SENATE
STATE OF MINNESOTA
NINETY-SECOND SESSION

S.F. No. 340

(SENATE AUTHORS: DIBBLE)

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01/25/2021	163	Introduction and first reading Referred to Health and Human Services Finance and Policy

A bill for an act

relating to health care; authorizing pharmacists to dispense HIV preexposure prophylaxis and HIV postexposure prophylaxis without a prescription; amending Minnesota Statutes 2020, sections 151.01, subdivision 27; 151.06, subdivision 6; 151.37, by adding subdivisions; 214.122; 256B.0625, subdivision 13; 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) A health plan that covers antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, 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, except as provided in paragraph (b).

(b) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, a

health plan is not required to cover all of the therapeutically equivalent versions without prior authorization or a step therapy protocol requirement so long as at least one therapeutically equivalent version is covered without requiring prior authorization or the use of a step therapy protocol.

Sec. 2. **[62Q.524] COVERAGE FOR HIV PREEXPOSURE PROPHYLAXIS AND HIV POSTEXPOSURE PROPHYLAXIS.**

(a) A health plan that provides prescription coverage must provide coverage for preexposure and postexposure prophylaxis dispensed by a pharmacist under section 151.37, subdivision 17 or 18, under the same terms of coverage that would apply had the prescription drug been dispensed according to a valid prescription drug order.

(b) A health plan is not required to cover preexposure prophylaxis or postexposure prophylaxis if dispensed by an out-of-network pharmacy unless the health plan covers prescription drugs dispensed by out-of-network pharmacies.

(c) A health plan is not required to cover preexposure prophylaxis dispensed by a pharmacist as authorized by section 151.37, subdivision 17, if the enrollee has already received a 60-day supply within a two-year period unless the preexposure prophylaxis drug is dispensed by the pharmacist pursuant to a valid prescription drug order.

(d) A health plan company must not prohibit or permit a pharmacy benefit manager to prohibit a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis as a term or condition of a pharmacy in-network contract.

Sec. 3. Minnesota Statutes 2020, 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 administration used for the treatment of alcohol or opioid dependence; 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, 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, 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; ~~and~~

(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) the administration of HIV preexposure prophylaxis and HIV postexposure prophylaxis as authorized under section 151.37, subdivision 17 or 18.

Sec. 4. Minnesota Statutes 2020, section 151.06, subdivision 6, is amended to read:

Subd. 6. **Information provision; sources of lower cost prescription drugs.** (a) The board shall publish a page on its website that provides regularly updated information concerning:

(1) patient assistance programs offered by drug manufacturers, including information on how to access the programs;

(2) the insulin safety net program established in section 151.74, including information on how to access the program;

(3) the prescription drug assistance program established by the Minnesota Board of Aging under section 256.975, subdivision 9;

(4) the websites through which individuals can access information concerning eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other government-funded programs that help pay for the cost of health care;

(5) availability of providers that are authorized to participate under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b;

(6) having a discussion with the pharmacist or the consumer's health care provider about alternatives to a prescribed drug, including a lower cost or generic drug if the drug prescribed is too costly for the consumer; ~~and~~

(7) the availability of HIV preexposure and HIV postexposure prophylaxis, including how to obtain these drugs with or without a prescription, in accordance with section 151.37, subdivision 17 or 18; and

~~(7)~~ (8) any other resource that the board deems useful to individuals who are attempting to purchase prescription drugs at lower costs.

(b) The board must prepare educational materials, including brochures and posters, based on the information it provides on its website under paragraph (a). The materials must be in a form that can be downloaded from the board's website and used for patient education by pharmacists and by health care practitioners who are licensed to prescribe. The board is not required to provide printed copies of these materials.

(c) The board shall require pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established under paragraph (a).

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

Subd. 17. **HIV preexposure prophylaxis.** (a) For purposes of this subdivision, the following definitions apply:

(1) "preexposure prophylaxis" means a fixed dose combination of tenofovir disoproxil fumarate (TDF) (300 milligrams) with emtricitabine (FTC) (200 milligrams), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in United States Centers for Disease Control and Prevention (CDC) guidelines; and

(2) "CDC guidelines" means the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2017 Update: A Clinical Practice Guidelines" or any subsequent guidelines published by the CDC.

(b) A pharmacist may dispense HIV preexposure prophylaxis without a prescription drug order in accordance with this subdivision.

(c) Before dispensing a preexposure prophylaxis to a patient, a pharmacist must complete a training program approved by the board on the use of preexposure prophylaxis and postexposure prophylaxis. The training program must include information on financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including patient assistance programs offered by drug manufacturers and the AIDS drug assistance program administered by the Department of Human Services. The board must approve a training program in consultation with the Board of Medical Practice, the commissioners of human services and health, and other relevant stakeholders by January 1, 2022.

