| 31.4 | ARTICLE 4 |
|------|-------------------|
| 31.5 | PHARMACY BENEFITS |

| 191.1 | ARTICLE 5 |
|--------------------------------------|--|
| 191.2 | PHARMACY BENEFITS |
| 191.3 | Section 1. [62Q.83] FORMULARY CHANGES. |
| 191.4 191.5 | Subdivision 1. Definitions. (a) For purposes of this section, the following terms have the meanings given. |
| 191.6 | (b) "Drug" has the meaning given in section 151.01, subdivision 5. |
| 191.7 | (c) "Enrollee" has the meaning given in section 62Q.01, subdivision 2b. |
| 191.8 191.9 | (d) "Formulary" means a current list of covered prescription drug products that is subject to periodic review and update. |
| 191.10 | (e) "Health plan" has the meaning given in section 62Q.01, subdivision 3. |
| 191.11 191.12 | (f) "Pharmacy benefit manager" has the meaning given in section 62W.02, subdivision 15. |
| 191.13 | (g) "Prescription" has the meaning given in section 151.01, subdivision 16a. |
| 191.14 191.15 191.16 191.17 | Subd. 2. Formulary changes. (a) Except as provided in paragraphs (b) and (c), a health plan must not, with respect to an enrollee who was previously prescribed the drug during the plan year, remove a drug from the health plan's formulary or place a drug in a benefit category that increases the enrollee's cost for the duration of the enrollee's plan year. |
| 191.18 | (b) Paragraph (a) does not apply if a health plan changes the health plan's formulary: |
| 191.19 191.20 | (1) for a drug that has been deemed unsafe by the United States Food and Drug Administration (FDA); |
| 191.21 | (2) for a drug that has been withdrawn by the FDA or the drug manufacturer; or |
| 191.22 191.23 191.24 | (3) when an independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes with respect to a drug's use for reasons related to previously unknown and imminent patient harm. |
| 191.25 191.26 191.27 | (c) Paragraph (a) does not apply if a health plan removes a brand name drug from the health plan's formulary or places a brand name drug in a benefit category that increases the enrollee's cost if the health plan: |
| 191.28 191.29 | (1) adds to the health plan's formulary a generic or multisource brand name drug rated as therapeutically equivalent according to the FDA Orange Book, a biologic drug rated as |

| 191.30 191.31 | interchangeable according to the FDA Purple Book, or a biosimilar at the same or lower cost to the enrollee; and |
|------------------|--|
| 192.1 | (2) provides at least a 60-day notice to prescribers, pharmacists, and affected enrollees. |
| 1/2.1 | |
| 192.2 | EFFECTIVE DATE. This section is effective January 1, 2026, and applies to health |
| 192.3 | plans offered, sold, issued, or renewed on or after that date. |
| 192.4 | Sec. 2. Minnesota Statutes 2024, section 256B.0625, subdivision 13, is amended to read: |
| 192.5 | Subd. 13. Drugs. (a) Medical assistance covers drugs, except for fertility drugs when |
| 192.6 | specifically used to enhance fertility, if prescribed by a licensed practitioner and dispensed |
| 192.7 | by a licensed pharmacist, by a physician enrolled in the medical assistance program as a |
| 192.8 | dispensing physician, or by a physician, a physician assistant, or an advanced practice |
| 192.9 | registered nurse employed by or under contract with a community health board as defined |
| 192.10 | in section 145A.02, subdivision 5, for the purposes of communicable disease control. |
| 192.11 | (b) The dispensed quantity of a prescription drug must not exceed a 34-day supply unless |
| 192.11 | authorized by the commissioner or as provided in paragraph (h) or the drug appears on the |
| 192.12 | 90-day supply list published by the commissioner. The 90-day supply list shall be published |
| 192.14 | by the commissioner on the department's website. The commissioner may add to, delete |
| 192.14 | from, and otherwise modify the 90-day supply list after providing public notice and the |
| 192.16 | opportunity for a 15-day public comment period. The 90-day supply list may include |
| 192.17 | cost-effective generic drugs and shall not include controlled substances. |
| | |
| 192.18 | (c) For the purpose of this subdivision and subdivision 13d, an "active pharmaceutical |
| 192.19 | ingredient" is defined as a substance that is represented for use in a drug and when used in |
| 192.20 | the manufacturing, processing, or packaging of a drug becomes an active ingredient of the |
| 192.21 | drug product. An "excipient" is defined as an inert substance used as a diluent or vehicle |
| 192.22 | for a drug. The commissioner shall establish a list of active pharmaceutical ingredients and |
| 192.23 | excipients which are included in the medical assistance formulary. Medical assistance covers |
| 192.24 | selected active pharmaceutical ingredients and excipients used in compounded prescriptions |
| 192.25 | when the compounded combination is specifically approved by the commissioner or when |
| 192.26 | a commercially available product: |
| 192.27 | (1) is not a therapeutic option for the patient; |
| 192.28 | (2) does not exist in the same combination of active ingredients in the same strengths |
| 192.29 | as the compounded prescription; and |
| 192.30 | (3) cannot be used in place of the active pharmaceutical ingredient in the compounded |
| 192.31 | prescription. |
| 192.32 | (d) Medical assistance covers the following over-the-counter drugs when prescribed by |
| 192.33 | a licensed practitioner or by a licensed pharmacist who meets standards established by the |
| 193.1 | commissioner, in consultation with the board of pharmacy: antacids, acetaminophen, family |
| 193.2 | planning products, aspirin, insulin, products for the treatment of lice, vitamins for adults |
| 193.3 | with documented vitamin deficiencies, vitamins for children under the age of seven and |
| | , |

| 93.4 | pregnant or nursing women, and any other over-the-counter drug identified by the |
|-------|--|
| 93.5 | commissioner, in consultation with the Formulary Committee, as necessary, appropriate, |
| 93.6 | and cost-effective for the treatment of certain specified chronic diseases, conditions, or |
| 93.7 | disorders, and this determination shall not be subject to the requirements of chapter 14. A |
| 93.8 | pharmacist may prescribe over-the-counter medications as provided under this paragraph |
| 93.9 | for purposes of receiving reimbursement under Medicaid. When prescribing over-the-counter |
| 93.10 | drugs under this paragraph, licensed pharmacists must consult with the recipient to determine |
| 93.11 | necessity, provide drug counseling, review drug therapy for potential adverse interactions, |
| 93.12 | and make referrals as needed to other health care professionals. |
| 93.13 | (e) Effective January 1, 2006, medical assistance shall not cover drugs that are coverable |
| 93.14 | under Medicare Part D as defined in the Medicare Prescription Drug, Improvement, and |
| 93.15 | Modernization Act of 2003, Public Law 108-173, section 1860D-2(e), for individuals eligible |
| 93.16 | for drug coverage as defined in the Medicare Prescription Drug, Improvement, and |
| 93.17 | Modernization Act of 2003, Public Law 108-173, section 1860D-1(a)(3)(A). For these |
| 93.18 | individuals, medical assistance may cover drugs from the drug classes listed in United States |
| 93.19 | Code, title 42, section 1396r-8(d)(2), subject to this subdivision and subdivisions 13a to |
| 93.20 | 13g, except that drugs listed in United States Code, title 42, section 1396r-8(d)(2)(E), shall |
| 93.21 | not be covered. |
| | (0.14 1) 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 |
| 93.22 | (f) Medical assistance covers drugs acquired through the federal 340B Drug Pricing |
| 93.23 | Program and dispensed by 340B covered entities and ambulatory pharmacies under common |
| 93.24 | ownership of the 340B covered entity. Medical assistance does not cover drugs acquired |
| 93.25 | through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies. |
| 93.26 | (g) Notwithstanding paragraph (a), medical assistance covers self-administered hormonal |
| 93.27 | contraceptives prescribed and dispensed by a licensed pharmacist in accordance with section |
| 93.28 | 151.37, subdivision 14; nicotine replacement medications prescribed and dispensed by a |
| 93.29 | licensed pharmacist in accordance with section 151.37, subdivision 15; and opiate antagonists |
| 93.30 | used for the treatment of an acute opiate overdose prescribed and dispensed by a licensed |
| 93.31 | pharmacist in accordance with section 151.37, subdivision 16. |
| 93.32 | (h) Medical assistance coverage for a prescription contraceptive must provide a 12-month |
| 93.32 | supply for any prescription contraceptive if a 12-month supply is prescribed by the |
| 93.34 | prescribing health care provider. The prescribing health care provider must determine the |
| 93.35 | appropriate duration for which to prescribe the prescription contraceptives, up to 12 months. |
| 94.1 | For purposes of this paragraph, "prescription contraceptive" means any drug or device that |
| 94.2 | requires a prescription and is approved by the Food and Drug Administration to prevent |
| 94.3 | pregnancy. Prescription contraceptive does not include an emergency contraceptive drug |
| 94.4 | approved to prevent pregnancy when administered after sexual contact. For purposes of this |
| 94.5 | paragraph, "health plan" has the meaning provided in section 62Q.01, subdivision 3. |
| | |
| 94.6 | (i) Notwithstanding a removal of a drug from the drug formulary under subdivision 13d, |
| 94.7 | except as provided in paragraphs (j) and (k), medical assistance covers a drug, with respect |
| 94.8 | to an enrollee who was previously prescribed the drug during the calendar year when the |

