COMMERCE DEPARTMENT

Evaluation of SF 990: Pharmacy and Provider Choice for Biological or Biosimilar Products

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 Senate File 990 would amend Minn. Stat. § 151.01 by creating a formal definition for biosimilar products and would require pharmacy benefit managers (PBMs) or health carriers that cover biological or biosimilar products to also cover therapeutically equivalent products. The mandate would also prohibit PBMs or health carriers from requiring or demonstrating a preference for a provider to prescribe, or a pharmacy to dispense, any particular biological or biosimilar product.

Health plan formularies often substitute generic drugs for brand-name drugs as a cost-savings strategy because generic drugs are usually chemically and therapeutically equivalent to the brand-name drug. However, biological products and biosimilars are not always interchangeable. While the proposed mandate would allow providers and patients to choose a biological product or a biosimilar, it is currently unknown if this would have negative clinical consequences due to dissimilarities between the drugs.

The price differential between biologics and biosimilars is not analogous to the price differential between brand-name and generic drugs. Studies that demonstrate savings from biosimilars note that increased marketplace competition could drive down the price of the biological products. Cost and coverage considerations are often barriers to the use of biosimilars.

Depending on the degree to which biosimilar products are preferred over biologics, monthly cost sharing could decrease between $40.41 and $121.24 per member in Year 1 and between $58.46 and $175.39 per member in Year 10. Because biosimilar products are less expensive than biologics, plans that require enrollees to pay coinsurance (a percentage of a drug's price) could pay less for each drug dispensed. Enrollees may still have to meet a pharmacy deductible (a minimum out-of-pocket amount) before the plan will cover a drug. Monthly plan expenditures for the non-public, fully insured population could also decrease between $12.15 and $36.46 per member in Year 1 and between $18.10 and $54.30 per member in Year 10.

The potential fiscal impact of this mandate is as follows:

- The State Employee Group Insurance Program (SEGIP) has determined that the mandate would have no fiscal impact because the bill explicitly states that Section 1 does not apply to SEGIP.
- Commerce has determined that this proposed mandate would likely not require defrayal under the Affordable Care Act because it is not related to any new requirement for specific care, treatment, or services.
- There is no estimated cost for public programs, as the state insurance mandate only applies to non-public, fully insured large, small, and individual plans and 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 Senate File 990 on pharmacy and provider choice for biological or biosimilar products 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.

Senate File 990 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

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.

a. 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

Senate File 990 is sponsored by Senators Nelson, Klein, and Newton and was introduced in the 92nd Legislature (2021–22) on February 15, 2021. This bill amends existing Minn. Stat. § 151.01 by adding a subdivision to define biosimilar products. It also adds a new statutory section related to alternative biological products to allow pharmacy and provider choice related to dispensing biological or biosimilar products.

If enacted, this bill would require pharmacy benefit managers (PBMs) and health carriers that cover biological or biosimilar products to provide equal coverage for therapeutically equivalent products. While the proposed bill would not require patients to switch products, it does prohibit PBMs and health carriers from requiring or demonstrating a preference for the prescribing or dispensing of any biological or biosimilar product by a pharmacy or health care provider.

For the purposes of this report, "biologics," "biological products," or "reference drugs" refers to the biological products approved by the Food and Drug Administration (FDA). "Biosimilar products" refers to the biological products that the FDA has determined provide the same benefits as biological products.

Related Health Conditions

Although no specific health conditions are outlined in this bill, biological and biosimilar products are often used to treat and cure diseases such as autoimmune disease, cancer, psoriasis, and rheumatoid arthritis.[1]

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

[1] Marks, J. (2021). Biologic medications and side effects. *WebMD*. https://www.webmd.com/drug-medication/biologic-medications-and-side-effects#:~:text=Biologics%20can%20treat%20a%20variety,an%20infusion%20into%20a%20vein

Federal Laws Relevant to the Proposed Mandate

There are no federal laws pertaining to coverage of biological and biosimilar products. Both Medicare Parts B and D and qualified health plans established under the ACA have regulations that address the coverage of biological products.[2,3,4,5] However, these regulations do not require equivalent coverage for biological and biosimilar products, nor do they set requirements for how PBMs may incorporate biological and biosimilar products into formulary design. The Inflation Reduction Act of 2022 addresses price negotiation for certain biological and biosimilar drugs covered under Medicare Parts B and D, but the law does not mandate coverage of any particular product.[6] However, the act aims to lower the price of biologics primarily by promoting biosimilars.

