

2016 -- H 8224 SUBSTITUTE A

=====
LC005994/SUB A
=====

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2016

A N A C T

RELATING TO FOOD AND DRUGS -- UNIFORM CONTROLLED SUBSTANCES ACT--
REGULATION OF MANUFACTURING, DISTRIBUTING, PRESCRIBING,
ADMINISTERING, AND DISPENSING CONTROLLED SUBSTANCES

Introduced By: Representatives Bennett, Hull, Solomon, Regunberg, and Shekarchi

Date Introduced: May 18, 2016

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

1 SECTION 1. Sections 21-28-3.02, 21-28-3.18, 21-28-3.20 and 21-28-3.32 of the General
2 Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" are hereby amended to read
3 as follows:

4 **21-28-3.02. Registration requirements.** -- (a) Every person who manufactures,
5 distributes, prescribes, administers, or dispenses any controlled substance within this state or who
6 proposes to engage in the manufacture, distribution, prescribing, administering, or dispensing of
7 any controlled substance within this state, must obtain annually a registration issued by the
8 director of health in accordance with his or her rules.

9 (b) Persons registered by the director of health under this chapter to manufacture,
10 distribute, prescribe, administer, dispense, or conduct research with those substances may do so to
11 the extent authorized by their registration and in conformity with the other provisions of this
12 chapter.

13 (c) As a condition of the initial registration or renewal of the practitioner's authority to
14 prescribe controlled substances, all such practitioners shall be automatically registered with the
15 prescription drug monitoring database maintained by the department of health.

16 (d) By January 1, 2017, the director of health shall develop regulations for appropriate
17 training in best prescribing practices needed for license renewal.

18 **21-28-3.18. Prescriptions.** -- (a) An apothecary in good faith may sell and dispense

1 controlled substances in schedule II, III, IV and V to any person upon a valid prescription by a
2 practitioner licensed by law to prescribe or administer those substances, dated and signed by the
3 person prescribing on the day when issued and bearing the full name and address of the patient to
4 whom, or of the owner of the animal for which, the substance is dispensed and the full name,
5 address, and registration number under the federal law of the person prescribing, if he or she is
6 required by that law to be registered. If the prescription is for an animal, it shall state the species
7 of the animal for which the substance is prescribed.

8 (b) When filling a hard-copy prescription for a schedule II controlled substance, the
9 apothecary filling the prescription shall sign his or her full name and shall write the date of filling
10 on the face of the prescription.

11 (c) The prescription shall be retained on file by the proprietor of the pharmacy in which
12 it was filled for a period of two (2) years so as to be readily accessible for inspection by any
13 public officer or employee engaged in the enforcement of this chapter.

14 (d) (1) Hard copy prescriptions for controlled substances in schedule II shall be filed
15 separately and shall not be refilled.

16 (2) The director of health shall, after appropriate notice and hearing pursuant to § 42-35-
17 3, promulgate rules and regulations for the purpose of adopting a system for electronic data
18 transmission, including by facsimile, of prescriptions for controlled substances in schedule II, III
19 and IV.

20 (3) A practitioner may sign and transmit electronic prescriptions for controlled
21 substances and a pharmacy may dispense an electronically transmitted prescription in accordance
22 with the code of federal regulations, title 21 part 1300, et seq.

23 (e) A prescription for a schedule II narcotic substance to be compounded for the direct
24 administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal
25 infusion may be transmitted by the practitioner, or practitioner's agent, to the pharmacy by
26 facsimile. The facsimile will serve as the original prescription.

27 (f) A prescription for a schedule II substance for a resident of a long-term-care facility
28 may be transmitted by the practitioner, or the practitioner's agent, to the dispensing pharmacy by
29 facsimile. The facsimile serves as the original prescription.

30 (g) A prescription for a schedule II narcotic substance for a patient residing in a hospice
31 certified by Medicare under title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., or
32 licensed by the state, may be transmitted by the practitioner, or practitioner's agent, to the
33 dispensing pharmacy by facsimile. The practitioner, or the practitioner's agent, will note on the
34 prescription that the patient is a hospice patient. The facsimile serves as the original, written

1 prescription.

