SENATE
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DATE	D-PG	OFFICIAL STATUS
03/01/2023	1198	Introduction and first reading Referred to Health and Human Services
03/06/2023	1367	Author added Boldon See HF5247

A bill for an act

relating to health care; authorizing pharmacists to prescribe, dispense, and administer drugs to prevent the acquisition of human immunodeficiency virus; authorizing pharmacists to order, conduct, and interpret laboratory tests necessary for therapy that uses drugs to prevent the acquisition of human immunodeficiency virus; amending Minnesota Statutes 2022, sections 151.01, subdivisions 23, 27; 151.37, by adding a subdivision; 256B.0625, subdivisions 13, 13f; proposing coding for new law in Minnesota Statutes, chapter 62Q.

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 3. Minnesota Statutes 2022, section 151.01, subdivision 23, is amended to read:

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

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

Sec. 4. Minnesota Statutes 2022, 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; intramuscular and subcutaneous drug administration under a prescription drug order; drug regimen reviews; and drug or drug-related research;

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

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

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

(6) participation in administration of influenza vaccines and vaccines approved by the United States Food and Drug Administration related to COVID-19 or SARS-CoV-2 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 registered 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;

(7) 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, physician assistants, 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 registered 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;

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

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

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

(11) 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 (7); 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;

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

(13) participation in the placement of drug monitoring devices according to a prescription, protocol, or collaborative practice agreement~~.~~;

(14) prescribing, dispensing, and administering drugs for preventing the acquisition of human immunodeficiency virus (HIV) if the pharmacist meets the requirements in section 151.37, subdivision 17; and

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

Sec. 5. Minnesota Statutes 2022, section 151.37, is amended by adding a subdivision to read:

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

(b) By January 1, 2024, the board of pharmacy shall develop a standardized protocol for a pharmacist to follow in prescribing the drugs described in paragraph (a). In developing the protocol, the board may consult with community health advocacy groups, the board of medical practice, the board of nursing, the commissioner of health, professional pharmacy associations, and professional associations for physicians, physician assistants, and advanced practice registered nurses.

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

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

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

(f) A pharmacist is prohibited from delegating the prescribing authority provided under this subdivision to any other person. A pharmacist intern registered under section 151.101

may prepare the prescription, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

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

Sec. 6. Minnesota Statutes 2022, section 256B.0625, subdivision 13, is amended to read:

Subd. 13. **Drugs.** (a) Medical assistance covers drugs, except for fertility drugs when specifically used to enhance fertility, if prescribed by a licensed practitioner and dispensed by a licensed pharmacist, by a physician enrolled in the medical assistance program as a dispensing physician, or by a physician, a physician assistant, or an advanced practice registered nurse employed by or under contract with a community health board as defined in section 145A.02, subdivision 5, for the purposes of communicable disease control.

(b) The dispensed quantity of a prescription drug must not exceed a 34-day supply, unless authorized by the commissioner or the drug appears on the 90-day supply list published by the commissioner. The 90-day supply list shall be published by the commissioner on the department's website. The commissioner may add to, delete from, and otherwise modify the 90-day supply list after providing public notice and the opportunity for a 15-day public comment period. The 90-day supply list may include cost-effective generic drugs and shall not include controlled substances.

(c) For the purpose of this subdivision and subdivision 13d, an "active pharmaceutical ingredient" is defined as a substance that is represented for use in a drug and when used in the manufacturing, processing, or packaging of a drug becomes an active ingredient of the drug product. An "excipient" is defined as an inert substance used as a diluent or vehicle for a drug. The commissioner shall establish a list of active pharmaceutical ingredients and excipients which are included in the medical assistance formulary. Medical assistance covers selected active pharmaceutical ingredients and excipients used in compounded prescriptions when the compounded combination is specifically approved by the commissioner or when a commercially available product:

(1) is not a therapeutic option for the patient;

(2) does not exist in the same combination of active ingredients in the same strengths as the compounded prescription; and

(3) cannot be used in place of the active pharmaceutical ingredient in the compounded prescription.