31.6 Section 1. Minnesota Statutes 2024, section 256B.0625, subdivision 13c, is amended to 31.7 read:

Subd. 13c. Formulary Committee. The commissioner, after receiving recommendations 31.8 from professional medical associations and professional pharmacy associations, and consumer groups shall designate a Formulary Committee to carry out duties as described in subdivisions 13 to 13g. The Formulary Committee shall be comprised of at least five licensed physicians actively engaged in the practice of medicine in Minnesota, one of whom is an actively practicing psychiatrist, one of whom specializes in the diagnosis and treatment of rare diseases, one of whom specializes in pediatrics, and one of whom actively treats persons with disabilities; at least three licensed pharmacists actively engaged in the practice of pharmacy in Minnesota, one of whom practices outside the metropolitan counties listed in section 473.121, subdivision 4, one of whom practices in the metropolitan counties listed in section 473.121, subdivision 4, and one of whom is a practicing hospital pharmacist; at least two consumer representatives, all of whom must have a personal or professional connection to medical assistance; and one representative designated by the Minnesota Rare Disease Advisory Council established under section 256.4835; the remainder to be made up of health care professionals who are licensed in their field and have recognized knowledge in the clinically appropriate prescribing, dispensing, and monitoring of covered outpatient drugs. Members of the Formulary Committee shall not be employed by the Department of

drug was on the formulary, at the same level until January 1 of the calendar year following the year in which the commissioner removed the drug from the formulary. 194.11 (i) Paragraph (i) does not apply if the commissioner changes the drug formulary: (1) for a drug that has been deemed unsafe by the United States Food and Drug 194.12 194.13 Administration (FDA); (2) for a drug that has been withdrawn by the FDA or the drug manufacturer; or 194.14 (3) when an independent source of research, clinical guidelines, or evidence-based 194.15 194.16 standards has issued drug-specific warnings or recommended changes with respect to a drug's use for reasons related to previously unknown and imminent patient harm. (k) Paragraph (i) does not apply if the commissioner removes a brand name drug from 194.18 194.19 the formulary if the commissioner: (1) adds to the formulary a generic or multisource brand name drug rated as 194.20 194.21 therapeutically equivalent according to the FDA Orange Book, or a biologic drug rated as 194.22 interchangeable according to the FDA Purple Book, at the same or lower cost to the enrollee; 194.23 and 194.24 (2) provides at least a 60-day notice to prescribers, pharmacists, and affected enrollees. **EFFECTIVE DATE.** This section is effective January 1, 2026, or upon federal approval, 194.25 194.26 whichever is later. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained. Sec. 3. Minnesota Statutes 2024, section 256B.0625, subdivision 13c, is amended to read: 194.28 Subd. 13c. Formulary Committee. The commissioner, after receiving recommendations 194.29 194.30 from professional medical associations and professional pharmacy associations, and consumer groups shall designate a Formulary Committee to carry out duties as described in subdivisions 194.32 13 to 13g. The Formulary Committee shall be comprised of at least five licensed physicians actively engaged in the practice of medicine in Minnesota, one of whom is an actively practicing psychiatrist, one of whom specializes in the diagnosis and treatment of rare diseases, one of whom specializes in pediatrics, and one of whom actively treats persons with disabilities; at least three licensed pharmacists actively engaged in the practice of pharmacy in Minnesota, one of whom practices outside the metropolitan counties listed in section 473.121, subdivision 4, one of whom practices in the metropolitan counties listed in section 473.121, subdivision 4, and one of whom is a practicing hospital pharmacist; at least two consumer representatives, all of whom must have a personal or professional connection to medical assistance; and one representative designated by the Minnesota Rare 195.10 Disease Advisory Council established under section 256.4835; the remainder to be made 195.11 up of health care professionals who are licensed in their field and have recognized knowledge 195.12 in the clinically appropriate prescribing, dispensing, and monitoring of covered outpatient

Senate Language UEH2435-1

195.13 drugs. Members of the Formulary Committee shall not be employed by the Department of

| 31.25 | Human Services or have a personal interest in a pharmaceutical company, pharmacy benefits |
|-------|--|
| 31.26 | manager, health plan company, or their affiliate organizations, but the committee shall be |
| 31.27 | staffed by an employee of the department who shall serve as an ex officio, nonvoting member |
| 31.28 | of the committee. For the purposes of this subdivision, "personal interest" means that a |
| 31.29 | person owns at least five percent of the voting interest or equity interest in the entity, the |
| 31.30 | equity interest owned by a person represents at least five percent of that person's net worth, |
| 31.31 | or more than five percent of a person's gross income for the preceding year was derived |
| 31.32 | from the entity. A committee member must notify the committee of any potential conflict |
| 31.33 | of interest and recuse themselves from any communications, discussion, or vote on any |
| 31.34 | matter where a conflict of interest exists. A conflict of interest alone, without a personal |
| 32.1 | interest, does not preclude an applicant from serving as a member of the Formulary |
| 32.2 | Committee. Members may be removed from the committee for cause after a recommendation |
| 32.3 | for removal by a majority of the committee membership. For the purposes of this subdivision, |
| 32.4 | "cause" does not include offering a differing or dissenting clinical opinion on a drug or drug |
| 32.5 | class. The department's medical director shall also serve as an ex officio, nonvoting member |
| 32.6 | for the committee. Committee members shall serve three-year terms and may be reappointed |
| 32.7 | twice by the commissioner. The committee members shall vote on a chair and vice chair |
| 32.8 | from among their membership. The chair shall preside over all committee meetings, and |
| 32.9 | the vice chair shall preside over the meetings if the chair is not present. The Formulary |
| 32.10 | Committee shall meet at least three times per year. The commissioner may require more |
| 32.11 | frequent Formulary Committee meetings as needed. An honorarium of \$100 per meeting |
| 32.12 | and reimbursement for mileage shall be paid to each committee member in attendance. The |
| 32.13 | Formulary Committee expires June 30, 2027 <u>2029</u> . The Formulary Committee is subject to |
| 32.14 | the Open Meeting Law under chapter 13D. For purposes of establishing a quorum to transact |
| 32.15 | business, vacant committee member positions do not count in the calculation as long as at |
| 32.16 | least 60 percent of the committee member positions are filled. |

