Evaluation of HF58-2E

Report to the Minnesota Legislature pursuant to Minn. Stat. §62J.26

01/26/2022

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Contents

Executive Summary

House File 58-2E requires health plans and PBMs to file their prescription drug formularies and to use a real-time prescription drug benefit tool. The bill requirements do not establish any new benefit requirements for health plans; therefore the Minnesota Department of Commerce (Commerce) has determined that it is not a new state mandated benefit under the Affordable Care Act (ACA). The overall cost to the state is projected to be $26,654,413 in the next fiscal year, based on fiscal impact to SEGIP as estimated by MMB.

Introduction and Policy Context

Pursuant to Minn. Stat. § 62J.26, subd. 3, Commerce has been requested to perform an evaluation of House File 58. The purpose of the evaluation is to provide the legislature with a detailed analysis of the potential impacts of any mandated health benefit proposal.

House File 58-2E was first introduced during the 2021 legislative session and meets the definition of a mandated health benefit proposal under Minn. Stat. §62J.26, which outlines the following criteria:

> A mandated health benefit proposal" or "proposal" means a proposal that would statutorily require a health plan company to do the following:
>
> (i) provide coverage or increase the amount of coverage for the treatment of a particular disease, condition, or other health care need;
>
> (ii) provide coverage or increase the amount of coverage of a particular type of health care treatment or service or of equipment, supplies, or drugs used in connection with a health care treatment or service;
>
> (iii) provide coverage for care delivered by a specific type of provider;
>
> (iv) require a particular benefit design or impose conditions on cost-sharing for:
>
> (A) the treatment of a particular disease, condition, or other health care need;
>
> (B) a particular type of health care treatment or service; or
>
> (C) the provision of medical equipment, supplies, or a prescription drug used in connection with treating a particular disease, condition, or other health care need; or
>
> (v) impose limits or conditions on a contract between a health plan company and a health care provider.
>
> "Mandated health benefit proposal" does not include health benefit proposals amending the scope of practice of a licensed health care professional.

In producing its analysis, Commerce is required to consult with the Departments of Health (MDH) and Management and Budget (MMB). Per statute, evaluations must focus on the following areas:

- Scientific and medical information regarding the proposal, including potential for benefit and harm
- Overall public health and economic impact
- Background on the extent to which services/items in the proposal are utilized by the population
- Information on the extent to which service/items in the proposal are already covered by health plans, and to which health plans the proposal would impact

- Cost considerations regarding the potential of the proposal to increase cost of care, as well as its potential to increase enrollee premiums in impacted health plans
- The cost to the State if the proposal is determined to be a mandated benefit under the Affordable Care Act (ACA)

Commerce's subsequent evaluation addresses all areas noted above, with the caveat that with this particular bill there is a paucity of relevant data.

Bill Requirements and Impact

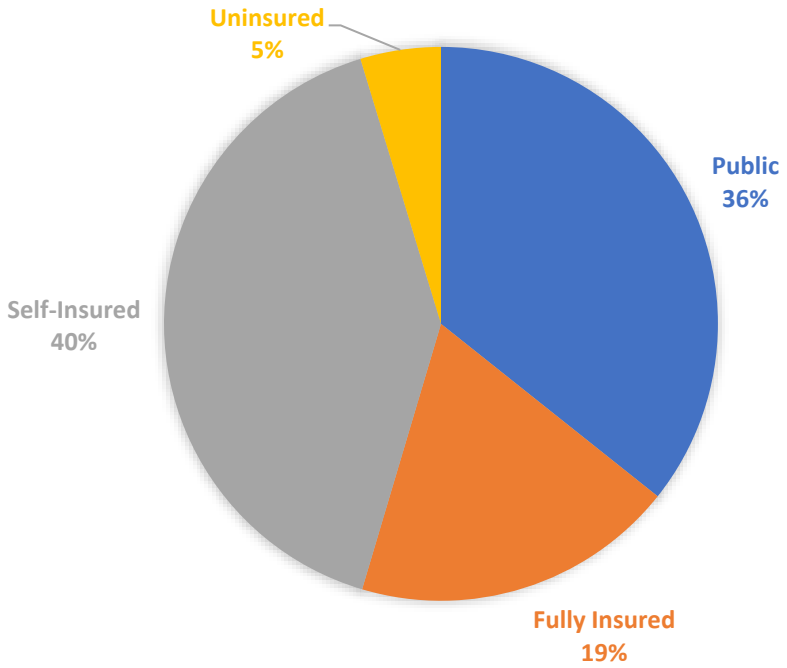
If enacted, HF58-2E would require health plans to file their prescription drug formularies and to use a real-time prescription drug benefit tool. House File 58 also adds additional prescription drug benefit and transparency disclosure requirements to existing statute.

