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S.F. No. 1778

(SENATE AUTHORS: BENSON)

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02/27/2019	550	Introduction and first reading Referred to Health and Human Services Finance and Policy

A bill for an act

relating to human services; modifying provisions governing drug payments under medical assistance; amending Minnesota Statutes 2018, sections 256.969, subdivision 9; 256B.0625, subdivisions 13, 13e, 13f; 256B.064, subdivision 1a.

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

Section 1. Minnesota Statutes 2018, section 256.969, subdivision 9, is amended to read:

Subd. 9. **Disproportionate numbers of low-income patients served.** (a) For admissions occurring on or after July 1, 1993, the medical assistance disproportionate population adjustment shall comply with federal law and shall be paid to a hospital, excluding regional treatment centers and facilities of the federal Indian Health Service, with a medical assistance inpatient utilization rate in excess of the arithmetic mean. The adjustment must be determined as follows:

(1) for a hospital with a medical assistance inpatient utilization rate above the arithmetic mean for all hospitals excluding regional treatment centers and facilities of the federal Indian Health Service but less than or equal to one standard deviation above the mean, the adjustment must be determined by multiplying the total of the operating and property payment rates by the difference between the hospital's actual medical assistance inpatient utilization rate and the arithmetic mean for all hospitals excluding regional treatment centers and facilities of the federal Indian Health Service; and

(2) for a hospital with a medical assistance inpatient utilization rate above one standard deviation above the mean, the adjustment must be determined by multiplying the adjustment that would be determined under clause (1) for that hospital by 1.1. The commissioner shall report annually on the number of hospitals likely to receive the adjustment authorized by

this paragraph. The commissioner shall specifically report on the adjustments received by public hospitals and public hospital corporations located in cities of the first class.

(b) Certified public expenditures made by Hennepin County Medical Center shall be considered Medicaid disproportionate share hospital payments. Hennepin County and Hennepin County Medical Center shall report by June 15, 2007, on payments made beginning July 1, 2005, or another date specified by the commissioner, that may qualify for reimbursement under federal law. Based on these reports, the commissioner shall apply for federal matching funds.

(c) Upon federal approval of the related state plan amendment, paragraph (b) is effective retroactively from July 1, 2005, or the earliest effective date approved by the Centers for Medicare and Medicaid Services.

(d) Effective July 1, 2015, disproportionate share hospital (DSH) payments shall be paid in accordance with a new methodology using 2012 as the base year. Annual payments made under this paragraph shall equal the total amount of payments made for 2012. A licensed children's hospital shall receive only a single DSH factor for children's hospitals. Other DSH factors may be combined to arrive at a single factor for each hospital that is eligible for DSH payments. The new methodology shall make payments only to hospitals located in Minnesota and include the following factors:

(1) a licensed children's hospital with at least 1,000 fee-for-service discharges in the base year shall receive a factor of 0.868. A licensed children's hospital with less than 1,000 fee-for-service discharges in the base year shall receive a factor of 0.7880;

(2) a hospital that has in effect for the initial rate year a contract with the commissioner to provide extended psychiatric inpatient services under section 256.9693 shall receive a factor of 0.0160;

(3) a hospital that has received payment from the fee-for-service program for at least 20 transplant services in the base year shall receive a factor of 0.0435;

(4) a hospital that has a medical assistance utilization rate in the base year between 20 percent up to one standard deviation above the statewide mean utilization rate shall receive a factor of 0.0468;

(5) a hospital that has a medical assistance utilization rate in the base year that is at least one standard deviation above the statewide mean utilization rate but is less than three standard deviations above the mean shall receive a factor of 0.2300; and

(6) a hospital that has a medical assistance utilization rate in the base year that is at least three standard deviations above the statewide mean utilization rate shall receive a factor of 0.3711.

(e) Any payments or portion of payments made to a hospital under this subdivision that are subsequently returned to the commissioner because the payments are found to exceed the hospital-specific DSH limit for that hospital shall be redistributed, proportionate to the number of fee-for-service discharges, to other DSH-eligible non-children's hospitals that have a medical assistance utilization rate that is at least one standard deviation above the mean.

(f) An additional payment adjustment shall be established by the commissioner under this subdivision for a hospital that provides high levels of administering high-cost drugs to enrollees in fee-for-service medical assistance. The commissioner shall consider factors including fee-for-service medical assistance utilization rates and payments made for drugs purchased through the 340B drug purchasing program and administered to fee-for-service enrollees. If any part of this adjustment exceeds a hospital's hospital-specific disproportionate share hospital limit, the commissioner shall make a payment to the hospital that equals the nonfederal share of the amount that exceeds the limit. The total nonfederal share of the amount of the payment adjustment under this paragraph shall not exceed $1,500,000.

EFFECTIVE DATE. This section is effective for discharges on or after April 1, 2019.

Sec. 2. Minnesota Statutes 2018, 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. ~~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 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.

EFFECTIVE DATE. This section is effective April 1, 2019, or upon federal approval, whichever is later. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained.

Sec. 3. Minnesota Statutes 2018, section 256B.0625, subdivision 13e, is amended to read:

Subd. 13e. **Payment rates.** (a) The basis for determining the amount of payment shall be the lower of the ~~actual acquisition~~ ingredient costs 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 means the lowest price charged by the provider to a patient who pays for the prescription by cash, check, or charge account and includes prices the pharmacy charges to a patient 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~~ $10.48 for ~~legend prescription drugs, except that~~ prescriptions filled with legend drugs meeting the definition of "covered outpatient drugs" according to United States Code, title 42, section 1396r-8(k)(2). The dispensing fee for intravenous solutions ~~which~~ that must be compounded by the pharmacist shall be ~~$8~~ $10.48 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 $10.48 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 discounts except time and cash discounts. The actual acquisition 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 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 ingredient cost of a drug ~~acquired through~~ for a provider participating in the federal 340B Drug Pricing Program shall be ~~estimated by the commissioner at wholesale acquisition cost minus 40 percent~~ either the 340B Drug Pricing Program ceiling price established by the Health Resources and Services Administration or the National Average Drug Acquisition Cost (NADAC), whichever is lower. 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~~ 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

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~~ 28.6 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.

