

SENATE
STATE OF MINNESOTA
EIGHTY-NINTH SESSION

S.F. No. 1425

(SENATE AUTHORS: ROSEN, Eaton, Hoffman, Benson and Marty)

DATE	D-PG	OFFICIAL STATUS
03/05/2015	572	Introduction and first reading Referred to Health, Human Services and Housing
03/18/2015	953	Comm report: To pass
	963	Second reading
	4868	Rule 47, returned to Health, Human Services and Housing
03/17/2016	5055	Comm report: To pass
	5092	Second reading
05/02/2016		Special Order: Amended Third reading Passed

A bill for an act

1.1
 1.2 relating to health; making changes concerning the collection and disposal of
 1.3 legend drugs as pharmaceutical waste; amending Minnesota Statutes 2014,
 1.4 sections 151.01, by adding a subdivision; 151.37, subdivisions 2, 6, 7, by adding
 1.5 a subdivision; proposing coding for new law in Minnesota Statutes, chapter 152.

1.6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.7 Section 1. Minnesota Statutes 2014, section 151.01, is amended by adding a
 1.8 subdivision to read:

1.9 Subd. 39. **Ultimate user.** "Ultimate user" means a natural person who possesses
 1.10 a legend drug that was lawfully obtained for personal use or for the use of a household
 1.11 member or for the use of an animal owned by the natural person or by a household member.

1.12 Sec. 2. Minnesota Statutes 2014, section 151.37, subdivision 2, is amended to read:

1.13 **Subd. 2. Prescribing and filing.** (a) A licensed practitioner in the course of
 1.14 professional practice only, may prescribe, administer, and dispense a legend drug, and
 1.15 may cause the same to be administered by a nurse, a physician assistant, or medical
 1.16 student or resident under the practitioner's direction and supervision, and may cause a
 1.17 person who is an appropriately certified, registered, or licensed health care professional
 1.18 to prescribe, dispense, and administer the same within the expressed legal scope of the
 1.19 person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a
 1.20 legend drug, without reference to a specific patient, by directing a licensed dietitian or
 1.21 licensed nutritionist, pursuant to section 148.634; a nurse, pursuant to section 148.235,
 1.22 subdivisions 8 and 9; physician assistant; medical student or resident; or pharmacist
 1.23 according to section 151.01, subdivision 27, to adhere to a particular practice guideline or
 1.24 protocol when treating patients whose condition falls within such guideline or protocol,

2.1 and when such guideline or protocol specifies the circumstances under which the legend
2.2 drug is to be prescribed and administered. An individual who verbally, electronically, or
2.3 otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall
2.4 not be deemed to have prescribed the legend drug. This paragraph applies to a physician
2.5 assistant only if the physician assistant meets the requirements of section 147A.18.

2.6 (b) The commissioner of health, if a licensed practitioner, or a person designated
2.7 by the commissioner who is a licensed practitioner, may prescribe a legend drug to an
2.8 individual or by protocol for mass dispensing purposes where the commissioner finds that
2.9 the conditions triggering section 144.4197 or 144.4198, subdivision 2, paragraph (b), exist.
2.10 The commissioner, if a licensed practitioner, or a designated licensed practitioner, may
2.11 prescribe, dispense, or administer a legend drug or other substance listed in subdivision 10
2.12 to control tuberculosis and other communicable diseases. The commissioner may modify
2.13 state drug labeling requirements, and medical screening criteria and documentation, where
2.14 time is critical and limited labeling and screening are most likely to ensure legend drugs
2.15 reach the maximum number of persons in a timely fashion so as to reduce morbidity
2.16 and mortality.

