Evaluation of HF 0743 – Prohibition of Step Therapy Protocols for Diabetes Treatment

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

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As requested by Minnesota Statute § 3.197: This report cost approximately $8,308.63 to prepare, including staff time, printing and mailing expenses.

Upon request, this material will be made available in an alternative format such as large print, Braille or audio recording. Printed on recycled paper. A 508 compliant version of this report is forthcoming.

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Introduction

In accordance with Minn. Stat. § 62J.26, the Minnesota Department of Commerce (Commerce), in consultation with the Minnesota Department of Health (MDH) and Minnesota Management and Budget (MMB), performs a detailed evaluation of all relevant benefit mandate proposals. For evaluation criteria and required evaluation components, please review the Evaluation Report Methodology, available at https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Bill Requirements

This House bill is sponsored by Rep. Howard and was introduced in the 94th Legislature (2025-26) on February 13, 2025.

If enacted, this bill would prohibit health issuers that cover diabetes treatment from using step therapy protocols to limit or exclude coverage for prescription insulin drugs. If enacted, any step therapy protocol requirements under the Medical Assistance program established by the Commissioner of Human Services would also need to comply with this prohibition.

This proposed mandate would apply to fully insured small and large group commercial health plans, individual market plans, the State Employee Group Insurance Program (SEGIP), and Minnesota Health Care Programs (e.g., Medical Assistance and MinnesotaCare). This would not apply to self-insured employer plans, grandfathered plans, and Medicare supplemental policies.

This bill would create Minn. Stat. § 62Q.1842 and amend Minnesota Statutes 2024, section 256B.0625, subdivision 13f.

Key Terms

For the purposes of this bill and its evaluation:

- "Diabetes" means the three types of diabetes defined by the Centers for Disease Control and Prevention (CDC), including type I diabetes, type II diabetes, and gestational diabetes.
- "Prescription insulin drug" means a prescription drug that contains insulin and is used to treat diabetes.
- "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self-administered drugs and drugs that are administered by a physician, advanced practice registered nurse, or physician assistant, are medically appropriate for a particular enrollee and are covered under a health plan.

Related Health Conditions and Associated Services

Diabetes is a chronic health condition that occurs when an individual's body does not make enough insulin or does not use the insulin it creates efficiently. If an individual with diabetes does not receive appropriate treatment, serious health conditions (e.g., heart disease, vision loss, kidney disease, and death) can occur.[1] As of 2020, 8.8% of Minnesotans had been diagnosed with either type I or type II diabetes.[2]

Treatment for diabetes can vary depending on the type.[1] Type I diabetes is treated with insulin as individuals with this type do not produce insulin or produce limited levels of insulin naturally. Type II and gestational diabetes can typically be managed through eating a healthy diet, maintaining a healthy weight, and getting regular physical activity. However, some individuals may also require insulin to maintain healthy blood sugar levels.

Public Comments Summary

Commerce solicited public input on the potential health benefit mandate through a request for information (RFI) posted to Commerce's website and the Minnesota State Register. The summary below represents only the opinions and input of the organizations who responded to the RFI.

Key Stakeholder Comment Themes

For this proposed mandate, Commerce received RFI responses from three commercial health issuers, one pharmaceutical organization, and one advocacy organization.

Many of the respondents questioned whether the language, as written, would prohibit step therapy for all insulin drugs, including those not currently on an issuer's formulary. Multiple respondents noted they were unable to fully assess the financial impact of this bill due to the lack of clarity in the language and absence of key details needed for an accurate analysis.

One respondent reported that step therapy causes delays in healthcare, which can lead to potentially adverse outcomes for patients in the short or long term. Alternatively, several respondents noted that step therapy aligns with evidence-based guidelines and helps to prevent fraud, waste, and abuse. Many respondents also noted that Minnesota has already enacted laws requiring step therapy protocols more broadly.

Cost Estimates Provided in Stakeholder Comments

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

- MMB assumes the proposed mandate will not have a fiscal impact. Insulin drugs are already covered without step therapy or prior authorization in the Advantage Plan. MMB assumes that the proposed mandate does not require health plans to cover all insulin drugs. If the bill requires a health issuer to provide coverage for all insulin drugs, regardless of whether they are included on the formulary, MMB would expect a considerable fiscal impact.

- Multiple respondents stated that they were unable to fully assess the financial impact of this bill without the key details needed for an accurate analysis.

Stakeholders' results may or may not reflect generalizable estimates for this mandate, depending on the methodology, data sources, and assumptions used for analysis.