| 195.14 | Human Services or have a personal interest in a pharmaceutical company, pharmacy benefits |
|--------|--|
| 195.15 | manager, health plan company, or their affiliate organizations, but the committee shall be |
| 195.16 | staffed by an employee of the department who shall serve as an ex officio, nonvoting member |
| 195.17 | of the committee. For the purposes of this subdivision, "personal interest" means that a |
| | person owns at least five percent of the voting interest or equity interest in the entity, the |
| | equity interest owned by a person represents at least five percent of that person's net worth, |
| | or more than five percent of a person's gross income for the preceding year was derived |
| | from the entity. A committee member must notify the committee of any potential conflict |
| 195.22 | of interest and recuse themselves from any communications, discussion, or vote on any |
| 195.23 | matter where a conflict of interest exists. A conflict of interest alone, without a personal |
| 195.24 | interest, does not preclude an applicant from serving as a member of the Formulary |
| 195.25 | Committee. Members may be removed from the committee for cause after a recommendation |
| 195.26 | for removal by a majority of the committee membership. For the purposes of this subdivision, |
| 195.27 | "cause" does not include offering a differing or dissenting clinical opinion on a drug or drug |
| 195.28 | class. The department's medical director shall also serve as an ex officio, nonvoting member |
| 195.29 | for the committee. Committee members shall serve three-year terms and may be reappointed |
| | twice by the commissioner. The committee members shall vote on a chair and vice chair |
| 195.31 | from among their membership. The chair shall preside over all committee meetings, and |
| 195.32 | the vice chair shall preside over the meetings if the chair is not present. The Formulary |
| | Committee shall meet at least three times per year. The commissioner may require more |
| | frequent Formulary Committee meetings as needed. An honorarium of \$100 per meeting |
| | and reimbursement for mileage shall be paid to each committee member in attendance. The |
| 195.36 | Formulary Committee expires June 30, 2027 2029. The Formulary Committee is subject to |
| 196.1 | the Open Meeting Law under chapter 13D. For purposes of establishing a quorum to transact |
| 196.2 | business, vacant committee member positions do not count in the calculation as long as at |
| 196.3 | least 60 percent of the committee member positions are filled. |
| 196.4 | EFFECTIVE DATE. This section is effective the day following final enactment. |
| 196.5 | Sec. 4. Minnesota Statutes 2024, section 256B.0625, subdivision 13d, is amended to read: |
| 196.6 | Subd. 13d. Drug formulary. (a) The commissioner shall establish a drug formulary. Its |
| 196.7 | establishment and publication shall not be subject to the requirements of the Administrative |
| 196.8 | Procedure Act, but the Formulary Committee shall review and comment on the formulary |
| 196.9 | contents. |
| 196.10 | (b) The formulary shall not include: |
| 196.11 | (1) drugs, active pharmaceutical ingredients, or products for which there is no federal |
| 196.12 | |
| 170.12 | |
| 196.13 | (2) over-the-counter drugs, except as provided in subdivision 13; |
| 106.14 | (2) drugs or active pharmaceutical ingradients when used for the treatment of impotence |

196.15 or erectile dysfunction;

| 96.16 96.17 | (4) drugs or active pharmaceutical ingredients for which medical value has not been established; |
|--|--|
| 96.18 96.19 96.20 | (5) drugs from manufacturers who have not signed a rebate agreement with the Department of Health and Human Services pursuant to section 1927 of title XIX of the Social Security Act; and |
| 96.21 96.22 | (6) medical cannabis flower as defined in section 342.01, subdivision 54, or medical cannabinoid products as defined in section 342.01, subdivision 52. |
| 96.23 96.24 96.25 96.26 96.27 96.28 | (c) If a single-source drug used by at least two percent of the fee-for-service medical assistance recipients is removed from the formulary due to the failure of the manufacturer to sign a rebate agreement with the Department of Health and Human Services, the commissioner shall notify prescribing practitioners within 30 days of receiving notification from the Centers for Medicare and Medicaid Services (CMS) that a rebate agreement was not signed. |
| 96.29 96.30 96.31 96.32 | (d) Within ten calendar days of any commissioner determination to change the drug formulary, the commissioner must provide written notice to all enrollees affected by the change. The notice must include a description of the change, the reason for the change, and the date the change will become effective. |
| 97.1 97.2 97.3 97.4 97.5 | (e) By January 15, 2026, and annually thereafter, the commissioner of human services must provide a report with data and information related to the effects on enrollees of drug formulary changes made in the prior calendar year to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance. The report must include but is not limited to data and information on: |
| 97.6 97.7 | (1) the number of times the formulary was changed; (2) the reasons for the formulary changes and how frequently the formulary was changed |
| 97.8 97.9 | for each reason; (3) the drugs that were removed from the formulary; |
| 97.10 97.11 | (4) for each drug that was removed from the formulary, the number of enrollees who were prescribed that drug when it was removed; |
| 97.12 97.13 | (5) for each drug that was removed from the formulary, whether a therapeutically equivalent drug was added; |
| 97.14 | (6) the drugs that were added to the formulary; |
| 97.15 97.16 | (7) the fiscal impacts to the Department of Human Services resulting from the changes to the formulary; and |
| 97.17 97.18 | (8) enrollee populations or medical conditions disproportionately affected by the formulary changes. |

Sec. 5. Minnesota Statutes 2024, section 256B.0625, subdivision 13e, is amended to read:

32.17 Sec. 2. Minnesota Statutes 2024, section 256B.0625, subdivision 13e, is amended to read:

32.18 Subd. 13e. Payment rates. (a) The basis for determining the amount of payment shall be the lower of the ingredient costs of the drugs plus the 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, unless the prescription savings club or prescription discount club is one in which an individual pays a recurring monthly access fee for unlimited access to a defined list of drugs for which the pharmacy does not bill the member or a payer on a per-standard-transaction basis. 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 professional dispensing fee shall be \$11.55 for 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 that must be compounded by the pharmacist shall be \$11.55 per claim. The professional dispensing fee for prescriptions filled with over-the-counter drugs meeting the definition of covered outpatient drugs shall be \$11.55 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 33.4 than the number of units contained in the manufacturer's original package. The pharmacy 33.5 dispensing fee for prescribed over-the-counter drugs not meeting the definition of covered outpatient drugs shall be \$3.65 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 33.7 33.8 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 for a drug is the lowest of the National Average Drug Acquisition Cost (NADAC) shall be used to determine the ingredient cost of a drug: the Minnesota actual acquisition cost (MNAAC). as defined in paragraph (i); or the maximum allowable cost. For drugs for which a NADAC, MNAAC, or maximum allowable cost is not reported, the commissioner shall estimate the ingredient cost at the wholesale acquisition cost minus two percent. The ingredient cost of a drug for a provider participating in the federal 340B Drug Pricing Program shall be either the 340B Drug Pricing Program ceiling price established by the Health Resources and Services Administration or, the NADAC, the MNAAC, or the maximum allowable cost, whichever is lower lowest. 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 the actual acquisition cost of the drug product and no higher than the NADAC of the generic product. Establishment

Subd. 13e. Payment rates. (a) The basis for determining the amount of payment shall 197.21 be the lower of the ingredient costs of the drugs plus the professional dispensing fee; or the 197.22 usual and customary price charged to the public. The usual and customary price means the 197.23 lowest price charged by the provider to a patient who pays for the prescription by cash, 197.24 check, or charge account and includes prices the pharmacy charges to a patient enrolled in 197.25 a prescription savings club or prescription discount club administered by the pharmacy or 197.26 pharmacy chain, unless the prescription savings club or prescription discount club is one 197.27 in which an individual pays a recurring monthly access fee for unlimited access to a defined 197.28 list of drugs for which the pharmacy does not bill the member or a payer on a per-standard-transaction basis. The amount of payment basis must be reduced to reflect all 197.30 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 professional dispensing fee shall be \$11.55 for 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 that must be compounded by the pharmacist shall be \$11.55 per claim. The professional dispensing fee for prescriptions filled with over-the-counter drugs meeting the definition of covered outpatient drugs shall be \$11.55 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 for quantities equal to or greater than the number of units 198.12 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 198.14 number of units contained in the manufacturer's original package. The ingredient cost for 198.15 a drug is the lower of the National Average Drug Acquisition Cost (NADAC) shall be used 198.16 to determine the ingredient cost of a drug, the Minnesota actual acquisition cost (MNAAC) as defined in paragraph (i), or the maximum allowable cost. For drugs for which a NADAC, a MNAAC, or a maximum allowable cost is not reported, the commissioner shall estimate 198.19 the ingredient cost at the wholesale acquisition cost minus two percent. The ingredient cost 198.20 of a drug for a provider participating in the federal 340B Drug Pricing Program shall be either the 340B Drug Pricing Program ceiling price established by the Health Resources and Services Administration or, the NADAC, the MNAAC, or the maximum allowable cost, whichever is lower. Wholesale acquisition cost is defined as the manufacturer's list 198.24 price for a drug or biological to wholesalers or direct purchasers in the United States, not 198.25 including prompt pay or other discounts, rebates, or reductions in price, for the most recent 198.26 month for which information is available, as reported in wholesale price guides or other 198.27 publications of drug or biological pricing data. The maximum allowable cost of a multisource 198.28 drug may be set by the commissioner and it shall be comparable to the actual acquisition

198.29 cost of the drug product 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.

