

Evaluation of HF 3592: Cost-Sharing Limits for Prescription Drugs and Related Medical Supplies Prescribed to Treat a Chronic Disease

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

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Executive Summary

This proposed mandate would require health plans to limit cost-sharing for drugs and supplies related to chronic diseases. Specifically, cost-sharing for these drugs and supplies would be limited to \$25 per 1-month supply for each prescription drug and no more than \$50 per 1-month supply in total. The definition of "chronic disease" in the proposed mandate refers to diabetes, asthma, and allergies that require the use of epinephrine auto-injectors.

Out-of-pocket (OOP) costs can reduce medication adherence for chronic diseases, increase the use of high-cost services (such as hospital inpatient or emergency care), and also increase morbidity. A similar association has been shown in the coverage of supplies and equipment needed to manage chronic diseases. Historically underserved groups—including low-income families and racial and ethnic minorities—are more likely to report increased barriers to treatment and have poorer clinical outcomes. Strategies such as reduced cost-sharing that address barriers are shown to improve medication adherence and clinical outcomes and may have the greatest impact on reducing health disparities for these populations. The relationship between OOP costs and medication adherence is not the same at all levels of OOP cost, and the structure of OOP costs can also mediate individuals' adherence to treatment.

Actuarial analysis concluded that the average additional monthly cost of this mandate would be \$0.02 per member in Year 1 and would increase to \$0.03 per member in the 10th year of implementation. The average increase in monthly premiums would start at \$1.00 per member in Year 1 and reach \$1.34 per member in the 10th year of implementation. This report also provides detailed actuarial analyses for diabetes, asthma, and allergies that require the use of epinephrine auto-injectors.

The potential fiscal impact of this mandate is as follows:

- The State Employee Group Insurance Program estimates the cost of this legislation for the state plan to be \$92,880 for the partial Fiscal Year 2023 (FY 2023) and \$195,048 for FY 2024.
- Commerce has determined that this mandate would likely not require defrayal under the Affordable Care Act because it only alters cost-sharing requirements and does not define a new benefit.
- There is no estimated cost for public programs because the mandate applies only to non-public, individual, fully insured small and large group plans and SEGIP, unless otherwise indicated.

Pursuant to Minn. Stat. § 62J.26, subd. 3, the Minnesota Department of Commerce (Commerce) is required to perform an evaluation of the first engrossment of House File 3592 on cost-sharing limits for prescription drugs and related medical supplies prescribed to treat a chronic disease from the 92nd Legislature (2021–2022). 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 3592 meets the definition of a mandated health benefit proposal under Minn. Stat. § 62J.26, which indicates 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:

- provide coverage or increase the amount of coverage for the treatment of a particular (i) 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.

Introduction

- a. In accordance with § 62J.26, Commerce performs, in consultation with the Minnesota Department of Health (MDH) and Minnesota Management and Budget (MMB), a detailed evaluation of all relevant benefit mandate proposals. Evaluations focus on the following areas:
 - Scientific and medical information regarding the proposal, including the potential for benefit and harm
 - ii. Overall public health and economic impact
 - Background on the extent to which services/items in the proposal are utilized by the iii. population
 - Information on the extent to which services/items in the proposal are already covered iv. by health plans and which health plans the proposal would impact
 - ٧. 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
 - vi. The cost to the state if the proposal is determined to be a mandated benefit under the Affordable Care Act (ACA)
- b. As part of these evaluations, Commerce also seeks public feedback on the proposed benefit mandates. This public feedback is summarized and incorporated into the analysis.
- c. The following analysis describes the proposed benefit mandate's impact on the health care industry and the population health of Minnesotans.

Evaluation Components

For the purposes of this evaluation, we used the following terms to describe the impact of the proposed mandate:

Public health. The science and practice of protecting and improving the health and well-being of people and their communities. The field of public health includes many disciplines, such as medicine, public policy, biology, sociology, psychology and behavioral sciences, and economics and business.

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

Fiscal impact. The quantifiable cost to the state associated with implementation of the mandated health benefit proposal. The areas of potential fiscal impact that Commerce reviews for are the cost of defrayal of benefit mandates under the ACA, the cost to the State Employee Group Insurance Program (SEGIP), and the cost to other state public programs.

Bill Requirements

HF 3592 is sponsored by Representative Howard and was introduced in the 92nd Legislature (2021–22) on February 17, 2022.

If enacted, this bill would require health plans to limit cost-sharing for drugs which an enrollee is prescribed for treatment of a chronic disease. As defined in the bill, "chronic disease" refers to two chronic conditions (diabetes and asthma) as well as allergies that require the use of epinephrine autoinjectors.

This bill would require that cost-sharing be limited to no more than \$25 per 1-month supply for each prescription drug and no more than \$50 per 1-month supply in total for all related medical supplies for the covered conditions and allergies. Covered supplies include syringes, insulin pens, epinephrine autoinjectors, test strips, glucometers, continuous glucose monitors, and other medical supply items necessary to effectively and appropriately administer a drug prescribed to treat a chronic disease.

Related Health Conditions

The covered conditions and allergies under this proposed bill have the following prevalence in Minnesota:

- In 2020, 8.8% of Minnesota adults (about 390,000 individuals) were diagnosed with diabetes (type 1 or 2).1
- In 2018, approximately 1 in 20 children (5.1%) and 1 in 12 adults (8.3%) were reported as having asthma in Minnesota.²
- Although data are not available for Minnesota specifically, 1 in 50 Americans have allergies requiring an epinephrine auto-injector (anaphylaxis).3

Related State and Federal Laws

This section provides an overview of state and federal laws related to the proposed mandate and any external factors that provide context on the current policy trends related to this topic. The review of current state and federal laws considers how implementation of the proposed mandate may be affected by federal and Minnesota state health care laws.