2 (h) An apothecary, in lieu of a written prescription, may sell and dispense controlled
3 substances in schedules III, IV, and V to any person upon an oral prescription of a practitioner. In
4 issuing an oral prescription, the prescriber shall furnish the apothecary with the same information
5 as is required by subsection (a) of this section and the apothecary who fills the prescription shall
6 immediately reduce the oral prescription to writing and shall inscribe the information on the
7 written record of the prescription made. This record shall be filed and preserved by the proprietor
8 of the pharmacy in which it is filled in accordance with the provisions of subsection (c) of this
9 section. In no case may a prescription for a controlled substance listed in schedules III, IV, or V
10 be filled or refilled more than six (6) months after the date on which the prescription was issued
11 and no prescription shall be authorized to be refilled more than five (5) times. Each refilling shall
12 be entered on the face or back of the prescription and note the date and amount of controlled
13 substance dispensed and the initials or identity of the dispensing apothecary.

14 (i) In the case of an emergency situation as defined in federal law, an apothecary may
15 dispense a controlled substance listed in schedule II upon receiving an oral authorization of a
16 prescribing practitioner provided that:

17 (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the
18 patient during the emergency period and dispensing beyond the emergency period must be
19 pursuant to a written prescription signed by the prescribing practitioner.

20 (2) The prescription shall be immediately reduced to writing and shall contain all the
21 information required in subsection (a) of this section.

22 (3) The prescription must be dispensed in good faith in the normal course of professional
23 practice.

24 (4) Within seven (7) days after authorizing an emergency oral prescription, the
25 prescribing practitioner shall cause a prescription for the emergency quantity prescribed to be
26 delivered to the dispensing apothecary. The prescription shall have written on its face
27 "Authorization for emergency dispensing" and the date of the oral order. The prescription, upon
28 receipt by the apothecary, shall be attached to the oral emergency prescription that had earlier
29 been reduced to writing.

30 (j) (1) The partial filling of a prescription for a controlled substance listed in schedule II
31 is permissible, if the apothecary is unable to supply the full quantity called for in a prescription or
32 emergency oral prescription and he or she makes a notation of the quantity supplied on the face of
33 the prescription or oral emergency prescription that has been reduced to writing. The remaining
34 portion of the prescription may be filled within seventy-two (72) hours of the first partial filling,

1 however, if the remaining portion is not, or cannot be, filled within seventy-two (72) hours, the
2 apothecary shall notify the prescribing practitioner. No further quantity may be supplied beyond
3 seventy-two (72) hours without a new prescription.

4 (2) (i) A prescription for a schedule II controlled substance written for a patient in a long-
5 term care facility (LTCF), or for a patient with a medical diagnosis documenting a terminal
6 illness, may be filled in partial quantities to include individual dosage units. If there is a question
7 whether a patient may be classified as having a terminal illness, the pharmacist must contact the
8 practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing
9 practitioner have a corresponding responsibility to assure that the controlled substance is for a
10 terminally ill patient.

11 (ii) The pharmacist must record on the prescription whether the patient is "terminally ill"
12 or an "LTCF patient." A prescription that is partially filled, and does not contain the notation
13 "terminally ill" or "LTCF patient", shall be deemed to have been filled in violation of this chapter.

14 (iii) For each partial filling, the dispensing pharmacist shall record on the back of the
15 prescription (or on another appropriate record, uniformly maintained, and readily retrievable),
16 the:

- 17 (A) Date of the partial filling;
- 18 (B) Quantity dispensed;
- 19 (C) Remaining quantity authorized to be dispensed; and
- 20 (D) Identification of the dispensing pharmacist.

21 (iv) The total quantity of schedule II controlled substances dispensed in all partial fillings
22 must not exceed the total quantity prescribed.

23 (v) Schedule II prescriptions for patients in a LTCF, or patients with a medical diagnosis
24 documenting a terminal illness, are valid for a period not to exceed sixty (60) days from the issue
25 date, unless sooner terminated by the discontinuance of medication.

26 (k) Automated data processing systems. - As an alternative to the prescription record
27 keeping provision of subsection (h) of this section, an automated data processing system may be
28 employed for the record-keeping system if the following conditions have been met:

29 (1) The system shall have the capability of producing sight-readable documents of all
30 original and refilled prescription information. The term "sight-readable" means that an authorized
31 agent shall be able to examine the record and read the information. During the course of an on-
32 site inspection, the record may be read from the CRT, microfiche, microfilm, printout, or other
33 method acceptable to the director. In the case of administrative proceedings, records must be
34 provided in a paper printout form.

