SENATE
STATE OF MINNESOTA
NINETY-FIRST SESSION

S.F. No. 1960

(SENATE AUTHORS: JENSEN and Abeler)

DATE	D-PG	OFFICIAL STATUS
03/04/2019	625	Introduction and first reading Referred to Health and Human Services Finance and Policy
03/16/2020	5537a	Comm report: To pass as amended and re-refer to Finance See SF13, Art. 2, Sec. 2, 19-20, 23-25, 28-29

A bill for an act

relating to health; authorizing pharmacists to prescribe self-administered hormonal contraceptives, tobacco and nicotine cessation medications and products, and opiate antagonists for the treatment of acute opiate overdose; amending Minnesota Statutes 2018, sections 151.01, by adding a subdivision; 151.37, by adding subdivisions; 256B.0625, subdivision 13h; Minnesota Statutes 2019 Supplement, sections 151.01, subdivisions 23, 27; 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.529] COVERAGE FOR DRUGS PRESCRIBED AND DISPENSED BY PHARMACIES.**

(a) A health plan that provides prescription coverage must provide coverage for self-administered hormonal contraceptives, nicotine replacement medications, and opiate antagonists for the treatment of an acute opiate overdose prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 14, 15, or 16, under the same terms of coverage that would apply had the prescription drug been prescribed by a licensed physician, physician assistant, or advanced practice nurse practitioner.

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

Sec. 2. Minnesota Statutes 2019 Supplement, 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, or licensed advanced practice registered nurse. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A. 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.

Sec. 3. Minnesota Statutes 2019 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; 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 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; ~~and~~

(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 (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; 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.

Sec. 4. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to read:

Subd. 42. **Self-administered hormonal contraceptive.** "Self-administered hormonal contraceptive" means a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and is administered by the user.

Sec. 5. Minnesota Statutes 2018, section 151.37, is amended by adding a subdivision to read:

Subd. 14. **Self-administered hormonal contraceptives.** (a) A pharmacist is authorized to prescribe self-administered hormonal contraceptives if the intended use is contraception in accordance with this subdivision. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing self-administrated hormonal contraceptives. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; the Minnesota section of the American Congress of Obstetricians and Gynecologists; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses. The protocol must, at a minimum, include:

(1) requiring the patient to complete a self-screening tool to identify patient risk factors for the use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria for Contraceptive Use developed by the federal Centers for Disease Control and Prevention;

(2) requiring the pharmacist to review the screening tool with the patient;

(3) other assessments the pharmacist should make before prescribing self-administered hormonal contraceptives;

(4) situations when the prescribing of self-administered hormonal contraceptives by a pharmacist is contraindicated;

(5) situations when the pharmacist must refer a patient to the patient's primary care provider or, if the patient does not have a primary care provider, to a nearby clinic or hospital; and

(6) any additional information concerning the requirements and prohibitions in this subdivision that the board considers necessary.

(b) Before a pharmacist is authorized to prescribe a self-administered hormonal contraceptive to a patient under this subdivision, the pharmacist shall successfully complete a training program on prescribing self-administered hormonal contraceptives that is offered by a college of pharmacy or by 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.

(c) Before prescribing a self-administered hormonal contraceptive, the pharmacist shall follow the standardized protocol developed under paragraph (a), and if appropriate, may prescribe a self-administered hormonal contraceptive to a patient, if the patient is:

(1) 18 years of age or older; or

(2) under the age of 18 if the patient has previously been prescribed a self-administered hormonal contraceptive by a licensed physician, physician assistant, or advanced practice registered nurse.

(d) The pharmacist shall provide counseling to the patient on the use of self-administered hormonal contraceptives and provide the patient with a fact sheet that includes but is not limited to the contraindications for use of the drug, the appropriate method for using the drug, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the self-administered hormonal contraceptive prescribed by the pharmacist.

(e) If a pharmacist prescribes and dispenses a self-administered hormonal contraceptive under this subdivision, the pharmacist shall not prescribe a refill to the patient unless the patient has evidence of a clinical visit with a physician, physician assistant, or advanced practice registered nurse within the preceding three years.

(f) A pharmacist who is authorized to prescribe a self-administered hormonal contraceptive is prohibited from delegating the prescribing to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare a prescription for a self-administered hormonal contraceptive, 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 or collaborative agreement as authorized in this section and in section 151.01, subdivision 27.

Sec. 6. Minnesota Statutes 2018, section 151.37, is amended by adding a subdivision to read:

Subd. 15. **Nicotine replacement medications.** (a) A pharmacist is authorized to prescribe nicotine replacement medications approved by the United States Food and Drug Administration in accordance with this subdivision. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing nicotine replacement medications. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.

(b) Before a pharmacist is authorized to prescribe nicotine replacement medications under this subdivision, the pharmacist shall successfully complete a training program specifically developed for prescribing nicotine replacement medications that is offered by a college of pharmacy or by 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.

(c) Before prescribing a nicotine replacement medication, the pharmacist shall follow the appropriate standardized protocol developed under paragraph (a), and if appropriate, may dispense to a patient a nicotine replacement medication.

