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(SENATE AUTHORS: BOLDON)

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A bill for an act

relating to health; permitting Formulary Committee members with a potential conflict of interest to participate in committee communications and discussions; requiring the commissioner of human services to develop a public comment process for recommendations to the Formulary Committee; requiring the Formulary Committee to seek expertise from the Minnesota Rare Disease Advisory Council; amending Minnesota Statutes 2024, section 256B.0625, subdivisions 13f, 13g; Minnesota Statutes 2025 Supplement, section 256B.0625, subdivision 13c.

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

Section 1. Minnesota Statutes 2025 Supplement, section 256B.0625, subdivision 13c, is amended to read:

Subd. 13c. **Formulary Committee.** (a) The commissioner, after receiving recommendations 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.

(b) 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.

(c) Members of the Formulary Committee shall not be employed by the Department of Human Services or have a personal interest in a pharmaceutical company, pharmacy benefits manager, health plan company, or their affiliate organizations, but the committee shall be staffed by an employee of the department who shall serve as an ex officio, nonvoting member of the committee.

(d) 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.

(e) A committee member must notify the committee of any potential conflict of interest and recuse themselves from any ~~communications, discussion, or~~ vote on any matter where a conflict of interest exists. A conflict of interest alone, without a personal interest, does not preclude an applicant from serving as a member of the Formulary Committee. The commissioner must publicly disclose any conflict of interest form submitted by a committee member on the Department of Human Services' website at least 48 hours before any meeting of the Formulary Committee that includes the drug subject to the conflict of interest on the agenda.

(f) Members may be removed from the committee for cause after a recommendation for removal by a majority of the committee membership. For the purposes of this subdivision, "cause" does not include offering a differing or dissenting clinical opinion on a drug or drug class.

(g) The department's medical director shall also serve as an ex officio, nonvoting member for the committee.

(h) Committee members shall serve three-year terms and may be reappointed twice by the commissioner.

(i) The committee members shall vote on a chair and vice chair from among their membership. The chair shall preside over all committee meetings, and the vice chair shall preside over the meetings if the chair is not present.

(j) The Formulary Committee shall meet at least three times per year. The commissioner may require more frequent Formulary Committee meetings as needed.

(k) An honorarium of $100 per meeting and reimbursement for mileage shall be paid to each committee member in attendance.

(l) The Formulary Committee expires June 30, ~~2029~~ 2030.

(m) The Formulary Committee is subject to the Open Meeting Law under chapter 13D. Notwithstanding the foregoing, this paragraph does not prevent:

(1) Formulary Committee staff communication with the representative designated by the Minnesota Rare Disease Advisory Council or communication between Formulary Committee staff and Minnesota Rare Disease Advisory Council staff as long as a quorum of the Formulary Committee members are not included in the communication; or

(2) Formulary Committee members from seeking clinical expertise in advance of a Formulary Committee meeting. Any such experts may submit, and may be encouraged by Formulary Committee members to submit, public comments.

(n) For purposes of establishing a quorum to transact business, vacant committee member positions do not count in the calculation as long as at least 60 percent of the committee member positions are filled.

(o) In accordance with section 256.4835, subdivision 4, paragraph (a), clause (2), the Formulary Committee must, through the representative of the committee designated by the Minnesota Rare Disease Advisory Council, seek subject matter expertise and input from the Minnesota Rare Disease Advisory Council before taking action under the Formulary Committee's authority relating to prior authorization requirements under subdivision 13f or relating to placement of an orphan drug, as defined in section 152.01, subdivision 21, on the preferred drug list under subdivision 13g. The commissioner is prohibited from entering into or renewing a contract with a pharmacy benefit manager, as defined in section 62W.02, subdivision 15, that would limit the Formulary Committee's obligation and ability to seek the expertise and input described in this paragraph.

(p) Within 30 days of Federal Drug Administration approval or modification of an orphan drug, Formulary Committee staff must contact the representative designated by the Minnesota Rare Disease Advisory Council in writing to initiate the process of seeking subject matter expertise from the council. Formulary Committee staff must seek Rare Disease Advisory Council expertise before receiving a recommendation from the vendor contracted with the Department of Human Services for the purpose of participating in a preferred drug list and

supplemental rebate program. Once a recommendation is received from the vendor, Formulary Committee staff must share with the Rare Disease Advisory Council any work and documents created for the state that include a proposed action or proposed prior authorization requirement. Once public notice is issued of a Formulary Committee meeting, the Rare Disease Advisory Council may conduct public outreach activities related to any proposed action or proposed prior authorization requirement as long as no communications or activities include a quorum of the Formulary Committee, in compliance with the Open Meeting Law.

