State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-THIRD SESSION

H. F. No. 294

01/11/2023 Authored by Elkins and Bahner
The bill was read for the first time and referred to the Committee on Health Finance and Policy

A bill for an act

relating to health; requiring manufacturers to report and maintain prescription drug prices; requiring the filing of health plan prescription drug formularies; health care coverage; establishing requirements for a prescription benefit tool; requiring prescription drug benefit transparency and disclosure; amending Minnesota Statutes 2022, sections 62A.02, subdivision 1; 62J.497, subdivisions 1, 3; 62J.84, subdivisions 2, 6, 7, 8, 9; 151.071, subdivision 2; proposing coding for new law in Minnesota Statutes, chapters 62J; 62Q.

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

ARTICLE 1

REPORTING AND MAINTAINING PRESCRIPTION DRUG PRICES

Section 1. Minnesota Statutes 2022, section 62A.02, subdivision 1, is amended to read:

Subdivision 1. **Filing.** For purposes of this section, "health plan" means a health plan as defined in section 62A.011 or a policy of accident and sickness insurance as defined in section 62A.01. No health plan shall be issued or delivered to any person in this state, nor shall any application, rider, or endorsement be used in connection with the health plan, until a copy of its form and of the classification of risks and the premium rates pertaining to the form have been filed with the commissioner. The filing must include the health plan's prescription drug formulary. The filing for nongroup health plan forms shall include a statement of actuarial reasons and data to support the rate. For health benefit plans as defined in section 62L.02, and for health plans to be issued to individuals, the health carrier shall file with the commissioner the information required in section 62L.08, subdivision 8. For group health plans for which approval is sought for sales only outside of the small employer market as defined in section 62L.02, this section applies only to policies or contracts of accident and sickness insurance. All forms intended for issuance in the individual or small

employer market must be accompanied by a statement as to the expected loss ratio for the form. Premium rates and forms relating to specific insureds or proposed insureds, whether individuals or groups, need not be filed, unless requested by the commissioner.

Sec. 2. Minnesota Statutes 2022, section 62J.84, subdivision 2, is amended to read:

Subd. 2. **Definitions.** (a) For purposes of this section and section 62J.841, the terms defined in this subdivision have the meanings given.

(b) "Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under United States Code, title 42, section 262(K)(3).

(c) "Brand name drug" means a drug that is produced or distributed pursuant to:

(1) an original, new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or

(2) a biologics license application approved under United States Code, title 45, section 262(a)(c).

(d) "Commissioner" means the commissioner of health.

(e) "Generic drug" means a drug that is marketed or distributed pursuant to:

(1) an abbreviated new drug application approved under United States Code, title 21, section 355(j);

(2) an authorized generic as defined under Code of Federal Regulations, title 45, section 447.502; or

(3) a drug that entered the market the year before 1962 and was not originally marketed under a new drug application.

(f) "Manufacturer" means a drug manufacturer licensed under section 151.252, but does not include an entity required to be licensed under that section solely because the entity repackages or relabels drugs.

(g) "New prescription drug" or "new drug" means a prescription drug approved for marketing by the United States Food and Drug Administration for which no previous wholesale acquisition cost has been established for comparison.

(h) "Patient assistance program" means a program that a manufacturer offers to the public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs

by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or by other means.

(i) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision 8.

(j) "Price" means the wholesale acquisition cost as defined in United States Code, title 42, section 1395w-3a(c)(6)(B).

Sec. 3. Minnesota Statutes 2022, section 62J.84, subdivision 6, is amended to read:

Subd. 6. **Public posting of prescription drug price information.** (a) The commissioner shall post on the department's website, or may contract with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, to meet this requirement, the following information:

(1) a list of the prescription drugs reported under subdivisions 3, 4, and 5, and the manufacturers of those prescription drugs; ~~and~~

(2) information reported to the commissioner under subdivisions 3, 4, and 5~~.~~; and

(3) information reported to the commissioner under section 62J.841, subdivision 2.

(b) The information must be published in an easy-to-read format and in a manner that identifies the information that is disclosed on a per-drug basis and must not be aggregated in a manner that prevents the identification of the prescription drug.

