reviewed prior to starting any opioid. A ~~prescribing~~ practitioner, or designee as authorized by § 21-28-3.32(a)(3), ~~shall~~ must review the patient's prescribed controlled substance use in the prescription ~~monitoring~~ drug monitoring program prior to ~~refilling or~~ initiating opioid therapy ~~with an intrathecal pump~~, including opioid therapy delivered through an intrathecal pump. The review must include gathering a history of any prescribed methadone and buprenorphine. For patients ~~the prescribing practitioner is maintaining~~ being maintained on continuous opioid therapy for pain for three (3) months or longer, the ~~prescribing~~ practitioner ~~shall~~ must review information from the prescription ~~monitoring~~ drug monitoring program at least every three (3) months. Documentation of that review ~~shall~~ must be noted in the patient's medical record.

~~(c) The director of health shall develop regulations for prescribing practitioners on appropriate limits of opioid use in acute pain management. Initial prescriptions of opioids for acute pain management of outpatient adults shall not exceed thirty (30) morphine milligram equivalents~~

~~(MMEs) total daily dose per day for a maximum total of twenty (20) doses, and, for pediatric patients, the appropriate opioid dosage maximum per the department of health.~~

~~(d)~~(c) For the purposes of this section, acute pain management ~~shall~~ must not include management or treatment for chronic intractable pain ~~management~~, pain associated with a cancer diagnosis, pain related to sickle cell disease, palliative ~~or nursing home~~ end-of-life care, ~~intractable or chronic intractable pain, as provided in § 5-37.4-2,~~ or other ~~exception~~ exceptions in accordance with department of health regulations.

~~(e) Subsection (c) shall not apply to medications designed for the treatment of substance abuse or opioid dependence.~~

~~(f) On or before September 1, 2018, the director of health shall develop, and make available to healthcare practitioners, information on best practices for co-prescribing opioid antagonists to patients. The best practices information shall identify situations in which co-prescribing an opioid antagonist may be appropriate, including, but not limited to:~~

~~(1) In conjunction with a prescription for an opioid medication, under circumstances in which the healthcare practitioner determines the patient is at an elevated risk for an opioid drug overdose;~~

~~(2) In conjunction with medications prescribed pursuant to a course of medication therapy management for the treatment of a substance use disorder involving opioids; or~~

~~(3) Under any other circumstances in which a healthcare practitioner identifies a patient as being at an elevated risk for an opioid drug overdose.~~

~~(g) The best practices information developed pursuant to subsection (f) of this section shall include guidelines for determining when a patient is at an elevated risk for an opioid drug overdose, including, but not limited to, situations in which the patient:~~

~~(1) Meets the criteria provided in the opioid overdose toolkit published by the federal substance abuse and mental health service administration;~~

~~(2) Is receiving high dose, extended release, or long acting opioid medications;~~

~~(3) Has a documented history of an alcohol or substance use disorder, or a mental health disorder;~~

~~(4) Has a respiratory ailment or other co-morbidity that may be exacerbated by the use of opioid medications;~~

~~(5) Has a known history of intravenous drug use or misuse of prescription opioids;~~

~~(6) Has received emergency medical care or been hospitalized for an opioid overdose; or~~

~~(7) Uses opioids with antidepressants, benzodiazepines, alcohol, or other drugs.~~

~~(h) On or before September 1, 2018, the director of health and the secretary of the executive~~

~~office of health and human services shall develop strategies that include:~~

~~(1) Allowing practitioners in non-pharmacy settings to prescribe and dispense opioid antagonists; and~~

~~(2) Ensuring that opioid antagonists that are distributed in a non-pharmacy setting are eligible for reimbursement from any health insurance carrier, as defined under chapters 18, 19, 20, and 41 of title 27, and the Rhode Island medical assistance program, as defined under chapter 7.2 of title 42.~~

(d) The director of health may promulgate regulations for practitioners on opioid use in pain management.

21-28-3.20.1. Authority of practitioner to prescribe, administer, and dispense — Cancer, palliative care, and chronic intractable pain.

(a) A practitioner~~, in good faith and in the course of his or her professional practice managing pain associated with a cancer diagnosis, palliative or nursing home care, intractable or chronic intractable pain as provided in § 5-37.4-2, or other condition allowed by department of health regulations pursuant to the exception in § 21-28-3.20(d), may prescribe, administer, and dispense controlled substances without regard to the CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022.~~

~~(b) The director of health may promulgate those rules and regulations necessary to effectuate the provisions of this section and ensure that rules governing pain management associated with a cancer diagnosis, palliative or nursing home care, intractable or chronic intractable pain as provided in § 5-37.4-2, or other condition allowed by department of health regulations pursuant to the exception created in § 21-28-3.20(d), shall:~~

~~(1) Take into consideration the individualized needs of patients covered by this section; and~~

~~(2) Make provisions for practitioners, acting in good faith, and in the course of their profession, and managing pain associated with their patients' illness to use their best judgment notwithstanding any statute, rule, or regulation to the contrary.~~ may prescribe, administer, or dispense controlled substances not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in chronic intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records.