As part of the bill, manufacturers would not be allowed to increase the wholesale acquisition cost of the drug in the next calendar year if the drug was on the previous year's publicly posted formulary. The bill amends Minn. Stat. §§ 62A.02, subdivision. 1; 62J.497, subdivisions. 1 and 3; 62J.84, subdivisions 1, 2, 4, 8, and 9, and proposes new code for law under Chapters 62J and 62Q.

The full text of the bill is available in the Appendix of this document.

The bill would apply to all fully insured health plans regulated in Minnesota, plus the State Employee Group Insurance Program (SEGIP). Requirements in the bill would not apply to all other self-insured employer plans, state public programs, grandfathered plans, short-term plans, and Medicare and Medicare supplemental policies. Figure 1 shows a breakdown of health insurance coverage in Minnesota by type (including uninsured).

Figure 1. Minnesota Insurance Coverage 2019



Source: Minnesota Department of Health. Chartbook Section 2. Trends and Variations in Health Insurance Coverage. Accessed at https://www.health.state.mn.us/data/economics/chartbook/docs/section2.pdf.

State and Federal Law

This evaluation must consider the interaction between state and federal law—specifically as it pertains to the potential for the bill to be considered a state benefit mandate as understood under Section 1311(d)(3) of the ACA (45 CFR § 155.170), which indicates that states must defray the costs of new mandates related to specific care or treatment not offered under the general essential health benefits (EHB) package in the given state's benchmark plan. The state is only required to defray associated costs that would not have been provided by the health carrier without the requirements of the new mandate prior to January 1, 2012. Cost of defrayal applies only to qualified health plans (QHPs), meaning plans on Minnesota's individual, on-exchange market. [1]

Evaluation of Mandated Health Benefit Proposal

This evaluation is based on Commerce's interpretation of the criteria under Minn. Stat. §62J.26, subd. 2, which includes the following:

- Solicitation of feedback from stakeholders by publishing a request for information notice in the State Register
- Scoping review of available literature in relevant databases
- Hybrid umbrella/systematic literature review of available resources
- Consultation with MDH and MMB
- Solicitation of comments from health plans, including request for actuarial analysis
- Internal actuarial analysis

In Commerce's evaluation, the requirements of HF58-2E do not constitute a benefit mandate as understood under Section 1311(d)(3) of the ACA. Prescription drug services are specifically identified as an EHB and therefore must already be covered under all ACA-compliant plans. House File 58 requires work from health plans, including development of a prescription benefit tool and the filing of various transparency and disclosure items. House File 58 also establishes a requirement for health plans to file their formularies with Commerce, which already reviews health plan formularies to ensure compliance with both state and federal law. The items in HF58-2E are not explicitly related to specific care or treatment, and therefore would not constitute a benefit mandate as understood under the ACA.

Scientific and Medical Analysis

The bill text of HF58-2E addresses prescription drug costs and transparency generally, and does not identify any specific health conditions that would allow for analysis on the comparative benefit or harm from alternative forms of treatment. As such, Commerce can only provide general analysis with the data that are available currently regarding utilization and cost of prescription drugs. Additionally, subsequent analysis will focus primarily on the text of the bill itself, as well as impact of similar bills in other states.

Public Health, Economic, and Fiscal Impact

The impact of HF58-2E on general public health is difficult to determine in the absence of an associated disease or condition with the bill. Commerce will focus on general concepts regarding prescription drug coverage,

[1] 45 CFR Parts 147, 155, and 156 Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule. Accessed at https://www.govinfo.gov/content/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

existing statutes in Minnesota, and similar proposals in other states (including information regarding their impact when possible) in the subsequent sections.

For the purposes of this and subsequent sections, the following definitions apply:

Public Health: The science and practice of protecting and improving the health and wellbeing of people and their communities. The field of public health includes many disciplines such as epidemiology, biostatistics, environmental health, social and behavioral sciences (includes health education), health policy and management (includes health services administration).