(c) The commissioner shall not post to the department's website or a private entity contracting with the commissioner shall not post any information described in this section if the information is not public data under section 13.02, subdivision 8a; or subject to section 62J.841, subdivision 2, paragraph (e), is trade secret information under section 13.37, subdivision 1, paragraph (b); or subject to section 62J.841, subdivision 2, paragraph (e), is trade secret information pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended. If a manufacturer believes information should be withheld from public disclosure pursuant to this paragraph, the manufacturer must clearly and specifically identify that information and describe the legal basis in writing when the manufacturer submits the information under this section. If the commissioner disagrees with the manufacturer's request to withhold information from public disclosure, the commissioner shall provide the manufacturer written notice that the information will be publicly posted 30 days after the date of the notice.

(d) If the commissioner withholds any information from public disclosure pursuant to this subdivision, the commissioner shall post to the department's website a report describing the nature of the information and the commissioner's basis for withholding the information from disclosure.

(e) To the extent the information required to be posted under this subdivision is collected and made available to the public by another state, by the University of Minnesota, or through an online drug pricing reference and analytical tool, the commissioner may reference the availability of this drug price data from another source including, within existing appropriations, creating the ability of the public to access the data from the source for purposes of meeting the reporting requirements of this subdivision.

Sec. 4. Minnesota Statutes 2022, section 62J.84, subdivision 7, is amended to read:

Subd. 7. **Consultation.** (a) The commissioner may consult with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, the University of Minnesota, or the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section and section 62J.841; in posting information pursuant to subdivision 6; and in taking any other action for the purpose of implementing this section and section 62J.841.

(b) The commissioner may consult with representatives of the manufacturers to establish a standard format for reporting information under this section and section 62J.841 and may use existing reporting methodologies to establish a standard format to minimize administrative burdens to the state and manufacturers.

Sec. 5. Minnesota Statutes 2022, section 62J.84, subdivision 8, is amended to read:

Subd. 8. **Enforcement and penalties.** (a) A manufacturer may be subject to a civil penalty, as provided in paragraph (b), for:

(1) failing to submit timely reports or notices as required by this section and section 62J.841;

(2) failing to provide information required under this section and section 62J.841; ~~or~~

(3) providing inaccurate or incomplete information under this section and section 62J.841; or

(4) failing to comply with section 62J.481, subdivisions 2, paragraph (e), and 4.

(b) The commissioner shall adopt a schedule of civil penalties, not to exceed $10,000 per day of violation, based on the severity of each violation.

(c) The commissioner shall impose civil penalties under this section and section 62J.841 as provided in section 144.99, subdivision 4.

(d) The commissioner may remit or mitigate civil penalties under this section and section 62J.481 upon terms and conditions the commissioner considers proper and consistent with public health and safety.

(e) Civil penalties collected under this section and section 62J.841 shall be deposited in the health care access fund.

Sec. 6. Minnesota Statutes 2022, section 62J.84, subdivision 9, is amended to read:

Subd. 9. **Legislative report.** (a) No later than May 15, ~~2022~~ 2024, and by January 15 of each year thereafter, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section and section 62J.841, including but not limited to the effectiveness in addressing the following goals:

(1) promoting transparency in pharmaceutical pricing for the state, health carriers, and other payers;

(2) enhancing the understanding on pharmaceutical spending trends; and

(3) assisting the state, health carriers, and other payers in the management of pharmaceutical costs and limiting formulary changes due to prescription drug cost increases during a coverage year.

(b) The report must include a summary of the information submitted to the commissioner under subdivisions 3, 4, and 5, and section 62J.841.

Sec. 7. **[62J.841] REPORTING PRESCRIPTION DRUG PRICES; FORMULARY DEVELOPMENT AND PRICE STABILITY.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the terms in this subdivision have the meanings given them.

(b) "Average wholesale price" means the customary reference price for sales by a drug wholesaler to a retail pharmacy, as established and published by the manufacturer.

(c) "National drug code" means the numerical code maintained by the United States Food and Drug Administration and includes the label code, product code, and package code.

(d) "Wholesale acquisition cost" has the meaning given in United States Code, title 42, section 1395w-3a(c)(6)(B).

(e) "Unit" has the meaning given in United States Code, title 42, section 1395w-3a(b)(2).

