COMMERCE DEPARTMENT

Evaluation of HF 626: Unrestricted Access for Diagnosis and Treatment of Rare Diseases

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

JANUARY 2023

This report was prepared by the American Institutes for Research (AIR), with actuarial analysis by Actuarial Research Corporation (ARC), at the request of the Minnesota Department of Commerce. AIR and ARC created this document for internal use by the Minnesota Department of Commerce pursuant to Contract No. 216732. The document assumes reader familiarity with the proposed mandated health benefits currently under consideration by the Minnesota State Legislature. The document was prepared solely to assist the Minnesota Department of Commerce. No other use of this document or the information or conclusions contained herein is authorized.

Defrayal analysis completed by the Minnesota Department of Commerce is independent of AIR's evaluation.

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The report is printed on recycled paper. A 508 compliant version of this report is forthcoming.

Contents

Executive Summary

This proposed mandate would require insurance plans to allow people with rare diseases unrestricted access to diagnosis and treatment for their condition by health care providers, including providers who are outside of a plan's network. Rare diseases include but are not limited to acute lymphoblastic leukemia, amyotrophic lateral sclerosis, cystic fibrosis, and myasthenia gravis.

Health plans can vary widely in the degree to which they cover diagnosis and treatment of rare diseases. Plans may limit access to rare disease specialists through provider network rules, or they may impose utilization controls (such as prior authorization or step therapy) before the plan will cover the needed services. This can lead to delays in diagnosis or treatment, disrupt care coordination, and create significant complexities for individuals and families in navigating insurance coverage. Early diagnosis of rare diseases can be critical for achieving optimal health outcomes, especially for children.

Individuals with rare conditions may see specialists more frequently and incur higher costs than individuals with chronic conditions. The top cost drivers for individuals with rare conditions are inpatient care and medication. The number of available therapies for rare conditions, along with their respective costs, is growing, resulting in increasing costs for payers. However, these therapies may be life changing in the treatment of rare conditions. Currently, health plans vary in the use of evidence to manage coverage of rare diseases in a way that reflects best clinical practices.

Actuarial analysis concluded that the average additional monthly cost of this mandate would be $349.42 per member in Year 1 and increase to $489.47 per member in the 10th year of implementation. The average increase in monthly premiums would start at $7.28 per member in Year 1 and reach $11.13 per member in the 10th year of implementation. The actuarial analysis for this evaluation is based on several rare conditions. However, given the extensive list of rare diseases, actuarial analysis for all potential conditions is beyond the scope of this report.

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 $2,012,400 for partial Fiscal Year 2024 (FY24) and $4,226,040 for FY25.
- Commerce has determined that this proposed mandate would likely not require defrayal under the Affordable Care Act because it only alters cost-sharing for enrollees by allowing out-of-network practitioners to be treated no more restrictively than in-network providers.
- There is no estimated cost for public programs because the mandate only applies to non-public, individual, fully insured small and large group plans and to SEGIP, unless explicitly stated.

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 626 on unrestricted access for the diagnosis and treatment of rare diseases 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 626 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:

(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.

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:

    i. Scientific and medical information regarding the proposal, including the potential for benefit and harm

    ii. Overall public health and economic impact

    iii. Background on the extent to which services/items in the proposal are utilized by the population

    iv. Information on the extent to which services/items in the proposal are already covered by health plans and which health plans the proposal would impact

    v. 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

House File 626 is sponsored by Representative Reyer and was introduced in the 92nd Legislature (2021–2022) on February 1, 2021. The bill proposes to amend the definition of rare conditions in the current Minn. Stat. § 256B.0625 and require health plans to allow people with rare diseases unrestricted access to health care services (i.e., diagnosis and treatment of rare diseases) by licensed health care providers, including providers outside of a plan's network. Rare diseases include but are not limited to acute lymphoblastic leukemia, amyotrophic lateral sclerosis, cystic fibrosis, and myasthenia gravis.

Related Health Conditions

A rare disease or condition is defined as any disease or condition

- that affects fewer than 200,000 persons in the United States and is chronic, serious, life altering, or life threatening;
- that affects less than 200,000 persons in the United States and for which a drug for treatment has been designated pursuant to United States Code, Title 21, Section 360bb;
- that is labeled as a rare disease or condition on the Genetic and Rare Diseases Information Center list created by the National Institutes of Health; or
- for which a patient
  - has received two or more clinical consultations from a primary care provider or specialty provider;
  - has documentation in their medical record of a developmental delay through standardized assessment, developmental regression, failure to thrive, or progressive multisystemic involvement; and
  - had laboratory or clinical testing that failed to provide a definitive diagnosis or resulted in conflicting diagnoses.

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 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 and provides examples of similar legislation or policies in other states.

Federal Laws Relevant to the Proposed Mandate

There are no federal laws directly requiring unrestricted access to health care for patients with rare diseases; however, there are several laws related to rare diseases. One example is the Orphan Drug Act, which was enacted to provide incentives and reduce barriers to promote research and development of orphan drugs, which are typically unprofitable and otherwise unpursued novel therapies used to treat rare diseases.[1] Additionally, there were three bills introduced, one of which passed, in the 116th Congress (2019–2020) related to closing loopholes, ensuring fairness, and affirming the importance of the Orphan Drug Act.[2,3,4] The proposed mandate may have an impact on the research and development of drugs and diagnostic tools to diagnose and treat rare diseases and address barriers associated with medication affordability, testing, and treatment.

Minnesota State Laws Relevant to the Proposed Mandate

Under Minn. Stat. § 62K.11, which addresses balance billing, health carriers are permitted to bill enrollees for out-of-network services if the enrollee agrees in writing in advance of the noncovered service.[5] Additionally, under Minn. Stat. § 62Q.55, emergency services are covered "whether provided by participating or nonparticipating providers and whether provided within or outside the health carrier's service area."[6] Health carriers must consider various factors before denying coverage of emergency services. The state does not have more general statutes that address the conditions for or extent of out-of-network coverage by health plans.