Minnesota State Laws Relevant to the Proposed Mandate

Minnesota statutes include provisions that set conditions for when a prescription drug can be substituted. Per Minn. Stat. § 62W.075, therapeutic alternative prescription drugs can only be substituted for a prescribed drug for medical reasons that benefit the patient, and the substitution must be approved by the prescribing practitioner.[7] In consideration of this statute, the proposed changes under statue 62W.0751 follow similar provisions for substitution of biological and biosimilar products.

State Comparison

In recent years, almost all states have implemented regulations and requirements pertaining to biological and biosimilar product substitutions, such as Colorado statute 12-42.5-102, enacted in 2015, concerning substitution between biological products; Iowa pharmacy regulation chapter 155A, revised in 2017; and Michigan compiled law section 333.17755, approved in 2018.[8] These laws include provisions that overlap with the proposed mandate, such as patient notification when a drug is substituted, communication with a prescriber regarding substitutions, equivalent coverage across drug types, easing of requirements around switching drug types, requirements for pharmacies to retain substitution records, and FDA certification of interchangeability.

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[2] Centers for Medicare & Medicaid Services. (2019). Covered medical and other health services. In *Medicare benefit policy manual* (Chap. 15, §§ 50 and 110.3). U.S. Government Printing Office.
[3] Services and Supplies Incident to a Physician's Professional Services: Conditions, 42 U.S.C. § 410.26(a)(8) (1997). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.26
[4] Voluntary Medicare Prescription Drug Benefit, 42 U.S. CFR § 423.100 (2005). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-C/section-423.100. Concerns, services, and supplies incident to a physician's professional services.
[5] Prescription Drug Benefits, 45 U.S. CFR § 156.122 (2022). https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-156/subpart-B/section-156.122
[6] Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry, Public Law 117–169, U.S.C. § 11002 (2022). https://www.congress.gov/117/plaws
[7] Therapeutic Alternative Prescription Drug, Minnesota Code § 62W.075 (2022). https://www.revisor.mn.gov/statutes/cite/62W.075
[8] Witkos, R., & Tercyak, P. (2019, May 3). *State laws and legislation related to biologic medications and substitution of biosimilars.* National Conference of State and Legislatures. https://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx.

Public Comments Summary

To assess the public health, economic, and fiscal impact of SF 990, 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 that could inform 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 summarized in 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 10 stakeholder comments. Five stakeholders were not in favor of this bill, three were in favor, and two expressed no opinion but provided comments regarding cost implications and advantages and disadvantages of the bill. The types of stakeholders that submitted responses included health care organizations and health care providers, state and commercial health insurance plans, and other industry professionals. Stakeholder interviews were conducted with five of the respondents.

Several stakeholders noted that the competitive and evolving market between biological reference drugs and biosimilars and between biosimilars can have varying impacts on drug pricing. However, these stakeholders had differing opinions on the nature of those impacts. One health insurance carrier stated that competition in the market for biological and biosimilar products has led to dramatic drug price changes on a quarterly basis, making it difficult to adjust benefits and offerings for members and predict fiscal impacts. This stakeholder also emphasized that the market is changing rapidly and thus any legislation could quickly become outdated.

Another stakeholder noted that because drug manufacturers' rebates on biological and biosimilar products drive high drug prices, the pricing parity created by this mandate would mitigate that effect. However, a different stakeholder stated that this bill would reduce competition in the market and prevent the negotiation of discounts and rebates that drive down prices for health plans and consumers. Many stakeholders remarked that the impact on prices and market behavior may be

difficult to predict given the many unknowns that exist regarding drug rebates and manufacturing negotiations.

Health care organizations and providers noted that current benefit structures, in which health carriers cover only some biosimilars, increase costs for hospitals. One stakeholder explained, "With up to six products in one biosimilar category, if each payer mandates a different product, the provider must absorb the cost of managing this complex inventory to assure coverage and reimbursement." Stakeholders in support of the proposed mandate believed that it will enhance patient care by expanding access to biosimilars and establishing coverage and reimbursement parity, enabling patients and providers to utilize the lowest cost medications available. These stakeholders believed that the uptake of biosimilars in Minnesota is higher than in other parts of the country and that increased choice for providers and patients will continue to increase the uptake of biosimilars.

Some industry groups believed that the proposed mandate limits the practice of biosimilar substitution and drives up costs for patients. PBMs suggest that biosimilar substitution drives costs down and that enrollee premiums and patient cost sharing may increase if substitution is not allowed. One stakeholder stated, "By requiring health plans to cover all approved products in a class (regardless of net cost), it effectively creates an incentive for all manufacturers to raise their prices." Other stakeholders suggested that the loss of rebates resulting from the parity between biosimilar and reference products could disincentivize manufacturers from lowering prices.

