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State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. **2635**

03/20/2019 Authored by Mann and Morrison

The bill was read for the first time and referred to the Committee on Health and Human Services Policy

- 1.1 A bill for an act
- 1.2 relating to health; authorizing pharmacists to prescribe self-administered hormonal
- 1.3 contraceptives, tobacco and nicotine cessation medications and products, opiate
- 1.4 antagonists, and travel medications; amending Minnesota Statutes 2018, sections
- 1.5 151.01, subdivisions 23, 27, by adding a subdivision; 256B.0625, subdivision 13h;
- 1.6 proposing coding for new law in Minnesota Statutes, chapter 151.
- 1.7 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
- 1.8 Section 1. Minnesota Statutes 2018, section 151.01, subdivision 23, is amended to read:
- 1.9 Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed
- 1.10 doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of
- 1.11 dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, or licensed
- 1.12 advanced practice registered nurse. For purposes of sections 151.15, subdivision 4; 151.216;
- 1.13 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461,
- 1.14 "practitioner" also means a physician assistant authorized to prescribe, dispense, and
- 1.15 administer under chapter 147A. For purposes of sections 151.15, subdivision 4; 151.252,
- 1.16 subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means
- 1.17 a dental therapist authorized to dispense and administer under chapter 150A. For purposes
- 1.18 of sections 151.252, subdivision 3, and 151.461, "practitioner" also means a pharmacist
- 1.19 who is prescribing self-administered hormonal contraceptives, tobacco and nicotine cessation
- 1.20 medications and products, and opiate antagonists.
- 1.21 Sec. 2. Minnesota Statutes 2018, section 151.01, subdivision 27, is amended to read:
- 1.22 Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:
- 1.23 (1) interpretation and evaluation of prescription drug orders;

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

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

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

2.12 (5) participation in administration of influenza vaccines to all eligible individuals six
2.13 years of age and older and all other vaccines to patients 13 years of age and older by written
2.14 protocol with a physician licensed under chapter 147, a physician assistant authorized to
2.15 prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized to
2.16 prescribe drugs under section 148.235, provided that:

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

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

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

2.20 (C) contraindications and precautions to the vaccine;

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

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

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

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

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

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

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

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

3.11 (6) participation in the initiation, management, modification, and discontinuation of
3.12 drug therapy according to a written protocol or collaborative practice agreement between:
3.13 (i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists,
3.14 or veterinarians; or (ii) one or more pharmacists and one or more physician assistants
3.15 authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice
3.16 nurses authorized to prescribe, dispense, and administer under section 148.235. Any changes
3.17 in drug therapy made pursuant to a protocol or collaborative practice agreement must be
3.18 documented by the pharmacist in the patient's medical record or reported by the pharmacist
3.19 to a practitioner responsible for the patient's care;

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

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

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

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

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

3.28 (ii) a written protocol with a community health board medical consultant or a practitioner
3.29 designated by the commissioner of health, as allowed under section 151.37, subdivision
3.30 13; and

3.31 (11) prescribing self-administered hormonal contraceptives, tobacco and nicotine
3.32 cessation medications and products, and opiate antagonists pursuant to section 152.216.

4.1 Sec. 3. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to
4.2 read:

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

4.7 Sec. 4. **[151.216] PHARMACIST PRESCRIBING.**

4.8 Subdivision 1. **Self-administered hormonal contraceptives.** (a) A pharmacist is
4.9 authorized to prescribe self-administered hormonal contraceptives, when the intended use
4.10 is contraception, to a person who is:

4.11 (1) at least 18 years of age, regardless of whether the person has evidence of a previous
4.12 prescription from a practitioner other than a pharmacist for a self-administered hormonal
4.13 contraceptive; or

4.14 (2) under 18 years of age, only if the person has evidence of a previous prescription
4.15 from a practitioner other than a pharmacist for a self-administered hormonal contraceptive.

4.16 (b) A pharmacist who prescribes self-administered hormonal contraceptives must:

4.17 (1) successfully complete a training program specifically developed for the prescribing
4.18 of self-administered hormonal contraceptives that is provided by a college of pharmacy or
4.19 by a continuing education provider that is accredited by the Accreditation Council for
4.20 Pharmacy Education, or a program approved by the board;

4.21 (2) follow the standardized protocol developed under this subdivision;

4.22 (3) provide the patient with a fact sheet that includes but is not limited to the
4.23 contraindications for use of the drug, the appropriate method for using the drug, the need
4.24 for medical follow-up, and any additional information listed in Minnesota Rules, part
4.25 6800.0910, subpart 2, that is required to be given to a patient during the counseling process;
4.26 and

4.27 (4) provide the patient with a written record of the self-administered hormonal
4.28 contraceptive prescribed by the pharmacist.