State Comparison

There is limited legislation in other states pertaining to unrestricted access to health care services for patients with rare diseases. At most, states are developing research committees to better understand barriers that patients with rare diseases encounter. For example, in 2021, the Virginia legislature created an executive council for the purpose of understanding health care policy gaps and the barriers patients face when accessing care for rare diseases.[7]

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[1] Orphan Drug Act, 21 U.S.C. § 316 (1992). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-316

[2] Affirming the Importance of the Orphan Drug Act, Celebrating the Over 750 New Orphan Therapies Approved Since Its Creation, and Recognizing the Need to Continue Supporting Research and Development for Rare Diseases, H.Res.242, 116th Congress (2019-2020). https://www.congress.gov/bill/116th-congress/house-resolution/242?q=%7B%22search%22%3A%5B%22orphan+drugs%22%2C%22orphan%22%2C%22drugs%22%5D%7D&s=1&r=1

[3] Fairness in Orphan Drug Exclusivity Act, H.R.4712, 116th Congress (2019-2020). https://www.congress.gov/bill/116th-congress/house-bill/4712?q=%7B%22search%22%3A%5B%22orphan+drugs%22%2C%22orphan%22%2C%22drugs%22%5D%7D&s=1&r=2

[4] Closing Loopholes for Orphan Drugs Act, H.R.4538, 116th Congress (2019-2020). https://www.congress.gov/bill/116th-congress/house-bill/4538?q=%7B%22search%22%3A%5B%22orphan+drugs%22%2C%22orphan%22%2C%22drugs%22%5D%7D&s=1&r=4

[5] Balance Billing Prohibited, MN § 62K.11 (2022). https://www.revisor.mn.gov/statutes/cite/62K.11

[6] Emergency Services, MN § 62Q.55 (2022). https://www.revisor.mn.gov/statutes/cite/62Q.55

[7] Rare Disease Council, Article 19 VA § 32.1-73 (2022). https://law.lis.virginia.gov/vacodefull/title32.1/chapter2/article19/

Public Comments Summary

To assess the public health, economic, and fiscal impact of HF 626, 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. Interviews were conducted with a subset of stakeholders that provided resources or comments that prompted follow-up questions to gather more detail on the impact the proposed mandate might have on Minnesotans. Interview protocols and processes were reviewed and conducted in accordance with an institutional review board in 45-minute virtual sessions. Feedback obtained in these interviews is included throughout this section.

Any studies, laws, and other resources identified by stakeholders, through public comment or interviews, 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 14 stakeholder comments. Two of the stakeholders were not in favor of the bill, 11 were in favor, and one expressed no opinion but mentioned cost implications of the proposed mandate. The types of stakeholder groups that submitted responses included state and commercial health carriers, organizations conducting research and outreach on rare diseases, and individuals impacted by rare diseases. A stakeholder interview was conducted with one of the respondents.

Stakeholders in favor of the proposed mandate believe it would provide Minnesotans with the necessary tools and support to diagnose and treat rare diseases. Being able to diagnose or treat a rare disease sooner would improve individuals' mental health and limit unnecessary wait times and doctor visits not resulting in a diagnosis or treatment. One stakeholder noted that "the average individual with a rare disease waits between 7–8 years to receive a diagnosis and 76% of US physicians reported difficulties coordinating with other physicians when managing patients with diagnosed or probable rare diseases."[8] Stakeholders also noted that while evidence on the cost impact of the diagnosis and treatment of rare diseases is limited, a U.S. Government Accountability Office (GAO) study found that costs—including direct medical costs (e.g., costs of outpatient visits or drugs), direct nonmedical costs (e.g., costs to modify one's home to accommodate a wheelchair), and indirect costs (e.g., loss of

[8] Shire. (2013, April). Rare disease impact report: Insights from patients and the medical community. https://globalgenes.org/wp-content/uploads/2013/04/ShireReport-1.pdf

income or diminished quality of life)—can be substantial to the patient, health care payer, and U.S. government.[9] Stakeholders stressed that early access to diagnosis and treatment of rare diseases is imperative and that this proposal could help address that issue.

Stakeholders noted the high prevalence of rare diseases in children and stated that this mandate would be critical in reducing the long and frequent diagnostic delays that are associated with increased risk of morbidity and mortality for rare conditions. Stakeholders also noted that while this is technically a benefit mandate, it is better thought of as a bill designed to increase access to appropriate providers. The treatment window can be very narrow for many rare conditions, particularly those that arise in childhood, and the downstream costs associated with delayed diagnoses are considerable. Stakeholders also mentioned other economic considerations, such as the need for parents to leave work to care for children.

Stakeholders flagged health disparities as an important consideration, as they believe this mandate could reduce the obstacles to diagnosis and access that exist for families who have previously faced health care access barriers. They noted that all families, particularly low-income families, may face considerable financial hardship and difficult decisions when having to use out-of-network specialists. Stakeholders recognized that getting children and other individuals to the right specialist can increase the use of more expensive treatments, such as gene therapy. But they also said that the expense must be balanced against the negative consequences of forgoing such treatment and that getting individuals, particularly children, to specialists who can provide appropriate treatment is a moral imperative that outweighs costs.

Stakeholders not in support of this bill believe that, although it could increase access to specialty drugs, it would do so at a high cost. Some insurance plans do not require authorization for medical services related to the diagnosis and nonpharmacological treatment of rare diseases. However, many insurance plans require prior authorization for pharmacological treatment of rare diseases. This is because prior authorization allows health carriers to steer patients toward affordable sites of care; without this tool, medical benefit drug costs rise significantly. This bill would bypass prior authorization for specialty drugs in the treatment of rare diseases, and health carrier stakeholders are concerned costs will increase exponentially. These stakeholders also noted that increased costs would pass through to premiums, making costs higher for all enrollees.