¹ Minnesota Department of Health. (2022, March 10). Diabetes in Minnesota [Webpage]. https://www.health.state.mn.us/diseases/diabetes/data/diabetesfacts.html

² Minnesota Department of Health. (2022, March 10). Asthma dataquick facts [Webpage]. https://www.health.state.mn.us/diseases/asthma/data/index.html#:~:text=How%20common%20is%20asthma%20in,422%2C703%20Mi nnesotans%20who%20have%20asthma

³ Asthma & Allergy Foundation of America. (2022, November 21). Anaphylaxis in America. https://aafa.org/asthma-allergy-research/ourresearch/anaphylaxis-in-america/#:~:text=lt%20found%20that%20anaphylaxis%2C%20a,closer%20to%20one%20in%2020

Federal Laws Relevant to the Proposed Mandate

Chronic disease management is included as an essential health benefit (EHB) as defined under section 1302(b) of the ACA. However, the ACA does not specify cost-sharing requirements related to chronic disease management. The recently passed Inflation Reduction Act of 2022 will limit cost sharing to \$35 per month for Medicare enrollees who require insulin, starting January 1, 2023.4 The Act does not specifically address cost-sharing for other drugs named under the proposed mandate, such as those for the treatment of asthma or allergies.

Minnesota State Laws Relevant to the Proposed Mandate

Minn. Stat. § 62Q.81, subd. 4, requires coverage of chronic diseases as an EHB, but the law does not cover cost-sharing for prescription drugs and related medical supplies prescribed to treat a chronic disease.⁵ This Minnesota statute was created to be in compliance with the ACA.

State Comparison

No comparable policies in other states were found in the review.

Public Comments Summary

To assess the public health, economic, and fiscal impact of HF 3592, Commerce solicited stakeholder engagement on the potential health benefit mandate. The public submitted comments in response to Minnesota's RFI process, which enabled the state to collect information from consumers, health plans, advocacy organizations, and other stakeholders. This process helped Commerce gather opinions, identify special considerations, and secure additional resources to support the evaluation. This section includes a summary of the key themes collected from stakeholders that submitted comments.

Any studies, laws, and other resources identified by stakeholders through public comment were evaluated based on criteria used for the literature scan. Please refer to the Methodology section for analysis of the reviewed literature. Responses to the RFI may not be fully representative of all stakeholders or of the opinions of those impacted by the proposed mandate.

Stakeholder Engagement Analysis

For this proposed mandate, Commerce received four stakeholder comments. Three of the stakeholders expressed no opinion but provided facts and information, and one does not support the proposed

⁴ Centers for Medicare & Medicaid Services. (2022, December 6). *Inflation Reduction Act: CMS implementation timeline*. https://www.cms.gov/files/document/10522-inflation-reduction-act-timeline.pdf

⁵ Health Plan Companies: Essential Health Benefit Package Requirements, Minnesota Statutes § 62Q.81 (2019). https://www.revisor.mn.gov/statutes/2019/cite/62Q.81

mandate. The types of stakeholders who submitted responses included health care providers, state and commercial health insurance carriers, and pharmacy benefit managers.

Stakeholders noted that the proposed mandate does not make a specific exemption for highdeductible health plans (HDHPs), and thus the federal requirements for HDHPs would preempt application of the state benefit mandate until the annual deductible is met. Stakeholders did not specify whether exemptions for HDHPs or cost-sharing requirements would apply to HDHP enrollees.

Stakeholders also explained that cost-sharing caps, such as those proposed in the bill, do not solve the problem of high drug prices because imposing caps does not hold drug manufacturers accountable for drug costs. In addition, they mentioned that cost-sharing is a method that pharmacy benefit managers use to manage drug price changes. Caps on cost-sharing limit the drug tier-based decision-making process health plans use to lower drugs costs for patients.

One stakeholder commented that because the proposed health benefit mandates only apply to fully insured plans, they may have the potential to drive more employer groups to switch to self-insured coverage to avoid potential costs associated with benefit mandates. This stakeholder referenced a source that showed enrollment changes in self-insured and fully insured plans since 2011. This source indicates that, while enrollment has increased for self-insured private health care plans and decreased in fully insured private health care plans, enrollment in public health care plans has also increased simultaneously. The source does not provide data indicating whether a causal relationship exists between the state insurance mandates and employer selection of self-insured plans given other variables that may account for changes in enrollment.^{6,7}

Stakeholders and MMB provided the following cost estimates related to the proposed health benefit mandate:

- MMB provided Commerce with the estimated fiscal impact of the proposed mandate as calculated by SEGIP. For FY 2023, SEGIP's health plan administrators estimate a potential cost increase of \$0.09 per member per month (PMPM) for medical and \$0.03 PMPM for prescription drug and supply (see the Fiscal Impact section).
- The estimated cost increase of the proposed legislation for commercial plans is \$3.20 PMPM (i.e., the total cost of medical supplies and diabetic and asthmatic drugs), which would pass through to premiums. If the scope of health conditions was broadened to include EHBs, then the estimated cost increase would be \$4.05 PMPM.

⁶ Minnesota Department of Health. (2022, July). Trends and variation in health insurance coverage (Chartbook Section 2). https://www.health.state.mn.us/data/economics/chartbook/docs/section2.pdf

⁷ The federal Employee Retirement Income Security Act of 1974 (ERISA) preempts state laws that "relate to" a covered employee benefit plan. Under ERISA, a state cannot deem a self-funded employee benefit plan as insurance for the purpose of imposing state regulation. Therefore, self-funded (or self-insured) plans may be exempt from abiding by a state-imposed health benefit mandate.