Economic Impact: The general financial impact of a drug, service, or item on the population prescribing or utilizing a particular drug, service or item for a particular health condition.

Fiscal Impact: The quantifiable dollar amount associated with the implementation of the mandated health benefit proposal. The areas of potential fiscal impact that Commerce reviews for are for the cost of defrayal of benefit mandates as understood under the ACA, the cost to SEGIP, and the cost to state public programs. The fiscal impact is expressed in number of dollars required for the state to implement a proposal.

In summary, the public health impact, as understood using the definition above, would likely be favorable if HF58-2E were enacted. In the absence of a specific condition being addressed by HF58-2E, Commerce has made a favorable public health assessment based on the principle that increased coverage and transparency equals increased utilization. Public health is positively impacted when individuals with chronic health conditions are better able to access medications without financial barriers, and with better knowledge of potential cost to them.

The Department assumes that HF58-2E would reduce financial barriers for consumers obtaining prescription medications, and further assumes that a reduction in cost-sharing would increase utilization of services, including prescription drugs.[2][3] Due to the broad nature of the bill, an economic impact is difficult to estimate. Commerce assumes the bill to limit mid-year formulary drug changes — which could potentially have an impact on steering enrollees to lower lost drugs (based on net cost from manufacturer rebates). Additionally, this limitation could also potentially lead to adding utilization management techniques to certain medications that could be added to the formulary.

House File 58 is anticipated to carry a fiscal impact to the state. As part of Commerce's evaluation, as required by 62J.26 subd. 2, the Department consulted with MMB on the impact of the bill. According to MMB, implementation of HF58-2E will incur a cost to SEGIP in each of the following fiscal years:

Table 1 – Projected Fiscal Impact of HF58-2E

Fiscal Year	2022	2023	2024	2025	2026
State Fiscal Impact (SEGIP)[4]	$0	$12,692,578	$26,654,413	$27,987,133	$29,386,490

[2] Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. JAMA. 2007 Jul 4;298(1):61-9. doi: 10.1001/jama.298.1.61. PMID: 17609491; PMCID: PMC6375697.

[3] Dickson S, Reynolds I. Estimated Changes in Manufacturer and Health Care Organization Revenue Following List Price Reductions for Hepatitis C Treatments. *JAMA Netw Open.* 2019;2(7):e196541. doi:10.1001/jamanetworkopen.2019.6541

[4] Figures in this table represent the cost to the state from SEGIP impact. The total cost impact to the SEGIP plan—specifically, adding in the employee share of the overall premium—will be higher.

As HF58-2E is not considered to be an ACA benefit mandate and does not apply to public programs, the total fiscal impact to the state is equal to SEGIP cost estimates listed above.

Current Utilization

Given that HF58-2E does not address any specific health condition, this report's evaluation regarding utilization focuses on commonly prescribed prescription medications both locally and nationally. Healthcare spending continues to increase in the U.S. and accounts for nearly 20 percent of total gross domestic product.[5] Increased spending in the healthcare industry can be in part attributed to prescription drug coverage, which accounts for nearly 10 percent of overall expenditures.

Data regarding local utilization of prescription drugs comes from recently enacted reporting requirements under Minn. Stat. §62K.07, which requires reporting on prescription drug utilization and cost. Each regulated carrier offering prescription drug benefits in its individual or small group health plans must provide to the Department data regarding the following:

1. The 25 most frequently prescribed drugs in the previous calendar year.
2. The 25 most costly prescribed drugs as a portion of total annual expenditures in the previous calendar year.
3. The 25 prescription drugs that caused the greatest increase in total spending in previous calendar year.
4. The projected impact of the cost of prescription drugs on next year's premiums.
5. Whether any health plan offered requires enrollees to pay cost-sharing on covered prescription drugs in an amount greater than the health plan would pay for the drug absent the applicable cost-sharing and after any rebate amount.
6. Whether third-party payments, such as drug manufacturer discounts or coupons that cover all or a portion of the enrollee's cost-sharing, apply towards the enrollee's cost-sharing obligations.

