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A bill for an act

relating to health care; sunsetting the Drug Formulary Committee; requiring the commissioner of human services to submit to the legislature a proposed reformulation of the Drug Formulary Committee ensuring public input; requiring the medical assistance drug formulary and preferred drug list to include any drug that is FDA approved for the treatment or prevention of HIV/AIDS; requiring a public hearing before a drug may be deleted from the preferred drug list; prohibiting the deletion of a drug from the preferred drug list solely for economic or fiscal reasons; amending Minnesota Statutes 2018, section 256B.0625, subdivisions 13c, 13d, 13g; Minnesota Statutes 2019 Supplement, section 256B.0625, subdivision 13f.

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

Section 1. Minnesota Statutes 2018, section 256B.0625, subdivision 13c, is amended to read:

Subd. 13c. **Formulary Committee.** 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. The Formulary Committee shall be comprised of four licensed physicians actively engaged in the practice of medicine in Minnesota one of whom must be actively engaged in the treatment of persons with mental illness; at least three licensed pharmacists actively engaged in the practice of pharmacy in Minnesota; and one consumer representative; 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 Human Services, but the committee shall be staffed by an employee of the department who shall serve as an ex officio, nonvoting member of the

committee. The department's medical director shall also serve as an ex officio, nonvoting member for the committee. Committee members shall serve three-year terms and may be reappointed by the commissioner. The Formulary Committee shall meet at least twice 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 Formulary Committee expires June 30, ~~2022~~ 2021.

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

Sec. 2. Minnesota Statutes 2018, section 256B.0625, subdivision 13d, is amended to read:

Subd. 13d. **Drug formulary.** (a) The commissioner shall establish a drug formulary. Its establishment and publication shall not be subject to the requirements of the Administrative Procedure Act, but the Formulary Committee shall review and comment on the formulary contents.

(b) The formulary shall not include:

(1) drugs, active pharmaceutical ingredients, or products for which there is no federal funding;

(2) over-the-counter drugs, except as provided in subdivision 13;

(3) drugs or active pharmaceutical ingredients used for weight loss, except that medically necessary lipase inhibitors may be covered for a recipient with type II diabetes;

(4) drugs or active pharmaceutical ingredients when used for the treatment of impotence or erectile dysfunction;

(5) drugs or active pharmaceutical ingredients for which medical value has not been established;

(6) 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

(7) medical cannabis as defined in section 152.22, subdivision 6.

(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.

(d) Notwithstanding any law to the contrary, the commissioner shall not remove from the drug formulary any class of drugs that have been approved by the federal Food and Drug Administration for the treatment or prevention of HIV/AIDs.

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

Sec. 3. Minnesota Statutes 2019 Supplement, section 256B.0625, subdivision 13f, is amended to read:

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

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

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

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

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

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

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

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

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

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

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

(d) 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.

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

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

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

(h) Notwithstanding any law to the contrary, prior authorization shall not be required or utilized for any class of drugs that are approved by the federal Food and Drug Administration for the treatment or prevention of HIV/AIDs.

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

Sec. 4. Minnesota Statutes 2018, 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 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.

(b) The commissioner may add to, delete from, and otherwise modify the preferred drug list, after consulting with the Formulary Committee and appropriate medical specialists and providing public notice and the opportunity for public comment.

(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, "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) Notwithstanding paragraph (b), 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, in consultation with the commissioner of health, shall consider any implications the deletion or modification may have on state public health policies or initiatives and any impact 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 providing adequate notice to the public prior to the hearing that specifies the drug the commissioner is proposing to delete or modify, any medical or clinical analysis that the commissioner has relied on in proposing the deletion or modification, and evidence that the commissioner has consulted with the commissioner of health and has evaluated the impact of the proposed deletion or modification on public health and health disparities. No drug shall be deleted from the preferred drug list solely based on economic or fiscal reasons.

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

Sec. 5. **PROPOSED DRUG FORMULARY COMMITTEE.**

By March 1, 2021, the commissioner of human services, in consultation with relevant professional associations and consumer groups, shall submit to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services a proposed reformulation of the Drug Formulary Committee that includes:

(1) the proposed membership of the committee, including adequate representation of consumers and health care professionals with expertise in clinical prescribing; and

(2) proposed policies and procedures for the operation of the committee that ensures public input, including providing public notice and gathering public comments on the committee's recommendations and proposed actions.

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