4.29 (c) A pharmacist who prescribes self-administered hormonal contraceptives is prohibited
4.30 from:

4.31 (1) prescribing and dispensing self-administered hormonal contraceptives to a patient
4.32 who does not have evidence of a clinical visit with a practitioner other than a pharmacist

5.1 within the three years immediately following the pharmacist's initial prescription of a
5.2 self-administered hormonal contraceptive to the patient; and

5.3 (2) delegating the prescribing of a self-administered hormonal contraceptive to any other
5.4 person. A pharmacist may allow a pharmacist intern registered pursuant to section 151.101
5.5 to prepare a prescription for a self-administered hormonal contraceptive, provided that the
5.6 prescription shall not be processed or dispensed until it is reviewed, approved, and signed
5.7 by the pharmacist.

5.8 (d) The board shall develop a standardized protocol that pharmacists must follow to
5.9 prescribe self-administered hormonal contraceptives. In developing the protocol, the board
5.10 shall:

5.11 (1) consult with the Minnesota Board of Medical Practice; the Minnesota Board of
5.12 Nursing; the commissioner of health; the Minnesota section of the American Congress of
5.13 Obstetricians and Gynecologists; professional pharmacy associations; and professional
5.14 associations of physicians, physician assistants, and advanced practice registered nurses;
5.15 and

5.16 (2) ensure that the protocol includes, at a minimum:

5.17 (i) a provision requiring the patient to complete a self-screening tool that will identify
5.18 patient risk factors for the use of self-administered hormonal contraceptives, based on the
5.19 current United States Medical Eligibility Criteria for Contraceptive Use developed by the
5.20 federal Centers for Disease Control and Prevention, and requiring the pharmacist to review
5.21 the completed self-screening tool;

5.22 (ii) instructions concerning how pharmacists should review the completed self-screening
5.23 tool;

5.24 (iii) instructions concerning any other assessments a pharmacist should make before
5.25 prescribing self-administered hormonal contraceptives;

5.26 (iv) instructions about situations in which the prescribing of self-administered hormonal
5.27 contraceptives by a pharmacist is contraindicated;

5.28 (v) instructions for situations in which a pharmacist should refer the patient to the patient's
5.29 primary care provider or, if the patient does not have a primary care provider, to a nearby
5.30 clinic or hospital; and

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

6.1 Subd. 2. Tobacco and nicotine cessation medications and products and opiate
6.2 antagonists. (a) A pharmacist is authorized to prescribe nicotine replacement products
6.3 approved by the United States Food and Drug Administration and opiate antagonists.

6.4 (b) A pharmacist who prescribes products or medications under this subdivision must:

6.5 (1) successfully complete a training program specifically developed for the prescribing
6.6 of the product or medication that is provided by a college of pharmacy or by a continuing
6.7 education provider that is accredited by the Accreditation Council for Pharmacy Education,
6.8 or a program approved by the board;

6.9 (2) follow the appropriate standardized protocol developed under this subdivision;

6.10 (3) provide the patient with a fact sheet that includes but is not limited to the indications
6.11 and contraindications for use of the product or medication, the appropriate method for using
6.12 the product or medication, the need for medical follow-up, and any additional information
6.13 listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient
6.14 during the counseling process; and

6.15 (4) provide the patient with a written record of the product or medication prescribed by
6.16 the pharmacist.

6.17 (c) A pharmacist who prescribes products or medications under this subdivision is
6.18 prohibited from delegating the prescribing of the product or medication to any other person,
6.19 but may allow a pharmacist intern registered pursuant to section 151.101 to prepare a
6.20 prescription for such product or medication, provided that such prescription shall not be
6.21 processed or dispensed until it is reviewed, approved, and signed by the pharmacist.

6.22 (d) The board shall develop standardized protocols that pharmacists must follow in order
6.23 to prescribe products and medications under this subdivision. In developing the protocols,
6.24 the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board
6.25 of Nursing; the commissioner of health; professional pharmacy associations; and professional
6.26 associations of physicians, physician assistants, and advanced practice registered nurses.

6.27 (e) Nothing in this subdivision prohibits a pharmacist from participating in the initiation,
6.28 management, modification, and discontinuation of therapy through a protocol as allowed
6.29 in this section or section 151.37, subdivisions 2 and 13.

6.30 Subd. 3. Insurance coverage. All state and federal laws governing insurance coverage
6.31 of self-administered contraceptive drugs, tobacco and nicotine cessation medications and
6.32 products, and opiate antagonists shall apply when those products are prescribed by a
6.33 pharmacist under this section.

7.1 Sec. 5. Minnesota Statutes 2018, section 256B.0625, subdivision 13h, is amended to read:

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

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

7.9 (2) formulating a medication treatment plan;

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

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

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

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

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

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

7.22 (9) prescribing products or medications as permitted under section 151.216, in accordance
7.23 with standardized protocols developed by the Board of Pharmacy.

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

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

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

7.30 (2) have graduated from an accredited college of pharmacy on or after May 1996, or
7.31 completed a structured and comprehensive education program approved by the Board of

8.1 Pharmacy and the American Council of Pharmaceutical Education for the provision and
8.2 documentation of pharmaceutical care management services that has both clinical and
8.3 didactic elements;

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

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

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

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

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