02/22/17 REVISOR ACF/LP 17-3456 as introduced

SENATE STATE OF MINNESOTA NINETIETH SESSION

S.F. No. 1509

(SENATE AUTHORS: ABELER, Kiffmeyer, Lourey and Hayden)

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02/27/2017
795
Introduction and first reading
Referred to Health and Human Services Finance and Policy
03/13/2017
03/14/2017
1462
Author added Kiffmeyer; Lourey
See SF3656, Art. 34, Sec. 9-10
See SF799, Sec. 5

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1.1 A bill for an act

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relating to human services; modifying provisions for dispensing certain drugs under medical assistance; modifying payment rates for certain drugs under medical assistance; amending Minnesota Statutes 2016, section 256B.0625, subdivisions 13, 13e.

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

- Section 1. Minnesota Statutes 2016, 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

Section 1.

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;

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- (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. Over-the-counter medications must be dispensed in a quantity that is the lowest of: (1) the number of dosage units contained in the manufacturer's original package; (2) the number of dosage units required to complete the patient's course of therapy; or (3) if applicable, the number of dosage units dispensed from a system using retrospective billing, as provided under subdivision 13e, paragraph (b).
- (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

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13g, except that drugs listed in United States Code, title 42, section 1396r-8(d)(2)(E), shall not be covered.

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(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.

Sec. 2. Minnesota Statutes 2016, section 256B.0625, subdivision 13e, is amended to read:

Subd. 13e. Payment rates. (a) Effective April 1, 2017, or upon federal approval, whichever is later, the basis for determining the amount of payment shall be the lower of the actual acquisition costs ingredient cost of the drugs or the maximum allowable cost by the commissioner plus the fixed professional dispensing fee; or the usual and customary price charged to the public. The usual and customary price is defined as the lowest price charged by the provider to a patient who pays for the prescription by cash, check, or charge account and includes those prices the pharmacy charges to customers enrolled in a prescription savings club or prescription discount club administered by the pharmacy or pharmacy chain. The amount of payment basis must be reduced to reflect all discount amounts applied to the charge by any third-party provider/insurer agreement or contract for submitted charges to medical assistance programs. The net submitted charge may not be greater than the patient liability for the service. The pharmacy professional dispensing fee shall be \$3.65 \$11.35 for legend prescription drugs prescriptions filled with legend drugs meeting the definition of "covered outpatient drugs" according to United States Code, title 42, section 1396r-8(k)(2), except that the dispensing fee for intravenous solutions which must be compounded by the pharmacist shall be \$8 \$11.35 per bag, \$14 per bag for cancer chemotherapy products, and \$30 per bag for total parenteral nutritional products dispensed in one liter quantities, or \$44 per bag for total parenteral nutritional products dispensed in quantities greater than one liter. The professional dispensing fee for prescriptions filled with over-the-counter drugs meeting the definition of covered outpatient drugs shall be \$11.35 for dispensed quantities equal to or greater than the number of units contained in the manufacturer's original package. The professional dispensing fee shall be prorated based on the percentage of the package dispensed when the pharmacy dispenses a quantity less than the number of units contained in the manufacturer's original package. The pharmacy dispensing fee for prescribed over-the-counter drugs not meeting the definition of covered outpatient drugs shall be \$3.65, except that the fee shall be \$1.31 for retrospectively billing pharmacies when billing for quantities less than the number of units contained in the manufacturer's original package. Actual acquisition cost includes quantity and other special

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discounts except time and cash discounts. The actual acquisition for quantities equal to or greater than the number of units contained in the manufacturer's original package and shall be prorated based on the percentage of the package dispensed when the pharmacy dispenses a quantity less than the number of units contained in the manufacturer's original package. The National Average Drug Acquisition Cost (NADAC) shall be used to determine the ingredient cost of a drug shall be estimated by the commissioner at wholesale acquisition cost plus four percent for independently owned pharmacies located in a designated rural area within Minnesota, and at wholesale acquisition cost plus two percent for all other pharmacies. A pharmacy is "independently owned" if it is one of four or fewer pharmacies under the same ownership nationally. A "designated rural area" means an area defined as a small rural area or isolated rural area according to the four-category classification of the Rural Urban Commuting Area system developed for the United States Health Resources and Services Administration. Effective January 1, 2014, the actual acquisition For drugs for which a NADAC is not reported, the commissioner shall estimate the ingredient cost at wholesale acquisition cost minus two percent. The commissioner shall establish the ingredient cost of a drug acquired through the federal 340B Drug Pricing Program shall be estimated by the commissioner at wholesale acquisition cost minus 40 percent at a 340B Drug Pricing Program maximum allowable cost. The 340B Drug Pricing Program maximum allowable cost shall be comparable to, but no higher than, the 340B Drug Pricing Program ceiling price established by the Health Resources and Services Administration. Wholesale acquisition cost is defined as the manufacturer's list price for a drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. The maximum allowable cost of a multisource drug may be set by the commissioner and it shall be comparable to, but the actual acquisition cost of the drug product and no higher than, the maximum amount paid by other third-party payors in this state who have maximum allowable cost programs and no higher than the NADAC of the generic product. Establishment of the amount of payment for drugs shall not be subject to the requirements of the Administrative Procedure Act.