The information provided regarding top prescribing and top spending categories in Minnesota is useful to reference for understanding what prescription drugs might be impacted if HF58-2E were to become law. The top 25 most prescribed drugs are likely to be included on formularies fairly consistently, and could feasibly be locked into the formulary in subsequent years following a health plan's filing. Hypothetically, the more commonly prescribed drugs could be subject to manufacturer price increases. Additionally, the top 25 most expensive drugs prescribed could be locked in as well and subject to fluctuation. Any substantive increase in price would be passed down to employers and consumers.

The top 25 drugs are referenced in a report that be accessed via the Minnesota Legislative Reference Library.[6]

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[5] Micah Hartman et al.; "**National Health Care Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions**"; *Health Affairs* 37(1): 150-160; January 2018. Note that the "retail prescription drugs" category excludes drugs purchased directly from physicians or hospitals (e.g., infusion drugs)

[6] https://mn.gov/commerce-stat/pdfs/2022-prescription-drug-cost-summary.pdf

Current Health Insurance Coverage

Prescription drugs are specifically identified under the ACA as one of 10 required EHBs. House File 58 establishes new requirements for health plans in terms of providing cost transparency and adds some restrictions to health plans, PBMs operating with a health plan, to alter a formulary during a plan year based on cost increases of a drug. Currently, health plans and PBMs are generally permitted to alter formularies when adding new drugs, or when removing them due to safety concerns. Commerce has never received notification of drugs having been removed from a formulary due to changes in wholesale acquisition costs.

Impact on Insurance Coverage

The impact of HF58-2E on insurance coverage is contingent on how prescription drug coverage is provided by a carrier. Many carriers in Minnesota delegate all pharmacy benefits to PBMs, while others sometimes may meet the definition of a PBM under Minn. Stat. §62W. House File 58 adds restrictions to how and when prescription drugs may be added or removed from a health plan formulary. In many instances, the requirements of HF58-2E restrict the ability of health plans, and by proxy, PBMs, to make significant alterations to a formulary (excepting adding drugs or instances of a drug needing to be removed for safety concerns).

Currently, Commerce, in conjunction with MDH, reviews health plan formularies for inclusion of adequate numbers of drugs, with a specific focus on certain health conditions as determined by Centers for Medicare & Medicaid Services (CMS).

Commerce acknowledges that formularies are subject to change following approval of a health plan filing for a number of reasons. Prescription drugs may be added to a formulary as they are approved for use by the U.S. Food and Drug Administration (FDA), or may be removed for safety concerns by the same governing body.

Commerce uses tools developed by CMS to evaluate numbers of drugs health plans include in their formularies by category and class. Additionally, Commerce staff use CMS tools to assess whether or not a disproportionate number of drugs in certain categories and classes are subject to health plan utilization review requirements.

As noted previously, Commerce has not been notified when drugs have been removed or added to formularies based on wholesale acquisition cost changes.

Impact on Cost

The overall cost impact of HF58-2E is difficult to predict, given that the bill does not address any specific health condition. If enacted, HF58-2E would allow health plans to modify formularies under limited circumstances, most of which are beneficial to the consumer. Although the potential consumer benefit associated with HF58-2E is important, this evaluation must also consider the impact to the cost of services overall as a result of enactment of a bill.

Ultimately, cost considerations must consider the following:

- Supply and demand of medications associated with higher-cost, chronic and acute conditions
- Likelihood of consumers to utilize additional information on prescription drug pricing

Commerce solicited feedback from stakeholders and other interested Minnesotans regarding the impact of this proposal. Several commenters noted that the cost impact of the bill could vary some year to year depending on actions made by drug manufacturers. Health plans and stakeholders all noted the potential for increases in overall cost of medications due to manufacturer prices being locked in.

Much of the analysis regarding the potential for impact on cost is based on a combination of the Department's own analysis in conjunction with stakeholder feedback.

The prices of certain drugs could feasibly be increased due to the language of HF58-2E, which would not allow for price-based changes to health plan formularies during the year. That reasoning for this position is that locking in formularies based on price may contribute to proliferation of additional drugs to the market that are very similar to existing medications (but at a much higher cost). Without the ability to negotiate prices due to the locked-in formulary, health plans, plan sponsors, and PBMs would potentially need to contend with increased cost from manufacturers.

Formulary changes during a plan year may still occur when beneficial to the consumer (e.g., moving a prescription drug to a lower tier or when a drug must be removed due to safety concerns).