- As for general administration and implementing costs, initial operational costs are estimated to be between \$100,000 and \$150,000 for the transition, including updating prescription drug or medical supply copay cap processes.
- Cost estimates shared in RFI responses may reflect different methodologies, data sources, and assumptions than those used in the actuarial analysis for this evaluation. Therefore, stakeholders' results may or may not reflect generalizable estimates for the mandate.

Evaluation of Mandated Health Benefit Proposal

The methodology for relevant sections of these evaluations is described in the corresponding evaluation below and consisted of a three-pronged approach:

- Medical/scientific review
- Actuarial analysis to assess economic impact
- Defrayal analysis to assess fiscal impact

Methodology

This evaluation used critical review of research databases to identify scientific, medical, and regulatory sources relevant to the mandate. The literature scan utilized

- ١. key scientific, medical, and regulatory terms that emerged from the initial review of the proposed mandate;
- II. additional key terms that were identified and reviewed by AIR's technical and subject matter experts, Commerce, and MDH; and
- III. additional terms and research questions following public comment and stakeholder engagement interviews.

The key terms guided the search for relevant literature in PubMed and the National Bureau of Economic Research (NBER). PubMed was used to identify relevant biomedical literature and NBER to identify relevant literature that might address the potential public health, economic, and fiscal impacts of the mandate. The inclusion factors prioritized peer-reviewed literature and independently conducted research on any articles or databases identified through public comment. In addition, criteria included publication within the last 10 years, relevance to the proposed health benefit mandate, generalizability of the findings, and quality of the research, as guided by the Joanna Briggs Institute Clinical Appraisal Tools. The analysis included identified key themes and shared patterns related to the medical, economic, or legal impact of the proposed health benefit mandate.

Public Health Impact

Higher out-of-pocket (OOP) costs for medications due to increased cost-sharing or lack of coverage are associated with reduced medication adherence for chronic diseases. 8,9,10,11 Decreased medication adherence is linked to increased utilization of high-cost services (such as hospital inpatient or emergency care) and increased morbidity.^{8,9} Higher cost-sharing is also associated with an increase in the number of days in the hospital for individuals living with type 2 diabetes. 9 Similarly, higher costsharing for families with children who have asthma was shown to reduce utilization of both necessary and unnecessary treatments^{10,11} and was associated with increased asthma-related hospitalizations. Conversely, for individuals with chronic conditions, such as diabetes, successful blood glucose control can reduce the risk of complications such as stroke, renal disease, cardiovascular disease, and death.9

The relationship between cost-sharing and disease management is not limited to medication adherence. A similar association has been shown for coverage of supplies and equipment needed to manage chronic diseases and their successful management. A study examining cost-sharing and coverage for glucose monitoring test strips found worsened clinical markers of disease management for those with high cost-sharing for glucose test strips and higher medication adherence for those with low cost-sharing. This relationship between high cost-sharing and low utilization was less significant for those with type 1 diabetes, who require continuous glucose monitoring. 12

Certain populations with chronic conditions may be more impacted by cost-sharing. For example, lowincome families with high levels of cost-sharing report more barriers to treatment for children with asthma. 11 Race and ethnicity are linked to the prevalence and outcomes of disease, with Black, Indigenous, and other people of color facing greater type 2 diabetes prevalence and morbidity. Strategies to address barriers to access, such as by reducing cost-sharing, are linked to improved medication adherence and clinical outcomes and may have the greatest impact on reducing health disparities for these populations.¹³

2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

⁸ Nelson, D. R., Heaton, P., Hincapie, A., Ghodke, S., & Chen, J. (2021). Differential cost-sharing undermines treatment adherence to combination therapy: Evidence from diabetes treatment. Diabetes Therapy, 12(8), 2149-2164. https://doi.org/10.1007/s13300-021-

⁹ Thornton Snider, J., Seabury, S., Lopez, J., McKenzie, S., & Goldman, D. P. (2016). Impact of type 2 diabetes medication cost-sharing on patient outcomes and health plan costs. American Journal of Managed Care, 22(6), 433-440. https://pubmed.ncbi.nlm.nih.gov/27355811/

¹⁰ Karaca-Mandic, P., Jena, A. B., Joyce, G. F., & Goldman, D. P. (2012). Out-of-pocket medication costs and use of medications and health care services among children with asthma. JAMA, 307(12), 1284. https://doi.org/10.1001/jama.2012.340

¹¹ Fung, V., Graetz, I., Galbraith, A., Hamity, C., Huang, J., Vollmer, W. M., Hsu, J., & Wu, A. C. (2014). Financial barriers to care among lowincome children with asthma. JAMA Pediatrics, 168(7), 649. https://doi.org/10.1001/jamapediatrics.2014.79

¹² Xie, Y., Agiro, A., Bowman, K., & DeVries, A. (2017). Lowering cost share may improve rates of home glucose monitoring among patients with diabetes using insulin. Journal of Managed Care & Specialty Pharmacy. https://www.jmcp.org/doi/10.18553/jmcp.2017.23.8.884?url_ver=Z39.88-

¹³ Spanakis, E. K., & Golden, S. H. (2013). Race/ethnic difference in diabetes and diabetic complications. Current Diabetes Reports, 13(6), 814-823. https://doi.org/10.1007/s11892-013-0421-9

Economic Impact

The costs for the treatment for chronic diseases are linked to increasing OOP costs in health plan designs because plans are seeking cost-containment strategies for the growing population of individuals impacted by chronic disease. Cost-sharing as a market-based strategy is often linked to the 1993 Rand Health Insurance Experiment study, 14,15 which showed that the imposition of cost-sharing reduced the utilization of health services without evidence of impact on clinical outcomes. On the other hand, more current and generalizable peer-reviewed studies indicate that cost-sharing is related to health outcomes for individuals with chronic disease. 16 Using higher cost-sharing as a strategy to achieve cost savings may not fully take into account the impact of higher cost-sharing on downstream clinical outcomes.¹⁶

The relationship between OOP costs and medication adherence is not the same at all OOP cost levels. As one study found, individuals whose OOP costs were below \$33 per month were more likely to make selections based on the perceived value or medical necessity of a particular treatment. They were not more or less likely to choose a more costly medication, and their decisions reflected value and necessity as opposed to only cost. However, cost-sharing above \$33 per month showed that individuals' decisions were driven by cost and were less associated with medical necessity. 17 The proposed mandate limits cost-sharing to \$25, which may reduce the impact of cost-sharing on clinical outcomes and avoid other unnecessary expenditures by allowing individuals to make decisions based not on cost but on medical necessity.