Other stakeholders thought that the mandate was important but that the language in the mandate would not improve uptake of biosimilars. They noted that there are two hurdles for biosimilar uptake: (a) formulary design that does not encourage the uptake of biosimilars and (b) provider reluctance to prescribe biosimilars due to reimbursement and knowledge gaps. They suggested that additional language is needed to encourage provider uptake of biosimilars and that, as currently written, the mandate is unlikely to reduce costs for health plans or change consumer premiums.

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 shows enrollment changes in self-insured and fully insured plans since 2011. This source indicates that while enrollment trends have 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 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.[9,10]

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

- MMB provided Commerce with SEGIP's estimate, which affirmed that they expect no fiscal impact to SEGIP (see the Fiscal Impact section).
- A commercial health carrier estimated that the forgone cost savings from the proposed benefit mandate would be $1.62 per member per month (PMPM) for medical benefit impact and $10.25 PMPM for pharmacy benefit impact.
- Another commercial health carrier stated the following: "Biological or biosimilars today represent $8.50 PMPM. If this benefit mandate proposal were enacted, it would greatly increase that percentage, and it is estimated that this proposal would have an additional $1.45 PMPM cost impact, which would be passed on to premiums."
- A PBM estimated that the potential cost to plans would be $1.45 PMPM across all commercial lines of business, due to the loss of cost-savings opportunities associated with market competition.
- 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

[9] 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

[10] 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.

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

Health plan formularies rely on substitution of generic drugs for brand-name drugs as a cost-savings strategy because generic drugs are typically chemically and therapeutically equivalent to the brand-name products. However, biological and biosimilar products are not always interchangeable.[11] As of 2022, only one biosimilar had been designated as interchangeable with its reference biological product, while others were classified as similar.[12] So-called naïve patients—those who have not taken the reference biologics or the biosimilars—may not recognize the differences between the biologics and the biosimilars (or the differences between different biosimilars) because their treatment response is not yet known. For a patient on an established biologic or biosimilar, a change of product, based on provider choice and/or insurance coverage, may negatively affect the safety and effectiveness of the treatment.[11] While the proposed mandate would allow providers and patients to choose a reference product or a biosimilar, it is currently unknown if this would have negative clinical consequences due to dissimilarities between the drugs.[13] Interchangeability concerns may be a key

[11] Chambers, J. D., Lai, R. C., Margaretos, N. M., Panzer, A. D., Cohen, J. T., & Neumann, P. J. (2020). Coverage for biosimilars vs reference products among US commercial health plans. *JAMA*, *323*(19), 1972–1973. https://doi.org/10.1001/jama.2020.2229
[12] Mulcahy, A., Buttorff, C., Finegold, K., El-Kilani, Z., Oliver, J. F., Murphy, S., & Jessup, A. (2022). Projected US savings from biosimilars, 2021–2025. *American Journal of Managed Care*, *28*(7). https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025
[13] Rocco, P., Selletti, S., & Minghetti, P. (2018). Biosimilar switching and related medical liability. *Journal of Forensic and Legal Medicine*, *55*, 93–94. https://doi.org/10.1016/j.jflm.2018.02.018

factor in provider and pharmacist hesitation to prescribe biosimilars or to switch a patient who is using a reference product to a less expensive biosimilar.[14,15,16]

Provider knowledge gaps regarding the interchangeability and effectiveness of different drugs may increase the challenges associated with interchangeability and biosimilar uptake.[17,18] While such knowledge gaps can play a role in the use of reference products, utilization may be more often driven by providers' reliance on clinical evidence that supports switching between a reference product and a biosimilar.[19] Furthermore, most providers cited the protocols of their practice and insurance coverage as the main factors that drive the choice between biosimilars and reference products.[20] Thus, the degree to which providers will increase or decrease prescription of biosimilars under the proposed mandate remains unknown.

Economic Impact

The price differential between reference products and biosimilars is not analogous to the price differential between brand-name and generic drugs, as generics may cost 50% less than brand-name drugs. The price differential between reference products and biosimilars is considerably less than that between generics and brand-name drugs.[17] There are many variables, such as manufacturing processes, that are associated with the cost of biosimilars. However, the emergence of new biosimilar medications has increased marketplace competition and resulted in lower costs for some biosimilars.[17,21] Studies that demonstrate savings from biosimilars note that increased marketplace competition could drive down the price of the reference products.[22] While some research has shown considerable savings from biosimilars, health plans may rely on rebates from reference products to

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[14] Okoro, R. N. (2021). Biosimilar medicines uptake: The role of the clinical pharmacist. *Exploratory Research in Clinical and Social Pharmacy, 1*, 100008. https://doi.org/10.1016/j.rcsop.2021.100008