33.27

34.1

34.2

34.4

34.5

34.6

34.7

34.8

34.15

34.16

34.17

34.18

34.19

- (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) 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) If a pharmacy dispenses a multisource drug, the ingredient cost shall be the <u>lesser</u> of the NADAC of the generic product, the MNAAC of the generic product, or the maximum allowable cost of the generic product 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. If prior authorization is granted, the ingredient cost shall be the lesser of the NADAC of the brand name product, the MNAAC of the brand name product, or the maximum allowable cost of the brand name product. A generic product includes a generic drug, an authorized generic drug, and a biosimilar biological product as defined in Code of Federal Regulations, title 42, section 423.4. A brand name product includes a brand name drug, a brand name biological product, and an unbranded biological product as defined in Code of Federal Regulations, title 42, section 423.4.
- (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 MNAAC, or the maximum allowable cost set by the commissioner. If average sales price is, MNAAC, and the maximum allowable cost are unavailable, the amount of payment must be lower of the usual and customary cost submitted by the provider, or the wholesale acquisition cost, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. The commissioner shall discount the payment rate for drugs obtained through the federal 340B Drug Pricing Program by 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.

198.30 of the amount of payment for drugs shall not be subject to the requirements of the 198.31 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.
- 199.4 (c) 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) If a pharmacy dispenses a multisource drug, the ingredient cost shall be the lesser

 of the NADAC of the generic product, the MNAAC of the generic product, or the maximum
 allowable cost of the generic product 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. If prior authorization is granted, the ingredient
 cost shall be the lesser of the NADAC of the brand name product, the MNAAC of the brand
 name product, or the maximum allowable cost of the brand name product. A generic product
 includes a generic drug, an authorized generic drug, and a biosimilar biological product as
 defined in Code of Federal Regulations, title 42, section 423.4. A brand name product
 product as defined in Code of Federal Regulations, title 42, section 423.4.
- (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 MNAAC, or the maximum allowable cost set by the commissioner. If the average sales price is, the MNAAC, and the maximum allowable cost are unavailable, the amount of payment must be lower of the usual and customary cost submitted by the provider, or the wholesale acquisition cost, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. The commissioner shall discount the payment rate for drugs obtained through the federal 340B Drug Pricing Program by 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 establish maximum allowable cost rates for specialty pharmacy products 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 selerosis, 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 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 maximum allowable cost to prevent access to care issues.

34.32

34.33

34.34

35.1

35.3

35.4

35.5 35.6

35.7

35.8

35.9 35.10

35.11

35.12 35.13

35.15

35.17

36.1

36.2

(g) (f) Home infusion therapy services provided by home infusion therapy pharmacies must be paid at rates according to subdivision 8d.

(h) (g) 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 specialty prescription drugs and a single statewide cost of dispensing for nonspecialty prescription drugs 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 minority members of the legislative committees with jurisdiction over medical assistance pharmacy reimbursement. Notwithstanding section 256.01, subdivision 42, this paragraph does not expire.

(i) (h) The commissioner shall increase the ingredient cost reimbursement calculated in paragraphs (a) and (f) (e) by 1.8 percent the amount of the wholesale drug distributor tax

(f) The commissioner may establish maximum allowable cost rates for specialty pharmacy products 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 selerosis, 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 maximum allowable cost

Senate Language UEH2435-1

200.14 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

200.16 products, the current derivery system and standard of early in the state, and access to care 200.17 issues. The commissioner shall have the discretion to adjust the maximum allowable cost

200.18 to prevent access to care issues.

200.19 (g) (f) Home infusion therapy services provided by home infusion therapy pharmacies 200.20 must be paid at rates according to subdivision 8d.

200.21 (h) (g) The commissioner shall contract with a vendor to conduct a cost of dispensing 200.22 survey for all pharmacies that are physically located in the state of Minnesota that dispense 200.23 outpatient drugs under medical assistance. The commissioner shall ensure that the vendor 200.24 has prior experience in conducting cost of dispensing surveys. Each pharmacy enrolled with 200.25 the department to dispense outpatient prescription drugs to fee-for-service members must 200.26 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 specialty prescription drugs and a single statewide cost of dispensing for nonspecialty prescription drugs 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 two 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 minority members of the legislative committees with jurisdiction over medical assistance pharmacy reimbursement. Notwithstanding section 256.01, subdivision 42, this paragraph does not expire.

201.5 (i) (h) The commissioner shall increase the ingredient cost reimbursement calculated in 201.6 paragraphs (a) and (f) (e) by 1.8 percent the amount of the wholesale drug distributor tax

for prescription and nonprescription drugs subject to the wholesale drug distributor tax under section 295.52.

36.4

36.5

36.6

36.7

36.10

36.11

36.13

36.14

36.15

36.17

36.18

36.19

36.21

36.22

36.23

(i) The commissioner shall contract with a vendor to create the MNAAC through a periodic survey of enrolled pharmacy providers. Each pharmacy enrolled with the department to dispense outpatient prescription drugs must respond to the periodic surveys. The commissioner may sanction a pharmacy under section 256B.064 for failure to respond. The current MNAAC rates must be publicly available on the department's or vendor's website. The commissioner must require that the MNAAC is measured and calculated at least quarterly, but the MNAAC can be measured and calculated more frequently. The commissioner must ensure that the vendor has an appeal process available to providers for the time between the measurement and calculation of the periodically updated MNAAC rates if price fluctuations result in a MNAAC that is lower than what enrolled providers can purchase a drug for. Establishment of the MNAAC and survey reporting requirements are not subject to the requirements of the Administrative Procedure Act. Data provided by pharmacies for the measurement and calculation of the MNAAC is nonpublic data as defined under section 13.02, subdivision 9.

EFFECTIVE DATE. This section is effective January 1, 2027, 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 2024, section 256B.064, subdivision 1a, is amended to read:

Subd. 1a. Grounds for sanctions. (a) The commissioner may impose sanctions against any individual or entity that receives payments from medical assistance or provides goods or services for which payment is made from medical assistance for any of the following: (1) fraud, theft, or abuse in connection with the provision of goods and services to recipients of public assistance for which payment is made from medical 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 individual or entity 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 an individual or entity could be excluded from participation in the Medicare program under section 1128, 1128A, or 1866(b)(2) of the Social Security Act. For the purposes of this section, goods or services for which payment is made from medical assistance includes but is not limited to care and services identified in section 256B.0625 or provided pursuant to any federally approved waiver.

Senate Language UEH2435-1

| | for prescription and nonprescription drugs subject to the wholesale drug distributor tax |
|-------|--|
| 201.8 | under section 295.52. |
| 201.9 | (i) The commissioner shall contract with a vendor to create MNAAC through a peri |

(i) The commissioner shall contract with a vendor to create MNAAC through a periodic survey of enrolled pharmacy providers. Each pharmacy enrolled with the department to dispense outpatient prescription drugs must respond to the periodic surveys. The commissioner may sanction a pharmacy under section 256B.064 for failure to respond. The current MNAAC rates must be publicly available on the department's or vendor's website.

The commissioner must require that the MNAAC is measured and calculated at least quarterly, but the MNAAC can be measured and calculated more frequently. The commissioner must ensure that the vendor has an appeal process available to providers for the time between the measurement and calculation of the periodically updated MNAAC rates if price fluctuations result in a MNAAC that is lower than the price at which enrolled providers can purchase a drug. Establishment of the MNAAC and survey reporting requirements shall not be subject to the requirements of the Administrative Procedure Act.