Subd. 2. **Price reporting.** (a) Beginning March 31, 2024, and by March 31 each year thereafter, a manufacturer must report to the commissioner the information in paragraph (b) for every drug with a wholesale acquisition cost of $100 or more for a 30-day supply or for a course of treatment lasting less than 30 days, as applicable to the next calendar year.

(b) A manufacturer shall report a drug's:

(1) national drug code, labeler code, and the manufacturer name associated with the labeler code;

(2) brand name, if applicable;

(3) generic name, if applicable;

(4) wholesale acquisition cost for one unit;

(5) measure that constitutes a wholesale acquisition cost unit;

(6) average wholesale price; and

(7) status as brand name or generic.

(c) The effective date of the information described in paragraph (b) must be included in the report to the commissioner.

(d) A manufacturer must report the information described in this subdivision in the form and manner specified by the commissioner.

(e) Information reported under this subdivision is classified as public data not on individuals, as defined in section 13.02, subdivision 14, and must not be classified by the manufacturer as trade secret information, as defined in section 13.37, subdivision 1, paragraph (b).

(f) A manufacturer's failure to report the information required by this subdivision is grounds for disciplinary action under section 151.071, subdivision 2.

Subd. 3. **Public posting of prescription drug price information.** By May 1 of each year, beginning May 1, 2024, the commissioner must post the information reported under subdivision 2 on the department's website, as required by section 62J.84, subdivision 6.

Subd. 4. **Price change.** (a) If a drug subject to price reporting under subdivision 2 is included in the formulary of a health plan submitted to and approved by the commissioner

of commerce for the next calendar year under section 62A.02, subdivision 1, the manufacturer must not increase the wholesale acquisition cost of the drug for the next calendar year.

(b) A manufacturer's failure to meet the requirements of paragraph (a) is grounds for disciplinary action under section 151.071, subdivision 2.

Sec. 8. Minnesota Statutes 2022, section 151.071, subdivision 2, is amended to read:

Subd. 2. **Grounds for disciplinary action.** The following conduct is prohibited and is grounds for disciplinary action:

(1) failure to demonstrate the qualifications or satisfy the requirements for a license or registration contained in this chapter or the rules of the board. The burden of proof is on the applicant to demonstrate such qualifications or satisfaction of such requirements;

(2) obtaining a license by fraud or by misleading the board in any way during the application process or obtaining a license by cheating, or attempting to subvert the licensing examination process. Conduct that subverts or attempts to subvert the licensing examination process includes, but is not limited to: (i) conduct that violates the security of the examination materials, such as removing examination materials from the examination room or having unauthorized possession of any portion of a future, current, or previously administered licensing examination; (ii) conduct that violates the standard of test administration, such as communicating with another examinee during administration of the examination, copying another examinee's answers, permitting another examinee to copy one's answers, or possessing unauthorized materials; or (iii) impersonating an examinee or permitting an impersonator to take the examination on one's own behalf;

(3) for a pharmacist, pharmacy technician, pharmacist intern, applicant for a pharmacist or pharmacy license, or applicant for a pharmacy technician or pharmacist intern registration, conviction of a felony reasonably related to the practice of pharmacy. Conviction as used in this subdivision includes a conviction of an offense that if committed in this state would be deemed a felony without regard to its designation elsewhere, or a criminal proceeding where a finding or verdict of guilt is made or returned but the adjudication of guilt is either withheld or not entered thereon. The board may delay the issuance of a new license or registration if the applicant has been charged with a felony until the matter has been adjudicated;

(4) for a facility, other than a pharmacy, licensed or registered by the board, if an owner or applicant is convicted of a felony reasonably related to the operation of the facility. The

board may delay the issuance of a new license or registration if the owner or applicant has been charged with a felony until the matter has been adjudicated;

(5) for a controlled substance researcher, conviction of a felony reasonably related to controlled substances or to the practice of the researcher's profession. The board may delay the issuance of a registration if the applicant has been charged with a felony until the matter has been adjudicated;

(6) disciplinary action taken by another state or by one of this state's health licensing agencies:

(i) revocation, suspension, restriction, limitation, or other disciplinary action against a license or registration in another state or jurisdiction, failure to report to the board that charges or allegations regarding the person's license or registration have been brought in another state or jurisdiction, or having been refused a license or registration by any other state or jurisdiction. The board may delay the issuance of a new license or registration if an investigation or disciplinary action is pending in another state or jurisdiction until the investigation or action has been dismissed or otherwise resolved; and