[15] Greene, L., Singh, R. M., Carden, M. J., Pardo, C. O., & Lichtenstein, G. R. (2019). Strategies for overcoming barriers to adopting biosimilars and achieving goals of the Biologics Price Competition and Innovation Act: A survey of managed care and specialty pharmacy professionals. *Journal of Managed Care & Specialty Pharmacy, 25*, 904–912. https://www.jmcp.org/doi/10.18553/jmcp.2019.18412?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[16] Rupert, D. J., Jordan, A. M., Ziemian, M. A., Brown, R. M., Fleming, N. S., & Lefebvre, R. C. (2022). Understanding US physician and pharmacist attitudes toward biosimilar products: A qualitative study. *BioDrugs, 36*(5), 645–655. https://doi.org/10.1007/s40259-022-00545-7

[17] Dolan, C. (2018). Opportunities and challenges in biosimilar uptake in oncology. *American Journal of Managed Care, 24*(11 Suppl), S237–S243. https://www.ajmc.com/view/opportunities-challenges-biosimilar-uptake-oncology

[18] Cohen, H., Beydoun, D., Chien, D., Lessor, T., McCabe, D., Muenzberg, M., Popovian, R., & Uy, J. (2016). Awareness, knowledge, and perceptions of biosimilars among specialty physicians. *Advances in Therapy, 33*(12), 2160–2172. https://doi.org/10.1007/s12325-016-0431-5

[19] Hemmington, A., Dalbeth, N., Jarrett, P., Fraser, A. G., Broom, R., Browett, P., & Petrie, K. J. (2017). Medical specialists' attitudes to prescribing biosimilars. *Pharmacoepidemiology and Drug Safety*, *26*(5), 570–577. https://doi.org/10.1002/pds.4186

[20] Yang, J., Blinzler, K., Lankin, J., Vijayakumar, S., Maculaitis, M. C., & Shelbaya, A. (2021). Evolving perceptions, utilization, and real-world implementation experiences of oncology monoclonal antibody biosimilars in the USA: Perspectives from both payers and physicians. *BioDrugs*, *36*(1), 71–83. https://doi.org/10.1007/s40259-021-00509-3

[21] Rajakannan, T., & Lee, M. (2022, February). *Will interchangeable biosimilars do to biologics what generic drugs did to brand name medications? Biosimilars and cost saving.* American Institutes for Research. *https://www.air.org/sites/default/files/2022-11/Biosimilar-Cost-Brief-Nov-2022.pdf*. https://www.air.org/sites/default/files/2022-11/Biosimilar-Cost-Brief-Nov-2022.pdf

[22] Mulcahy, A., Buttorff, C., Finegold, K., El-Kilani, Z., Oliver, J. F., Murphy, S., & Jessup, A. (2022). Projected US savings from biosimilars, 2021–2025. *American Journal of Managed Care*, *28*(7). https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025

reduce drug costs, and the loss of those rebates may not be offset by savings from the use of biosimilars.[17]

Plan design may also be a factor that incentivizes the use of biological and biosimilar products. "Preferred plan" design requires a patient to have tried a biosimilar drug before accessing the nonpreferred reference product, whereas "on par" plans do not prioritize one type of drug over the other. In 2019, only 14% of commercial health plans in the United States had a preferred plan design, 33% had a nonpreferred design, and 53% were on par plans. Nonpreferred plan design may slow the uptake of biosimilars, but it is unclear whether these plan designs drive utilization of reference products. The variation in plan design regarding reference products and biosimilars may be driven by the rebate and negotiation practices of plans and drug manufacturers.[11,23] Barriers to the use of biosimilars have been linked to cost and coverage considerations, such as manufacturer, health plan, and associated PBM practices that can drive the use of certain reference products.[17]

Limitations

The variety of drivers associated with the use of reference products and biosimilars may obscure the individual factors that drive utilization trends; therefore, it is unknown how SF 990 will impact these trends. The evolving and proprietary nature of rebates, formulary design, and other market strategies used by health plans allows little insight into how plans and PBMs will react to this mandate. In addition, patients and providers select reference products and biosimilars based on clinical need, practice protocols, and insurance coverage. Therefore, future utilization of reference products and biosimilars is difficult to predict.

Actuarial Analysis[24]

Objective

This actuarial analysis includes an analysis of current prevalence, cost and beneficiary cost sharing, and projection of potential costs of expanding coverage.

Assumptions and Approach

MDH provided Actuarial Research Corporation (ARC) with tabulations from Minnesota's All-Payer Claims Database (APCD) for the period 2017–19 that included specified biologic and biosimilar claims. According to MDH, the APCD includes approximately 40% of the total commercial market in Minnesota. These tabulations served as a snapshot of current prevalence and costs.

