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State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-SECOND SESSION

H. F. No. 3854

02/28/2022 Authored by Hollins
The bill was read for the first time and referred to the Committee on Health Finance and Policy

1.1 A bill for an act
1.2 relating to health care; authorizing pharmacists to prescribe, dispense, and
1.3 administer drugs to prevent the acquisition of human immunodeficiency virus;
1.4 authorizing pharmacists to order, conduct, and interpret laboratory tests necessary
1.5 for therapy that uses drugs to prevent the acquisition of human immunodeficiency
1.6 virus; amending Minnesota Statutes 2020, sections 151.01, subdivisions 23, 27;
1.7 151.37, by adding a subdivision; proposing coding for new law in Minnesota
1.8 Statutes, chapter 62Q.

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

1.10 Section 1. [62Q.1842] PROHIBITION ON USE OF STEP THERAPY FOR
1.11 ANTIRETROVIRAL DRUGS.

1.12 Subdivision 1. Definitions. (a) For purposes of this section, the following definitions
1.13 apply.

1.14 (b) "Health plan" has the meaning given in section 62Q.01, subdivision 3, and includes
1.15 health coverage provided by a managed care plan or a county-based purchasing plan
1.16 participating in a public program under chapter 256B or 256L or an integrated health
1.17 partnership under section 256B.0755.

1.18 (c) "Step therapy protocol" has the meaning given in section 62Q.184.

1.19 Subd. 2. Prohibition on use of step therapy protocols. A health plan that covers
1.20 antiretroviral drugs that are medically necessary for the prevention of HIV/AIDS, including
1.21 preexposure prophylaxis and postexposure prophylaxis, must not limit or exclude coverage
1.22 for the antiretroviral drugs by requiring prior authorization or by requiring an enrollee to
1.23 follow a step therapy protocol.

2.1 Sec. 2. [62Q.524] COVERAGE FOR DRUGS TO PREVENT THE ACQUISITION
2.2 OF HUMAN IMMUNODEFICIENCY VIRUS.

2.3 (a) A health plan that provides prescription drug coverage must provide coverage in
2.4 accordance with this section for:

2.5 (1) any antiretroviral drug approved by the United States Food and Drug Administration
2.6 (FDA) for preventing the acquisition of human immunodeficiency virus (HIV) that is
2.7 prescribed, dispensed, or administered by a pharmacist who meets the requirements described
2.8 in section 151.37, subdivision 17; and

2.9 (2) any laboratory testing necessary for therapy that uses the drugs described in clause
2.10 (1) that is ordered, performed, and interpreted by a pharmacist who meets the requirements
2.11 described in section 151.37, subdivision 17.

2.12 (b) A health plan must provide the same terms of prescription drug coverage for drugs
2.13 to prevent the acquisition of HIV that are prescribed or administered by a pharmacist if the
2.14 pharmacist meets the requirements described in section 151.37, subdivision 17, as would
2.15 apply had the drug been prescribed or administered by a physician, physician assistant, or
2.16 advanced practice registered nurse. The health plan may require pharmacists or pharmacies
2.17 to meet reasonable medical management requirements when providing the services described
2.18 in paragraph (a) if other providers are required to meet the same requirements.

2.19 (c) A health plan must reimburse an in-network pharmacist or pharmacy for the drugs
2.20 and testing described in paragraph (a) at a rate equal to the rate of reimbursement provided
2.21 to a physician, physician assistant, or advanced practice registered nurse if providing similar
2.22 services.

2.23 (d) A health plan is not required to cover the drugs and testing described in paragraph
2.24 (a) if provided by a pharmacist or pharmacy that is out-of-network unless the health plan
2.25 covers similar services provided by out-of-network providers. A health plan must ensure
2.26 that the health plan's provider network includes in-network pharmacies that provide the
2.27 services described in paragraph (a).