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

[9] Dicken, J. (2021). *Rare diseases: Although limited, available evidence suggests that medical and other costs can be substantial* (GAO-22-104235). Government Accountability Office. https://www.gao.gov/assets/gao-22-104235.pdf#:~:text=RARE%20DISEASES%20Although%20Limited%2C%20Available%20Evidence%20Suggests%20Medical,variety%20of%20factors.many%20different%20rare%20diseases%20%28See%20figure.%29

source that showed enrollment changes in self-insured and fully insured plans since 2011. This source indicated 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. The source does not provide data to indicate 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.[10,11]

Stakeholders and MMB provided the following cost estimates related to unrestricted access for the diagnosis and treatment of a rare disease or condition:

- MMB provided Commerce with SEGIP's estimate of the fiscal impact of the proposed mandate. For FY 2024, SEGIP's health plan administrators estimate a potential per member per month (PMPM) increased average cost of $2.60 (range: $1.00–$4.20 PMPM).
- A commercial health carrier estimates the impact of this mandate on plan liability at approximately $4.20 PMPM.
- Another commercial health carrier estimated that the cost impact could be as high as $1.25 PMPM, assuming members who meet the criteria for having a rare disease and receive high-cost care are now eligible to go to any provider for additional and/or more expensive care.
- 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

[10] 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

[11] 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.

Methodology for Analysis of Reviewed Literature

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

I. 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

Challenges accessing care are associated with worsened clinical outcomes and quality of life for individuals living with rare conditions.[12,13] Across health plans, variations in coverage, utilization management (such as prior authorization and step therapy), and plan tiering create access barriers for individuals with rare conditions.[14,15] Further, disparities in requirements to obtain treatment, such as variation in diagnostic tests and criteria across plans, are associated with delays in treatment and continuity-of-care challenges for individuals seeking care with a new health plan.[14] Many of the treatment criteria and diagnostic testing variants were not consistent with clinical practice guidelines (where available or applicable) or FDA label indications.[14] The variation in coverage across plans for the same medication—such as coverage for orphan drugs (novel therapies used for rare conditions or

[12] Diaz, G. A., Crowe, J., & Hopkin, J. (2022). Health insurance literacy and health services access barriers in Niemann–Pick disease: The patient and caregiver voice. *Orphanet Journal of Rare Diseases*, *17*, Article 332. https://doi.org/10.1186/s13023-022-02490-8
[13] Pasquini, T. L. S., Goff, S. L., & Whitehill, J. M. (2021). Navigating the U.S. health insurance landscape for children with rare diseases: A qualitative study of parents' experiences. *Orphanet Journal of Rare Diseases,* 16, Article 313. https://doi.org/10.1186/s13023-021-01943-w
[14] Margaretos, N. M., Bawa, K., Engmann, N. J., & Chambers, J. D. (2022). Patients' access to rare neuromuscular disease therapies varies across US private insurers. *Orphanet Journal of Rare Diseases,* 17, Article 36. https://doi.org/10.1186/s13023-022-02182-3
[15] Robinson, S. W., Brantley, K., Liow, C., & Teagarden, J. R. (2014). An early examination of access to select orphan drugs treating rare diseases in health insurance exchange plans. *Journal of Managed Care & Specialty Pharmacy, 20*(10), 997–1004. https://doi.org/10.18553/jmcp.2014.20.10.997

clinical presentations) and high-frequency utilization management for therapies that treat rare conditions—creates significant complexities for individuals and families in navigating insurance coverage.[16] Utilization management by plans may prioritize symptom management strategies rather than treatment to address the pathology of disease, which may be achieved with orphan drugs.[17] If plans contract with multiple drug manufacturers, different prioritization of particular therapies may occur, along with varied frequency or robustness of evidence reviews that support plans' coverage decisions. Limited evidence for rare condition therapies may contribute to this variation in coverage.[16]

Early diagnosis of rare diseases can be critical for achieving optimal health outcomes.[19] For children, there are more difficulties obtaining a diagnosis for rare conditions than for other chronic conditions.[18] Individuals living with rare conditions may face considerable diagnostic delays,[19,20] which can lead to more complex clinical management and poorer prognosis.[21] There are considerable knowledge gaps pertaining to rare diseases among providers, and individuals with rare conditions note that they have difficulty navigating coverage to access providers who specialize in or understand their condition.[18] Frequent visits with specialists who treat rare conditions may be needed in a variety of locations that are often outside of a plan's network. Navigating insurance complexities places a burden on patients, families, and caregivers. In addition, health literacy, or lack thereof, may affect the ability of patients, families, and caregivers to understand the coverage provided by a plan and successfully coordinate and advocate for needed services or care.[20,22,23]

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[16] Margaretos, N. M., Bawa, K., Engmann, N. J., & Chambers, J. D. (2022). Patients' access to rare neuromuscular disease therapies varies across US private insurers. *Orphanet Journal of Rare Diseases, 17*, Article 36. https://doi.org/10.1186/s13023-022-02182-3

[17] Feinstein, J. A., Bruckner, A. L., Chastek, B., Anderson, A., & Roman, J. (2022). Clinical characteristics, healthcare use, and annual costs among patients with dystrophic epidermolysis bullosa. *Orphanet Journal of Rare Diseases*, *17*, Article 367. https://doi.org/10.1186/s13023-022-02509-0

[18] Pasquini, T. L. S., Goff, S. L., & Whitehill, J. M. (2021). Navigating the U.S. health insurance landscape for children with rare diseases: A qualitative study of parents' experiences. *Orphanet Journal of Rare Diseases, 16*, Article 313. https://doi.org/10.1186/s13023-021-01943-w

[19] Navarrete-Opazo, A. A., Singh, M., Tisdale, A., Cutillo, C. M., & Garrison, S. R. (2021). Can you hear us now? The impact of health-care utilization by rare disease patients in the United States. *Genetics in Medicine*, *23*(11), 2194–2201. https://doi.org/10.1038/s41436-021-01241-7