The structure of OOP costs can also mediate individuals' adherence to treatment. In a study that showed an association between high cost-sharing and lower adherence for individuals with type 2 diabetes, a fixed copayment was associated with higher cost of treatment for health plans compared to higher cost-sharing. However, the study notes that due to the progressive nature of diabetes, shortterm costs associated with higher treatment adherence may be balanced by the long-term savings for plans that come from improved disease management and better clinical outcomes.¹⁸

¹⁴ Brook, R. H., Keeler, E. B., Lohr, K. N., Newhouse, J. P., Ware, J. E., Rogers, W. H., Davies, A. R., Sherbourne, C. D., Goldberg, G. A., Camp, P., Kamberg, C., Leibowitz, A., Keesey, J., & Reboussin, D. (2006, December 6). The Health Insurance Experiment: A classic RAND study speaks to the current health care reform debate. RAND Corporation. https://www.rand.org/pubs/research_briefs/RB9174.html

¹⁵ Referenced but excluded from analysis in literature review due to exclusion criteria.

¹⁶ Chandra, A., Flack, E., & Obermeyer, Z. (2021). The health costs of cost-sharing. SSRN Electronic Journal. https://doi.org/10.2139/ssrn.3801882

¹⁷ Nelson, D. R., Heaton, P., Hincapie, A., Ghodke, S., & Chen, J. (2021). Differential cost-sharing undermines treatment adherence to combination therapy: Evidence from diabetes treatment. Diabetes Therapy, 12(8), 2149-2164. https://doi.org/10.1007/s13300-021-01098-8

¹⁸ Henk, H. J., Lopez, J. M. S., & Bookhart, B. K. (2018). Novel type 2 diabetes medication access and effect of patient cost-sharing. *Journal* of Managed Care & Specialty Pharmacy, 24(9), 847-855. https://doi.org/10.18553/jmcp.2018.24.9.847

Limitations

Studies that analyzed the impact of high OOP costs on chronic conditions may not reflect the entire scope of potential cost implications, such as work absences due to poor clinical outcomes and increases in short- and long-term disability claims due to poor disease management. In chronic disease management, the cost of nonadherence associated with high cost-sharing may be underestimated due to longitudinal and feasibility considerations in assessing clinical outcomes. ¹⁹ To date, most studies evaluating the impact of cost-sharing on clinical outcomes and overall health care costs are only able to extrapolate from hospitalization and adherence data.²⁰

Actuarial Analysis²¹

This proposed mandate would require health plans to cap the level of enrollee cost-sharing for drugs prescribed to treat chronic conditions. The conditions targeted by this mandate are diabetes, asthma, and allergies requiring the use of epinephrine auto-injectors. This actuarial analysis includes the current prevalence of these targeted conditions, current levels of coverage and beneficiary costsharing, and projected potential effects of the mandate on cost-sharing and overall premiums. There is additional discussion of potential long-term medical savings resulting from increased drug availability and compliance with reduced beneficiary cost-sharing.

Assumptions and Approach

MDH provided ARC with tabulations from Minnesota's All-Payer Claims Database (MN APCD) for all targeted chronic condition diagnoses and National Drug Codes (NDCs) for associated drugs and related supplies for 2017–2019. This information included the current prevalence of associated disease, drug utilization, and beneficiary cost-sharing for diabetes, asthma, and allergies requiring use of epinephrine auto-injectors for Minnesota commercial health plan beneficiaries.

The following criteria were used to identify beneficiaries with one of the targeted chronic conditions and claims for associated drugs and related supplies:

- Beneficiaries were identified as having a chronic condition if they had one of the International Classification of Diseases 10th Revision (ICD-10) diagnosis codes listed in Appendix C.
- MDH used Medi-Span generic product identifier (GPI) information to pull all NDCs for insulin, noninsulin antidiabetic medications, diabetic supplies, inhalers, and epinephrine auto-injectors.

¹⁹ Henk, H. J., Lopez, J. M. S., & Bookhart, B. K. (2018). Novel type 2 diabetes medication access and effect of patient cost-sharing. Journal of Managed Care & Specialty Pharmacy, 24(9), 847–855. https://doi.org/10.18553/jmcp.2018.24.9.847

²⁰ Chandra, A., Flack, E., & Obermeyer, Z. (2021). The health costs of cost-sharing. SSRN Electronic Journal. https://doi.org/10.2139/ssrn.3801882

²¹ Michael Sandler and Anthony Simms are actuaries for Actuarial Research Corporation (ARC). They are members of the American Academy of Actuaries and meet the qualification standards of the American Academy of Actuaries to render the actuarial opinions contained herein.

MDH tabulated the number of beneficiaries from 2017 to 2019 who utilized prescription drugs and related services for the targeted chronic conditions as well as beneficiary cost-sharing amounts for prescription drugs and related supplies, with an additional tabulation for OOP beneficiary expenditures exceeding \$25 in a given month for a given drug category or \$50 total in a given month to address the disease. The historical beneficiary cost-sharing figures were projected to 2024 using projection factors derived from the prescription drug OOP trends from the National Health Expenditure data.

