# SENATE
## STATE OF MINNESOTA
## EIGHTY-EIGHTH SESSION

# S.F. No. 2284

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| 03/04/2014 | 5960 | Introduction and first reading<br>Referred to Health, Human Services and Housing |
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A bill for an act

relating to health; setting requirements for the designation of specialty drugs and the filling of specialty drug prescriptions; allowing retail community pharmacies to fill mail-order prescriptions; placing limits on the use of maximum allowable cost pricing; proposing coding for new law in Minnesota Statutes, chapter 151.

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

Section 1. **[151.71] DEFINITIONS.**

(a) For purposes of sections 151.71 to 151.74, the following definitions apply.

(b) "Health plan" has the meaning provided in section 62Q.01, subdivision 3.

(c) "Health plan company" has the meaning provided in section 62Q.01, subdivision 4.

(d) "Managed care organization" has the meaning provided in section 62Q.01, subdivision 5.

(e) "Pharmacy benefit manager" means an entity that contracts with pharmacies on behalf of a health plan, state agency, health plan company, managed care organization, or other third-party payor to provide pharmacy benefit services or administration.

Sec. 2. **[151.72] SPECIALTY DRUGS.**

Subdivision 1. **Designation of specialty drugs.** (a) The Board of Pharmacy, in consultation with the commissioner of human services and the formulary committee established under section 256B.0625, subdivision 13e, shall specify the prescription drugs that may be considered specialty drugs by a pharmacy benefit manager under this section. In specifying the prescription drugs that may be considered specialty drugs, the board shall take into account whether:

(1) the prescription drug is used to treat a patient with a complex, chronic, or rare medical condition that is progressive, can be debilitating or fatal if left untreated or undertreated, or for which there is no known cure, including but not limited to multiple sclerosis, hepatitis C, cystic fibrosis, some cancers, HIV, and rheumatoid arthritis;

(2) the prescription drug is not generally stocked at community retail pharmacies;

(3) the prescription drug has special handling, storage, inventory, or distribution requirements; and

(4) patients receiving the prescription drug require complex education and maintenance, including but not limited to complex dosing, intensive monitoring, and clinical oversight.

(b) The board shall publish in the State Register, every six months, a list of the prescription drugs that the board has designated as specialty drugs.

(c) For purposes of this section, "specialty drug" means a prescription drug that requires special handling, special administration, unique inventory management, a high level of patient monitoring, or more intense patient support than conventional therapies.

Subd. 2. **Requirements for pharmacy benefit managers.** (a) If a pharmacy benefit manager intends to designate certain prescription drugs as specialty drugs on a formulary, the pharmacy benefits manager shall designate only prescription drugs that are on the list of specialty drugs published by the board under subdivision 1.

(b) A pharmacy benefit manager shall allow any licensed pharmacy or licensed pharmacist in the state to fill a prescription for a specialty drug at the specialty pharmacy rate, if the pharmacy or pharmacist:

(1) has a contract with the pharmacy benefit manager;

(2) has the specialty drug in inventory or has ready access to the specialty drug; and

(3) is capable of complying with any special handling, special administration, inventory management, patient monitoring, patient education and maintenance, and any other patient support requirements for the specialty drug.

(c) A pharmacy benefit manager shall reimburse the pharmacy or pharmacist for a specialty drug at the same rate that it applies to other pharmacies or pharmacists for filling a prescription for that specialty drug.

**EFFECTIVE DATE.** This section is effective August 1, 2014, and applies to pharmacy benefit manager contracts with pharmacies and pharmacists entered into or renewed on or after that date.

Sec. 3. **[151.73] FILLING MAIL ORDER PRESCRIPTIONS.**

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

(b) "Covered individual" means an individual receiving prescription drug coverage under a health plan, as defined in section 62Q.01, subdivision 3, through a pharmacy benefit manager, or through an employee benefit plan established or maintained by a plan sponsor.

(c) "Mail-order pharmacy" means a pharmacy licensed under this chapter that:

(1) has the primary business of receiving prescription drug orders by mail or electronic transmission;

(2) dispenses prescribed drugs to patients through the use of mail or a private delivery service; and

(3) primarily consults with patients by mail or electronic means.

(d) "Plan sponsor" has the meaning provided in section 151.61, subdivision 4.

(e) "Retail community pharmacy" means a pharmacy that is open to the public, serves walk-in customers, and allows individuals to whom a prescription drug is being dispensed the opportunity to consult with a pharmacist face-to-face.

Subd. 2. **Requirements for pharmacy benefit managers.** (a) A pharmacy benefit manager that is under contract with, or under the control of, a plan sponsor shall permit a covered individual to fill a prescription at:

(1) any mail-order pharmacy; or

(2) any retail community pharmacy that is part of the network of pharmacies offered to the plan sponsor or by the pharmacy benefit manager, if the pharmacy agrees to dispense the prescription drug for a price that is substantially the same as the price offered to a mail-order pharmacy.