Data provided by pharmacies for the measurement and calculation of the MNAAC are

201.23 **EFFECTIVE DATE.** This section is effective January 1, 2027, or upon federal approval, 201.24 whichever is later. The commissioner of human services must notify the revisor of statutes when federal approval is obtained.

01.26 Sec. 6. Minnesota Statutes 2024, section 256B.064, subdivision 1a, is amended to read:

201.22 nonpublic data as defined in section 13.02, subdivision 9.

Subd. 1a. Grounds for sanctions. (a) The commissioner may impose sanctions against 201.28 any individual or entity that receives payments from medical assistance or provides goods 201.29 or services for which payment is made from medical assistance for any of the following: 201.30 (1) fraud, theft, or abuse in connection with the provision of goods and services to recipients 201.31 of public assistance for which payment is made from medical assistance; (2) a pattern of 201.32 presentment of false or duplicate claims or claims for services not medically necessary; (3) 201.33 a pattern of making false statements of material facts for the purpose of obtaining greater compensation than that to which the individual or entity 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 an individual or entity could be excluded from participation in the Medicare program under section 1128, 1128A, or 1866(b)(2) of the Social Security Act. For the purposes of this section, goods or services for which payment is made from medical assistance includes but is not limited to care and services identified in section 256B.0625 or provided pursuant to 202.11 any federally approved waiver.

| 37.8 37.9 37.10 | (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). |
|--|--|
| 37.11 37.12 37.13 | (c) The commissioner may impose sanctions against a pharmacy provider for failure to respond to a Minnesota drug acquisition cost survey under section 256B.0625, subdivision 13e, paragraph (i). |
| 37.14 37.15 37.16 | <u>EFFECTIVE DATE.</u> This section is effective January 1, 2027, or upon federal approval whichever is later. The commissioner of human services <u>shall</u> notify the revisor of statutes when federal approval is obtained. |
| 37.17 37.18 | Sec. 4. Minnesota Statutes 2024, section 256B.69, subdivision 6d, is amended to read: Subd. 6d. Prescription drugs. (a) The commissioner may exclude or modify coverage |
| 37.19 37.20 37.21 | for prescription drugs from the prepaid managed care contracts entered into under this section in order to increase savings to the state by collecting additional prescription drug rebates. |
| 37.22 37.23 37.24 37.25 37.26 37.27 | (b) The contracts must maintain incentives for the managed care plan to manage drug costs and utilization and may require that the managed care plans maintain an open drug formulary. In order to manage drug costs and utilization, the contracts may authorize the managed care plans to use preferred drug lists and prior authorization. The contracts must require that the managed care plans enter into contracts with the state pharmacy benefit manager under section 256B.696 to administer the pharmacy benefit. |
| 37.28 37.29 | (c) This subdivision is contingent on federal approval of the managed care contract changes and the collection of additional prescription drug rebates. |
| 38.1 38.2 | Sec. 5. [256B.696] PRESCRIPTION DRUGS; STATE PHARMACY BENEFIT MANAGER. |
| 38.3 38.4 | <u>Subdivision 1.</u> <u>Definitions. (a) For the purposes of this section, the following terms have the meanings given.</u> |
| 38.5 38.6 | (b) "Managed care enrollees" means medical assistance and MinnesotaCare enrollees receiving coverage from managed care plans. |
| 38.7 38.8 38.9 | (c) "Managed care plans" means health plans and county-based purchasing organizations providing coverage to medical assistance and MinnesotaCare enrollees under the managed care delivery system. |
| 38.10 38.11 | (d) "State pharmacy benefit manager" means the pharmacy benefit manager that is a prepaid ambulatory plan as defined in Code of Federal Regulations, title 42, section 438.2, |

selected pursuant to the procurement process in subdivision 2.

38.10

| | (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 $\frac{h}{g}$. |
|--------------------------------------|---|
| | (c) The commissioner may impose sanctions against a pharmacy provider for failure to respond to a Minnesota drug acquisition cost survey under section 256B.0625, subdivision 13e, paragraph (i). |
| 202.18 202.19 202.20 | EFFECTIVE DATE. This section is effective January 1, 2027, or upon federal approva whichever is later. The commissioner of human services must notify the revisor of statutes when federal approval is obtained. |
| 202.21 | Sec. 7. Minnesota Statutes 2024, section 256B.69, subdivision 6d, is amended to read: |
| 202.22 202.23 202.24 202.25 | |
| 202.28 202.29 202.30 | (b) The contracts must maintain incentives for the managed care plan to manage drug costs and utilization and may require that the managed care plans maintain an open drug formulary. In order to manage drug costs and utilization, the contracts may authorize the managed care plans to use preferred drug lists and prior authorization. The contracts must require that the managed care plans enter into contracts with the state's selected pharmacy benefit manager vendor to administer the pharmacy benefit. |
| 202.32 202.33 | (c) This subdivision is contingent on federal approval of the managed care contract changes and the collection of additional prescription drug rebates. |
| 204.10 204.11 | Sec. 9. [256B.696] PRESCRIPTION DRUGS; STATE PHARMACY BENEFIT MANAGER. |
| 204.12 204.13 | Subdivision 1. <u>Definitions.</u> (a) For purposes of this section, the following terms have the meanings given. |
| 204.17 204.18 | (c) "Managed care enrollees" means medical assistance and MinnesotaCare enrollees receiving coverage from managed care plans. |
| 204.14 204.15 204.16 | (b) "Managed care plans" means health plans and county-based purchasing organization providing coverage to medical assistance and MinnesotaCare enrollees under the managed care delivery system. |

(d) "State pharmacy benefit manager" means the pharmacy benefit manager selected

204.20 pursuant to the procurement process in subdivision 2.

Senate Language UEH2435-1

204.19

| 8.13 8.14 | Subd. 2. Procurement process. (a) The commissioner must, through a competitive procurement process in compliance with paragraph (b), select a single pharmacy benefit |
|--------------|---|
| 8.15 | manager to comply with the requirements set forth in subdivision 3. |
| | |
| 8.16 8.17 | (b) The commissioner must, when selecting the single pharmacy benefit manager, do the following: |
| | |
| 8.18 8.19 | (1) accept applications for entities seeking to become the single pharmacy benefit manager; |
| 8.20 8.21 | (2) establish eligibility criteria an entity must meet in order to become the single pharmacy benefit manager; and |
| 8.22 | (3) enter into a master contract with a single pharmacy benefit manager. |
| 8.23 | (c) The contract required under paragraph (b), clause (3), must include a prohibition on: |
| 8.24 | (1) the single pharmacy benefit manager requiring an enrollee to obtain a drug from a |
| 8.25 | pharmacy owned or otherwise affiliated with the single pharmacy benefit manager; and |
| 8.26 | (2) paying or reimbursing a pharmacy or pharmacist for the ingredient drug product |
| 8.27 | component of pharmacist services, including a prescription drug, less than the lesser of the |
| 8.28 | national average drug acquisition cost; the Minnesota actual acquisition cost (MNAAC) |
| 8.29 | under section 256B.0625, subdivision 13e, paragraph (i); or the maximum allowable cost |
| 8.30 | as defined in section 62W.08, of that pharmacy service or prescription drug, or, if the national |

average drug acquisition cost is unavailable, the wholesale acquisition cost minus two percent at the time the drug is administered or dispensed, plus a professional dispensing fee

39.1 39.2

subdivision 13e.