(d) If a pharmacist completes the training program required under paragraph (c), the pharmacist may dispense a preexposure prophylaxis to a patient if the patient:

(1) is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test, an antibody only test, or a rapid, point-of-care finger stick blood test approved by the United States Food and Drug Administration. If the test results are not provided directly to the pharmacist, the pharmacist must verify the test results to the pharmacist's satisfaction. If the patient does not provide evidence of a negative HIV test in accordance with this clause, the pharmacist must either administer an HIV test to the patient or provide the patient with information on where to locally obtain an HIV test. If the pharmacist does not receive documentation of a negative HIV test to the satisfaction of the pharmacist, the pharmacist may dispense up to a ten-day supply of preexposure prophylaxis to the patient if the patient satisfies clauses (2) and (3). If the patient tests positive for HIV, the pharmacist must direct the patient to the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist must provide the patient with a list of local providers and clinics;

(2) does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms; and

(3) does not report taking any contraindicated medications.

(e) The pharmacist must provide counseling to the patient on the ongoing use of preexposure prophylaxis. The counseling may include education on possible side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment as applicable for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for patients of childbearing capacity. The pharmacist must inform the patient that the patient must be seen by a health care provider to receive subsequent prescriptions of preexposure prophylaxis.

(f) After dispensing the preexposure prophylaxis to the patient, the pharmacist must, with the patient's consent, inform the patient's primary care provider that the pharmacist has dispensed preexposure prophylaxis to the patient and has provided the required counseling in accordance with paragraph (e). If the patient does not have a primary care provider or refuses consent to notify the patient's primary care provider, the pharmacist must provide the patient with a list of providers to contact regarding ongoing care for preexposure prophylaxis. The pharmacist must maintain a record of the services provided to the patient and of the preexposure prophylaxis dispensed to the patient. The record must be maintained in the same manner required for prescription drug orders dispensed under this section.

Sec. 6. Minnesota Statutes 2020, section 151.37, is amended by adding a subdivision to read:

Subd. 18. **HIV postexposure prophylaxis.** (a) For purposes of this subdivision, the following definitions apply:

(1) "postexposure prophylaxis" means any of the following:

(i) tenofovir disoproxil fumarate (TDF) (300 milligrams) with emtricitabine (FTC) (200 milligrams), taken once daily, in combination with either raltegravir (400 milligrams), taken twice daily, or dolutegravir (50 milligrams), taken once daily;

(ii) tenofovir disoproxil fumarate (TDF) (300 milligrams) and emtricitabine (FTC) (200 milligrams), taken once daily, in combination with darunavir (800 milligrams) and ritonavir (100 milligrams), taken once daily; or

(iii) another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in the CDC guidelines; and

(2) "CDC guidelines" means the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV-United States, 2016" or any subsequent guidelines published by the CDC.

(b) A pharmacist may dispense a postexposure prophylaxis without a prescription drug order in accordance with this subdivision.

(c) Before dispensing a postexposure prophylaxis to a patient, a pharmacist must complete a training program approved by the board on the use of preexposure prophylaxis and postexposure prophylaxis. The training program must include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including patient assistance programs offered by drug manufacturers and the AIDS drug assistance program administered by the Department of Human Services. The board must approve a training program in consultation with the Board of Medical Practice, the commissioners of human services and health, and other relevant stakeholders by January 1, 2022.

(d) If a pharmacist completes the training program required under paragraph (c), the pharmacist may dispense a complete course of postexposure prophylaxis to a patient after the pharmacist:

(1) screens the patient and determines that exposure occurred within the previous 72 hours and the patient meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines; and

(2) provides HIV testing to the patient that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (United States Code, title 42, section 263a) or the pharmacist determines that the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this subdivision, the pharmacist may dispense postexposure prophylaxis to the patient.

(e) The pharmacist must provide counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines. The counseling may include education on possible side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment for HIV and sexually transmitted diseases. The pharmacist must inform the patient of the availability of preexposure prophylaxis for individuals who are at substantial risk of acquiring HIV.

(f) After dispensing the postexposure prophylaxis to the patient, the pharmacist must, with the patient's consent, inform the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist must provide the patient with a list of providers to contact regarding follow up care for postexposure prophylaxis. The pharmacist must maintain a record of the services provided to the patient and the postexposure prophylaxis dispensed to the patient. The record must be maintained in the same manner required for prescription drug orders dispensed under this section.

Sec. 7. Minnesota Statutes 2020, section 214.122, is amended to read:

214.122 INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS.

(a) The Board of Medical Practice and the Board of Nursing shall at least annually inform licensees who are authorized to prescribe prescription drugs of the availability of the Board of Pharmacy's website that contains information on resources and programs to assist patients with the cost of prescription drugs. The boards shall provide licensees with the website address established by the Board of Pharmacy under section 151.06, subdivision 6, and the materials described under section 151.06, subdivision 6, paragraph (b). The boards shall also ensure that licensees are provided with information on the insulin safety net program established in section 151.74, and a link to the Board of Pharmacy's information sheet on how patients can apply for the program.

(b) Licensees must make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established by the Board of Pharmacy under section 151.06, subdivision 6.

(c) The Board of Medical Practice and the Board of Nursing shall ensure that licensees are provided with information regarding the availability of preexposure or postexposure prophylaxis if the licensee has patients who are at high risk for HIV or may have been potentially exposed to HIV.

Sec. 8. Minnesota Statutes 2020, 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.

(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) Notwithstanding paragraph (a), medical assistance covers preexposure prophylaxis dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 17, and postexposure prophylaxis dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 18.