1 (2) The information shall include, but not be limited to, the prescription requirements and
2 records of dispensing as indicated in subsection (h) of this section.

3 (3) The individual pharmacist responsible for completeness and accuracy of the entries to
4 the system must provide documentation of the fact that prescription information entered into the
5 computer is correct. In documenting this information, the pharmacy shall have the option to
6 either:

7 (i) Maintain a bound log book, or separate file, in which each individual pharmacist
8 involved in the dispensing shall sign a statement each day attesting to the fact that the prescription
9 information entered into the computer that day has been reviewed and is correct as shown. The
10 book or file must be maintained at the pharmacy employing that system for a period of at least
11 two (2) years after the date of last dispensing; or

12 (ii) Provide a printout of each day's prescription information. That printout shall be
13 verified, dated, and signed by the individual pharmacist verifying that the information indicated is
14 correct. The printout must be maintained at least two (2) years from the date of last dispensing.

15 (4) An auxiliary record-keeping system shall be established for the documentation of
16 refills if the automated, data-processing system is inoperative for any reason. The auxiliary
17 system shall ensure that all refills are authorized by the original prescription and that the
18 maximum number of refills is not exceeded. When this automated data processing system is
19 restored to operation, the information regarding prescriptions filled and refilled during the
20 inoperative period shall be entered into the automated, data-processing system within ninety-six
21 (96) hours.

22 (5) Any pharmacy using an automated, data-processing system must comply with all
23 applicable state and federal laws and regulations.

24 (6) A pharmacy shall make arrangements with the supplier of data processing services or
25 materials to ensure that the pharmacy continues to have adequate and complete prescription and
26 dispensing records if the relationship with the supplier terminates for any reason. A pharmacy
27 shall ensure continuity in the maintenance of records.

28 (7) The automated, data-processing system shall contain adequate safeguards for security
29 of the records to maintain the confidentiality and accuracy of the prescription information.
30 Safeguards against unauthorized changes in data after the information has been entered and
31 verified by the registered pharmacist shall be provided by the system.

32 (l) Prescriptions for controlled substances as found in schedules II will become void
33 unless dispensed within ninety (90) days of the original date of the prescription and in no event
34 shall more than a thirty-day (30) supply be dispensed at any one time.

1 (1) In prescribing controlled substances in schedule II, practitioners may write up to three
2 (3)- separate prescriptions, each for up to a one-month supply, each signed and dated on the date
3 written. For those prescriptions for the second and/or third month, the practitioner must write the
4 earliest date each of those subsequent prescription may be filled, with directions to the pharmacist
5 to fill no earlier than the date specified on the face of the prescription.

6 (m) The prescriptions in schedules III, IV, and V will become void unless dispensed
7 within one hundred eighty (180) days of the original date of the prescription. For purposes of this
8 section, a "dosage unit" shall be defined as a single capsule, tablet, or suppository, or not more
9 than one five (5) ml. of an oral liquid.

10 (1) Prescriptions in Schedule III cannot be written for more than one hundred (100)
11 dosage units and not more than one hundred (100) dosage units may be dispensed at one time.

12 (2) Prescriptions in Schedule IV and V may be written for up to a ninety-day (90) supply
13 based on directions. No more than three hundred and sixty (360) dosage units may be dispensed
14 at one time.

15 (n) A pharmacy shall transmit prescription information to the prescription monitoring
16 database at the department of health within one business day following the dispensing of an
17 opioid prescription.

18 (o) The pharmacist shall inform patients verbally or in writing about the proper disposal
19 of expired, unused, or unwanted medications, including the location of local disposal sites as
20 listed on the department of health website.

21 (p) The pharmacist shall inform patients verbally or in writing in the proper use of any
22 devices necessary for the administration of controlled substances.

23 **21-28-3.20. Authority of practitioner to prescribe, administer, and dispense.** – (a) A
24 practitioner, in good faith and in the course of his or her professional practice only, may
25 prescribe, administer, and dispense controlled substances, or he or she may cause the controlled
26 substances to be administered by a nurse or intern under his or her direction and supervision.