[20] Bogart, K., Hemmesch, A., Barnes, E., Blissenbach, T., Beisang, A., Engel, P., Tolar, J., Schacker, T., Schimmenti, L., Brown, N., Morrison, K., Albright, T., Klein, M., Coleman, J., Nelsen, K., Blaylark, R., LaFond, K., Berkowitz, S., Schultz, K. A., & Hansen, K. (2022). Healthcare access, satisfaction, and health-related quality of life among children and adults with rare diseases. *Orphanet Journal of Rare Diseases*, *17*, Article 196. https://doi.org/10.1186/s13023-022-02343-4

[21] Yates, J., Gutiérrez-Sacristán, A., Jouhet, V., LeBlanc, K., Esteves, C., DeSain, T. N., Benik, N., Stedman, J., Palmer, N., Mellon, G., Kohane, I., & Avillach, P. (2021). Finding commonalities in rare diseases through the undiagnosed diseases network. *Journal of the American Medical Informatics Association*, *28*(8), 1694–1702. https://doi.org/10.1093/jamia/ocab05

[22] Diaz, G. A., Crowe, J., & Hopkin, J.. (2022). Health insurance literacy and health services access barriers in Niemann–Pick disease: The patient and caregiver voice. *Orphanet Journal of Rare Diseases, 17*, Article 332. https://doi.org/10.1186/s13023-022-02490-8

[23] Robinson, S. W., Brantley, K., Liow, C., & Teagarden, J. R. (2014). An early examination of access to select orphan drugs treating rare diseases in health insurance exchange plans. *Journal of Managed Care & Specialty Pharmacy, 20*(10), 997–1004. https://doi.org/10.18553/jmcp.2014.20.10.997

Economic Impact

Impact on Consumers. Lack of coverage for services or treatment of rare conditions can result in extraordinary out-of-pocket (OOP) costs for families,[24,25] leading some individuals and families with children who have rare conditions to enroll in multiple insurances for coverage of those conditions.[24] Individuals with rare conditions may utilize specialists more frequently than those with other conditions,[26] and, overall, service utilization rates and costs are significantly higher for individuals with rare conditions than those with common conditions. Individuals and families affected by rare conditions may experience relatively high expenditures resulting from lack of coverage, out-of-network coverage, and/or cost-sharing.[27,28] The top cost drivers for individuals with rare conditions are inpatient care and medication.[29]

Cost and Feasibility for Health Plans. The number of available therapies for rare conditions, along with the cost of therapies, is growing.[30] Orphan drugs are available for over 300 rare conditions but carry substantial costs for payers.[31] However, these drugs may be life changing in the treatment of rare conditions. Currently, few health plans use clinical management and cost-effectiveness evaluations to manage rare diseases in a way that reflects best clinical practices.[31] Given the costs of rare conditions, opportunities exist for rare disease guideline development[32,33] that may improve payer utilization management strategies while avoiding the access hurdles that result in poor clinical outcomes and significant cost burden for patients.

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[24] Pasquini, T. L. S., Goff, S. L., & Whitehill, J. M. (2021). Navigating the U.S. health insurance landscape for children with rare diseases: A qualitative study of parents' experiences. *Orphanet Journal of Rare Diseases, 16*, Article 313. https://doi.org/10.1186/s13023-021-01943-w

[25] Diaz, G. A., Crowe, J., & Hopkin, J.. (2022). Health insurance literacy and health services access barriers in Niemann–Pick disease: The patient and caregiver voice. *Orphanet Journal of Rare Diseases, 17,* Article 332. https://doi.org/10.1186/s13023-022-02490-8

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[27] Navarrete-Opazo, A. A., Singh, M., Tisdale, A., Cutillo, C. M., & Garrison, S. R. (2021). Can you hear us now? The impact of health-care utilization by rare disease patients in the United States. *Genetics in Medicine, 23*(11), 2194–2201. https://doi.org/10.1038/s41436-021-01241-7

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[29] Yang, G., Cintina, I., Pariser, A., Oehrlein, E., Sullivan, J., & Kennedy, A. (2022). The national economic burden of rare disease in the United States in 2019. *Orphanet Journal of Rare Diseases*, *17*, Article 163. https://doi.org/10.1186/s13023-022-02299-5

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[31] Handfield, R., & Feldstein, J. (2013). Insurance companies' perspectives on the orphan drug pipeline. *American Health & Drug Benefits, 6*(9), 589–598. https://pubmed.ncbi.nlm.nih.gov/24991385/

[32] Pai, M., Yeung, C. H. T., Akl, E. A., Darzi, A., Hillis, C., Legault, K., Meerpohl, J. J., Santesso, N., Taruscio, D., Verhovsek, M., Schünemann, H. J., & Iorio, A. (2019). Strategies for eliciting and synthesizing evidence for guidelines in rare diseases. *BMC Medical Research Methodology, 19*, Article 67. https://doi.org/10.1186/s12874-019-0713-0

[33] Yates, J., Gutiérrez-Sacristán, A., Jouhet, V., LeBlanc, K., Esteves, C., DeSain, T. N., Benik, N., Stedman, J., Palmer, N., Mellon, G., Kohane, I., & Avillach, P. (2021). Finding commonalities in rare diseases through the undiagnosed diseases network. *Journal of the American Medical Informatics Association*, *28*(8), 1694–1702. https://doi.org/10.1093/jamia/ocab050

Limitations

Given the array of rare conditions and treatments, the literature may not address all relevant considerations appropriate for assessing the potential impact of HF 626. For example, although orphan drugs are commonly referenced in the literature, they have limited use, and thus relevant comparative effectiveness evidence is limited. The heterogeneity of rare diseases[33] also restricts the extent to which existing literature can support generalized policies, and many studies are not able to fully control for confounding variables.

Actuarial Analysis[34]

This proposed mandate authorizes unrestricted access to medical assistance/services from a licensed health care provider related to the diagnosis, monitoring, and treatment of a rare disease or condition. This actuarial analysis includes analysis of current prevalence of qualifying diagnosis, cost and beneficiary cost-sharing, and projection of potential total costs of expanded coverage.

Assumptions and Approach

MDH provided ARC with tabulations from Minnesota's All-Payer Claims Database for 2017–2019 that included all relevant diagnoses for select rare diseases. According to MDH, the database includes approximately 40% of the total commercial market in Minnesota. These tabulations served as a snapshot of current prevalence.