(ii) revocation, suspension, restriction, limitation, or other disciplinary action against a license or registration issued by another of this state's health licensing agencies, failure to report to the board that charges regarding the person's license or registration have been brought by another of this state's health licensing agencies, or having been refused a license or registration by another of this state's health licensing agencies. The board may delay the issuance of a new license or registration if a disciplinary action is pending before another of this state's health licensing agencies until the action has been dismissed or otherwise resolved;

(7) for a pharmacist, pharmacy, pharmacy technician, or pharmacist intern, violation of any order of the board, of any of the provisions of this chapter or any rules of the board or violation of any federal, state, or local law or rule reasonably pertaining to the practice of pharmacy;

(8) for a facility, other than a pharmacy, licensed by the board, violations of any order of the board, of any of the provisions of this chapter or the rules of the board or violation of any federal, state, or local law relating to the operation of the facility;

(9) engaging in any unethical conduct; conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient; or pharmacy practice that is professionally incompetent, in that it may create

unnecessary danger to any patient's life, health, or safety, in any of which cases, proof of actual injury need not be established;

(10) aiding or abetting an unlicensed person in the practice of pharmacy, except that it is not a violation of this clause for a pharmacist to supervise a properly registered pharmacy technician or pharmacist intern if that person is performing duties allowed by this chapter or the rules of the board;

(11) for an individual licensed or registered by the board, adjudication as mentally ill or developmentally disabled, or as a chemically dependent person, a person dangerous to the public, a sexually dangerous person, or a person who has a sexual psychopathic personality, by a court of competent jurisdiction, within or without this state. Such adjudication shall automatically suspend a license for the duration thereof unless the board orders otherwise;

(12) for a pharmacist or pharmacy intern, engaging in unprofessional conduct as specified in the board's rules. In the case of a pharmacy technician, engaging in conduct specified in board rules that would be unprofessional if it were engaged in by a pharmacist or pharmacist intern or performing duties specifically reserved for pharmacists under this chapter or the rules of the board;

(13) for a pharmacy, operation of the pharmacy without a pharmacist present and on duty except as allowed by a variance approved by the board;

(14) for a pharmacist, the inability to practice pharmacy with reasonable skill and safety to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills. In the case of registered pharmacy technicians, pharmacist interns, or controlled substance researchers, the inability to carry out duties allowed under this chapter or the rules of the board with reasonable skill and safety to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills;

(15) for a pharmacist, pharmacy, pharmacist intern, pharmacy technician, medical gas dispenser, or controlled substance researcher, revealing a privileged communication from or relating to a patient except when otherwise required or permitted by law;

(16) for a pharmacist or pharmacy, improper management of patient records, including failure to maintain adequate patient records, to comply with a patient's request made pursuant to sections 144.291 to 144.298, or to furnish a patient record or report required by law;

(17) fee splitting, including without limitation:

(i) paying, offering to pay, receiving, or agreeing to receive, a commission, rebate, kickback, or other form of remuneration, directly or indirectly, for the referral of patients;

(ii) referring a patient to any health care provider as defined in sections 144.291 to 144.298 in which the licensee or registrant has a financial or economic interest as defined in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the licensee's or registrant's financial or economic interest in accordance with section 144.6521; and

(iii) any arrangement through which a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved in any manner, directly or indirectly, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefit manager, or other person paying for the prescription or, in the case of veterinary patients, the price for the filled prescription that is charged to the client or other person paying for the prescription, except that a veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified, in writing and with each prescription dispensed, about the arrangement, unless such arrangement involves pharmacy services provided for livestock, poultry, and agricultural production systems, in which case client notification would not be required;

(18) engaging in abusive or fraudulent billing practices, including violations of the federal Medicare and Medicaid laws or state medical assistance laws or rules;

(19) engaging in conduct with a patient that is sexual or may reasonably be interpreted by the patient as sexual, or in any verbal behavior that is seductive or sexually demeaning to a patient;

(20) failure to make reports as required by section 151.072 or to cooperate with an investigation of the board as required by section 151.074;

(21) knowingly providing false or misleading information that is directly related to the care of a patient unless done for an accepted therapeutic purpose such as the dispensing and administration of a placebo;