(b) Pharmacies dispensing prescriptions to residents of long-term care facilities using an automated drug distribution system meeting the requirements of section 151.58, or a packaging system meeting the packaging standards set forth in Minnesota Rules, part 6800.2700, that govern the return of unused drugs to the pharmacy for reuse, may employ retrospective billing for prescription drugs dispensed to long-term care facility residents. A retrospectively billing pharmacy must submit a claim only for the quantity of medication

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used by the enrolled recipient during the defined billing period. A retrospectively billing pharmacy must use a billing period not less than one calendar month or 30 days.

- (c) An additional dispensing fee of \$.30 may be added to the dispensing fee paid to pharmacists for legend drug prescriptions dispensed to residents of long-term care facilities when a unit dose blister card system, approved by the department, is used. Under this type of dispensing system, the pharmacist must dispense a 30-day supply of drug. The National Drug Code (NDC) from the drug container used to fill the blister card must be identified on the claim to the department. The unit dose blister card containing the drug must meet the packaging standards set forth in Minnesota Rules, part 6800.2700, that govern the return of unused drugs to the pharmacy for reuse. A pharmacy provider using packaging that meets the standards set forth in Minnesota Rules, part 6800.2700, is required to credit the department for the actual acquisition cost of all unused drugs that are eligible for reuse, unless the pharmacy is using retrospective billing. The commissioner may permit the drug clozapine to be dispensed in a quantity that is less than a 30-day supply.
- (d) Whenever a maximum allowable cost has been set for If a pharmacy dispenses a multisource drug, payment shall be the lower of the usual and customary price charged to the public or the ingredient cost shall be the NADAC of the generic product or the maximum allowable cost established by the commissioner unless prior authorization for the brand name product has been granted according to the criteria established by the Drug Formulary Committee as required by subdivision 13f, paragraph (a), and the prescriber has indicated "dispense as written" on the prescription in a manner consistent with section 151.21, subdivision 2.
- (e) The basis for determining the amount of payment for drugs administered in an outpatient setting shall be the lower of the usual and customary cost submitted by the provider, 106 percent of the average sales price as determined by the United States

 Department of Health and Human Services pursuant to title XVIII, section 1847a of the federal Social Security Act, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. If average sales price is unavailable, the amount of payment must be lower of the usual and customary cost submitted by the provider, the wholesale acquisition cost, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. Effective January 1, 2014, the commissioner shall discount the payment rate for drugs obtained through the federal 340B Drug Pricing Program by 20 percent. The payment for drugs administered in an outpatient setting shall be made to the administering facility or practitioner. A retail or specialty pharmacy dispensing a drug for administration in an outpatient setting is not eligible for direct reimbursement.

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(f) The commissioner may negotiate lower reimbursement rates establish maximum
<u>allowable cost rates</u> for specialty pharmacy products than the rates that are lower than the
ingredient cost formulas specified in paragraph (a). The commissioner may require
individuals enrolled in the health care programs administered by the department to obtain
specialty pharmacy products from providers with whom the commissioner has negotiated
lower reimbursement rates able to provide enhanced clinical services and willing to accept
the specialty pharmacy reimbursement. Specialty pharmacy products are defined as those
used by a small number of recipients or recipients with complex and chronic diseases that
require expensive and challenging drug regimens. Examples of these conditions include,
but are not limited to: multiple sclerosis, HIV/AIDS, transplantation, hepatitis C, growth
hormone deficiency, Crohn's Disease, rheumatoid arthritis, and certain forms of cancer.
Specialty pharmaceutical products include injectable and infusion therapies, biotechnology
drugs, antihemophilic factor products, high-cost therapies, and therapies that require complex
care. The commissioner shall consult with the formulary committee to develop a list of
specialty pharmacy products subject to this paragraph maximum allowable cost
reimbursement. In consulting with the formulary committee in developing this list, the
commissioner shall take into consideration the population served by specialty pharmacy
products, the current delivery system and standard of care in the state, and access to care
issues. The commissioner shall have the discretion to adjust the reimbursement rate maximum
allowable cost to prevent access to care issues.

- (g) Home infusion therapy services provided by home infusion therapy pharmacies must be paid at rates according to subdivision 8d.
- (h) Effective for prescriptions filled on or after April 1, 2017, or upon federal approval, whichever is later, the commissioner shall increase the ingredient cost reimbursement calculated in paragraphs (a) and (f) by two percent for prescription and nonprescription drugs subject to the wholesale drug distributor tax under section 295.52.