The 2017–2019 chronic condition diagnoses prevalence, as tabulated by MDH, was 4.3% for diabetes, 4.1% for asthma, and 1.5% for allergies requiring use of an epinephrine auto-injector for the full commercial population included in APCD (which, per MDH, includes approximately 40% of the total commercial market in Minnesota). The proportion of diagnosed beneficiaries utilizing drugs in the treatment of one of the targeted chronic conditions was 79.0% for diabetes, 75.4% for asthma, and 21.6% for allergy. For diabetes-induced utilization, data from a 2013 National Health Interview Survey found that 14% of adults with diabetes reported cost-related noncompliance.²² This implies that the 21% nonadherence in the Minnesota historical data could be reduced by up to 67%. Another study reported that a 36% reduction in copays reduced the number of nonadherent patients by 30%. This analysis assumed that diabetes nonadherence would be reduced by 45% with the introduction of the monthly cap on beneficiary cost-sharing.

For asthma, studies show inhaler adherence can vary widely, from 22% to 78%. Minnesota's historical adherence rate, 75.4%, is very close to the top of that range already, and less than half of currently adherent asthma patients have a cost-sharing amount that exceeds the cap instituted by the proposed mandate. This analysis assumed asthma inhaler nonadherence would be reduced by 30% with the introduction of the monthly cap.

For allergies requiring the use of epinephrine auto-injectors, an NIH study showed minimal association between epinephrine auto-injector adherence and socioeconomic status.²³ Additionally, allergies requiring epinephrine differ from diabetes and asthma in terms of how often an affected beneficiary can or will utilize the prescription drugs or related supplies. This analysis assumed epinephrine autoinjector utilization would increase from the current historical rate of 21.6% by 20% (or a factor of 1.2) to a projected 25.9% with the introduction of the monthly cap on beneficiary cost-sharing. The overall Minnesota population projections for 2024–2033 are based on the figures published by the Minnesota State Demographic Center and on historical levels of non-public health insurance coverage from Minnesota Public Health Data Access. Because of this, the analysis assumed 65% of the total state population would be included in the non-public insured population.

²² Morello, C. M., & Hirsch, J. D. (2017). Strategies for addressing the cost of nonadherence in diabetes. American Journal of Managed Care, 23(13 Suppl). https://pubmed.ncbi.nlm.nih.gov/28978217/

²³ Abrams, E. M., Singer, A. G., Lix, L., Katz, A., Yogendran, M., & Simons, F. E. R. (2017). Adherence with epinephrine autoinjector prescriptions in primary care. Allergy, Asthma & Clinical Immunology, 13, Article 46. https://doi.org/10.1186/s13223-017-0218-5

Results

Table 1 shows the results of the total projected disease prevalence, projected new or induced drug utilization, and projected total utilization for each of the three targeted chronic conditions.

Table 2 shows the total projected OOP PMPMs for drug-only and for all medical supplies as well as the amount of the OOP PMPM that exceeds the \$25 and \$50 per month thresholds for drug-only and for all medical supplies, respectively.

Table 3 shows the total projected utilization with the introduction of the monthly cost-sharing limit; the total projected expenditures that would have been covered by beneficiary cost-sharing under current law but would be transferred to plan paid expenditures under the proposed mandate; and the projected PMPM effect for the total non-public insured population for each of the three targeted chronic conditions individually as well as in total.

Table 1. Total Projected Chronic Condition Disease Prevalence and Prescription Drug Utilization²⁴

	Popula	tion	Dis	ease prevale	nce	Proje	cted new/inc	luced	Projected total utilization		
	Total MN pop	Non-public insured pop	Diabetes	Asthma	Allergy	Diabetes	Asthma	Allergy	Diabetes	Asthma	Allergy
2024	5,834,936	3,792,708	164,676	155,006	55,841	15,577	11,442	2,414	145,637	128,309	14,483
2025	5,870,258	3,815,668	165,673	155,944	56,179	15,672	11,511	2,428	146,519	129,086	14,570
2026	5,904,930	3,838,205	166,652	156,865	56,511	15,764	11,579	2,443	147,385	129,848	14,657
2027	5,938,797	3,860,218	167,608	157,765	56,835	15,855	11,645	2,457	148,230	130,593	14,741
2028	5,971,790	3,881,664	168,539	158,642	57,150	15,943	11,710	2,470	149,053	131,318	14,823
2029	6,003,838	3,902,495	169,443	159,493	57,457	16,028	11,773	2,484	149,853	132,023	14,902
2030	6,034,892	3,922,680	170,320	160,318	57,754	16,111	11,834	2,497	150,628	132,706	14,979
2031	6,064,909	3,942,191	171,167	161,115	58,042	16,191	11,893	2,509	151,378	133,366	15,054
2032	6,093,866	3,961,013	171,984	161,885	58,319	16,269	11,949	2,521	152,100	134,003	15,126
2033	6,121,752	3,979,139	172,771	162,625	58,586	16,343	12,004	2,532	152,796	134,616	15,195

²⁴ The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and SEGIP, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to data only for fully insured plans and SEGIP, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 2. Total Projected Out-of-Pocket PMPM and Out-of-Pocket PMPM Exceeding Mandated Thresholds²⁵