(b) Concern about a patient's substance use disorder or the possibility of a substance use disorder in and of itself is not a reason to withhold or prohibit prescribing, administering, or dispensing controlled substances for the therapeutic purpose of treatment of a person for chronic intractable pain. Provided, however, practitioners must check the patient's prescribed controlled

substances use in the prescription drug monitoring program, verify the patient's methadone use, refer the patient to a substance use disorder specialist, as appropriate, and enter into a written patient treatment agreement in accordance with regulations promulgated by the department.

(c) The provisions of subsection (a) of this section provide no authority to a practitioner to prescribe, administer, or dispense controlled substances to a person the practitioner knows or should know to be using the prescribed, administered, or dispensed controlled substance nontherapeutically.

(d) Nothing in this section shall be construed to prohibit a practitioner or pharmacist from denying a prescription based on their best clinical judgment.

(e) Nothing in this section shall deny the right of the director to deny, revoke, or suspend the license of any practitioner or discipline any practitioner who:

(1) Prescribes, administers, or dispenses a controlled substance that is nontherapeutic in nature or nontherapeutic in the manner in which it is prescribed, administered, or dispensed, or fails to keep complete and accurate ongoing records of the diagnosis and treatment plan;

(2) Fails to keep complete and accurate records of controlled substances received, prescribed, dispensed, and administered, and disposal of drugs as required by law or of controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq. A practitioner shall keep records of controlled substances received, prescribed, dispensed and administered, and disposal of these drugs shall include the date of receipt of the drugs, the sale or disposal of the drugs by the practitioner, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person;

(3) Writes false or fictitious prescriptions for controlled substances as prohibited by law, or for controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq.; or

(4) Prescribes, administers, or dispenses in a manner that is inconsistent with provisions of the law, or the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq., any controlled substance.

(f) The director of health may promulgate those rules and regulations necessary to effectuate the provisions of this section.

SECTION 2. Chapter 5-37.4 of the General Laws entitled "Intractable Pain Treatment" is hereby repealed in its entirety.

~~CHAPTER 5-37.4~~

~~Intractable Pain Treatment~~

~~**5-37.4-1. Title.**~~

~~This chapter shall be known and may be cited as the "Intractable Pain Treatment Act."~~

~~**5-37.4-2. Definitions.**~~

~~For purposes of this chapter:~~

~~(1) "Chronic intractable pain" means pain that is: excruciating; constant; incurable, and of such severity that it dominates virtually every conscious moment; and/or produces mental and physical debilitation. A diagnosis and written documentation of chronic intractable pain made by a physician licensed in the state of Rhode Island specializing in pain management, oncology, or similar specialty defined in regulations shall constitute proof that the patient suffers from chronic intractable pain.~~

~~(2) "Director" means the director of the department of health of the state of Rhode Island.~~

~~(3) "Intractable pain" means a pain state that persists beyond the usual course of an acute disease or healing of an injury or results from a chronic disease or condition that causes continuous or intermittent pain over a period of months or years. Unless the context clearly indicates otherwise, the term intractable pain includes chronic intractable pain.~~

~~(4) "Practitioner" means healthcare professionals licensed to distribute, dispense, or administer controlled substances in the course of professional practice as defined in § 21-28-1.02(41).~~

~~(5) "Therapeutic purpose" means the use of controlled substances for the treatment of pain in appropriate doses as indicated by the patient's medical record. Any other use is nontherapeutic.~~

~~**5-37.4-3. Controlled substances.**~~

~~(a) A practitioner may prescribe, administer, or dispense controlled substances not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records. No practitioner shall be subject to disciplinary action by the board solely for prescribing, administering, or dispensing controlled substances when prescribed, administered, or dispensed for a therapeutic purpose for a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records.~~

~~(b) The provisions of subsection (a) of this section do not apply to those persons being treated by a practitioner for chemical dependency because of their use of controlled substances not related to the therapeutic purposes of treatment of intractable pain.~~

~~(c) The provisions of subsection (a) of this section provide no authority to a practitioner to prescribe, administer, or dispense controlled substances to a person the practitioner knows or should know to be using the prescribed, administered, or dispensed controlled substance~~

~~nontherapeutically.~~

~~(d) Drug dependency or the possibility of drug dependency in and of itself is not a reason to withhold or prohibit prescribing, administering, or dispensing controlled substances for the therapeutic purpose of treatment of a person for intractable pain, nor shall dependency relating solely to this prescribing, administering, or dispensing subject a practitioner to disciplinary action by the director.~~

~~(e) In coordination with §§ 21-28-3.20 and 21-28-3.20.1, the director of health may promulgate rules and regulations necessary to effectuate the purpose of this chapter and ensure that patients with intractable or chronic intractable pain are treated or referred to an appropriate specialist.~~

~~(f) Nothing in this section shall be construed to prohibit a practitioner or pharmacist from denying a prescription based on their best clinical judgment.~~

~~(g) Nothing in this section shall deny the right of the director to deny, revoke, or suspend the license of any practitioner or discipline any practitioner who:~~