A Milliman study promulgated by the Pharmaceutical Care Management Association (PCMA) points to the potential financial costs associated with "frozen formularies," which in part describes some provisions of HF58-2E. The Milliman study specifically identifies the term, "negative formulary changes" in describing any change by a health plan that 1) increases the cost-sharing amount by moving a drug to a higher tier for an enrollee; 2) removes a drug from the formulary; or 3) adds more restrictive utilization management criteria to a particular drug.[7]

House File 58 does include more leeway in terms of allowing for changes to formularies during the year — most notably by having language indicating that health plan companies may remove brand name drugs from a formulary so long as there is a generic or multisource brand name drug "rated as therapeutically equivalent" available. The Milliman study does address points to this to a degree, but it is worth reiterating in this evaluation.

Another Milliman study points to the concept of utilization management and its impact on prescription drug use, indicating that utilization management decreases overall utilization. HF58-2E heavily restricts the ability of health plans and PBMs to perform utilization management, specifically by indicating that this practice is prohibited should any existing enrollees be taking a medication possibly subject to a policy change.[8]

Another study regarding elasticities (the general economic concept of measuring sensitivity of one economic factor to another) in pricing of prescription medications suggested that there is a high degree of variability in patient utilization of prescription medications that takes into consideration 1) price of the medication, 2) degree of patient cost-sharing, and 3) ease of access to the medication itself (such as being able to access the medication at a standalone pharmacy). Prescription drug prices are noted to be inelastic by some studies, which, to the point of this analysis, would suggest that cost changes may have little to do with supply and demand.[9]

Impact on Health Insurance Premiums

While Commerce's analysis indicates that it is unlikely that the bill would produce substantive increases in premiums for consumers, the precise premium impact that the bill would have is difficult to fully quantify. The

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[7] Liner, DM, Margiott, TA. Estimated cost of potential "frozen formulary" legislation: Fully insured commercial payer impact, 2021-2025. Commissioned by the Pharmaceutical Care Management Association, January 25, 2021. Accessed at https://www.pcmanet.org/wp-content/uploads/2021/02/Milliman_Frozen-Formulary-Report_FINAL.pdf

[8] https://olis.oregonlegislature.gov/liz/2018R1/Downloads/CommitteeMeetingDocument/141979

[9] Gatwood, J, Gibson, TB, Chernew, ME, Farr, AM, Vogtmann, E, and Fendrick, AM. Price elasticity and medication use: cots sharing across multiple clinical conditions. Accessed at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2014.20.11.1102

main provisions of the bill promote transparency in pricing for consumers, which, theoretically, may reduce utilization of higher cost medications. [10,11]

Health plans may add drugs to their formularies at any point in time, or make modifications when they intend to reduce cost-sharing amounts for their enrollees, or remove a brand name drug in favor of a generic (and less costly) equivalent. Health plans are permitted to alter utilization management of drugs, so long as 60-day notice is provided to the enrollee.

House File 58 allows for additions of drugs to formularies at any given point during the plan year. Historically, health plans have been allowed to add drugs to their formulary at any time, so long as the additions are not subject to any excess of utilization management criteria. Because premiums remain constant over a single plan year, these changes have no premium impact during that time. Premiums may be impacted by prescription drug cost and utilization.

Transparency in pricing of prescription drugs, if utilized by physicians and patients, could lead to less use of higher cost medications when a lower cost alternative is available. Studies have indicated that there is a knowledge gap regarding physician knowledge of prescription drug costs.[12] Overcoming this gap could lead to fewer prescriptions for higher cost drugs, once physicians are aware of the actual costs of certain medications.

Summary of Comments Received

The Department placed a request for information in the November 22, 2021 publication of the State Register, requesting comments regarding all mandated health benefit proposals, including HF58-2E. The Department received feedback from health plans, generally, and from industry stakeholders.

In summary, the comments received from health plans and stakeholders indicated that there would be potential for increased cost associated with the passage of HF58-2E.

ACA Benefit Mandate Impact and Analysis

House File 58-2E would not be considered a state benefit mandate as understood under the ACA. The ACA stipulates that states mandating requirements from carriers to cover treatment for an illness not previously covered would relate to specific care, treatment, and services. HF58-2E has no such requirement, and also does not appear to fit under the exceptions to the mandated benefits provision of the ACA. A state may enact requirements unrelated to specific care, treatment, or services and not be responsible for defraying the cost, generally falling into the following:

1. ***Provider Types.*** Mandates that require a covered service to be covered by additional health care provider types.