Beneficiaries were identified as having a rare disease if they had a claim with one of the International Classification of Diseases 10th Revision (ICD-10) codes listed in Appendix C. Prevalence was very low, totaling about 0.1% across all diseases. Tabulations for Creutzfeldt-Jakob disease and myasthenia gravis had to be partially redacted because there were cells with less than 11 enrollees in each year. Due to the low prevalence and its implication for final PMPM amounts, only three of these diseases were researched, analyzed, and tabulated for the purposes of this actuarial analysis. Myeloid leukemia and cystic fibrosis were chosen because they were the most prevalent among the rare diseases identified, and sickle cell disease was chosen because its inclusion was specifically suggested by MDH. The analysis can be expanded to the other diseases in future years, if desired.

The overall Minnesota population projections for 2024–2033 are based on the figures published by the Minnesota State Demographic Center and on the historical levels of non-public health insurance coverage provided by Minnesota Public Health Data Access. The analysis assumed that 65% of the total state population would be included in the non-public insured population.

[34] 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.

A literature review was conducted to obtain information about treatment costs and coverage for each of the three diseases analyzed. The resulting analysis outlines the total potential expenditures statewide directly associated with these targeted rare diseases, but given the data limitations, no current law snapshot of coverage and expenditures could be used to calculate a net effect.

Myeloid Leukemia

A 2018 research report examined commercially insured patients from 2014 to 2016. It found that chronic leukemia had a prevalence twice that of acute leukemia, and the analysis assumed the same prevalence for chronic and acute myeloid leukemia.[35]

In the report, average expenditures per patient in the first 12 months following initial diagnosis for acute and chronic leukemia were $463,414 and $88,913, respectively, and patients were responsible for $5,147 and $3,480 of those respective amounts. Surviving patients incurred costs of around $800,000 and $200,000 over the course of 3 years following diagnosis for acute and chronic leukemia, respectively, and paid $8,797 and under $7,800 for those respective amounts. Costs for treatment skew toward the first year of diagnosis, before dropping significantly (but not to pre-cancer amounts) and leveling off. Based on this finding, it was assumed that the first year of treatment following diagnosis would have the larger first-year costs noted above and that subsequent years would have level expenses, reflecting the annualized remaining portion of the 3-year totals.

In a 2022 study[36] stated that 50% to 80% of acute myeloid leukemia patients in remission relapse and that their 5-year survival rate after relapse is around 10%. Based on this, it was assumed that 15% of acute myeloid leukemia cases each year were first-year cases. A 2013 study[37] stated that, without proper treatment through tyrosine kinase inhibitors, survival for chronic myeloid leukemia patients is between 5 and 6 years and that at least 30% of patients do not follow treatment regimens. Based on this, it was assumed that 6% of chronic myeloid leukemia cases each year were first-year cases.

The 2018 research report[38] found that treatment costs over 3 years for blood cancers were due to the provision of services of many different types. Hospital services for inpatients alone accounted for 55% of total expenditures in the first month of treatment, not including outpatient hospital, bone marrow

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[35] Dieguez, G., & Carloto, J. (2022, February). *The landscape of biomarker testing coverage in the United States.* Milliman. https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx

[36] Huggar, D., Knoth, R. L., Copher, R., Cao, Z., Lipkin, C., McBride, A., & LeBlanc, T. W. (2022, October 28). Economic burden in US patients with newly diagnosed acute myeloid leukemia receiving intensive induction chemotherapy. *Future Medicine, 18*(32). https://www.futuremedicine.com/doi/10.2217/fon-2022-0706

[37] Dusetzina, S. B., Winn, A. N., Abel, G. A., Huskamp, H. A., & Keating, N. L. (2013). Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *Journal of Clinical Oncology, 32,* 306–311. https://pubmed.ncbi.nlm.nih.gov/24366936/

[38] Dieguez, G., Ferro, C., & Rotter, D. (2018, October). *The cost burden of cancer care: A longitudinal analysis of commercially insured patients diagnosed with blood cancer*. Milliman. https://www.lls.org/sites/default/files/Milliman%20study%20cost%20burden%20of%20blood%20cancer%20care.pdf

or stem cell transplants, or radiation oncology. After the first month, drug expenses make up one third of costs. Based on this, total allowed costs were projected for the years 2024–2033 using projection factors derived from private health insurance trends from the National Health Expenditure (NHE) data blended at 55% Hospital, 33% Prescription Drug, and 12% Physician and Clinical.

OOP costs, however, were found to be driven by professional and outpatient hospital services, which are responsible for 35% and 25% of all OOP costs in the first 12 months of treatment, respectively. Based on this, total cost-sharing was projected for the years 2024–2033 using projection factors derived from OOP trends from the NHE data blended at 35% Hospital, 20% Prescription Drug, and 45% Physician and Clinical.

Given the serious nature of both acute and chronic myeloid leukemia, it was assumed that once access to care was unrestricted, all patients would seek treatment.

Cystic Fibrosis

In 2019 a survey of people with cystic fibrosis[39] found that 23% of privately insured respondents skipped or reduced medication doses or delayed the filling of a prescription due to cost. Further, 5.3% of respondents skipped visits to cystic fibrosis care centers due to costs, and 3.7% delayed a care center visit even when they did not feel well. It was assumed that the unrestricted access being mandated would have some impact on OOP costs and therefore on utilization, so a 6% upward adjustment was applied to total costs in 2% increments over the first 3 years of projections to reflect this. Annual median health care costs per participant were estimated from responses and were found to equal $8,244, though this could include expenses not directly related to cystic fibrosis. On the assumption that 75% of this amount was attributable to cystic fibrosis, the 2019 annual cost share was estimated to be $6,183.