equal to the amount of the dispensing fee if it were determined pursuant to section 256B.0625,

| 204.21 | Subd. 2. Procurement process. (a) The commissioner must, through a competitive |
|------------------|--|
| 204.22 | procurement process in compliance with paragraph (b), select a single pharmacy benefit |
| 204.23 | manager to comply with the requirements set forth in subdivision 3. The single pharmacy |
| 204.24 | benefit manager selected under this subdivision must be a prepaid ambulatory health plan, |
| 204.25 | as defined in Code of Federal Regulations, title 42, section 438.2. |
| 204.26 | (b) When selecting the single pharmacy benefit manager, the commissioner must: |
| 204.27 204.28 | (1) accept applications for entities seeking to become the single pharmacy benefit manager; |
| 204.29 | (2) establish eligibility criteria an entity must meet in order to become the single pharmacy |
| 204.30 | benefit manager; and |
| 204.31 | (3) enter into a master contract with a single pharmacy benefit manager. |
| 205.1 205.2 | (c) The contract required under paragraph (b), clause (3), must include provisions that prohibit the single pharmacy benefit manager from: |
| 205.3 | (1) requiring, enticing, or coercing an enrollee to obtain pharmacy services, including |
| 205.4 | a prescription drug, from a pharmacy owned or otherwise affiliated with the single pharmacy |
| 205.5 | benefit manager; |
| 205.16 | (5) paying or reimbursing a pharmacy or pharmacist for the ingredient drug product |
| 205.17 | component of pharmacist services, including a prescription drug, less than the lesser of |
| 205.18 | national average drug acquisition cost; the Minnesota actual acquisition cost (MNAAC) as |
| 205.19 | defined in section 256B.0625, subdivision 13e, paragraph (i); or the maximum allowable |
| 205.20 | cost as defined in section 62W.08 of that pharmacy service or prescription drug, or, if the |

Senate Language UEH2435-1

205.10 the services and are also in network;

205.24 256B.0625, subdivision 13e; and

(4) directly or indirectly retroactively denying or reducing a claim or aggregate of claims

(3) requiring an enrollee to obtain pharmacy services, including a prescription drug,

national average drug acquisition cost is unavailable, the wholesale acquisition cost minus

pharmacy services or have a prescription dispensed at, or pharmacy services provided by, a particular pharmacy owned or affiliated with the single pharmacy benefit manager if there are other nonaffiliated pharmacies that have the ability to dispense the medication or provide

(2) communicating to an enrollee, in any manner, that the enrollee is required to obtain

205.22 two percent at the time the drug is administered or dispensed, plus a professional dispensing

fee equal to the amount of the dispensing fee if it were determined pursuant to section

205.13 205.14 for pharmacy services, including prescription drugs, after adjudication of the claim or

205.15 aggregate of claims;

205.6

| 9.3 | (d) Applicants for the single pharmacy benefit manager must disclose to the commissione |
|------|--|
| 9.4 | the following during the procurement process: |
| 9.5 | (1) any activity, policy, practice, contract, or arrangement of the single pharmacy benefit |
| 9.6 | manager that may directly or indirectly present any conflict of interest with the pharmacy |
| 9.7 | benefit manager's relationship with or obligation to the Department of Human Services, a |
| 9.8 | health plan company, or county-based purchasing organization; |
| 9.9 | (2) all common ownership, members of a board of directors, managers, or other control |
| 9.10 | of the pharmacy benefit manager or any of the pharmacy benefit manager's affiliated |
| 9.11 | companies with: |
| 9.12 | (i) a health plan company administering the medical assistance or MinnesotaCare benefits |
| 9.13 | or an affiliate of the health plan company; |
| 9.14 | (ii) a county-based purchasing organization; |
| 9.15 | (iii) an entity that contracts on behalf of a pharmacy or any pharmacy services |
| 9.16 | administration organization and its affiliates; |
| 9.17 | (iv) a drug wholesaler or distributor and its affiliates; |
| 9.18 | (v) a third-party payer and its affiliates; or |
| 9.19 | (vi) a pharmacy and its affiliates that are enrolled to provide medical assistance or |
| 9.20 | MinnesotaCare; |
| 9.21 | (3) any direct or indirect fees, charges, or any kind of assessments imposed by the |
| 9.22 | pharmacy benefit manager on pharmacies licensed in this state with which the pharmacy |
| 9.23 | benefit manager shares common ownership, management, or control, or that are owned, |
| 9.24 | managed, or controlled by any of the pharmacy benefit manager's affiliated companies; |
| 9.25 | (4) any direct or indirect fees, charges, or any kind of assessments imposed by the |
| 9.26 | pharmacy benefit manager on pharmacies licensed in this state; and |
| 9.27 | (5) any financial terms and arrangements between the pharmacy benefit manager and a |
| 9.28 | prescription drug manufacturer or labeler, including formulary management, drug substitution |
| 9.29 | programs, educational support claims processing, or data sales fees. |
| 9.30 | Subd. 3. Drug coverage. (a) The commissioner may require the pharmacy benefit |
| 9.31 | manager to modify utilization review limitations, requirements, and strategies imposed by |
| 9.32 | managed care plans on prescription drug coverage. |

| 205.25 | (6) denying a pharmacy or pharmacist the right to participate as a contract provider under |
|------------------|--|
| 205.26 205.27 | the health plan if the pharmacy or pharmacist agrees to provide pharmacy services, including but not limited to prescription drugs that meet the terms and requirements set forth by the |
| 205.27 | health plan and agrees to the terms of reimbursement set forth by the health plan company. |
| | |
| 205.29 | (d) Applicants for the single pharmacy benefit manager must disclose to the commissioner |
| 205.30 | the following during the procurement process: |
| 205.31 | (1) any activity, policy, practice, contract, or arrangement of the single pharmacy benefit |
| 205.32 | manager that may directly or indirectly present any conflict of interest with the pharmacy |
| 206.1 | benefit manager's relationship with or obligation to the Department of Human Services, a |
| 206.2 | health plan company, or a county-based purchasing organization; |
| 206.3 | (2) all common ownership, members of a board of directors, managers, or other control |
| 206.4 | of the pharmacy benefit manager or any of the pharmacy benefit manager's affiliated |
| 206.5 | companies with: |
| 206.6 | (i) a health plan company administering medical assistance or MinnesotaCare benefits |
| 206.7 | in Minnesota or an affiliate of the health plan company; |
| 206.8 | (ii) a county-based purchasing organization; |
| 206.9 | (iii) an entity that contracts on behalf of a pharmacy or any pharmacy services |
| 206.10 | administration organization and its affiliates; |
| 206.11 | (iv) a drug wholesaler or distributor and its affiliates; |
| 206.12 | (v) a third-party payer and its affiliates; or |
| 206.13 | (vi) a pharmacy and its affiliates; |
| 200.13 | (11) a pharmacy and its armacos, |
| 20614 | |
| 206.14 206.15 | (3) any direct or indirect fees, charges, or any kind of assessments imposed by the pharmacy benefit manager on pharmacies licensed in Minnesota with which the pharmacy |
| 206.15 | benefit manager shares common ownership, management, or control, or that are owned, |
| 206.17 | managed, or controlled by any of the pharmacy benefit manager's affiliated companies; |
| 207.10 | |
| 206.18 206.19 | (4) any direct or indirect fees, charges, or any kind of assessments imposed by the pharmacy benefit manager on pharmacies licensed in Minnesota; and |
| | |
| 206.20 | (5) any financial terms and arrangements between the pharmacy benefit manager and a |
| 206.21 | prescription drug manufacturer or labeler, including formulary management, drug substitution |
| 206.22 | programs, educational support claims processing, or data sales fees. |
| 206.23 | Subd. 3. Drug coverage. (a) The commissioner may require the state pharmacy benefit |
| 206.24 | manager to modify utilization review limitations, requirements, and strategies imposed by |
| 206.25 | managed care plans on prescription drug coverage. |