(b) A pharmacy benefit manager may not impose cost-sharing or other requirements on a covered individual who elects to fill a prescription at a retail community pharmacy that is part of the network of pharmacies served by the pharmacy benefit manager that are different from the cost-sharing or other requirements that the pharmacy benefit manager imposes on a covered individual who elects to fill a prescription at a mail-order pharmacy.

(c) A pharmacy benefit manager shall use the same pricing benchmarks, indices, and formulas, and the same prescription drug codes, when reimbursing pharmacies under this section, regardless of whether the pharmacy is a mail-order pharmacy or a retail community pharmacy.

**EFFECTIVE DATE.** This section is effective August 1, 2014, and applies to pharmacy benefit manager contracts with pharmacies, pharmacists, and plan sponsors entered into or renewed on or after that date.

Sec. 4. **[151.74] MAXIMUM ALLOWABLE COST PRICING.**

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

(b) "Maximum allowable cost" means:

(1) a maximum reimbursement amount for a group of therapeutically and pharmaceutically equivalent multiple-source drugs that are listed in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration; or

(2) any similar reimbursement amount that is used by a pharmacy benefit manager to reimburse pharmacies for multiple-source drugs.

(c) "Nationally available" means that all pharmacies in Minnesota can purchase the drug, without limitation, from regional or national wholesalers, and that the product is not obsolete or temporarily unavailable.

(d) "Therapeutically equivalent" means the drug is identified as therapeutically or pharmaceutically equivalent or "A" rated by the United States Food and Drug Administration.

Subd. 2. **Limits on use of maximum allowable cost pricing.** (a) A pharmacy benefit manager may not place a prescription drug on a maximum allowable cost pricing index or create for a prescription drug a maximum allowable cost rate until after the six-month period of generic exclusivity, and only if the prescription drug has three or more nationally available and therapeutically equivalent drugs.

(b) A pharmacy benefit manager shall remove a prescription drug from a maximum allowable cost pricing index, or eliminate the maximum allowable cost rate, if the criterion related to the number of nationally available and therapeutically equivalent drugs in paragraph (a) cannot be met due to changes in the national marketplace for prescription drugs. The removal of the drug or elimination of the rate must be made in a timely manner.

Subd. 3. **Notice requirements for use of maximum allowable cost pricing.** A pharmacy benefit manager shall disclose to a pharmacy with which it has contracted:

(1) at the beginning of each calendar year, the basis of the methodology and the sources used to establish the maximum allowable cost pricing index or maximum allowable cost rates used by the pharmacy benefit manager; and

(2) at least once every seven business days, the maximum allowable cost pricing index or maximum allowable cost rates used by the pharmacy benefit manager, provided in a readily accessible and useable format that retains a record of index or rate changes.

Subd. 4. **Contesting a rate.** A pharmacy benefit manager shall establish a procedure by which a pharmacy may contest a maximum allowable cost pricing index or maximum

allowable cost rate. The procedure established must require a pharmacy benefit manager to respond to a pharmacy that has contested a pricing index or rate within 15 calendar days. If the pharmacy benefit manager changes the pricing index or rate, the change must:

(1) become effective on the date on which the pharmacy initiated proceedings under this subdivision; and

(2) apply to all pharmacies in the pharmacy network served by the pharmacy benefit manager.

Subd. 5. **Patient data.** (a) A pharmacy benefit manager must adhere to the criteria specified in this subdivision when handling personally identifiable utilization and claims data or other sensitive patient data.

(b) A pharmacy benefit manager shall notify the health plan sponsor if it intends to sell, lease, or rent utilization or claims data for individuals covered by the health plan sponsor that the pharmacy benefit manager possesses. A pharmacy benefit manager shall notify the health plan sponsor 30 days before selling, leasing, or renting utilization or claims data, and provide the health plan sponsor with the name of the potential purchaser of the data and information on the expected use. A pharmacy benefit manager shall not sell, lease, or rent utilization or claims data without written approval from the health plan sponsor.

(c) The pharmacy benefit manager must also allow each individual covered by a health plan the opportunity to opt out of the sharing of utilization or claims data for that individual. A pharmacy benefit manager shall not initially contact covered individuals without the written permission of the health plan sponsor, and must obtain the written permission of the covered individual for any ongoing contact with the individual.

(d) A pharmacy benefit manager shall not transmit any personally identifiable utilization or claims data to a pharmacy owned by a pharmacy benefit manager, unless the patient has voluntarily elected, in writing, to fill a particular prescription at the pharmacy owned by the pharmacy benefit manager.

**EFFECTIVE DATE.** This section is effective August 1, 2014, and applies to pharmacy benefit manager contracts with pharmacies, pharmacists, and plan sponsors entered into or renewed on or after that date.