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LC001373/SUB A
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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. 2019

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A N A C T

RELATING TO FOOD AND DRUGS -- UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Representatives Amore, Serodio, Ruggiero, and Kazarian

Date Introduced: February 14, 2019

Referred To: House Health, Education & Welfare

(by request)

It is enacted by the General Assembly as follows:

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

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; produces mental and physical debilitation; and may produce a desire to commit suicide for the sole purpose of stopping the pain. A diagnosis of chronic intractable pain made by a physician licensed in any of the states or the District of Columbia and supported by written documentation of the diagnosis by the treating physician shall constitute proof that the patient suffers from chronic intractable pain.

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

~~(2)~~(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.

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

~~(4)~~(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 non-therapeutically.

(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) Practitioners shall not refuse treatment under this chapter for the sole reason that a patient requires intensive treatment.

(f) Pharmacists shall not refuse to refill a prescription related to the diagnosis of intractable or chronic intractable pain.

(g) In coordination with §§ 21-28-3.20 and 21-28-3.20.1, the director of health shall promulgate rules and regulations necessary to effectuate the purpose of this chapter and ensure that patients with intractable or chronic intractable pain are treated with dignity and not unduly denied the medications needed to treat their conditions.

~~(e)~~(h) 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 on-going 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.

~~(f)~~(i) 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 2. Section 21-28-3.20 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" is hereby amended to read as follows:

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

(a) A practitioner, in good faith and in the course of his or her 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 direction and supervision.

(b) The prescription-monitoring program shall be reviewed prior to starting any opioid. A prescribing practitioner, or designee as authorized by § 21-28-3.32(a)(3), shall review the

prescription-monitoring program prior to refilling or initiating opioid therapy with an intrathecal pump. For patients the prescribing practitioner is maintaining on continuous opioid therapy for pain for three (3) months or longer, the prescribing practitioner shall review information from the prescription-monitoring program at least every three (3) months. Documentation of that review shall be noted in the patient's medical record.

(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) For the purposes of this section, acute pain management shall not include chronic pain management, pain associated with a cancer diagnosis, palliative or nursing home care, intractable or chronic intractable pain, as provided in chapter 37.4 of title 5, or other exception 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 health-care 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 health-care 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 health-care 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.

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

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 chapter 37.4 of title 5, 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, or he or she may cause the controlled substances to be administered by a nurse or intern under his or her direction and supervision without regard to the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain.

(b) Practitioners, in the course of their professional practice, shall not refuse treatment to patients covered under this section for the sole reason that these patients require intensive treatment.

(c) Pharmacists, upon receiving the proper documentation that a person suffers from a condition set forth in this section, shall not refuse to fill a prescription related to the diagnosis. Documentation related to the filling of a prescription under this subsection shall only be required by the pharmacist upon the initial filling of the prescription.

(d) The director of health shall 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 chapter 37.4 of title 5, 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;

(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; and

(3) Ensure that patients covered by this section are treated with dignity and not unduly denied the medications needed to treat their conditions.

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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This act would exclude chronic intractable pain from the definition of "acute pain management", for purposes of prescribing, administering and dispensing controlled substances by a practitioner. The act would prescribe new guidelines for the treatment of "chronic intractable pain" based upon the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain.

This act would take effect upon passage.

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