

**2021 -- S 0384 SUBSTITUTE A**

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LC001588/SUB A  
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**STATE OF RHODE ISLAND**

**IN GENERAL ASSEMBLY  
JANUARY SESSION, A.D. 2021**

A N A C T

RELATING TO FOOD AND DRUGS -- UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Senators Lawson, Lombardi, Burke, Murray, Euer, Cano, Sosnowski, and Kallman

Date Introduced: February 25, 2021

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Sections 5-37.4-2 and 5-37.4-3 of the General Laws in Chapter 5-37.4 entitled  
2 "Intractable Pain Treatment" are hereby amended to read as follows:

3 **5-37.4-2. Definitions.**

4 For purposes of this chapter:

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

11 ~~(1)~~(2) "Director" means the director of the department of health of the state of Rhode  
12 Island.

13 ~~(2)~~(3) "Intractable pain" means a pain state that persists beyond the usual course of an acute  
14 disease or healing of an injury or results from a chronic disease or condition that causes continuous  
15 or intermittent pain over a period of months or years. Unless the context clearly indicates otherwise,  
16 the term intractable pain includes chronic intractable pain.

17 ~~(3)~~(4) "Practitioner" means health care professionals licensed to distribute, dispense, or  
18 administer controlled substances in the course of professional practice as defined in § 21-28-  
19 1.02(41).

1           ~~(4)~~(5) "Therapeutic purpose" means the use of controlled substances for the treatment of  
2 pain in appropriate doses as indicated by the patient's medical record. Any other use is  
3 nontherapeutic.

4           **5-37.4-3. Controlled substances.**

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

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

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

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

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

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

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

33           (1) Prescribes, administers, or dispenses a controlled substance that is nontherapeutic in  
34 nature or nontherapeutic in the manner in which it is prescribed, administered, or dispensed, or fails

1 to keep complete and accurate on-going records of the diagnosis and treatment plan;

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

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

12 (4) Prescribes, administers, or dispenses in a manner which is inconsistent with provisions  
13 of the law, or the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §  
14 801, et seq., any controlled substance.

15 ~~(h)~~ A practitioner may administer a controlled substance prescribed by a practitioner and  
16 not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner  
17 for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in  
18 the practitioner's medical records. No practitioner shall be subject to disciplinary action by the  
19 director solely for administering controlled substances when prescribed or dispensed for a  
20 therapeutic purpose for a person diagnosed and treated by a practitioner for a condition resulting in  
21 intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical  
22 records of the patient.

23 SECTION 2. Section 21-28-3.20 of the General Laws in Chapter 21-28 entitled "Uniform  
24 Controlled Substances Act" is hereby amended to read as follows:

25 **21-28-3.20. Authority of practitioner to prescribe, administer, and dispense.**

26 (a)(1) A practitioner, in good faith and in the course of his or her professional practice only,  
27 may prescribe, administer, and dispense controlled substances, or he or she may cause the  
28 controlled substances to be administered by a nurse or intern under his or her direction and  
29 supervision.

30 (2) When issuing an initial prescription for an opiate to an adult patient, a practitioner shall  
31 not exceed the maximum daily dose requirements established by the department of health.

32 (3) Except as provided in subsection (a)(4) of this section, a practitioner shall not issue an  
33 opiate prescription to a minor for more than twenty (20) doses at any time. Prior to issuing an opiate  
34 prescription to a minor, a practitioner shall discuss with the parent or guardian of the minor the

1 risks associated with opiate use and the reasons why the prescription is necessary. The practitioner  
2 shall document his or her discussion with the parent or guardian in the medical record.

3 (4) Notwithstanding the limitations referenced in subsection (a)(3) of this section, if, in the  
4 professional medical judgment of a practitioner, a greater dosage or supply of an opiate is required  
5 to treat the minor patient's acute medical condition or is necessary for the treatment of chronic pain  
6 management, sickle cell related pain, intractable pain treatment as defined in chapter 37.4 of title  
7 5, pain associated with a cancer diagnosis, or for palliative care, then the practitioner may issue a  
8 prescription for the quantity needed to treat the acute medical condition, chronic pain, sickle cell  
9 related pain, intractable pain, pain associated with a cancer diagnosis, or pain experienced while  
10 the patient is in palliative care, provided that this dosage shall not exceed the maximum daily  
11 dosage permitted for the treatment of this pain as set forth in the department of health regulations.  
12 The condition triggering the prescription of an opiate shall be documented in the minor patient's  
13 medical record, and the practitioner shall indicate that a non-opiate alternative was not appropriate  
14 to address the medical condition.

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

17 (b) The prescription-monitoring program shall be reviewed prior to starting any opioid. A  
18 prescribing practitioner, or designee as authorized by § 21-28-3.32(a)(3), shall review the  
19 prescription-monitoring program prior to refilling or initiating opioid therapy with an intrathecal  
20 pump. For patients the prescribing practitioner is maintaining on continuous opioid therapy for pain  
21 for three (3) months or longer, the prescribing practitioner shall review information from the  
22 prescription-monitoring program at least every three (3) months. Documentation of that review  
23 shall be noted in the patient's medical record.

24 (c) The director of health shall develop regulations for prescribing practitioners on  
25 appropriate limits of opioid use in acute pain management. Initial prescriptions of opioids for acute  
26 pain management of outpatient adults shall not exceed thirty (30) morphine milligram equivalents  
27 (MMEs) total daily dose per day for a maximum total of twenty (20) doses, and, for pediatric  
28 patients, the appropriate opioid dosage maximum per the department of health.

29 (d) For the purposes of this section, acute pain management shall not include chronic pain  
30 management, pain associated with a cancer diagnosis, palliative or nursing home care, [intractable](#)  
31 [or chronic intractable pain, as provided in § 5-37.4-2](#), or other exception in accordance with  
32 department of health regulations.

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

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

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

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

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

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

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

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

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

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

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

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

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

25 (h) On or before September 1, 2018, the director of health and the secretary of the executive  
26 office of health and human services shall develop strategies that include:

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

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

33 SECTION 3. Chapter 21-28 of the General Laws entitled "Uniform Controlled Substances  
34 Act" is hereby amended by adding thereto the following section:

1           **21-28-3.20.1. Authority of practitioner to prescribe, administer, and dispense --**

2           **Cancer, palliative care and chronic intractable pain.**

3           (a) A practitioner, in good faith and in the course of his or her professional practice  
4 managing pain associated with a cancer diagnosis, palliative or nursing home care, intractable or  
5 chronic intractable pain as provided in § 5-37.4-2, or other condition allowed by department of  
6 health regulations pursuant to the exception in § 21-28-3.20(d), may prescribe, administer, and  
7 dispense controlled substances without regard to the 2016 CDC Guideline for Prescribing Opioids  
8 for Chronic Pain.

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

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

16           (2) Make provisions for practitioners, acting in good faith, and in the course of their  
17 profession, and managing pain associated with their patients' illness to use their best judgment  
18 notwithstanding any statute, rule or regulation to the contrary.

19           SECTION 4. This act shall take effect upon passage.

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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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1           This act would define "chronic intractable pain" for purposes of intractable pain  
2 management. This act would also allow medical practitioners, when dealing with pain management  
3 associated with intractable or chronic pain, to prescribe, administer, and dispense controlled  
4 substances without regard to the 2016 CDC Guidelines for prescribing opioids for chronic pain.

5           This act would take effect upon passage.

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