2.28 Sec. 3. Minnesota Statutes 2020, section 151.01, subdivision 23, is amended to read:

2.29 Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed
2.30 doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of
2.31 dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, licensed
2.32 advanced practice registered nurse, or licensed physician assistant. For purposes of sections
2.33 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision

3.1 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to
3.2 dispense and administer under chapter 150A. For purposes of sections 151.252, subdivision
3.3 3, and 151.461, "practitioner" also means a pharmacist authorized to prescribe
3.4 self-administered hormonal contraceptives, nicotine replacement medications, or opiate
3.5 antagonists under section 151.37, subdivision 14, 15, or 16, or authorized to prescribe drugs
3.6 to prevent the acquisition of human immunodeficiency virus (HIV) under section 151.37,
3.7 subdivision 17.

3.8 Sec. 4. Minnesota Statutes 2020, section 151.01, subdivision 27, is amended to read:

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

3.10 (1) interpretation and evaluation of prescription drug orders;

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

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

3.20 (4) participation in drug and therapeutic device selection; drug administration for first
3.21 dosage and medical emergencies; intramuscular and subcutaneous administration used for
3.22 the treatment of alcohol or opioid dependence; drug regimen reviews; and drug or
3.23 drug-related research;

3.24 (5) drug administration, through intramuscular and subcutaneous administration used
3.25 to treat mental illnesses as permitted under the following conditions:

3.26 (i) upon the order of a prescriber and the prescriber is notified after administration is
3.27 complete; or

3.28 (ii) pursuant to a protocol or collaborative practice agreement as defined by section
3.29 151.01, subdivisions 27b and 27c, and participation in the initiation, management,
3.30 modification, administration, and discontinuation of drug therapy is according to the protocol
3.31 or collaborative practice agreement between the pharmacist and a dentist, optometrist,
3.32 physician, podiatrist, or veterinarian, or an advanced practice registered nurse authorized
3.33 to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy

4.1 or medication administration made pursuant to a protocol or collaborative practice agreement
4.2 must be documented by the pharmacist in the patient's medical record or reported by the
4.3 pharmacist to a practitioner responsible for the patient's care;

4.4 (6) participation in administration of influenza vaccines and vaccines approved by the
4.5 United States Food and Drug Administration related to COVID-19 or SARS-CoV-2 to all
4.6 eligible individuals six years of age and older and all other vaccines to patients 13 years of
4.7 age and older by written protocol with a physician licensed under chapter 147, a physician
4.8 assistant authorized to prescribe drugs under chapter 147A, or an advanced practice registered
4.9 nurse authorized to prescribe drugs under section 148.235, provided that:

4.10 (i) the protocol includes, at a minimum:

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

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

4.13 (C) contraindications and precautions to the vaccine;

4.14 (D) the procedure for handling an adverse reaction;

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

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

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

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

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

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

4.28 (v) the pharmacist complies with guidelines for vaccines and immunizations established
4.29 by the federal Advisory Committee on Immunization Practices, except that a pharmacist
4.30 does not need to comply with those portions of the guidelines that establish immunization
4.31 schedules when administering a vaccine pursuant to a valid, patient-specific order issued
4.32 by a physician licensed under chapter 147, a physician assistant authorized to prescribe

5.1 drugs under chapter 147A, or an advanced practice registered nurse authorized to prescribe
5.2 drugs under section 148.235, provided that the order is consistent with the United States
5.3 Food and Drug Administration approved labeling of the vaccine;

5.4 (7) participation in the initiation, management, modification, and discontinuation of
5.5 drug therapy according to a written protocol or collaborative practice agreement between:
5.6 (i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists,
5.7 or veterinarians; or (ii) one or more pharmacists and one or more physician assistants
5.8 authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice
5.9 registered nurses authorized to prescribe, dispense, and administer under section 148.235.
5.10 Any changes in drug therapy made pursuant to a protocol or collaborative practice agreement
5.11 must be documented by the pharmacist in the patient's medical record or reported by the
5.12 pharmacist to a practitioner responsible for the patient's care;