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[23] Okoro, R. N. (2021, March). Biosimilar medicines uptake: The role of the clinical pharmacist. *Exploratory Research in Clinical and Social Pharmacy*, *1*, 100008. https://doi.org/10.1016/j.rcsop.2021.100008

[24] 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.

Beneficiaries were identified as using biologics and biosimilars in a pharmacy setting if they had a claim with one of the National Drug Codes (NDCs) or Healthcare Common Procedure Coding System (HCPCS) codes listed in Appendix C.

This analysis focused specifically on potential changes resulting from substituting biologics for biosimilars, so the analysis included only biologics and their biosimilars that both appeared in historical claims. For pharmacy claims, the included drugs were Neulasta and Neupogen (data for Procrit and its biosimilar were redacted because they pertained to less than 11 beneficiaries for all years). For medical claims, the included drugs were Avastin, Herceptin, Lucentis, Neupogen, and Remicade (data for other drugs were incomplete, with either the biologic or biosimilar being absent or redacted).

The overall Minnesota population projections for 2024–33 are based on the figures published by the Minnesota State Demographic Center and on the historical non-public health insurance coverage levels from Minnesota Public Health Data Access. The analysis assumed that 65% of the total state population would be included in the non-public insured population. Costs were projected for years 2024–33 using Prescription Drug Expenditure and Physician and Clinical projection factors for pharmacy drugs and medical drugs, respectively. These factors were derived from private health insurance trends from the National Health Expenditure (NHE) data.

Results

Table 1 shows projected prevalence and costs for biologics with biosimilars under current law based on the historical claims data. PMPM cost sharing for beneficiaries utilizing a biologic or biosimilar begins at $334.25 in Year 1 and increases to $483.80 in the 10th and final year of the projection. Total non-public insured population PMPM expenditures attributable to the use of biologics and biosimilars begin at $111.30 in Year 1 and increase to $165.76 by Year 10. It is worth noting that just two drug categories, Herceptin and Remicade, account for just over 85% of the total expenditures for biologics and biosimilars. In 2024, the first year of the projection, plan paid expenditures per beneficiary are $1.2 million for Herceptin and $672,000 for Remicade.

Tables 2–4 show potential projected changes in prevalence, expenditures, cost sharing, PMPM for beneficiaries using biologics and biosimilars, and net effect on total non-public insured PMPM. The figures are based on low, moderate, and high adoption of biosimilars (i.e., 25%, 50%, and 75% of biologics replaced with biosimilars, respectively).

Depending on the degree to which biosimilar products are preferred over biologics, PMPM cost sharing for beneficiaries utilizing these products decreases between $40.41 and $121.24 in Year 1 and between $58.46 and $175.39 in Year 10. Total non-public insured population PMPM expenditures have the potential to decrease between $12.15 and $36.46 in Year 1 and between $18.10 and $54.30 in Year 10. On average, a 1% shift from biologics to biosimilars decreases PMPM cost sharing for utilizing beneficiaries by $1.97 and total non-public insured population PMPM expenditures by $0.60.

Data Sources

- Minnesota state population projections are from *Long-Term Population Projections for Minnesota*, published by the Minnesota State Demographic Center.[25]
- Minnesota non-public health insurance coverage levels are from Minnesota Public Health Data Access.[26]
- Trends and projection factors are derived from National Health Expenditure data compiled by the Centers for Medicare and Medicaid Services.[27]
- Minnesota Department of Health tabulations from the Minnesota APCD for 2017–19 were used for the estimation of diagnosis prevalence of select rare diseases.

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

Table 1. Projected Expenditures for Biologics and Biosimilars: Current Law[28]

	Total MN pop	Non-public insured pop	Biologic/bio-similar pop	Plan paid	Cost sharing	Total costs	Cost-sharing PMPM for biologic/ biosimilar pop	Total non-public insured pop PMPM
2024	5,834,936	3,792,708	49,237	$5,065,528,964	$197,488,442	$5,263,017,406	$334.25	$111.30
2025	5,870,258	3,815,668	49,535	$5,361,267,940	$208,928,764	$5,570,196,704	$351.48	$117.09
2026	5,904,930	3,838,205	49,828	$5,651,788,353	$219,829,393	$5,871,617,747	$367.65	$122.71
2027	5,938,797	3,860,218	50,114	$5,939,077,934	$230,324,934	$6,169,402,868	$383.00	$128.21
2028	5,971,790	3,881,664	50,392	$6,232,737,295	$240,939,793	$6,473,677,088	$398.44	$133.81
2029	6,003,838	3,902,495	50,663	$6,542,953,923	$251,871,891	$6,794,825,814	$414.30	$139.72
2030	6,034,892	3,922,680	50,925	$6,857,207,363	$262,860,557	$7,120,067,919	$430.15	$145.67
2031	6,064,909	3,942,191	51,178	$7,194,532,321	$274,723,771	$7,469,256,092	$447.33	$152.08
2032	6,093,866	3,961,013	51,422	$7,546,953,565	$287,065,485	$7,834,019,050	$465.21	$158.78
2033	6,121,752	3,979,139	51,658	$7,915,074,522	$299,902,466	$8,214,976,988	$483.80	$165.76