	Out-of-pocket PMPM: Rx only			Out-of-pocket PMPM: all supplies			Out-of-pocket PMPM > \$25: Rx only			Out-of-pocket PMPM > \$50: all supplies		
	Diabetes	Asthma	Allergy	Diabetes	Asthma	Allergy	Diabetes	Asthma	Allergy	Diabetes	Asthma	Allergy
2024	\$24.59	\$15.34	\$7.04	\$24.79	\$15.35	\$7.04	\$17.35	\$9.15	\$5.36	\$15.39	\$7.11	\$4.61
2025	\$25.29	\$15.77	\$7.24	\$25.49	\$15.79	\$7.24	\$17.84	\$9.41	\$5.52	\$15.83	\$7.32	\$4.74
2026	\$25.97	\$16.20	\$7.43	\$26.18	\$16.22	\$7.43	\$18.33	\$9.66	\$5.67	\$16.26	\$7.51	\$4.87
2027	\$26.67	\$16.64	\$7.63	\$26.89	\$16.65	\$7.63	\$18.82	\$9.92	\$5.82	\$16.69	\$7.72	\$5.00
2028	\$27.52	\$17.17	\$7.88	\$27.74	\$17.18	\$7.88	\$19.42	\$10.24	\$6.00	\$17.22	\$7.96	\$5.16
2029	\$28.44	\$17.74	\$8.14	\$28.67	\$17.76	\$8.14	\$20.07	\$10.58	\$6.20	\$17.80	\$8.23	\$5.33
2030	\$29.53	\$18.42	\$8.45	\$29.77	\$18.44	\$8.45	\$20.84	\$10.99	\$6.44	\$18.48	\$8.54	\$5.54
2031	\$30.67	\$19.13	\$8.78	\$30.91	\$19.15	\$8.78	\$21.64	\$11.41	\$6.69	\$19.19	\$8.87	\$5.75
2032	\$31.84	\$19.86	\$9.11	\$32.10	\$19.88	\$9.11	\$22.46	\$11.85	\$6.95	\$19.93	\$9.21	\$5.97
2033	\$33.06	\$20.62	\$9.46	\$33.33	\$20.64	\$9.46	\$23.33	\$12.30	\$7.21	\$20.69	\$9.57	\$6.20

²⁵ The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and SEGIP, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to data only for fully insured plans and SEGIP, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 3. Total Projected Utilization and Net Effect of Cost-Sharing Limit on Total Non-Public Insured PMPM²⁶

	Population		Projected total utilization			Projected current law cost-sharing expenditures exceeding threshold				Projected total non-public insured PMPM expenditures			
	Total MN pop	Non-public insured pop	Diabetes	Asthma	Allergy	Diabetes	Asthma	Allergy	Total	Diabetes	Asthma	Allergy	Total
2024	5,834,936	3,792,708	145,637	128,309	14,483	\$2,526,285	\$1,173,759	\$77,680	\$3,777,725	\$0.67	\$0.31	\$0.02	\$1.00
2025	5,870,258	3,815,668	146,519	129,086	14,570	\$2,613,939	\$1,214,485	\$80,375	\$3,908,799	\$0.69	\$0.32	\$0.02	\$1.02
2026	5,904,930	3,838,205	147,385	129,848	14,657	\$2,700,918	\$1,254,897	\$83,050	\$4,038,864	\$0.70	\$0.33	\$0.02	\$1.05
2027	5,938,797	3,860,218	148,230	130,593	14,741	\$2,789,300	\$1,295,961	\$85,767	\$4,171,029	\$0.72	\$0.34	\$0.02	\$1.08
2028	5,971,790	3,881,664	149,053	131,318	14,823	\$2,894,089	\$1,344,648	\$88,989	\$4,327,726	\$0.75	\$0.35	\$0.02	\$1.11
2029	6,003,838	3,902,495	149,853	132,023	14,902	\$3,007,010	\$1,397,113	\$92,462	4,496,584	\$0.77	\$0.36	\$0.02	\$1.15
2030	6,034,892	3,922,680	150,628	132,706	14,979	\$3,138,482	\$1,458,197	\$96,504	\$4,693,183	\$0.80	\$0.37	\$0.02	\$1.20
2031	6,064,909	3,942,191	151,378	133,366	15,054	\$3,275,056	\$1,521,652	\$100,704	\$4,897,411	\$0.83	\$0.39	\$0.03	\$1.24
2032	6,093,866	3,961,013	152,100	134,003	15,126	\$3,416,895	\$1,587,553	\$105,065	\$5,109,513	\$0.86	\$0.40	\$0.03	\$1.29
2033	6,121,752	3,979,139	152,796	134,616	15,195	\$3,564,173	\$1,655,981	\$109,594	\$5,329,747	\$0.90	\$0.42	\$0.03	\$1.34

²⁶ The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and SEGIP, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to data only for fully insured plans and SEGIP, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Diabetes, with both the highest prevalence and highest projected utilization of the three targeted chronic conditions, as well as the highest current monthly beneficiary cost-sharing, has the greatest projected expenditures and net PMPM effect, starting at \$0.67 in Year 1 and increasing to \$0.90 in the 10th and final year of the projection. Asthma, with slightly lower prevalence, projected utilization, and current monthly beneficiary cost-sharing, has projected expenditures about half that of diabetes, with a net PMPM effect starting at \$0.31 in Year 1 and increasing to \$0.42 in Year 10. Allergies requiring the use of an epinephrine auto-injector have much lower prevalence and projected utilization as well as significantly lower current beneficiary cost-sharing. The net PMPM effect of the cost-sharing limit would be just \$0.02 in Year 1 and would increase to \$0.03 in Year 10 of the projection period. In total, the net PMPM effect that would likely be passed to the total non-public insured population through premiums starts as \$1.00 in Year 1 and increases to \$1.34 in Year 10 of the projection period.

A comprehensive actuarial analysis and modeling of projected downstream medical savings resulting from increased drug adherence by beneficiaries with one of the three chronic conditions targeted by this proposed mandate was beyond the scope of this project. A literature review was conducted to identify potential areas and levels of savings and possible avenues of additional analysis.