A 2018 study[40] assessing claims from 2010 to 2016 for people with cystic fibrosis found that in 2016 mean expenditures per person with cystic fibrosis were $130,879. The study also found that 64% of these expenditures were for outpatient pharmaceuticals, 23% were for inpatient services, and 13% were for outpatient services. It was assumed that the same split existed in cost-sharing, so costs were projected for years 2024–2033 using projection factors derived from private health insurance trends from NHE data blended at 29% Hospital, 64% Prescription Drug, and 7% Physician and Clinical.

Sickle Cell Disease

[39] Seyoum, S., Regenstein, M., & Nolan, L. (2020, December). *Cost, coverage, and the underuse of medications among people with CF*. The George Washington University, Milken Institute School of Public Health. https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1056&context=sphhs_policy_briefs

[40] Grosse, S., Do, T. Q. N., Vu, M., Feng, L. B., Berry, J. G., & Sawicki, G. S. (2018). Healthcare expenditures for privately insured US patients with cystic fibrosis, 2010–2016. *Pediatric Pulmonology, 53,* 1611–1618. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6688469/

A 2019 study[41] of 2017 commercial data found that sickle cell disease (SCD) patients incur $3,206 per month on average in combined medical and prescription costs. This amount was annualized for use in projections based on an assumed annual allowed amount per person of $38,472. The study also found that inpatient hospitalizations are responsible for 55% of annual allowed costs and emergency department/outpatient services (ED/OS) for another 20%. Based on this finding, costs were projected for the years 2024–2033 using projection factors derived from private health insurance trends from NHE data blended at 75% Hospital, 15% Prescription Drug, and 10% Physician and Clinical. The study also noted that a large portion of beneficiaries are not utilizing the health care system to its fullest extent. For example, 65% of commercial SCD patients are not under the care of a hematologist, and only 12.9% are utilizing disease-modifying therapies. It was assumed that the removal of access restrictions would have some effect on cost-sharing and by extension on utilization, and to reflect this a 10% upward adjustment was applied to total allowed costs in 2% increments over 5 years of the projection.

A 2022 study[42] of commercial claims data from the period 2007–2018 found that mean annual expenditures related to SCD were $32,311 for females and $35,203 for males and that mean annual OOP costs were $1,333 for males and $1,393 for females. Based on this, it was assumed that cost-sharing is the same across both medical and pharmacy benefits, at around 4%.

Results

Table 1 shows projected prevalence, expenditures, cost-sharing, PMPM per myeloid leukemia beneficiary, and total non-public insured PMPM.

Average calculated PMPM cost-sharing for myeloid leukemia starts at $254.82 in Year 1 and increases to $363.10 in the 10th and final year of the projection. Total non-public insured population PMPM expenditures, which the analysis assumes would be passed through to all beneficiaries via premiums, start at $4.09 in Year 1 and increase to $6.16 in the 10th and final year of the projection.

Table 2 shows projected prevalence, expenditures, cost-sharing, PMPM per cystic fibrosis beneficiary, and total non-public insured PMPM.

Average calculated PMPM cost-sharing for cystic fibrosis starts at $562.44 in Year 1 and increases to $774.69 in the 10th and final year of the projection. Total non-public insured population PMPM

[41] Bazell, C., Dieguez, G., Ferro, C., & Mirchandani, H. (2019, October). *A claims-based analysis of sickle cell disease: Prevalence, disease complications, and costs*. Milliman. https://assets.milliman.com/ektron/A_claims-based_analysis_of_sickle_cell_disease_Prevalence_disease_complications_and_costs.pdf

[42] Johnson, K., Jiao, B., Ramsey, S. D., Bender, M. A., Devine, B., & Basu, A. (2022). Lifetime medical costs attributable to sickle cell disease among nonelderly individuals with commercial insurance. *Blood Advances, 7,* 365–374. https://ashpublications.org/bloodadvances/article/doi/10.1182/bloodadvances.2021006281/485129/Lifetime-medical-costs-attributable-to-sickle-cell

expenditures, which the analysis assumes would be passed through to all beneficiaries via premiums, start at $2.85 in Year 1 and increase to $4.40 in the 10th and final year of the projection.

Table 3 shows projected prevalence, expenditures, cost-sharing, PMPM per SCD beneficiary, and total non-public insured PMPM.

Average calculated PMPM cost-sharing for SCD starts at $182.73 in Year 1 and increases to $265.08 in the 10th and final year of the projection. Total non-public insured population PMPM expenditures, which the analysis assumes would be passed through to all beneficiaries via premiums, start at $0.34 in Year 1 and increase to $0.57 in the 10th and final year of the projection.

Table 4 shows the results of the total projected prevalence across all included rare diseases, total expenditures, and total non-public insured PMPM attributable to diagnosis and treatment of these particular rare diseases.

Average calculated PMPM cost-sharing for these rare diseases starts at $349.42 in Year 1 and increases to $489.47 in the 10th and final year of the projection. Total non-public insured population PMPM expenditures, which the analysis assumes would be passed through to all beneficiaries through premiums, start at $7.28 in Year 1 and increase to $11.13 in the 10th and final year of the projection.

Table 1. Total Projected Expenditures Related to Diagnosis and Treatment of Myeloid Leukemia[43]

	Population			Myeloid leukemia total costs			
	Total MN pop	Non-public insured pop	Myeloid leukemia pop	Plan paid	Cost-sharing	Cost-sharing PMPM for myeloid leukemia beneficiaries	Total non-public insured pop PMPM
2024	5,834,936	3,792,708	1,175	$185,965,075.07	$3,591,537.32	$254.82	$4.09
2025	5,870,258	3,815,668	1,182	$196,646,285.46	$3,784,552.02	$266.90	$4.29
2026	5,904,930	3,838,205	1,189	$207,072,929.25	$3,967,783.46	$278.18	$4.50
2027	5,938,797	3,860,218	1,195	$217,224,711.82	$4,142,438.94	$288.77	$4.69
2028	5,971,790	3,881,664	1,202	$228,522,336.20	$4,330,877.93	$300.24	$4.91
2029	6,003,838	3,902,495	1,209	$240,616,565.37	$4,528,894.44	$312.29	$5.14
2030	6,034,892	3,922,680	1,215	$253,260,388.52	$4,733,451.35	$324.71	$5.38
2031	6,064,909	3,942,191	1,221	$266,318,155.51	$4,937,523.07	$337.04	$5.63
2032	6,093,866	3,961,013	1,227	$279,993,268.57	$5,149,370.99	$349.83	$5.89
2033	6,121,752	3,979,139	1,232	$294,312,099.75	$5,369,247.79	$363.10	$6.16