207.29 pharmacies;

|).1 | (b) The state pharmacy benefit manager is responsible for processing all point of sale |
|------|--|
| 0.2 | outpatient pharmacy claims under the managed care delivery system. Managed care plans |
| 0.3 | must use the state pharmacy benefit manager pursuant to the terms of the master contract |
|).4 | required under subdivision 2, paragraph (b), clause (3). The pharmacy benefit manager |
|).5 | selected is the exclusive pharmacy benefit manager used by health plan companies and |
| 0.6 | county-based purchasing organizations when providing coverage to enrollees. The |
|).7 | commissioner may require the managed care plans and pharmacy benefit manager to directly |
| 8.0 | exchange data and files for members enrolled with managed care plans. |
|).9 | (c) All payment arrangements between the Department of Human Services, managed |
| 0.10 | care plans, and the state pharmacy benefit manager must comply with state and federal |
|).10 | statutes, regulations adopted by the Centers for Medicare and Medicaid Services, and any |
|).11 | other agreement between the department and the Centers for Medicare and Medicaid Services. |
|).12 | The commissioner may change a payment arrangement to comply with this paragraph. |
| 1.13 | The commissioner may change a payment arrangement to compry with this paragraph. |
|).14 | (d) The commissioner must administer and oversee this section to: |
|).15 | (1) ensure proper administration of prescription drug benefits for managed care enrollees; |
|).15 | and |
|).10 | <u>and</u> |
| 0.17 | (2) increase the transparency of prescription drug prices and other information for the |
| 0.18 | benefit of pharmacies. |
|).19 | Subd. 4. Prescription drug disclosures. (a) The state pharmacy benefit manager must, |
| 0.20 | on request from the commissioner, disclose to the commissioner all sources of payment the |
|).21 | state pharmacy benefit manager receives for prescribed drugs, including any financial |
|).22 | benefits, drug rebates, discounts, credits, clawbacks, fees, grants, chargebacks, |
|).23 | reimbursements, or other payments related to services provided for a managed care plan. |
| | |
|).24 | (b) Each managed care plan must disclose to the commissioner, in the format specified |
|).25 | by the commissioner, the entity's administrative costs associated with providing pharmacy |
| 0.26 | services under the managed care delivery system. |
|).27 | (c) The state pharmacy benefit manager must provide a written quarterly report to the |
|).28 | commissioner containing the following information from the immediately preceding quarter: |
| | |
|).29 | (1) the prices the state pharmacy benefit manager negotiated for prescribed drugs under |
| 0.30 | the managed care delivery system. The price must include any rebates the state pharmacy |
| 0.31 | benefit manager received from the drug manufacturer; |
| | |
| | |
| | |

(2) any rebate amounts the state pharmacy benefit manager passed on to individual

40.32

40.33

pharmacies;

| 16.26 | (b) The state pharmacy benefit manager is responsible for processing all point of sale |
|-------|--|
| 06.27 | outpatient pharmacy claims under the managed care delivery system. Managed care plans |
| 06.28 | must use the state pharmacy benefit manager pursuant to the terms of the master contract |
| 06.29 | required under subdivision 2, paragraph (b), clause (3). The pharmacy benefit manager |
| 06.30 | selected is the exclusive pharmacy benefit manager used by health plan companies and |
| 06.31 | county-based purchasing organizations when providing coverage to enrollees. The |
| 07.1 | commissioner may require the managed care plans and state pharmacy benefit manager to |
|)7.2 | directly exchange data and files for members enrolled with managed care plans. |
|)7.3 | (c) All payment arrangements between the Department of Human Services, managed |
|)7.4 | care plans, and the state pharmacy benefit manager must comply with state and federal |
|)7.5 | statutes, regulations adopted by the Centers for Medicare and Medicaid Services, and any |
| 07.6 | other agreement between the department and the Centers for Medicare and Medicaid Services. |
|)7.7 | The commissioner may change a payment arrangement to comply with this paragraph. |
|)7.8 | (d) The commissioner must administer and oversee this section to: |
|)7.9 | (1) ensure proper administration of prescription drug benefits for managed care enrollees; |
| 07.10 | and |
| 07.11 | (2) increase the transparency of prescription drug prices and other information for the |
| 07.12 | benefit of pharmacies. |
| | |
| 07.13 | Subd. 4. Prescription drug disclosures. (a) The state pharmacy benefit manager must, |
|)7.14 | on request from the commissioner, disclose to the commissioner all sources of payment the |
|)7.15 | pharmacy benefit manager receives for prescribed drugs, including drug rebates, discounts, |
| 07.16 | credits, clawbacks, fees, grants, chargebacks, reimbursements, or other financial benefits |
|)7.17 | or payments related to services provided for a managed care plan. |
| 07.18 | (b) Each managed care plan must disclose to the commissioner, in the format specified |
| 7.19 | by the commissioner, the entity's administrative costs associated with providing pharmacy |
| 07.20 | services under the managed care delivery system. |
| 07.21 | (c) The state pharmacy benefit manager must provide a written quarterly report to the |
| 7.22 | commissioner containing the following information from the immediately preceding quarter: |
| 07.23 | (1) the prices the state pharmacy benefit manager negotiated for prescribed drugs under |
| 7.24 | the managed care delivery system. The prices must include any rebates the state pharmacy |
|)7.25 | benefit manager received from the drug manufacturer; |
| 07.26 | (2) unredacted copies of contracts between the state pharmacy benefit manager and |
|)7.27 | enrolled pharmacies; |
| 7 28 | (3) any repate amounts the state pharmacy benefit manager passed on to individual |

| 41.1 41.2 | (3) any changes to the information previously disclosed <u>under</u> subdivision 2, paragraph (d); and |
|---|---|
| 41.3 41.4 | (4) any other information required by the commissioner, including unredacted copies of contracts between the pharmacy benefit manager and enrolled pharmacies. |
| 41.5 41.6 | (d) The commissioner may request and collect additional information and clinical data from the state pharmacy benefit manager. |
| 41.7 41.8 41.9 | (e) At the time of contract execution, renewal, or modification, the commissioner must modify the reporting requirements under its managed care contracts as necessary to meet the requirements of this subdivision. |
| 41.10 41.11 41.12 | Subd. 5. Program authority. (a) To accomplish the requirements of subdivision 3, the commissioner, in consultation with the Formulary Committee established under section 256B.0625, subdivision 13c, has the authority to: |
| 41.13 | (1) adopt or develop a preferred drug list for managed care plans; |
| 41.14 41.15 41.16 41.17 | (2) at the commissioner's discretion, engage in price negotiations with prescription drug manufacturers, wholesalers, or group purchasing organizations in place of the state pharmacy benefit manager to obtain price discounts and rebates for prescription drugs for managed care enrollees; and |
| 41.18 | (3) develop and manage a drug formulary for managed care plans. |
| 41.19 41.20 | (b) The commissioner may contract with one or more entities to perform any of the functions described in paragraph (a). |
| 41.21 41.22 41.23 41.24 41.25 | Subd. 6. Pharmacies. The commissioner may review contracts between the state pharmacy benefit manager and pharmacies for compliance with this section and the master contract required under subdivision 2, paragraph (b), clause (3). The commissioner may amend any term or condition of a contract that does not comply with this section or the master contract. |
| 41.26 41.27 | <u>Subd. 7.</u> <u>Federal approval.</u> <u>The commissioner must seek any necessary federal approvals to implement this section.</u> |
| 41.28 41.29 41.30 41.31 | EFFECTIVE DATE. Subdivisions 1 to 6 are effective January 1, 2027, or upon federal approval, whichever is later. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained. Subdivision 7 is effective the day following final enactment. |
| 42.1 42.2 | Sec. 6. DIRECTION TO THE COMMISSIONER OF HUMAN SERVICES; DIRECTED PHARMACY DISPENSING PAYMENTS. |
| 42.3 | (a) For plan year 2026, the commissioner shall provide a directed pharmacy dispensing |

payment of \$1.84 per filled prescription under the medical assistance program to eligible outpatient retail pharmacies in Minnesota to improve and maintain access to pharmaceutical