2.17 (c) A licensed practitioner that dispenses for profit a legend drug that is to be
2.18 administered orally, is ordinarily dispensed by a pharmacist, and is not a vaccine, must
2.19 file with the practitioner's licensing board a statement indicating that the practitioner
2.20 dispenses legend drugs for profit, the general circumstances under which the practitioner
2.21 dispenses for profit, and the types of legend drugs generally dispensed. It is unlawful to
2.22 dispense legend drugs for profit after July 31, 1990, unless the statement has been filed
2.23 with the appropriate licensing board. For purposes of this paragraph, "profit" means (1)
2.24 any amount received by the practitioner in excess of the acquisition cost of a legend drug
2.25 for legend drugs that are purchased in prepackaged form, or (2) any amount received
2.26 by the practitioner in excess of the acquisition cost of a legend drug plus the cost of
2.27 making the drug available if the legend drug requires compounding, packaging, or other
2.28 treatment. The statement filed under this paragraph is public data under section 13.03.
2.29 This paragraph does not apply to a licensed doctor of veterinary medicine or a registered
2.30 pharmacist. Any person other than a licensed practitioner with the authority to prescribe,
2.31 dispense, and administer a legend drug under paragraph (a) shall not dispense for profit.
2.32 To dispense for profit does not include dispensing by a community health clinic when the
2.33 profit from dispensing is used to meet operating expenses.

2.34 (d) A prescription drug order for the following drugs is not valid, unless it can be
2.35 established that the prescription drug order was based on a documented patient evaluation,

3.1 including an examination, adequate to establish a diagnosis and identify underlying
3.2 conditions and contraindications to treatment:

3.3 (1) controlled substance drugs listed in section 152.02, subdivisions 3 to 5;

3.4 (2) drugs defined by the Board of Pharmacy as controlled substances under section
3.5 152.02, subdivisions 7, 8, and 12;

3.6 (3) muscle relaxants;

3.7 (4) centrally acting analgesics with opioid activity;

3.8 (5) drugs containing butalbital; or

3.9 (6) phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.

3.10 (e) For the purposes of paragraph (d), the requirement for an examination shall be
3.11 met if an in-person examination has been completed in any of the following circumstances:

3.12 (1) the prescribing practitioner examines the patient at the time the prescription
3.13 or drug order is issued;

3.14 (2) the prescribing practitioner has performed a prior examination of the patient;

3.15 (3) another prescribing practitioner practicing within the same group or clinic as the
3.16 prescribing practitioner has examined the patient;

3.17 (4) a consulting practitioner to whom the prescribing practitioner has referred the
3.18 patient has examined the patient; or

3.19 (5) the referring practitioner has performed an examination in the case of a
3.20 consultant practitioner issuing a prescription or drug order when providing services by
3.21 means of telemedicine.

3.22 (f) Nothing in paragraph (d) or (e) prohibits a licensed practitioner from prescribing
3.23 a drug through the use of a guideline or protocol pursuant to paragraph (a).

3.24 (g) Nothing in this chapter prohibits a licensed practitioner from issuing a
3.25 prescription or dispensing a legend drug in accordance with the Expedited Partner Therapy
3.26 in the Management of Sexually Transmitted Diseases guidance document issued by the
3.27 United States Centers for Disease Control.

3.28 (h) Nothing in paragraph (d) or (e) limits prescription, administration, or dispensing
3.29 of legend drugs through a public health clinic or other distribution mechanism approved
3.30 by the commissioner of health or a board of health in order to prevent, mitigate, or treat
3.31 a pandemic illness, infectious disease outbreak, or intentional or accidental release of a
3.32 biological, chemical, or radiological agent.

3.33 (i) No pharmacist employed by, under contract to, or working for a pharmacy located
3.34 within the state and licensed under section 151.19, subdivision 1, may dispense a legend
3.35 drug based on a prescription that the pharmacist knows, or would reasonably be expected
3.36 to know, is not valid under paragraph (d).

4.1 (j) No pharmacist employed by, under contract to, or working for a pharmacy located
 4.2 outside the state and licensed under section 151.19, subdivision 2 1, may dispense a legend
 4.3 drug to a resident of this state based on a prescription that the pharmacist knows, or would
 4.4 reasonably be expected to know, is not valid under paragraph (d).

4.5 (k) Nothing in this chapter prohibits the commissioner of health, if a licensed
 4.6 practitioner, or, if not a licensed practitioner, a designee of the commissioner who is
 4.7 a licensed practitioner, from prescribing legend drugs for field-delivered therapy in the
 4.8 treatment of a communicable disease according to the Centers For Disease Control and
 4.9 Prevention Partner Services Guidelines.

4.10 Sec. 3. Minnesota Statutes 2014, section 151.37, subdivision 6, is amended to read:

4.11 Subd. 6. **Exclusion for course of employment.** (a) Nothing in this chapter shall
 4.12 prohibit the possession of a legend drug by an employee, agent, or sales representative of
 4.13 a registered drug manufacturer, or an employee or agent of a registered drug wholesaler,
 4.14 or registered pharmacy, while acting in the course of employment.