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

5.14 (9) patient counseling on therapeutic values, content, hazards, and uses of drugs and
5.15 devices;

5.16 (10) offering or performing those acts, services, operations, or transactions necessary
5.17 in the conduct, operation, management, and control of a pharmacy;

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

5.20 (i) a written protocol as allowed under clause (7); or

5.21 (ii) a written protocol with a community health board medical consultant or a practitioner
5.22 designated by the commissioner of health, as allowed under section 151.37, subdivision 13;
5.23 ~~and~~

5.24 (12) prescribing self-administered hormonal contraceptives; nicotine replacement
5.25 medications; and opiate antagonists for the treatment of an acute opiate overdose pursuant
5.26 to section 151.37, subdivision 14, 15, or 16;

5.27 (13) prescribing, dispensing, and administering drugs for preventing the acquisition of
5.28 human immunodeficiency virus (HIV) if the pharmacist meets the requirements under
5.29 section 151.37, subdivision 17; and

5.30 (14) ordering, conducting, and interpreting laboratory tests necessary for therapies that
5.31 use drugs for preventing the acquisition of human immunodeficiency virus (HIV), if the
5.32 pharmacist meets the requirements under section 151.37, subdivision 17.

6.1 Sec. 5. Minnesota Statutes 2020, section 151.37, is amended by adding a subdivision to
6.2 read:

6.3 Subd. 17. **Drugs for preventing the acquisition of HIV.** (a) A pharmacist is authorized
6.4 to prescribe and administer drugs to prevent the acquisition of human immunodeficiency
6.5 virus (HIV) in accordance with this subdivision.

6.6 (b) By January 1, 2023, the board of pharmacy shall develop a standardized protocol
6.7 for a pharmacist to follow in prescribing the drugs described in paragraph (a). In developing
6.8 the protocol, the board may consult with community health advocacy groups, the board of
6.9 medical practice, the board of nursing, the commissioner of health, professional pharmacy
6.10 associations, and professional associations for physicians, physician assistants, and advanced
6.11 practice registered nurses.

6.12 (c) Before a pharmacist is authorized to prescribe a drug described in paragraph (a), the
6.13 pharmacist must successfully complete a training program specifically developed for
6.14 prescribing drugs for preventing the acquisition of HIV that is offered by a college of
6.15 pharmacy, a continuing education provider that is accredited by the Accreditation Council
6.16 for Pharmacy Education, or a program approved by the board. To maintain authorization
6.17 to prescribe, the pharmacist shall complete continuing education requirements as specified
6.18 by the board.

6.19 (d) Before prescribing a drug described in paragraph (a), the pharmacist shall follow the
6.20 appropriate standardized protocol developed under paragraph (b) and, if appropriate, may
6.21 dispense to a patient a drug described in paragraph (a).

6.22 (e) Before dispensing a drug described under paragraph (a) that is prescribed by the
6.23 pharmacist, the pharmacist must provide counseling to the patient on the use of the drugs
6.24 and must provide the patient with a fact sheet that includes the indications and
6.25 contraindications for the use of these drugs, the appropriate method for using these drugs,
6.26 the need for medical follow up, and any other additional information listed in Minnesota
6.27 Rules, part 6800.0910, subpart 2, that is required to be provided to a patient during the
6.28 counseling process.

6.29 (f) A pharmacist is prohibited from delegating the prescribing authority provided under
6.30 this subdivision to any other person. A pharmacist intern registered under section 151.101
6.31 may prepare the prescription, but before the prescription is processed or dispensed, a
6.32 pharmacist authorized to prescribe under this subdivision must review, approve, and sign
6.33 the prescription.

- 7.1 (g) Nothing in this subdivision prohibits a pharmacist from participating in the initiation,
7.2 management, modification, and discontinuation of drug therapy according to a protocol as
7.3 authorized in this section and in section 151.01, subdivision 27.