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[10] Doshi JA, Li P, Ladage VP, Pettit AR, Taylor EA. Impact of cost sharing on specialty drug utilization and outcomes: a review of the evidence and future directions. Am J Manag Care. 2016 Mar;22(3):188-97. PMID: 27023024.

[11] Hopson S, Saverno K, Liu LZ, AL-Sabbagh A, Orazem J, Costantino ME, Pasquale MK. Impact of Out-of-Pocket Costs on Prescription Fills Among New Initiators of Biologic Therapies for Rheumatoid Arthritis. J Manag Care Spec Pharm. 2016 Feb;22(2):122-30. doi: 10.18553/jmcp.2016.14261. Epub 2015 Dec 14. PMID: 27015251.

[12] Allan GM, Lexchin J, Wiebe N. Physician awareness of drug cost: a systematic review. PLoS Med. 2007 Sep;4(9):e283. doi: 10.1371/journal.pmed.0040283. PMID: 17896856; PMCID: PMC1989748.

2. ***Cost-Sharing.*** Mandates that require or change cost-sharing amounts for covered services, including deductibles, copayments, and coinsurance.

3. ***Delivery Methods***. Mandates that require health carriers to cover new methods of delivering covered services (telehealth for example).

4. ***Reimbursement Methods.*** Mandates that require health carriers to reimburse health care providers for covered services provided in new ways.

5. ***Dependent-Coverage.*** Mandates that require health carriers to define dependents in a certain way or to cover dependents under specific circumstances.

6. ***ACA Conforming Coverage.*** Mandates required to comply with ACA requirements.

Overall, the impact of HF58-2E on Minnesota consumers, as well as health plans, remains unclear. Health plans would be more restricted from making alterations to their formularies, which could potentially have a benefit for consumers attempting to obtain prescription drug coverage. With less worry of a formulary changing and a drug being removed due to cost considerations, consumers may be able to more seamlessly access (or continue to access) medications as prescribed. Alternatively, the inability for health plans to remove a prescription drug from their respective formulary due to cost considerations could result in higher health care costs. Additional information is needed to fully understand the potential impacts of HF58-2E, and it is difficult to fully model the potential for cost-reduction on the overall healthcare system.

Appendix

Bill Text

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 2020, 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 2020, 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 2020, 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 2020, 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.

Sec. 4. Minnesota Statutes 2020, 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 2020, 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 2020, section 62J.84, subdivision 9, is amended to read:

Subd. 9.Legislative report. (a) No later than January 15 of each year, beginning January 15, 2022, 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, 2022, 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, 2022, 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 2020, 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 2020, 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) "Backward compatible" means that the newer version of a data transmission standard would retain, at a minimum, the full functionality of the versions previously adopted, and would permit the successful completion of the applicable transactions with entities that continue to use the older versions.

(c) "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.

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

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

(f) "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.

(g) "Electronic prescription drug program" means a program that provides for

e-prescribing.

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

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

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

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

(l) "NCPDP Formulary and Benefits Standard" means the National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0, October 2005.

(m) "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.

(m) (n) "NCPDP SCRIPT Standard" means the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005, 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. Subsequently released versions of the NCPDP SCRIPT Standard may be used, provided that the new version of the standard is backward compatible to the current version adopted by the Centers for Medicare and Medicaid Services.

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

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

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

(p) (r) "Prescription-related information" means information regarding eligibility for drug benefits, medication history, or related health or drug information.

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

(t) "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 2020, 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. The NCPDP SCRIPT Standard shall be used to conduct the following transactions:

(1) get message transaction;

(2) status response transaction;

(3) error response transaction;
(4) new prescription transaction;
(5) prescription change request transaction;
(6) prescription change response transaction;
(7) refill prescription request transaction;
(8) refill prescription response transaction;
(9) verification transaction;
(10) password change transaction;
(11) cancel prescription request transaction; and
(12) cancel prescription response transaction.
(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, 2022.

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 quarter.
(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, 2023, and applies to health

16.8 plans offered, sold, issued, or renewed on or after that date.