[28] 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. Projected Expenditures for Biologics and Biosimilars: Low-Adoption Scenario[29]

	Total MN pop	Non-public insured pop	Biologic/ biosimilar pop	Plan paid	Cost sharing	Total costs	Cost-sharing PMPM for biologic/ biosimilar pop	Total non-public insured pop PMPM	Cost-sharing PMPM delta for biologic/ biosimilar pop	Total non-public insured pop PMPM net effect
2024	5,834,936	3,792,708	49,237	$4,512,441,075	$173,609,402	$4,686,050,477	$293.83	$99.15	$(40.41)	$(12.15)
2025	5,870,258	3,815,668	49,535	$4,775,878,121	$183,670,584	$4,959,548,705	$308.99	$104.30	$(42.49)	$(12.78)
2026	5,904,930	3,838,205	49,828	$5,034,666,732	$193,256,889	$5,227,923,620	$323.21	$109.31	$(44.44)	$(13.40)
2027	5,938,797	3,860,218	50,114	$5,290,579,636	$202,486,620	$5,493,066,255	$336.71	$114.21	$(46.29)	$(14.00)
2028	5,971,790	3,881,664	50,392	$5,552,172,042	$211,820,189	$5,763,992,231	$350.29	$119.20	$(48.16)	$(14.61)
2029	6,003,838	3,902,495	50,663	$5,828,513,342	$221,432,352	$6,049,945,694	$364.23	$124.46	$(50.07)	$(15.26)
2030	6,034,892	3,922,680	50,925	$6,108,455,409	$231,092,982	$6,339,548,391	$378.16	$129.77	$(51.98)	$(15.91)
2031	6,064,909	3,942,191	51,178	$6,408,947,192	$241,523,816	$6,650,471,008	$393.27	$135.48	$(54.06)	$(16.61)
2032	6,093,866	3,961,013	51,422	$6,722,886,867	$252,375,433	$6,975,262,301	$408.99	$141.44	$(56.22)	$(17.34)
2033	6,121,752	3,979,139	51,658	$7,050,811,973	$263,662,581	$7,314,474,554	$425.34	$147.66	$(58.46)	$(18.10)

[29] 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. Projected Expenditures for Biologics and Biosimilars: Moderate-Adoption Scenario[30]

	Total MN pop	Non-public insured pop	Biologic/ biosimilar population	Plan paid	Cost sharing	Total costs	Cost-sharing PMPM for biologic/ biosimilar pop	Total non-public insured pop PMPM	Cost-sharing PMPM delta for biologic/ biosimilar pop	Total non-public insured pop PMPM net effect
2024	5,834,936	3,792,708	49,237	$3,959,353,186	$149,730,362	$4,109,083,548	$253.42	$86.99	$(80.83)	$(24.30)
2025	5,870,258	3,815,668	49,535	$4,190,488,302	$158,412,404	$4,348,900,706	$266.50	$91.52	$(84.98)	$(25.57)
2026	5,904,930	3,838,205	49,828	$4,417,545,110	$166,684,384	$4,584,229,494	$278.77	$95.91	$(88.88)	$(26.80)
2027	5,938,797	3,860,218	50,114	$4,642,081,337	$174,648,305	$4,816,729,643	$290.42	$100.21	$(92.58)	$(28.00)
2028	5,971,790	3,881,664	50,392	$4,871,606,788	$182,700,586	$5,054,307,375	$302.13	$104.59	$(96.31)	$(29.22)
2029	6,003,838	3,902,495	50,663	$5,114,072,762	$190,992,813	$5,305,065,575	$314.16	$109.21	$(100.14)	$(30.51)
2030	6,034,892	3,922,680	50,925	$5,359,703,456	$199,325,407	$5,559,028,862	$326.18	$113.86	$(103.97)	$(31.81)
2031	6,064,909	3,942,191	51,178	$5,623,362,063	$208,323,861	$5,831,685,924	$339.22	$118.87	$(108.12)	$(33.21)
2032	6,093,866	3,961,013	51,422	$5,898,820,170	$217,685,381	$6,116,505,551	$352.77	$124.10	$(112.44)	$(34.67)
2033	6,121,752	3,979,139	51,658	$6,186,549,425	$227,422,695	$6,413,972,120	$366.88	$129.56	$(116.92)	$(36.20)