42.4

| 207.30 207.31 | (4) any changes to the information previously disclosed in accordance with subdivision 2, paragraph (d); and |
|--|--|
| 207.32 | (5) any other information required by the commissioner. |
| 208.1 208.2 | (d) The commissioner may request and collect additional information and clinical data from the state pharmacy benefit manager. |
| 208.3 208.4 208.5 | (e) At the time of contract execution, renewal, or modification, the commissioner must modify the reporting requirements under its managed care contracts as necessary to meet the requirements of this subdivision. |
| 208.6 208.7 208.8 | Subd. 5. Program authority. (a) To accomplish the requirements of subdivision 3, paragraph (d), the commissioner, in consultation with the Formulary Committee established under section 256B.0625, subdivision 13c, has the authority to: |
| 208.9 | (1) adopt or develop a preferred drug list for managed care plans; |
| 208.10 208.11 208.12 208.13 | (2) at the commissioner's discretion, engage in price negotiations with prescription drug manufacturers, wholesalers, or group purchasing organizations in place of the state pharmacy benefit manager to obtain price discounts and rebates for prescription drugs for managed care enrollees; and |
| 208.14 | (3) develop and manage a drug formulary for managed care plans. |
| 208.15 208.16 | (b) The commissioner may contract with one or more entities to perform any of the functions described in paragraph (a). |
| 208.17 208.18 208.19 208.20 208.21 | Subd. 6. Pharmacies. The commissioner may review contracts between the state pharmacy benefit manager and pharmacies for compliance with this section and the master contract required under subdivision 2, paragraph (b), clause (3). The commissioner may amend any term or condition of a contract that does not comply with this section or the master contract. |
| 208.22 208.23 | $\underline{\text{Subd. 7. }} \underline{\text{Federal approval.}} \underline{\text{The commissioner must seek any necessary federal approvals}} \underline{\text{to implement this section.}}$ |
| 208.24 208.25 208.26 208.27 | EFFECTIVE DATE. This section is effective January 1, 2027, or upon federal approval, whichever is later, except that subdivision 7 is effective the day following final enactment. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained. |
| 203.1 203.2 | Sec. 8. Minnesota Statutes 2024, section 256B.69, is amended by adding a subdivision to read: |
| 203.3 203.4 203.5 | Subd. 6i. Directed pharmacy dispensing payment. (a) The commissioner shall provide a directed pharmacy dispensing payment of \$4.50 per filled prescription to eligible outpatient retail pharmacies in Minnesota to improve and maintain access to pharmaceutical services |

| 42.6 | services in rural and underserved areas of the state. Managed care and county-based |
|-------|---|
| 42.7 | purchasing plans delivering services under Minnesota Statutes, section 256B.69 or 256B.692, |
| 42.8 | and any pharmacy benefit managers under contract with these entities, must pay the directed |
| 42.9 | pharmacy dispensing payment to eligible outpatient retail pharmacies for drugs dispensed |
| 42.10 | to medical assistance enrollees. The directed pharmacy dispensing payment is in addition |
| 42.11 | to, and must not supplant or reduce, any other dispensing fee paid by these entities to the |
| 42.12 | pharmacy. Entities paying the directed pharmacy dispensing payment must not reduce other |
| 42.13 | payments to the pharmacy as a result of payment of the directed pharmacy dispensing |
| 42.14 | payment. |
| 42.15 | (b) For purposes of this section, "eligible outpatient retail pharmacy" means an outpatient |
| 42.16 | retail pharmacy licensed under chapter 151 that is not owned, either directly or indirectly |
| 42.17 | or through an affiliate or subsidiary, by a pharmacy benefit manager licensed under chapter |
| 42.18 | 62W or a health carrier, as defined in Minnesota Statutes, section 62A.011, subdivision 2, |
| 42.19 | and that: |
| 42.20 | (1) is located in a medically underserved area or primarily serves a medically underserved |
| 42.20 | population, as defined by the United States Department of Health and Human Services |
| 42.21 | Health Resources and Services Administration under United States Code, title 42, section |
| 42.22 | 254; or |
| 42.23 | 254, 01 |
| 42.24 | (2) shares common ownership with 13 or fewer Minnesota pharmacies. |
| 42.25 | (c) In order to receive the directed pharmacy dispensing payment, a pharmacy must |
| 42.26 | submit to the commissioner a form, developed by the commissioner, attesting that the |
| 42.27 | pharmacy meets the requirements of paragraph (b). |
| 42.28 | (d) The commissioner shall set and adjust the amount of the directed pharmacy dispensing |
| 42.29 | payment to reflect the available state and federal funding. |
| | |
| 42.30 | (e) Managed care and county-based purchasing plans, and any pharmacy benefit managers |
| 42.31 | under contract with these entities, shall pay the directed pharmacy dispensing payment to |
| 42.32 | eligible outpatient retail pharmacies. The commissioner shall monitor the effect of this |
| 42.33 | requirement on access to pharmaceutical services in rural and underserved areas of the state. |
| 42.34 | If, for any contract year, federal approval is not received for this section, the commissioner |
| 43.1 | must adjust the capitation rates paid to managed care plans and county-based purchasing |
| 43.2 | plans for that contract year to reflect removal of this section. Contracts between managed |
| 43.3 | care plans and county-based purchasing plans, and any pharmacy benefit managers under |
| 43.4 | contract with these entities, and providers to whom this section applies, must allow recovery |
| 43.5 | of payments from those providers if capitation rates are adjusted in accordance with this |
| 43.6 | paragraph. Payment recoveries must not exceed the amount equal to any increase in rates |
| 43.7 | that results from this section. This section expires if federal approval is not received for this |

section at any time.

| 203.6 203.7 203.8 203.9 203.10 203.11 203.12 203.13 | in rural and underserved areas of Minnesota. Managed care and county-based purchasing plans delivering services under section 256B.69 or 256B.692, and any pharmacy benefit managers under contract with these entities, must pay the directed pharmacy dispensing payment to eligible outpatient retail pharmacies for drugs dispensed to medical assistance enrollees. The directed pharmacy dispensing payment is in addition to, and must not supplant or reduce, any other dispensing fee paid by these entities to the pharmacy. Entities paying the directed pharmacy dispensing payment must not reduce other payments to the pharmacy as a result of payment of the directed pharmacy dispensing payment. |
|--|--|
| 203.14 203.15 203.16 203.17 203.18 | (b) For purposes of this subdivision, "eligible outpatient retail pharmacy" means an outpatient retail pharmacy licensed under chapter 151 that is not owned, either directly or indirectly or through an affiliate or subsidiary, by a pharmacy benefit manager licensed under chapter 62W or a health carrier, as defined in section 62A.011, subdivision 2, and that: |
| 203.19 203.20 203.21 203.22 | (1) is located in a medically underserved area or primarily serves a medically underserved population, as defined by the United States Department of Health and Human Services Health Resources and Services Administration under United States Code, title 42, section 254; or |
| 203.23 | (2) shares common ownership with 12 or fewer Minnesota pharmacies. |
| 203.24 203.25 203.26 | (c) In order to receive the directed pharmacy dispensing payment, a pharmacy must submit to the commissioner a form, developed by the commissioner, attesting that the pharmacy meets the requirements of paragraph (b). |
| 203.27 | (d) Managed care and county-based purchasing plans, and any pharmacy benefit managers |
| 203.28 203.29 | under contract with these entities, shall pay the directed pharmacy dispensing payment to eligible outpatient retail pharmacies. The commissioner shall monitor the effect of this |
| 203.29 | requirement on access to pharmaceutical services in rural and underserved areas of |
| 203.31 | Minnesota. If, for any contract year, federal approval is not received for this subdivision, |
| 203.32 | the commissioner must adjust the capitation rates paid to managed care plans and |
| 203.33 | county-based purchasing plans for that contract year to reflect removal of this subdivision. |
| 203.34 | Contracts between managed care plans and county-based purchasing plans, and any pharmacy |
| 204.1 | benefit managers under contract with these entities, and providers to whom this subdivision |
| 204.2 | applies, must allow recovery of payments from those providers if capitation rates are adjusted |
| 204.3 | in accordance with this paragraph. Payment recoveries must not exceed the amount equal |
| 204.4 | to any increase in rates that results from this subdivision. This subdivision expires if federal |
| 204.5 | approval is not received for this subdivision at any time. |

(e) This subdivision expires on December 31, 2026.

Senate Language UEH2435-1

204.6

HHS Side-by-Side - Art 4

May 16, 2025 11:08 AM

House Language H2435-3

| 43.9 | EFFECTIVE DATE. This section is effective January 1, 2026, or upon federal approval |
|-------|---|
| 43.10 | whichever is later. The commissioner of human services shall notify the revisor of statutes |
| 43.11 | when federal approval is obtained. |

| 204.7 | EFFECTIVE DATE. This section is effective July 1, 2025, or upon federal approval |
|-------|---|
| 204.8 | whichever is later. The commissioner of human services shall notify the revisor of statutes |
| 204.9 | when federal approval is obtained. |