- An article published in May 2016 in Managed Healthcare Executive, cited significant savings 5 to 12 years down the road in patients who proactively addressed a diabetes diagnosis. Untreated or uncontrolled diabetes can cause long-term harm to the kidneys, eyes, heart, and blood vessels, among other long-term comorbidities, and treatment adherence can prevent many of these potential complications.²⁷
- An NIH study used propensity score methods to assess the effect of adherence on hospitalization and found that the rate of hospitalization decreased from 15% to 11.5% when antidiabetic drug adherence increased from 50% to 100%.²⁸
- One article demonstrated that a 20% increase in adherence can save \$1,074 annually in total health care spending for each patient with type 2 diabetes.²⁹
- An NIH study demonstrated that increasing inhaler adherence from 33% to 100% could save over \$950 in total health care expenditures per child.³⁰

²⁷ Appold, K. (2016, May 29). Three ways to increase compliance among diabetic patients. Managed Healthcare Executive. https://www.managedhealthcareexecutive.com/view/three-ways-increase-compliance-among-diabetic-patients

²⁸ Kennedy-Martin T., Boye, K. S., & Peng, X. (2017). Cost of medication adherence and persistence in type 2 diabetes mellitus: A literature review. Patient Preference and Adherence, 11, 1103–1117. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5501621/ ²⁹ Morello, C., & Hirsch, J. (2017, August 21). Strategies for addressing the cost of nonadherence in diabetes. American Journal of

Managed Care, 28. https://www.ajmc.com/view/strategies-for-addressing-cost-of-nonadherence-in-diabetes

³⁰ Rust, G., Zhang, S., McRoy, L., & Pisu, M. (2015). Potential savings from increasing adherence to inhaled corticosteroid therapy in Medicaid-enrolled children. American Journal of Managed Care, 21(3), 173-180. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4962558/

Data Sources

- Minnesota state population projections are from Long-Term Population Projections for Minnesota, published by the Minnesota State Demographic Center. 31
- Minnesota non-public health insurance coverage levels are from Minnesota Public Health Data Access.32
- Trends and projection factors are derived from National Health Expenditure data compiled by the Centers for Medicare & Medicaid Services as well as from the 2022 Medicare Trustees Report.³³
- MDH tabulations from Minnesota's All-Payer Claims Database for 2017–2019 were used for the estimation of chronic condition diagnosis prevalence and of historical utilization and beneficiary cost-sharing for drugs prescribed to treat the targeted chronic conditions.

Fiscal Impact

The potential fiscal impact of this legislation for the state includes the estimated cost to SEGIP as assessed by SEGIP in consultation with health plan administrators, the cost of defrayal of benefit mandates as understood under the ACA, and the estimated cost to public programs.

- SEGIP estimates the cost of this legislation for the state plan to be \$92,880 for the partial Fiscal Year 2023 (FY 2023) and \$195,048 for FY 2024.
- There are no defrayal costs assessed by Commerce.
- There is no estimated fiscal impact for public programs.

Fiscal Impact Estimate for SEGIP

MMB provided Commerce SEGIP's fiscal impact analysis, which assessed prevalence of applicable conditions in the membership of health plans that administer SEGIP, potential changes in utilization, and the potential for future high-cost cases. The partial fiscal year impact of the proposed legislation on SEGIP will equal \$92,880 for FY 2023 (\$0.09 PMPM medical + \$0.03 PMPM prescription drug and supply × 129,000 members × 6 months). By FY 2024, the estimated impact will equal \$195,048, and it will increase to \$204,800 in FY 2025.

ACA Mandate Impact and Analysis

The ACA defined 10 EHBs that must be included in non-grandfathered plans in the individual and smallgroup markets. Pursuant to section 1311(d)(3)(b) of the ACA, states may require qualified health plan issuers to cover benefits in addition to the 10 EHBs but must defray the costs of requiring issuers to

³¹ https://mn.gov/admin/assets/Long-Term-Population-Projections-for-Minnesota-DATA-feb2021 tcm36-469204.xlsx

³² https://data.web.health.state.mn.us/insurance basic

³³ https://www.cms.gov/files/zip/nhe-historical-and-projections-data.zip and https://www.cms.gov/files/document/2022-medicaretrustees-report.pdf

cover such benefits by making payments either to individual enrollees or directly to qualified health plan issuers on behalf of the enrollees.

Any state-required benefits enacted after December 31, 2011, other than for purposes of compliance with federal requirements, would be considered in addition to EHBs even if embedded in the state's selected benchmark plan.³⁴ States must identify the state-required benefits that are in addition to EHBs, and qualified health plan issuers must quantify the cost attributable to each additional required benefit based on an analysis performed in accordance with generally accepted actuarial principles and methodologies conducted by a member of the American Academy of Actuaries and must report this to the state.35

Commerce has determined that HF 3592 would not constitute a benefit mandate as defined under the ACA, as it does not relate to any new requirement for specific care, treatment, or services. Based on Commerce's precedent for such types of cost-sharing-specific bills—using HF 2056 and HF 447 on costsharing for follow-ups on diagnostic breast cancer screening as examples—there would be no defrayal requirement associated with passage of this bill.

Fiscal Impact for Public Program

There is no estimated cost for public programs, as the state insurance mandate only applies to nonpublic, fully insured large, small, and individual plans and SEGIP, unless explicitly stated.

³⁴ See 45 CFR §155.170(a)(2).

³⁵ See 45 CFR §155.170(a)(3) and §155.170(c).

Appendix A. Bill Text

A bill for an act relating to health; limiting cost-sharing for prescription drugs and related medical supplies prescribed to treat a chronic disease; amending Minn. Stat. 2020 § 256L.03, subdivision 5; Minn. Stat. 2021 Supplement § 256B.0631, subdivision 1; proposing coding for new law in Minn. Stat. chapter 62Q.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: Section 1. [62Q.481] COST-SHARING FOR PRESCRIPTION DRUGS AND RELATED MEDICAL SUPPLIES TO TREAT CHRONIC DISEASE. Subdivision 1. Cost-sharing limits.