[30] 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 4. Projected Expenditures for Biologics and Biosimilars: High-Adoption Scenario[31]

	Total MN pop	Non-public insured pop	Biologic/ biosimilar pop	Plan paid	Cost sharing	Total costs	Cost-sharing PMPM for biologic/ biosimilar pop	Total non-public insured pop PMPM	Cost-sharing PMPM delta for biologic/ biosimilar pop	Total non-public insured pop PMPM net effect
2024	5,834,936	3,792,708	49,237	$3,406,265,297	$125,851,322	$3,532,116,619	$213.00	$74.84	$(121.24)	$(36.46)
2025	5,870,258	3,815,668	49,535	$3,605,098,484	$133,154,223	$3,738,252,707	$224.01	$78.73	$(127.48)	$(38.35)
2026	5,904,930	3,838,205	49,828	$3,800,423,489	$140,111,879	$3,940,535,368	$234.33	$82.51	$(133.32)	$(40.20)
2027	5,938,797	3,860,218	50,114	$3,993,583,039	$146,809,991	$4,140,393,030	$244.13	$86.21	$(138.88)	$(42.00)
2028	5,971,790	3,881,664	50,392	$4,191,041,535	$153,580,983	$4,344,622,518	$253.98	$89.98	$(144.47)	$(43.83)
2029	6,003,838	3,902,495	50,663	$4,399,632,181	$160,553,274	$4,560,185,455	$264.09	$93.95	$(150.21)	$(45.77)
2030	6,034,892	3,922,680	50,925	$4,610,951,502	$167,557,832	$4,778,509,334	$274.19	$97.95	$(155.95)	$(47.72)
2031	6,064,909	3,942,191	51,178	$4,837,776,934	$175,123,906	$5,012,900,840	$285.16	$102.26	$(162.18)	$(49.82)
2032	6,093,866	3,961,013	51,422	$5,074,753,473	$182,995,329	$5,257,748,802	$296.56	$106.76	$(168.65)	$(52.01)
2033	6,121,752	3,979,139	51,658	$5,322,286,876	$191,182,809	$5,513,469,686	$308.41	$111.46	$(175.39)	$(54.30)

[31] 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.

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.

- This mandate is estimated to have no fiscal impact on the SEGIP.
- 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 with SEGIP's estimate, which affirmed that they expect no fiscal impact because Section 1, Subdivision 2d, explicitly states that Section 1 does not apply to SEGIP.

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 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.[32] 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.[33]

Commerce has determined that SF 990 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. Health carriers and PBMs would be prohibited from demonstrating a preference for a particular pharmacy or provider in the dispensing of biological products. This merely alters cost sharing for products already covered by either a health carrier or PBM. Based on Commerce's precedent for such types of bills—HF 1516 as an example—there would be no defrayal requirement associated with passage of this bill.

[32] See 45 CFR § 155.170(a)(2).
[33] See 45 CFR § 155.170(a)(3) and § 155.170(c).

Fiscal Impact for Public Programs

There is no estimated cost for public programs, as the state insurance mandate only applies to non-public, fully insured large, small, and individual plans and SEGIP, unless explicitly stated. SF 990 specifies that it does not apply to public health programs or to SEGIP (see Appendix A).

Appendix A. Bill Text

A bill for an act relating to health; allowing pharmacy and provider choice related to the prescribing and dispensing of biological products; requiring a report; amending Minn. Stat. 2020 § 151.01, by adding subdivisions; proposing coding for new law in Minn. Stat. chapter 62W.

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

Section 1.

[62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS.

Subdivision 1.

Definitions.

(a) For purposes of this section, the following definitions have the meanings given them.

(b) "Biological product" has the meaning provided in section 151.01, subdivision 40.

(c) "Biosimilar" or "biosimilar product" has the meaning provided in section 151.01, subdivision 43.

(d) "Interchangeable biological product" has the meaning provided in section 151.01, subdivision 41.

(e) "Reference biological product" has the meaning provided in section 151.01, subdivision 44.

Subd. 2.

Pharmacy and provider choice related to dispensing reference biological products, interchangeable biological products, or biosimilar products.

(a) A pharmacy benefit manager or health carrier must not require or demonstrate a preference for a pharmacy or health care provider to prescribe or dispense any of the following:

(1) a reference biological product;

(2) any product that is biosimilar to the reference biological product; or

(3) any product that is an interchangeable biological product, relative to the reference biological product.

(b) If a pharmacy benefit manager or health carrier elects coverage of a product listed in paragraph (a), clauses (1) to (3), it must also elect equivalent coverage for all of the products listed in paragraph (a), clauses (1) to (3).