Sec. 2. Minnesota Statutes 2024, 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~~.~~; and

(4) the commissioner must publicly disclose public comments received during the public comment period for each meeting on the Department of Human Services' website within 48 hours of receipt, not including weekends or holidays. All comments received must be retained and publicly available for ... years.

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 must not be required for liquid methadone if only one version of liquid methadone is available. If more than one version of liquid methadone is available, the commissioner shall ensure that at least one version of liquid methadone is available without prior authorization.

(e) Prior authorization may be required for an oral liquid form of a drug, except as described in paragraph (d). A prior authorization request under this paragraph must be automatically approved within 24 hours if the drug is being prescribed for a Food and Drug Administration-approved condition for a patient who utilizes an enteral tube for feedings or medication administration, even if the patient has current or prior claims for pills for that condition. If more than one version of the oral liquid form of a drug is available, the commissioner may select the version that is able to be approved for a Food and Drug Administration-approved condition for a patient who utilizes an enteral tube for feedings or medication administration. This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. By August 1, 2026, the commissioner shall design and implement a streamlined prior authorization form for patients who utilize an enteral tube for feedings or medication administration and are prescribed an oral liquid form of a drug. The form must include an option for a prescriber to check a box verifying that the patient utilizes an enteral tube for feedings or medication administration. This verification is sufficient to establish the need for the prior authorization automatic approval of the oral liquid form of the drug without the requirement of any additional prior authorization forms or further documentation. 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) 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.

(g) Prior authorization under this subdivision shall comply with section 62Q.184.

(h) Any step therapy protocol requirements established by the commissioner must comply with section 62Q.1841.

(i) Notwithstanding any law to the contrary, prior authorization or step therapy shall not be required or utilized for any class of drugs that is approved by the United States Food and Drug Administration for the treatment or prevention of HIV and AIDS.

Sec. 3. Minnesota Statutes 2024, section 256B.0625, subdivision 13g, is amended to read:

Subd. 13g. **Preferred drug list.** (a) The commissioner shall adopt and implement a preferred drug list by January 1, 2004. The commissioner may enter into a contract with a vendor for the purpose of participating in a preferred drug list and supplemental rebate program. The terms of the contract with the vendor must be publicly disclosed on the website of the Department of Human Services. The commissioner shall ensure that any contract meets all federal requirements and maximizes federal financial participation. The commissioner shall publish the preferred drug list annually in the State Register and shall maintain an accurate and up-to-date list on the agency website. The commissioner shall implement and maintain an accurate archive of previous versions of the preferred drug list, and make this archive available to the public on the website of the Department of Human Services beginning January 1, 2024.

(b) The commissioner may add to, delete from, and otherwise modify the preferred drug list~~,~~ after consulting with the Formulary Committee, the Rare Disease Advisory Council for a product designated as an orphan drug by the United States Food and Drug Administration (FDA) or indicated for orphan drug use by the FDA, and appropriate medical

specialists~~,~~; providing public notice and the opportunity for public comment~~,~~; and complying with the requirements of paragraph (f).

(c) The commissioner shall adopt and administer the preferred drug list as part of the administration of the supplemental drug rebate program. Reimbursement for prescription drugs not on the preferred drug list may be subject to prior authorization.

(d) For purposes of this subdivision, the following terms have the meanings given:

(1) "appropriate medical specialist" means a medical professional who prescribes the relevant class of drug as part of their practice; and

(2) "preferred drug list" means a list of prescription drugs within designated therapeutic classes selected by the commissioner, for which prior authorization based on the identity of the drug or class is not required.

(e) The commissioner shall seek any federal waivers or approvals necessary to implement this subdivision.

(f) Before the commissioner may delete a drug from the preferred drug list or modify the inclusion of a drug on the preferred drug list, the commissioner shall consider any implications that the deletion or modification may have on state public health policies or initiatives and any impact that the deletion or modification may have on increasing health disparities in the state. Prior to deleting a drug or modifying the inclusion of a drug, the commissioner shall also conduct a public hearing. The commissioner shall provide adequate notice to the public and the commissioner of health prior to the hearing that specifies the drug that the commissioner is proposing to delete or modify, and shall disclose any public medical or clinical analysis that the commissioner has relied on in proposing the deletion or modification and evidence that the commissioner has evaluated the impact of the proposed deletion or modification on public health and health disparities. The commissioner must publicly disclose the required analysis and evidence of evaluation compliance on the Department of Human Services' website at least 30 days before the hearing. Notwithstanding section 331A.05, a public notice of a Formulary Committee meeting must be published at least 30 days in advance of the meeting. The list of drugs to be discussed at the meeting must be announced at least 30 days before the meeting and must include the name and class of drug, the proposed action, and the proposed prior authorization requirements, if applicable.