4.15 (b) Nothing in this chapter shall prohibit an employee of the following entities, while
 4.16 acting in the course of employment, from possessing a legend drug for the purpose of
 4.17 disposing of the legend drug as pharmaceutical waste, provided that controlled substances
 4.18 listed in section 152.02, subdivisions 3 to 6, may only be collected and disposed of as
 4.19 allowed under section 152.105:

4.20 (1) a law enforcement ~~officer~~ agency;

4.21 (2) a hazardous waste transporter ~~licensed by the Department of Transportation that~~
 4.22 has notified the Pollution Control Agency of its activity;

4.23 (3) a facility permitted by the Pollution Control Agency to treat, store, or dispose of
 4.24 hazardous waste, including household hazardous waste;

4.25 (4) a facility licensed by the Pollution Control Agency or a metropolitan county,
 4.26 as defined in section 473.121, as a very small quantity generator collection program or a
 4.27 minimal generator or household hazardous waste collection program; or

4.28 (5) ~~a county that collects, stores, transports, or disposes of a legend drug pursuant to~~
 4.29 ~~a program in compliance with applicable federal law or a person authorized by the county~~
 4.30 ~~to conduct one or more of these activities; or~~

4.31 (6) a sanitary district organized under chapter 115, or a special law.

4.32 Sec. 4. Minnesota Statutes 2014, section 151.37, is amended by adding a subdivision
 4.33 to read:

5.1 Subd. 6a. **Collection of legend drugs by pharmacies.** A pharmacy licensed under
5.2 section 151.19 may collect a legend drug from an ultimate user, or from a long-term care
5.3 facility on behalf of an ultimate user who resides or resided at the long-term care facility,
5.4 for the purpose of disposing of the legend drug as pharmaceutical waste, provided that:

5.5 (1) a pharmacy may collect and dispose of controlled substances listed in section
5.6 152.02, subdivision 3 to 6, only as allowed under section 152.105; and

5.7 (2) a pharmacy that has established a controlled substance disposal program
5.8 pursuant to section 152.105 may also collect and dispose of noncontrolled substance
5.9 legend and nonlegend drugs, but only in the same manner in which it collects and disposes
5.10 of controlled substances.

5.11 Sec. 5. Minnesota Statutes 2014, section 151.37, subdivision 7, is amended to read:

5.12 **Subd. 7. Exclusion for prescriptions.** (a) Nothing in this chapter shall prohibit the
5.13 possession of a legend drug by a person for that person's use when it has been dispensed to
5.14 the person in accordance with a valid prescription issued by a practitioner.

5.15 (b) Nothing in this chapter shall prohibit a person, for whom a legend drug has
5.16 been dispensed in accordance with a written or oral prescription by a practitioner, from
5.17 designating a family member, caregiver, or other individual to handle the legend drug for
5.18 the purpose of assisting the person in obtaining or administering the drug or sending
5.19 the drug for destruction.

5.20 (c) Nothing in this chapter shall prohibit a person for whom a ~~prescription~~ legend drug
5.21 has been dispensed in accordance with a valid prescription issued by a practitioner from
5.22 transferring the legend drug to ~~a county that collects, stores, transports, or disposes of a~~
5.23 ~~legend drug pursuant to a program in compliance with applicable federal law or to a person~~
5.24 ~~authorized by the county to conduct one or more of these activities.~~ an entity identified in
5.25 subdivision 6. Controlled substances listed in section 152.02, subdivision 3 to 6, may only
5.26 be collected, stored, transported, and disposed of as allowed under section 152.105.

5.27 Sec. 6. **[152.105] DISPOSAL.**

5.28 Controlled substances listed in section 152.02, subdivisions 3 to 6, may be collected
5.29 and disposed of only pursuant to the provisions of Code of Federal Regulations, Title
5.30 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, that are applicable to the disposal of
5.31 controlled substances. Disposal of controlled substances and legend and nonlegend drugs
5.32 must also comply with the requirements of section 116.07 governing the disposal of
5.33 hazardous waste, and the rules promulgated thereunder.