(c) Nothing in this section must require switching from a prescribed product listed in paragraph (a), clauses (1) to (3), to another product listed in paragraph (a), clauses (1) to (3), that has a higher retail price.

(d) This section does not apply to coverage provided through a public health care program under chapter 256B or 256L, or health plan coverage through the State Employee Group Insurance Plan (SEGIP) under chapter 43A.

EFFECTIVE DATE.

This section is effective January 1, 2022.

Sec. 2.

Minn. Stat. 2020 § 151.01, is amended by adding a subdivision to read:

Subd. 43.

Biosimilar product.

"Biosimilar" or "biosimilar product" means a biological product that the United States Food and Drug Administration has:

(1) licensed, and determined to be "biosimilar" under United States Code, title 42, section 262(i)(2);

(2) determined to be "biosimilar," as set forth in the most recent edition or supplement of the United States Food and Drug Administration publication titled "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations"; or

(3) determined to be therapeutically equivalent, as set forth in the most recent edition or supplement of the United States Food and Drug Administration publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

EFFECTIVE DATE.

This section is effective January 1, 2022.

Sec. 3.

Minn. Stat. 2020 § 151.01, is amended by adding a subdivision to read:

Subd. 44.

Reference biological product.

"Reference biological product" means the single biological product for which the United States Food and Drug Administration has approved an initial biological product license application, against which other biological products are evaluated for licensure as biosimilar products or interchangeable biological products.

EFFECTIVE DATE.

This section is effective January 1, 2022.

Sec. 4. **STUDY OF PHARMACY AND PROVIDER CHOICE OF BIOLOGICAL PRODUCTS.**

The commissioner of health, within the limits of existing resources, shall analyze the effect of Minn. Stat. § 62W.0751, on the net price for different payors of biological products, interchangeable biological products, and biosimilar products. The commissioner of health shall report findings to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, and insurance, by December 15, 2023.

Appendix B. Key Search Terms for Literature Scan

Autoimmune disease

Biosimilar medicines

Biological products

Biosimilar products

Cancer

Immunotherapy drugs

Interchangeable biological products

Psoriasis

Rheumatoid arthritis

Targeted therapy drugs

Appendix C. Associated NDC or HCPCS Codes

Pharmacy Biologics and Biosimilars, Associated NDC or HCPCS Codes	
Biologic Name	**Code(s)**
Enbrel	58406045504, 58406043504, 58406042534, 58406002104, 58406043501, 58406001004
Humira	74379902, 74061602, 74937402, 74081702, 74024302
Lantus	00088222033
Neulasta	55513019001
Neupogen	55513020910, 55513092410, 55513020991, 55513054610, 55513054601, 55513053010, 55513092491, 55513053001
Procrit	59676031001, 59676032004, 59676030201, 59676030301, 59676034001
Remicade	57894003001
Rituxan	50242005306
Biosimilar Name (Reference Drug Name)	**Code(s)**
Fulphila (Neulasta)	67457083306
Nivestym (Neupogen)	00069029310
Retacrit (Procrit)	00069130810, 69130510
Udenyca (Neulasta)	'70114010101
Zarxio (Neupogen)	61314032610, 61314031810, 61314031801, 61314032601

Medical Biologics and Biosimilars, Associated Codes	
Biologic Name	**Code(s)**
Avastin	C9257
Herceptin	J9355, J9356
Humira	J0135
Lucentis	J2778
Neupogen	J1442, J1447
Procrit	J0885
Remicade	J1745
Rituxan	J9310, J9312
Enbrel	J1438

Medical Biologics and Biosimilars, Associated Codes	
Biosimilar Name(s) (Reference Drug Name)	**Code(s)**
Vegzelma® (Avastin)	C9257
Erelzi®/Eticovo™ (Enbrel)	C9399, J3590
Kanjinti® (Herceptin)	J9999
Abrilada™/Amjevita™ (Humira)	J3590
Cyltezo® (Humira)	J3590
Hadlima®/Hulio®/Hyrimoz® (Humira)	J0135
Yusimry™ (Humira)	J3590
Rezvoglar™ (Lantus)	J1815
Cimerli™ (Lucentis)	J3490, J3590, C9399
Releuko® (Neupogen)	J3590
Zarxio® (Neupogen)	Q5101
Inflectra® (Remicade)	Q5103
Renflexis® (Remicade)	Q5104
Mvasi® (Avastin)	Q5107
Fulphila® (Neulasta)	Q5108
Udenyca® (Neulasta)	Q5111
Nivestym® (Neupogen)	Q5110
Retacrit® (Procrit)	Q5105