A health plan must limit the amount of any enrollee cost-sharing for prescription drugs prescribed to treat a chronic disease to no more than \$25 per one-month supply for each prescription drug and to no more than \$50 per month in total for all related medical supplies. Subd. 2. **Definitions.**

- (a) For purposes of this section, the following definitions apply.
- (b) "Chronic disease" means diabetes, asthma, and allergies requiring the use of epinephrine autoinjectors.
- (c) "Cost-sharing" means co-payments and coinsurance.
- (d) "Related medical supplies" means syringes, insulin pens, epinephrine auto-injectors, test strips, glucometers, continuous glucose monitors, and other medical supply items necessary to effectively and appropriately administer a prescription drug prescribed to treat a chronic disease. EFFECTIVE DATE.

This section is effective January 1, 2023, and applies to health plans offered, issued, or renewed on or after that date. Sec. 2.

Minn. Stat. 2021 Supplement § 256B.0631, subdivision 1, is amended to read: Subdivision 1.

Cost-sharing.

- (a) Except as provided in subdivision 2, the medical assistance benefit plan shall include the following cost-sharing for all recipients, effective for services provided on or after September 1, 2011:
 - (1) \$3 per nonpreventive visit, except as provided in paragraph (b). For purposes of this subdivision, a visit means an episode of service which is required because of a recipient's symptoms, diagnosis, or established illness, and which is delivered in an ambulatory setting by a physician or physician assistant, chiropractor, podiatrist, nurse midwife, advanced practice nurse, audiologist, optician, or optometrist;

- (2) \$3.50 for nonemergency visits to a hospital-based emergency room, except that this copayment shall be increased to \$20 upon federal approval;
- (3) \$3 per brand-name drug prescription, \$1 per generic drug prescription, and \$1 per prescription for a brand-name multisource drug listed in preferred status on the preferred drug list, subject to a \$12 per month maximum for prescription drug co-payments. No co-payments shall apply to antipsychotic drugs when used for the treatment of mental illness;
- (4) a family deductible equal to \$2.75 per month per family and adjusted annually by the percentage increase in the medical care component of the CPI-U for the period of September to September of the preceding calendar year, rounded to the next higher five-cent increment; and
- (5) total monthly cost-sharing must not exceed five percent of family income. For purposes of this paragraph, family income is the total earned and unearned income of the individual and the individual's spouse, if the spouse is enrolled in medical assistance and also subject to the five percent limit on cost-sharing. This paragraph does not apply to premiums charged to individuals described under section § 256B.057, subdivision 9; and
- (6) cost-sharing for prescription drugs and related medical supplies to treat chronic disease must comply with the requirements of section 62Q.48.
- (b) Recipients of medical assistance are responsible for all co-payments and deductibles in this subdivision.
- (c) Notwithstanding paragraph (b), the commissioner, through the contracting process under sections 256B.69 and 256B.692, may allow managed care plans and county-based purchasing plans to waive the family deductible under paragraph (a), clause (4). The value of the family deductible shall not be included in the capitation payment to managed care plans and county-based purchasing plans. Managed care plans and county-based purchasing plans shall certify annually to the commissioner the dollar value of the family deductible.
- (d) Notwithstanding paragraph (b), the commissioner may waive the collection of the family deductible described under paragraph (a), clause (4), from individuals and allow long-term care and waivered service providers to assume responsibility for payment.
- (e) Notwithstanding paragraph (b), the commissioner, through the contracting process under section 256B.0756 shall allow the pilot program in Hennepin County to waive co-payments. The value of the co-payments shall not be included in the capitation payment amount to the integrated health care delivery networks under the pilot program.

EFFECTIVE DATE.

This section is effective January 1, 2023. Sec. 3.

Minn. Stat. 2020 § 256L.03, subdivision 5, is amended to read: Subd. 5.

Cost-sharing.

- (a) Co-payments, coinsurance, and deductibles do not apply to children under the age of 21 and to American Indians as defined in Code of Federal Regulations, title 42, section 600.5.
- (b) The commissioner shall adjust co-payments, coinsurance, and deductibles for covered services in a manner sufficient to maintain the actuarial value of the benefit to 94 percent. The cost-sharing changes described in this paragraph do not apply to eligible recipients or services exempt from costsharing under state law. The cost-sharing changes described in this paragraph shall not be implemented prior to January 1, 2016.
- (c) The cost-sharing changes authorized under paragraph (b) must satisfy the requirements for costsharing under the Basic Health Program as set forth in Code of Federal Regulations, title 42, sections 600.510 and 600.520.
- (d) Cost-sharing for prescription drugs and related medical supplies to treat chronic disease must comply with the requirements of section 62Q.48.

EFFECTIVE DATE.

This section is effective January 1, 2023.

Appendix B. Key Search Terms for Literature Scan

Anaphylaxis, syringes

Chronic diseases

Continuous glucose monitors

Diabetes, asthma

Epinephrine auto-injectors

Glucometers

Insulin pens

Respiratory disease

Respiratory illness

Test strips

Appendix C. Associated Codes

ICD-10 Code(s):

Name	Code(s)
Diabetes mellitus	E08-E13
Asthma	J45
Allergy status to drugs, medicaments and biological substances	Z88
Food allergy status medicaments	Z91.0–Z91.01

NDC Code(s):

Name	Code
Apidra (insulin for diabetes)	0088-2500-33
Humalog (insulin for diabetes)	0002-7510-01
Albuterol (inhaler for asthma)	0378-6992-52
Metaproterenol (inhaler for asthma)	49884-258-01
EpiPen (epinephrine auto-injector)	49502-500-02



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