[43] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to 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 Expenditures Related to Diagnosis and Treatment of Cystic Fibrosis[44]

	Population			Cystic fibrosis total costs			
	Total MN pop	Non-public insured pop	Cystic fibrosis pop	Plan paid	Cost-sharing	Cost-sharing PMPM for cystic fibrosis beneficiaries	Total non-public insured pop PMPM
2024	5,834,936	3,792,708	744	$129,907,361.86	$5,019,907.61	$562.44	$2.85
2025	5,870,258	3,815,668	748	$139,524,116.86	$5,237,712.13	$583.31	$3.05
2026	5,904,930	3,838,205	753	$149,337,326.01	$5,447,506.71	$603.11	$3.24
2027	5,938,797	3,860,218	757	$156,284,623.41	$5,651,789.95	$622.16	$3.37
2028	5,971,790	3,881,664	761	$164,129,915.42	$5,886,530.07	$644.42	$3.52
2029	6,003,838	3,902,495	765	$172,447,750.89	$6,137,499.78	$668.31	$3.68
2030	6,034,892	3,922,680	769	$181,368,838.23	$6,413,368.12	$694.75	$3.85
2031	6,064,909	3,942,191	773	$190,555,093.07	$6,683,549.17	$720.44	$4.03
2032	6,093,866	3,961,013	777	$200,166,455.81	$6,963,730.43	$747.07	$4.21
2033	6,121,752	3,979,139	780	$210,220,609.53	$7,254,224.22	$774.69	$4.40

[44] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to 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 Expenditures Related to Diagnosis and Treatment of Sickle Cell Disease[45]

	Population			Sickle cell disease total costs			
	Total MN pop	Non-public insured pop	Sickle cell disease pop	Plan paid	Cost-sharing	Cost-sharing PMPM for sickle cell disease beneficiaries	Total non-public insured pop PMPM
2024	5,834,936	3,792,708	284	$15,507,580.57	$622,664.95	$182.73	$0.34
2025	5,870,258	3,815,668	286	$16,796,930.78	$657,084.55	$191.67	$0.37
2026	5,904,930	3,838,205	287	$18,108,066.82	$689,456.53	$199.93	$0.39
2027	5,938,797	3,860,218	289	$19,423,391.65	$719,690.55	$207.51	$0.42
2028	5,971,790	3,881,664	291	$20,887,687.13	$753,608.91	$216.09	$0.45
2029	6,003,838	3,902,495	292	$22,031,206.95	$789,671.44	$225.22	$0.47
2030	6,034,892	3,922,680	294	$23,209,604.14	$826,707.35	$234.57	$0.49
2031	6,064,909	3,942,191	295	$24,425,810.20	$865,381.40	$244.33	$0.52
2032	6,093,866	3,961,013	297	$25,700,621.26	$905,684.92	$254.49	$0.54
2033	6,121,752	3,979,139	298	$27,036,599.13	$947,678.31	$265.08	$0.57

[45] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to 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 4. Total Projected Expenditures Related to Diagnosis and Treatment of Targeted Rare Diseases[46]

	Population				Total costs for rare diseases						
	Non-public insured pop	Myeloid leukemia pop	Cystic fibrosis pop	Sickle cell disease pop	Myeloid leukemia plan paid	Myeloid leukemia cost-sharing	Cystic fibrosis plan paid	Cystic fibrosis cost-sharing	Sickle cell disease plan paid	Sickle cell disease cost-sharing	Total non-public insured pop PMPM
2024	3,792,708	1,175	744	284	$185,965,075.07	$3,591,537.32	$129,907,361.86	$5,019,907.61	$15,507,580.57	$622,664.95	$7.28
2025	3,815,668	1,182	748	286	$196,646,285.46	$3,784,552.02	$139,524,116.86	$5,237,712.13	$16,796,930.78	$657,084.55	$7.71
2026	3,838,205	1,189	753	287	$207,072,929.25	$3,967,783.46	$149,337,326.01	$5,447,506.71	$18,108,066.82	$689,456.53	$8.13
2027	3,860,218	1,195	757	289	$217,224,711.82	$4,142,438.94	$156,284,623.41	$5,651,789.95	$19,423,391.65	$719,690.55	$8.48
2028	3,881,664	1,202	761	291	$228,522,336.20	$4,330,877.93	$164,129,915.42	$5,886,530.07	$20,887,687.13	$753,608.91	$8.88
2029	3,902,495	1,209	765	292	$240,616,565.37	$4,528,894.44	$172,447,750.89	$6,137,499.78	$22,031,206.95	$789,671.44	$9.29
2030	3,922,680	1,215	769	294	$253,260,388.52	$4,733,451.35	$181,368,838.23	$6,413,368.12	$23,209,604.14	$826,707.35	$9.73
2031	3,942,191	1,221	773	295	$266,318,155.51	$4,937,523.07	$190,555,093.07	$6,683,549.17	$24,425,810.20	$865,381.40	$10.17
2032	3,961,013	1,227	777	297	$279,993,268.57	$5,149,370.99	$200,166,455.81	$6,963,730.43	$25,700,621.26	$905,684.92	$10.64
2033	3,979,139	1,232	780	298	$294,312,099.75	$5,369,247.79	$210,220,609.53	$7,254,224.22	$27,036,599.13	$947,678.31	$11.13

[46] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to 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.

Data Sources

- Minnesota state population projections are from *Long-Term Population Projections for Minnesota,* published by the Minnesota State Demographic Center.[47]
- Minnesota non-public health insurance coverage levels are from Minnesota Public Health Data Access.[48]
- Trends and projection factors are derived from National Health Expenditure data compiled by the Centers for Medicare & Medicaid Services.[49]
- MDH tabulations of data from Minnesota's All-Payer Claims Database for 2017–2019 were used for the estimation of diagnosis prevalence of select rare diseases.

