SENATE
STATE OF MINNESOTA
EIGHTY-NINTH SESSION

S.F. No. 1425

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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	6574a	Special Order: Amended
	6574	Third reading Passed
05/16/2016	7028	Returned from House with amendment
	7028	Senate concurred and repassed bill
	7028	Third reading

A bill for an act

relating to health; adding provisions to the definition of the "practice of pharmacy"; making changes concerning the collection and disposal of legend drugs as pharmaceutical waste; requiring an opiate antagonist protocol; amending Minnesota Statutes 2014, sections 151.01, by adding a subdivision; 151.37, subdivisions 6, 7, by adding subdivisions; Minnesota Statutes 2015 Supplement, sections 151.01, subdivision 27; 151.37, subdivision 2; proposing coding for new law in Minnesota Statutes, chapter 152.

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

Section 1. Minnesota Statutes 2015 Supplement, section 151.01, subdivision 27, is amended to read:

Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:

(1) interpretation and evaluation of prescription drug orders;

(2) compounding, labeling, and dispensing drugs and devices (except labeling by a manufacturer or packager of nonprescription drugs or commercially packaged legend drugs and devices);

(3) participation in clinical interpretations and monitoring of drug therapy for assurance of safe and effective use of drugs, including the performance of laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988, United States Code, title 42, section 263a et seq., provided that a pharmacist may interpret the results of laboratory tests but may modify drug therapy only pursuant to a protocol or collaborative practice agreement;

(4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; drug regimen reviews; and drug or drug-related research;

(5) participation in administration of influenza vaccines to all eligible individuals six years of age and older and all other vaccines to patients 13 years of age and older

by written protocol with a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized to prescribe drugs under section 148.235, provided that:

(i) the protocol includes, at a minimum:

(A) the name, dose, and route of each vaccine that may be given;

(B) the patient population for whom the vaccine may be given;

(C) contraindications and precautions to the vaccine;

(D) the procedure for handling an adverse reaction;

(E) the name, signature, and address of the physician, physician assistant, or advanced practice registered nurse;

(F) a telephone number at which the physician, physician assistant, or advanced practice registered nurse can be contacted; and

(G) the date and time period for which the protocol is valid;

(ii) the pharmacist has successfully completed a program approved by the Accreditation Council for Pharmacy Education specifically for the administration of immunizations or a program approved by the board;

(iii) the pharmacist utilizes the Minnesota Immunization Information Connection to assess the immunization status of individuals prior to the administration of vaccines, except when administering influenza vaccines to individuals age nine and older;

(iv) the pharmacist reports the administration of the immunization to the Minnesota Immunization Information Connection; and

(v) the pharmacist complies with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices, except that a pharmacist does not need to comply with those portions of the guidelines that establish immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice nurse authorized to prescribe drugs under section 148.235, provided that the order is consistent with the United States Food and Drug Administration approved labeling of the vaccine;

(6) participation in the initiation, management, modification, and discontinuation of drug therapy according to a written protocol or collaborative practice agreement between: (i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists, or veterinarians; or (ii) one or more pharmacists and one or more physician assistants authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice nurses authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy made pursuant to a protocol or collaborative

practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;

(7) participation in the storage of drugs and the maintenance of records;

(8) patient counseling on therapeutic values, content, hazards, and uses of drugs and devices; ~~and~~

(9) offering or performing those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a pharmacy~~.~~; and

(10) participation in the initiation, management, modification, and discontinuation of therapy with opiate antagonists, as defined in section 604A.04, subdivision 1, pursuant to:

(i) a written protocol as allowed under clause (6); or

(ii) a written protocol with a community health board medical consultant or a practitioner designated by the commissioner of health, as allowed under section 151.37, subdivision 13.

Sec. 2. Minnesota Statutes 2014, section 151.01, is amended by adding a subdivision to read:

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

Sec. 3. Minnesota Statutes 2015 Supplement, section 151.37, subdivision 2, is amended to read:

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

otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18.

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

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

(d) A prescription drug order for the following drugs is not valid, unless it can be established that the prescription drug order was based on a documented patient evaluation, including an examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment:

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

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

(3) muscle relaxants;

(4) centrally acting analgesics with opioid activity;

(5) drugs containing butalbital; or

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

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

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

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

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

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

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

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

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

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

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

(j) No pharmacist employed by, under contract to, or working for a pharmacy <u>located outside the state and</u> licensed under section 151.19, subdivision ~~2~~ <u>1</u>, may dispense a legend

drug to a resident of this state based on a prescription that the pharmacist knows, or would reasonably be expected to know, is not valid under paragraph (d).

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

Sec. 4. Minnesota Statutes 2014, section 151.37, subdivision 6, is amended to read:

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

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

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

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

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

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

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

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

Sec. 5. Minnesota Statutes 2014, section 151.37, is amended by adding a subdivision to read:

Subd. 6a. **Collection of legend drugs by pharmacies.** A pharmacy licensed under section 151.19 may collect a legend drug from an ultimate user, or from a long-term care

facility on behalf of an ultimate user who resides or resided at the long-term care facility, for the purpose of disposing of the legend drug as pharmaceutical waste, provided that:

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

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

Sec. 6. Minnesota Statutes 2014, section 151.37, subdivision 7, is amended to read:

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

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

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

Sec. 7. Minnesota Statutes 2014, section 151.37, is amended by adding a subdivision to read:

Subd. 13. **Opiate antagonists protocol.** (a) The board shall develop an opiate antagonist protocol. When developing the protocol, the board shall consult with the Board of Medical Practice, the Board of Nursing, the commissioner of health, and professional associations of pharmacists, physicians, physician assistants, and advanced practice registered nurses.

(b) The commissioner of health shall provide the following items to medical consultants appointed under section 145A.04, subdivision 2a:

(1) educational materials concerning the need for, and opportunities to provide, greater access to opiate antagonists;

(2) the opiate antagonist protocol developed by the board under paragraph (a); and

(3) a notice of the liability protections under section 604A.04, subdivision 3, that are extended to cover the use of the opiate antagonist protocol developed under this subdivision.

(c) The commissioner of health may designate a practitioner who is authorized to prescribe opiate antagonists to enter into the written protocol developed under paragraph (a) with pharmacists practicing within one or more community health service areas, upon the request of the applicable community health board. A community health board making a request to the commissioner under this section must do so by October 1 for the subsequent calendar year.

(d) The immunity in section 604A.04, subdivision 3, is extended to both the commissioner of health and to the designated practitioner when prescribing according to the protocol under this subdivision. The commissioner of health and the designated practitioner are both deemed to be acting within the scope of employment for purposes of section 3.736, subdivision 9, when prescribing according to the protocol under this subdivision.

Sec. 8. **[152.105] DISPOSAL.**

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

Sec. 9. **EFFECTIVE DATE.**

Sections 1 to 8 are effective the day following final enactment.