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

34 (c) The director of health shall develop regulations for prescribing practitioners on

1 appropriate limits of opioid use in acute pain management. Initial prescriptions of opioids for
2 acute pain management of outpatient adults shall not exceed thirty (30) morphine milligram
3 equivalents (MMEs) total daily dose per day for a maximum total of twenty (20) doses, and, for
4 pediatric patients, the appropriate opioid dosage maximum per the department of health.

5 (d) For the purposes of this section, acute pain management shall not include chronic pain
6 management, pain associated with a cancer diagnosis, palliative or nursing home care, or other
7 exception in accordance with department of health regulations.

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

10 **21-28-3.32. Electronic prescription database.** -- (a) The information contained in any
11 prescription drug monitoring database maintained by the department of health pursuant to § 21-
12 28-3.18 of this chapter shall be disclosed only:

13 (1) To a practitioner who certifies that the requested information is for the purpose of
14 evaluating the need for, or providing medical treatment to, a current patient to whom the
15 practitioner is prescribing or considering prescribing a controlled substance;

16 (2) To a pharmacist who certifies that the requested information is for a current client to
17 whom the pharmacist is dispensing, or considering dispensing, a controlled substance;

18 (3) To an authorized designee of the practitioner and/or pharmacist to consult the
19 prescription drug monitoring database on the practitioner's and/or pharmacist's behalf, provided
20 that:

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

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

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

28 (iv) The practitioner or pharmacist remains responsible for ensuring access to the
29 database by the designee occurs in a manner that protects the confidentiality of information
30 obtained from the database and remains responsible for any breach of confidentiality;

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

33 (vi) The ultimate decision as to whether or not to prescribe or dispense a controlled
34 substance remains with the practitioner or pharmacist and is reasonably informed by the relevant

1 controlled substance history information obtained from the database.

2 (4) Pursuant to a valid search warrant based on probable cause to believe a violation of
3 federal or state criminal law has occurred and that specified information contained in the database
4 would assist in the investigation of the crime;

5 (5) To a patient who requests his or her own prescription information, or the parent or
6 legal guardian of a minor child who requests the minor child's prescription information;

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

11 (7) To any vendor or contractor with whom the department has contracted to establish or
12 maintain the electronic system of the prescription drug monitoring database; or

13 (8) To public or private entities for statistical, research, or educational purposes, after
14 removing the patient and prescriber information that could be used to identify individual patients.
15 This shall not include entities receiving a waiver from the institutional review board.

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

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

21 (2) Prescribing practitioner's name and drug enforcement administration prescriber
22 information number;

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

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

28 (5) The drug enforcement administration pharmacy number of the pharmacy filling the
29 prescription.

30 (c) The department shall disclose any information relating to a patient maintained in the
31 prescription drug monitoring database to that patient, at no cost to the patient, within thirty (30)
32 business days after the department receives a written request from the patient for the information.

33 This information shall include the records maintained by the department pursuant to subsection

34 (e). Notwithstanding the above, the department may, at the request of the law enforcement

1 agency, withhold for up to sixty (60) days following the conclusion of a law enforcement
2 investigation, the disclosure to the patient that information has been obtained pursuant to
3 subdivision (a)(3).

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
6 procedure specified by § 5-37.3-5(c).

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

14 (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 their own prescription information, and the name and contact information of the agency
27 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 (l) 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 drug
4 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.

12 SECTION 2. This act shall take effect upon passage.

=====
LC005994/SUB A
=====

EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

RELATING TO FOOD AND DRUGS -- UNIFORM CONTROLLED SUBSTANCES ACT--
REGULATION OF MANUFACTURING, DISTRIBUTING, PRESCRIBING,
ADMINISTERING, AND DISPENSING CONTROLLED SUBSTANCES

1 This act would require pharmacies to transmit prescription information to the prescription
2 monitoring database within one business day of dispensing an opioid, and to provide information
3 to patients about the proper use of medication devices and disposal of unused medications.
4 Prescriptions for acute pain management in adults would be limited to 30 morphine milligram
5 equivalents (MMEs) total daily dose per day for a maximum of 20 doses, or the appropriate
6 maximum daily opioid dosage for pediatric patients per department of health regulations, except
7 in certain circumstances.

8 It would require that the prescription drug monitoring database be reviewed prior to
9 starting any opioid.

10 This act would take effect upon passage.

=====
LC005994/SUB A
=====