(d) Medical assistance covers the following over-the-counter drugs when prescribed by a licensed practitioner or by a licensed pharmacist who meets standards established by the commissioner, in consultation with the board of pharmacy: antacids, acetaminophen, family planning products, aspirin, insulin, products for the treatment of lice, vitamins for adults with documented vitamin deficiencies, vitamins for children under the age of seven and pregnant or nursing women, and any other over-the-counter drug identified by the commissioner, in consultation with the Formulary Committee, as necessary, appropriate, and cost-effective for the treatment of certain specified chronic diseases, conditions, or disorders, and this determination shall not be subject to the requirements of chapter 14. A pharmacist may prescribe over-the-counter medications as provided under this paragraph for purposes of receiving reimbursement under Medicaid. When prescribing over-the-counter drugs under this paragraph, licensed pharmacists must consult with the recipient to determine necessity, provide drug counseling, review drug therapy for potential adverse interactions, and make referrals as needed to other health care professionals.

(e) Effective January 1, 2006, medical assistance shall not cover drugs that are coverable under Medicare Part D as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-2(e), for individuals eligible for drug coverage as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-1(a)(3)(A). For these individuals, medical assistance may cover drugs from the drug classes listed in United States Code, title 42, section 1396r-8(d)(2), subject to this subdivision and subdivisions 13a to 13g, except that drugs listed in United States Code, title 42, section 1396r-8(d)(2)(E), shall not be covered.

(f) Medical assistance covers drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B covered entities and ambulatory pharmacies under common ownership of the 340B covered entity. Medical assistance does not cover drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies.

(g) Notwithstanding paragraph (a), medical assistance covers self-administered hormonal contraceptives prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 14; nicotine replacement medications prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 15; and opiate antagonists used for the treatment of an acute opiate overdose prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 16.

(h) Medical assistance coverage of and reimbursement for antiretroviral drugs to prevent the acquisition of human immunodeficiency virus and any laboratory testing necessary for therapy that uses these drugs must meet the requirements that would otherwise apply to a health plan under section 62Q.524.

Sec. 7. Minnesota Statutes 2022, section 256B.0625, subdivision 13f, is amended to read:

Subd. 13f. **Prior authorization.** (a) The Formulary Committee shall review and recommend drugs which require prior authorization. The Formulary Committee shall establish general criteria to be used for the prior authorization of brand-name drugs for which generically equivalent drugs are available, but the committee is not required to review each brand-name drug for which a generically equivalent drug is available.

(b) Prior authorization may be required by the commissioner before certain formulary drugs are eligible for payment. The Formulary Committee may recommend drugs for prior authorization directly to the commissioner. The commissioner may also request that the Formulary Committee review a drug for prior authorization. Before the commissioner may require prior authorization for a drug:

(1) the commissioner must provide information to the Formulary Committee on the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs, information regarding whether the drug is subject to clinical abuse or misuse, and relevant data from the state Medicaid program if such data is available;

(2) the Formulary Committee must review the drug, taking into account medical and clinical data and the information provided by the commissioner; and

(3) the Formulary Committee must hold a public forum and receive public comment for an additional 15 days.

The commissioner must provide a 15-day notice period before implementing the prior authorization.

(c) Except as provided in subdivision 13j, prior authorization shall not be required or utilized for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

(1) there is no generically equivalent drug available; and

(2) the drug was initially prescribed for the recipient prior to July 1, 2003; or

(3) the drug is part of the recipient's current course of treatment.

This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. Prior authorization shall automatically be granted for 60 days for brand name drugs prescribed for treatment of mental illness within 60 days of when a generically equivalent drug becomes available, provided that the brand name drug was part of the recipient's course of treatment at the time the generically equivalent drug became available.

(d) The commissioner may require prior authorization for brand name drugs whenever a generically equivalent product is available, even if the prescriber specifically indicates "dispense as written-brand necessary" on the prescription as required by section 151.21, subdivision 2.

(e) Notwithstanding this subdivision, the commissioner may automatically require prior authorization, for a period not to exceed 180 days, for any drug that is approved by the United States Food and Drug Administration on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within the state. The Formulary Committee shall recommend to the commissioner general criteria to be used for the prior authorization of the drugs, but the committee is not required to review each individual drug. In order to continue prior authorizations for a drug after the 180-day period has expired, the commissioner must follow the provisions of this subdivision.

(f) Prior authorization under this subdivision shall comply with ~~section~~ sections 62Q.184 and 62Q.1842.

(g) Any step therapy protocol requirements established by the commissioner must comply with ~~section~~ sections 62Q.1841 and 62Q.1842.