~~(1) Prescribes, administers, or dispenses a controlled substance that is nontherapeutic in nature or nontherapeutic in the manner in which it is prescribed, administered, or dispensed, or fails to keep complete and accurate ongoing records of the diagnosis and treatment plan;~~

~~(2) Fails to keep complete and accurate records of controlled substances received, prescribed, dispensed, and administered, and disposal of drugs as required by law or of controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq. A practitioner shall keep records of controlled substances received, prescribed, dispensed and administered, and disposal of these drugs shall include the date of receipt of the drugs, the sale or disposal of the drugs by the practitioner, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person;~~

~~(3) Writes false or fictitious prescriptions for controlled substances as prohibited by law, or for controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C § 801 et seq.; or~~

~~(4) Prescribes, administers, or dispenses in a manner which is inconsistent with provisions of the law, or the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq., any controlled substance.~~

~~(h) A practitioner may administer a controlled substance prescribed by a practitioner and not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records. No practitioner shall be subject to disciplinary action by the~~

~~director solely for administering controlled substances when prescribed or dispensed for a therapeutic purpose for a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records of the patient.~~

SECTION 3. Section 21-28-1.02 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" is hereby repealed.

~~**21-28-1.02. Definitions. [Effective until January 1, 2023; see Sunset Provision note.]**~~

~~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 his or her qualified law enforcement agency to investigate prescription drug diversion.~~

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

~~(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.~~

~~(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.~~

~~(9) "Co-prescribing" means issuing a prescription for an opioid antagonist along with a prescription for an opioid analgesic.~~

~~(10) "Counterfeit substance" means a controlled substance that, 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 that 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.~~

~~(11) "CRT" means cathode ray tube used to impose visual information on a screen.~~

~~(12) "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.~~

~~(13) "Department" means the department of health of this state.~~

~~(14) "Depressant or stimulant drug" means:~~

~~(i) A drug that 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 that 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 that 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, that do not contain cocaine, ecgonine, or substance from which cocaine or ecgonine may be synthesized or made.~~

~~(iv) Any other drug or substance that contains any quantity of a substance that 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.~~

~~(15) "Director" means the director of health.~~

~~(16) "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.~~

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

~~(18) "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.~~

~~(19) "Downtime" means that period of time when a computer is not operable.~~

~~(20) "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.~~

~~(21) "Drug Enforcement Administration" means the Drug Enforcement Administration, United States Department of Justice or its successor.~~

~~(22) "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.~~

~~(23) "Hardware" means the fixed component parts of a computer.~~

~~(24) "Hospital" means an institution as defined in chapter 17 of title 23.~~

~~(25) "Imitation controlled substance" means a substance that is not a controlled substance, that 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 that 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.~~

~~(26) "Immediate precursor" means a substance:~~

~~(i) That 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) That 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.~~

~~(27) "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.~~

~~(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.~~

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

~~(30) "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. Marijuana shall not include "industrial hemp" or "industrial hemp products" which satisfy the requirements of chapter 26 of title 2, nor shall it include products that have been approved for marketing as a prescription medication by the U.S. Food and Drug Administration and legally prescribed.~~

~~(31) "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) that is chemically identical with any of the substances referred to in subsections 31(i) and (31)(ii).~~

~~(iv) Any other substance that 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.~~

~~(32) "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.~~

~~(33) "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.~~

~~(34) "Opioid analgesics" means and includes, but is not limited to, the medicines buprenophine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, pentazocine, propoxyphene as well as their brand names, isomers, and combinations, or other medications approved by the department.~~

~~(35) "Opioid antagonist" means naloxone hydrochloride and any other drug approved by the United States Food and Drug Administration for the treatment of opioid overdose.~~

~~(36) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.~~

~~(37) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a fluid ounce as applied to liquids.~~

~~(38) "Person" means any corporation, association, partnership, or one or more individuals.~~

~~(39) "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.~~

~~(40) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.~~

~~(41) "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.~~

~~(42) "Printout" means a hard copy produced by computer that is readable without the aid of any special device.~~

~~(43) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.~~

~~(44) "Qualified law enforcement agency" means the U.S. Food and Drug Administration, Drug Enforcement Administration, Federal Bureau of Investigation, Office of Inspector General of the U.S. Department of Health & Human Services, or the Medicaid Fraud and Patient Abuse Unit in the Office of the Attorney General.~~

~~(45) "Researcher" means a person authorized by the director of health to conduct a laboratory as defined in this chapter.~~

~~(46) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another, or to offer or agree to do the same.~~

~~(47) "Software" means programs, procedures, and storage of required information data.~~

~~(48) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in schedule I.~~

~~(49) "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.~~

~~(50) "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.~~

SECTION 4. This act shall take effect upon passage.

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LC001419/SUB A
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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 revise sections of the uniform controlled substances act to remove specific opioid dosage requirements and revise the uniform controlled substances act in accordance with current standards of professional practice and would repeal chapter 37.4 of title 5 relating to intractable pain treatment.

This act would take effect upon passage.

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LC001419/SUB A
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