(22) aiding suicide or aiding attempted suicide in violation of section 609.215 as established by any of the following:

(i) a copy of the record of criminal conviction or plea of guilty for a felony in violation of section 609.215, subdivision 1 or 2;

(ii) a copy of the record of a judgment of contempt of court for violating an injunction issued under section 609.215, subdivision 4;

(iii) a copy of the record of a judgment assessing damages under section 609.215, subdivision 5; or

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board must investigate any complaint of a violation of section 609.215, subdivision 1 or 2;

(23) for a pharmacist, practice of pharmacy under a lapsed or nonrenewed license. For a pharmacist intern, pharmacy technician, or controlled substance researcher, performing duties permitted to such individuals by this chapter or the rules of the board under a lapsed or nonrenewed registration. For a facility required to be licensed under this chapter, operation of the facility under a lapsed or nonrenewed license or registration; ~~and~~

(24) for a pharmacist, pharmacist intern, or pharmacy technician, termination or discharge from the health professionals services program for reasons other than the satisfactory completion of the program; and

(25) for a drug manufacturer, failure to comply with section 62J.841.

ARTICLE 2
PRESCRIPTION DRUG BENEFIT TRANSPARENCY

Section 1. Minnesota Statutes 2022, section 62J.497, subdivision 1, is amended to read:

Subdivision 1. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given.

(b) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(c) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription.

(d) "Electronic media" has the meaning given under Code of Federal Regulations, title 45, part 160.103.

(e) "E-prescribing" means the transmission using electronic media of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or group purchaser, either directly or through an intermediary, including an e-prescribing

network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser and two-way transmissions related to eligibility, formulary, and medication history information.

(f) "Electronic prescription drug program" means a program that provides for e-prescribing.

(g) "Group purchaser" has the meaning given in section 62J.03, subdivision 6.

(h) "HL7 messages" means a standard approved by the standards development organization known as Health Level Seven.

(i) "National Provider Identifier" or "NPI" means the identifier described under Code of Federal Regulations, title 45, part 162.406.

(j) "NCPDP" means the National Council for Prescription Drug Programs, Inc.

(k) "NCPDP Formulary and Benefits Standard" means the most recent version of the National Council for Prescription Drug Programs Formulary and Benefits Standard or the most recent standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(4)(D) of the Social Security Act and regulations adopted under it. The standards shall be implemented according to the Centers for Medicare and Medicaid Services schedule for compliance.

(l) "NCPDP Real-Time Prescription Benefit Standard" means the most recent National Council for Prescription Drug Programs Real-Time Prescription Benefit Standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(2) of the Social Security Act, and regulations adopted under it.

~~(l)~~ (m) "NCPDP SCRIPT Standard" means the most recent version of the National Council for Prescription Drug Programs SCRIPT Standard, or the most recent standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(4)(D) of the Social Security Act, and regulations adopted under it. The standards shall be implemented according to the Centers for Medicare and Medicaid Services schedule for compliance.

~~(m)~~ (n) "Pharmacy" has the meaning given in section 151.01, subdivision 2.

(o) "Pharmacy benefit manager" has the meaning given in section 62W.02, subdivision 15.

~~(n)~~ (p) "Prescriber" means a licensed health care practitioner, other than a veterinarian, as defined in section 151.01, subdivision 23.

~~(o)~~ (q) "Prescription-related information" means information regarding eligibility for drug benefits, medication history, or related health or drug information.

~~(p)~~ (r) "Provider" or "health care provider" has the meaning given in section 62J.03, subdivision 8.

(s) "Real-time prescription benefit tool" means a tool that is capable of being integrated into a prescriber's e-prescribing system and that provides a prescriber with up-to-date and patient-specific formulary and benefit information at the time the prescriber submits a prescription.

Sec. 2. Minnesota Statutes 2022, section 62J.497, subdivision 3, is amended to read:

Subd. 3. **Standards for electronic prescribing.** (a) Prescribers and dispensers must use the NCPDP SCRIPT Standard for the communication of a prescription or prescription-related information.

(b) Providers, group purchasers, prescribers, and dispensers must use the NCPDP SCRIPT Standard for communicating and transmitting medication history information.

(c) Providers, group purchasers, prescribers, and dispensers must use the NCPDP Formulary and Benefits Standard for communicating and transmitting formulary and benefit information.