(f) The commissioner may ~~negotiate lower reimbursement~~ establish maximum allowable cost rates 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. 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) The commissioner shall contract with a vendor to conduct a cost of dispensing survey for all pharmacies that are physically located in the state of Minnesota that dispense outpatient drugs under medical assistance. The commissioner shall ensure that the vendor has prior experience in conducting cost of dispensing surveys. Each pharmacy enrolled with the department to dispense outpatient prescription drugs to fee-for-service members must respond to the cost of dispensing survey. The commissioner may sanction a pharmacy under section 256B.064 for failure to respond. The commissioner shall require the vendor to measure a single statewide cost of dispensing for all responding pharmacies to measure the mean, mean weighted by total prescription volume, mean weighted by medical assistance prescription volume, median, median weighted by total prescription volume, and median weighted by total medical assistance prescription volume. The commissioner shall post a copy of the final cost of dispensing survey report on the department's website. The initial survey must be completed no later than January 1, 2021, and repeated every three years. The commissioner shall provide a summary of the results of each cost of dispensing survey and provide recommendations for any changes to the dispensing fee to the chairs and ranking

members of the legislative committees with jurisdiction over medical assistance pharmacy reimbursement.

(i) 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.

EFFECTIVE DATE. This section is effective April 1, 2019, or upon federal approval, whichever is later. Paragraph (i) expires if federal approval is denied. The commissioner of human services shall inform the revisor of statutes when federal approval is obtained or denied.

Sec. 4. Minnesota Statutes 2018, section 256B.0625, subdivision 13f, is amended to read:

Subd. 13f. **Prior authorization.** (a) The Formulary Committee shall review and recommend drugs which require prior authorization. The Formulary Committee shall establish general criteria to be used for the prior authorization of brand-name drugs for which generically equivalent drugs are available, but the committee is not required to review each brand-name drug for which a generically equivalent drug is available.

(b) Prior authorization may be required by the commissioner before certain formulary drugs are eligible for payment. The Formulary Committee may recommend drugs for prior authorization directly to the commissioner. The commissioner may also request that the Formulary Committee review a drug for prior authorization. Before the commissioner may require prior authorization for a drug:

(1) the commissioner must provide information to the Formulary Committee on the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs, information regarding whether the drug is subject to clinical abuse or misuse, and relevant data from the state Medicaid program if such data is available;

(2) the Formulary Committee must review the drug, taking into account medical and clinical data and the information provided by the commissioner; and

(3) the Formulary Committee must hold a public forum and receive public comment for an additional 15 days.

The commissioner must provide a 15-day notice period before implementing the prior authorization.

(c) Except as provided in subdivision 13j, prior authorization shall not be required or utilized for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

(1) there is no generically equivalent drug available; and

(2) the drug was initially prescribed for the recipient prior to July 1, 2003; or

(3) the drug is part of the recipient's current course of treatment.

This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. Prior authorization shall automatically be granted for 60 days for brand name drugs prescribed for treatment of mental illness within 60 days of when a generically equivalent drug becomes available, provided that the brand name drug was part of the recipient's course of treatment at the time the generically equivalent drug became available.

~~(d) Prior authorization shall not be required or utilized for any antihemophilic factor drug prescribed for the treatment of hemophilia and blood disorders where there is no generically equivalent drug available if the prior authorization is used in conjunction with any supplemental drug rebate program or multistate preferred drug list established or administered by the commissioner.~~

~~(e)~~ (d) The commissioner may require prior authorization for brand name drugs whenever a generically equivalent product is available, even if the prescriber specifically indicates "dispense as written-brand necessary" on the prescription as required by section 151.21, subdivision 2.

~~(f)~~ (e) Notwithstanding this subdivision, the commissioner may automatically require prior authorization, for a period not to exceed 180 days, for any drug that is approved by the United States Food and Drug Administration on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within the state. The Formulary Committee shall recommend to the commissioner general criteria to be used for the prior authorization of the drugs, but the committee is not required to review each individual drug. In order to continue prior authorizations for a drug after the 180-day period has expired, the commissioner must follow the provisions of this subdivision.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 5. Minnesota Statutes 2018, section 256B.064, subdivision 1a, is amended to read:

Subd. 1a. **Grounds for sanctions against vendors.** (a) The commissioner may impose sanctions against a vendor of medical care for any of the following: (1) fraud, theft, or abuse in connection with the provision of medical care to recipients of public assistance; (2) a pattern of presentment of false or duplicate claims or claims for services not medically necessary; (3) a pattern of making false statements of material facts for the purpose of obtaining greater compensation than that to which the vendor is legally entitled; (4) suspension or termination as a Medicare vendor; (5) refusal to grant the state agency access during regular business hours to examine all records necessary to disclose the extent of services provided to program recipients and appropriateness of claims for payment; (6) failure to repay an overpayment or a fine finally established under this section; (7) failure to correct errors in the maintenance of health service or financial records for which a fine was imposed or after issuance of a warning by the commissioner; and (8) any reason for which a vendor could be excluded from participation in the Medicare program under section 1128, 1128A, or 1866(b)(2) of the Social Security Act.

(b) The commissioner may impose sanctions against a pharmacy provider for failure to respond to a cost of dispensing survey under section 256B.0625, subdivision 13e, paragraph (h).

EFFECTIVE DATE. This section is effective April 1, 2019.