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 $2,012,400 for partial Fiscal Year 2024 (FY24) and $4,226,040 for FY25.
- 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, performed in consultation with SEGIP health plan administrators who provided individual standards and assumptions based in interpretation of the legislation. Health plan administrators utilized internal claims data to assess prevalence of rare condition in the membership of health plans that administer SEGIP, associated costs of treatment under current coverage, and projected changes in utilization of out-of-network providers. The average of the health plan administrator PMPM estimates provided an estimated fiscal impact estimate for SEGIP of $2,012,400 for partial FY24 and $4,226,040 for FY25 based on a 5% inflation projection of medical costs.

ACA Mandate Impact and Analysis

The ACA defined 10 essential health benefits (EHBs) that must be included in non-grandfathered plans in the individual and small-group markets. Pursuant to section 1311(d)(3)(b) of the ACA, states may

[47] https://mn.gov/admin/assets/Long-Term-Population-Projections-for-Minnesota-DATA-feb2021_tcm36-469204.xlsx
[48] https://data.web.health.state.mn.us/insurance_basic
[49] https://www.cms.gov/files/zip/nhe-historical-and-projections-data.zip

require qualified health plan issuers to cover benefits in addition to the 10 EHBs but must defray the costs of requiring issuers to 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.[50] 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.[51]

Commerce has determined that HF 626 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. This bill only alters cost-sharing for enrollees by allowing out-of-network practitioners to be treated no more restrictively than in-network providers.

Fiscal Impact for Public Programs

The state insurance mandate only applies to non-public, fully insured large, small, and individual plans and to SEGIP, unless explicitly stated. There is no estimated cost for public programs, with only amended language in the mandate indicated for plans under 256B.

[50] See 45 CFR §155.170(a)(2).
[51] See 45 CFR §155.170(a)(3) and §155.170(c).

Appendix A. Bill Text

Sec. 6. [62Q.451] UNRESTRICTED ACCESS TO SERVICES FOR THE DIAGNOSIS, MONITORING, AND TREATMENT OF RARE DISEASES.

(a) No health plan company may restrict the choice of an enrollee as to where the enrollee receives services from a licensed health care provider related to the diagnosis, monitoring, and treatment of a rare disease or condition. Except as provided in paragraph (c), for purposes of this section, "rare disease or condition" means any disease or condition:

(1) that affects fewer than 200,000 persons in the United States and is chronic, serious, life-altering, or life-threatening;

(2) that affects more than 200,000 persons in the United States and a drug for treatment has been designated as such pursuant to United States Code, title 21, section 360bb;

(3) that is labeled as a rare disease or condition on the Genetic and Rare Diseases Information Center list created by the National Institutes of Health; or

(4) for which a patient:

(i) has received two or more clinical consultations from a primary care provider or specialty provider;

(ii) has documentation in the patient's medical record of a developmental delay through standardized assessment, developmental regression, failure to thrive, or progressive multisystemic involvement; and

(iii) had laboratory or clinical testing that failed to provide a definitive diagnosis or resulted in conflicting diagnoses.

(b) Any services provided, referred for, or ordered by an out-of-network provider for a patient who, before receiving and being notified of a definitive diagnosis, satisfied the requirements in paragraph (a), clause (4), shall be governed by paragraph (d) even if the subsequent definitive diagnosis does not meet the definition of rare disease or condition in paragraph (a), clause (1), (2), or (3). Once the patient is definitively diagnosed with a disease or condition that does not meet the definition of rare disease or condition in paragraph (a), clause (1), (2), or (3), and the patient or a parent or guardian of a minor patient has been notified of the diagnosis, any services provided, referred for, or ordered by an out-of-network provider related to the diagnosis shall be governed by paragraph (d) for up to 60 days, providing time for care to be transferred to a qualified in-network provider and to schedule needed in-network appointments. After this 60-day period, subsequent services provided, referred for, or

ordered by an out-of-network provider related to the diagnosis are no longer governed by paragraph (d).

(c) A rare disease or condition does not include an infectious disease that has widely available and known protocols for diagnosis and treatment and that is commonly treated in a primary care setting, even if it affects less than 200,000 persons in the United States.

(d) Cost-sharing requirements and benefit or services limitations for the diagnosis and treatment of a rare disease or condition must not place a greater financial burden on the enrollee or be more restrictive than those requirements for in-network medical treatment.

(e) A health plan company must provide enrollees with written information on the content and application of this section and must train customer service representatives on the content and application of this section.

(f) This section does not apply to medications obtained from a retail pharmacy.

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

Sec. 7. Minn. Stat. 2020 § 256B.0625, is amended by adding a subdivision to read:

Subd. 68. **Services for the diagnosis, monitoring, and treatment of rare diseases.** Medical assistance coverage for services related to the diagnosis, monitoring, and treatment of a rare disease or condition must meet the requirements in section 62Q.451.

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

Appendix B. Key Search Terms for Literature Scan

Acute lymphoblastic leukemia (tentative)

Amyotrophic lateral sclerosis (tentative)

Clinical testing

Consensus statement

Cystic fibrosis (tentative)

Developmental delay

Developmental regression

Life-threatening conditions

Myasthenia gravis (tentative)

Rare diseases

Rare disease monitoring

Rare disease treatment

Appendix C. Associated Codes

Name	Code(s)
Acute lymphoblastic leukemia	C91.0, C91.00, C91.01, C91.02
Amyotrophic lateral sclerosis	G12.21
Creutzfeldt-Jakob disease	A81.0, A81.00, A81.01, A81.09
Cystic fibrosis	E84, E84.0, E84.1, E84.11, E84.19, E84.8, E84.9
Myasthenia gravis	G70.0, G70.00, G70.01
Myeloid leukemia	C92, C92.xx
Sickle cell disease	D57.xxx

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