(d) Providers, group purchasers, prescribers, and dispensers must use the national provider identifier to identify a health care provider in e-prescribing or prescription-related transactions when a health care provider's identifier is required.

(e) Providers, group purchasers, prescribers, and dispensers must communicate eligibility information and conduct health care eligibility benefit inquiry and response transactions according to the requirements of section 62J.536.

(f) Group purchasers and pharmacy benefit managers must use a real-time prescription benefit tool that complies with the NCPDP Real-Time Prescription Benefit Standard and that, at a minimum, notifies a prescriber:

(1) if a prescribed drug is covered by the patient's group purchaser or pharmacy benefit manager;

(2) if a prescribed drug is included on the formulary or preferred drug list of the patient's group purchaser or pharmacy benefit manager;

(3) of any patient cost-sharing for the prescribed drug;

(4) if prior authorization is required for the prescribed drug; and

(5) of a list of any available alternative drugs that are in the same class as the drug originally prescribed and for which prior authorization is not required.

EFFECTIVE DATE. This section is effective January 1, 2024.

Sec. 3. **[62Q.83] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND MANAGEMENT.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following terms have the meanings given them.

(b) "Drug" has the meaning given in section 151.01, subdivision 5.

(c) "Enrollee contract term" means the 12-month term during which benefits associated with health plan company products are in effect. For managed care plans and county-based purchasing plans under section 256B.69 and chapter 256L, it means a single calendar year.

(d) "Formulary" means a list of prescription drugs that has been developed by clinical and pharmacy experts and that represents the health plan company's medically appropriate and cost-effective prescription drugs approved for use.

(e) "Health plan company" has the meaning given in section 62Q.01, subdivision 4, and includes an entity that performs pharmacy benefits management for the health plan company. For purposes of this definition, "pharmacy benefits management" means the administration or management of prescription drug benefits provided by the health plan company for the benefit of the plan's enrollees and may include but is not limited to procurement of prescription drugs, clinical formulary development and management services, claims processing, and rebate contracting and administration.

(f) "Prescription" has the meaning given in section 151.01, subdivision 16a.

Subd. 2. **Prescription drug benefit disclosure.** (a) A health plan company that provides prescription drug benefit coverage and uses a formulary must make the plan's formulary and related benefit information available by electronic means and, upon request, in writing, at least 30 days prior to annual renewal dates.

(b) Formularies must be organized and disclosed consistent with the most recent version of the United States Pharmacopeia's (USP) Model Guidelines.

(c) For each item or category of items on the formulary, the specific enrollee benefit terms must be identified, including enrollee cost-sharing and expected out-of-pocket costs.

Subd. 3. **Formulary changes.** (a) Once a formulary has been established, a health plan company may, at any time during the enrollee's contract term:

(1) expand its formulary by adding drugs to the formulary;

(2) reduce co-payments or coinsurance; or

(3) move a drug to a benefit category that reduces an enrollee's cost.

(b) A health plan company may remove a brand name drug from the plan's formulary or place a brand name drug in a benefit category that increases an enrollee's cost only upon the addition to the formulary of a generic or multisource brand name drug rated as therapeutically equivalent according to the FDA Orange Book or a biologic drug rated as interchangeable according to the FDA Purple Book at a lower cost to the enrollee, and upon at least a 60-day notice to prescribers, pharmacists, and affected enrollees.

(c) A health plan company may change utilization review requirements or move drugs to a benefit category that increases an enrollee's cost during the enrollee's contract term upon at least a 60-day notice to prescribers, pharmacists, and affected enrollees, provided that these changes do not apply to enrollees who are currently taking the drugs affected by these changes for the duration of the enrollee's contract term.

(d) A health plan company may remove any drugs from the plan's formulary that have been deemed unsafe by the Food and Drug Administration, that have been withdrawn by either the Food and Drug Administration or the product manufacturer, or when an independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes in drug usage.

Subd. 4. **Not severable.** The provisions of this section shall not be severable from article 1 of this act. If any provision of article 1 of this act or its application to any individual, entity, or circumstance is found to be void for any reason, this section shall be void also.

EFFECTIVE DATE. This section is effective January 1, 2024, and applies to health plans offered, sold, issued, or renewed on or after that date.