(d) The pharmacist shall provide counseling to the patient on the use of the nicotine replacement medication and provide the patient with a fact sheet that includes but is not limited to the indications and contraindications for use of a nicotine replacement medication, the appropriate method for using the medication or product, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the medication prescribed by the pharmacist.

(e) A pharmacist who is authorized to prescribe a nicotine replacement medication under this subdivision is prohibited from delegating the prescribing of the medication to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare a prescription for the medication, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

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

Sec. 7. Minnesota Statutes 2018, section 151.37, is amended by adding a subdivision to read:

Subd. 16. **Opiate antagonists for the treatment of an acute opiate overdose.** (a) A pharmacist is authorized to prescribe opiate antagonists for the treatment of an acute opiate overdose. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing an opiate antagonist. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.

(b) Before a pharmacist is authorized to prescribe an opiate antagonist under this subdivision, the pharmacist shall successfully complete a training program specifically developed for prescribing opiate antagonists for the treatment of an acute opiate overdose that is offered by a college of pharmacy or by 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.

(c) Before prescribing an opiate antagonist under this subdivision, the pharmacist shall follow the appropriate standardized protocol developed under paragraph (a), and if appropriate, may dispense to a patient an opiate antagonist.

(d) The pharmacist shall provide counseling to the patient on the use of the opiate antagonist and provide the patient with a fact sheet that includes but is not limited to the indications and contraindications for use of the opiate antagonist, the appropriate method for using the opiate antagonist, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the opiate antagonist prescribed by the pharmacist.

(e) A pharmacist who prescribes an opiate antagonist under this subdivision is prohibited from delegating the prescribing of the medication to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare the prescription for the opiate antagonist, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(f) 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. 8. Minnesota Statutes 2019 Supplement, 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, physician assistant, or a nurse practitioner 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.

Sec. 9. Minnesota Statutes 2018, section 256B.0625, subdivision 13h, is amended to read:

Subd. 13h. **Medication therapy management services.** (a) Medical assistance covers medication therapy management services for a recipient taking prescriptions to treat or prevent one or more chronic medical conditions. For purposes of this subdivision, "medication therapy management" means the provision of the following pharmaceutical care services by a licensed pharmacist to optimize the therapeutic outcomes of the patient's medications:

(1) performing or obtaining necessary assessments of the patient's health status;

(2) formulating a medication treatment plan, which may include prescribing medications or products in accordance with section 151.37, subdivision 14, 15, or 16;

(3) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;

(4) performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;

(5) documenting the care delivered and communicating essential information to the patient's other primary care providers;

(6) providing verbal education and training designed to enhance patient understanding and appropriate use of the patient's medications;

(7) providing information, support services, and resources designed to enhance patient adherence with the patient's therapeutic regimens; and

(8) coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.

Nothing in this subdivision shall be construed to expand or modify the scope of practice of the pharmacist as defined in section 151.01, subdivision 27.

(b) To be eligible for reimbursement for services under this subdivision, a pharmacist must meet the following requirements:

(1) have a valid license issued by the Board of Pharmacy of the state in which the medication therapy management service is being performed;

(2) have graduated from an accredited college of pharmacy on or after May 1996, or completed a structured and comprehensive education program approved by the Board of Pharmacy and the American Council of Pharmaceutical Education for the provision and documentation of pharmaceutical care management services that has both clinical and didactic elements;

(3) be practicing in an ambulatory care setting as part of a multidisciplinary team or have developed a structured patient care process that is offered in a private or semiprivate patient care area that is separate from the commercial business that also occurs in the setting, or in home settings, including long-term care settings, group homes, and facilities providing assisted living services, but excluding skilled nursing facilities; and

(4) make use of an electronic patient record system that meets state standards.

(c) For purposes of reimbursement for medication therapy management services, the commissioner may enroll individual pharmacists as medical assistance providers. The commissioner may also establish contact requirements between the pharmacist and recipient, including limiting the number of reimbursable consultations per recipient.

(d) If there are no pharmacists who meet the requirements of paragraph (b) practicing within a reasonable geographic distance of the patient, a pharmacist who meets the requirements may provide the services via two-way interactive video. Reimbursement shall be at the same rates and under the same conditions that would otherwise apply to the services provided. To qualify for reimbursement under this paragraph, the pharmacist providing the services must meet the requirements of paragraph (b), and must be located within an ambulatory care setting that meets the requirements of paragraph (b), clause (3). The patient must also be located within an ambulatory care setting that meets the requirements of paragraph (b), clause (3). Services provided under this paragraph may not be transmitted into the patient's residence.

(e) Medication therapy management services may be delivered into a patient's residence via secure interactive video if the medication therapy management services are performed electronically during a covered home care visit by an enrolled provider. Reimbursement shall be at the same rates and under the same conditions that would otherwise apply to the services provided. To qualify for reimbursement under this paragraph, the pharmacist providing the services must meet the requirements of paragraph (b) and must be located within an ambulatory care setting that meets the requirements of paragraph (b), clause (3).