Evaluation Limitations

The evaluation of the potential public health and economic impacts for this mandate was limited by several factors. First, it is not feasible to conduct an actuarial analysis for this proposed mandate as the Minnesota All Payer Claims Database does not capture data relating to step therapy protocols. There is data available on the utilization and cost elements of diabetes treatment, but these elements are not specific to the prohibition of step therapy protocols under this proposed mandate. As a result, it would be challenging to assess the impact of step therapy on diabetes treatment or to identify barriers associated with step therapy protocols. Additionally, while there is a plethora of information on diabetes treatment, literature relating to prohibition of step therapy for diabetes treatment is limited. There is also insufficient evidence on the corresponding cost implications for issuers to allow for a well-rounded literature review.

State Fiscal Impact

The potential state fiscal impact of this legislation includes the estimated cost to SEGIP as assessed by MMB in consultation with health plan administrators, the cost of defrayal of benefit mandates as understood under the Patient Protection and Affordable Care Act (ACA), and the estimated cost to Minnesota Health Care Programs.

- There is no estimated cost for SEGIP because the required services associated with the bill are covered in the program's medical benefit package.
- Commerce has determined that this proposed mandate would not require defrayal under the ACA.
- This proposed mandate would apply to Minnesota Health Care Programs (e.g., Medical Assistance and MinnesotaCare).

Fiscal Impact Estimate for SEGIP

MMB does not estimate any fiscal impact to the state plan from this proposed mandate. SEGIP currently provides coverage in its medical benefit package for the relevant services listed in the bill, including insulin drugs without step therapy or prior authorization. MMB assumes that this proposed mandate does not require coverage for all insulin drugs (e.g., all brands of insulin).

Affordable Care Act Mandate Impact and Analysis

States may require qualified health plan issuers to cover benefits in addition to the 10 essential health benefits (EHBs) defined by the ACA but must defray the costs, either through payments to individual enrollees or directly to issuers, and can partially defray the costs of proposed mandates if some of the care, treatment, or services

are already covered in the state's benchmark plan or mandated by federal law, pursuant to section 1311(d)(3)(b) of the ACA. For further defrayal requirements and methodology, please visit https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

If enacted, Commerce assumes this bill would not constitute an additional benefit mandate, as it does not relate to any new requirements for specific care, treatment, or services that are not already covered by Minnesota's EHB Benchmark Plan. The Minnesota EHB Benchmark Plan includes coverage for insulin as a blood glucose regulator prescription drug. The proposed mandate only alters step therapy protocols associated with required coverage.

Fiscal Impact of State Public Programs

This proposed mandate would apply to Minnesota Health Care Programs (e.g., Medical Assistance and MinnesotaCare) and may have a cost. Minnesota Health Care Programs manage prescription drugs, including insulin, using a preferred drug list (PDL) which may incur costs due to the management of these treatment options using the PDL. However, a fiscal estimate has not yet been completed on this proposed mandate.

Appendix A. Bill Text

Section 1. **[62Q.1842] STEP THERAPY PROTOCOL FOR INSULIN; PROHIBITION.**

Subdivision 1. **Definitions.**

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

(b) "Diabetes" means the three types of diabetes defined by the Centers for Disease Control and Prevention, including type I diabetes, type II diabetes, and gestational diabetes.

(c) "Prescription insulin drug" has the meaning given in section 62Q.48, subdivision 2.

(d) "Step therapy protocol" has the meaning given in section 62Q.184, subdivision 1.

Subd. 2. **Prohibition on use of step therapy protocol.** A health plan that provides coverage for the treatment of diabetes must not limit or exclude coverage by mandating step therapy protocol requirements for prescription insulin drugs.

EFFECTIVE DATE. This section is effective January 1, 2027, and applies to health plans offered, issued, or renewed on or after that date.

Sec. 2. Minnesota Statutes 2024, section 256B.0625, subdivision 13f, is amended to read:

Subd. 13f. **Prior authorization.**

(a) The Formulary Committee shall review and recommend drugs which require prior authorization. The Formulary Committee shall establish general criteria to be used for the prior authorization of brand-name drugs for which generically equivalent drugs are available, but the committee is not required to review each brand-name drug for which a generically equivalent drug is available.

(b) Prior authorization may be required by the commissioner before certain formulary drugs are eligible for payment. The Formulary Committee may recommend drugs for prior authorization directly to the commissioner. The commissioner may also request that the Formulary Committee review a drug for prior authorization. Before the commissioner may require prior authorization for a drug:

(1) the commissioner must provide information to the Formulary Committee on the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs, information regarding whether the drug is subject to clinical abuse or misuse, and relevant data from the state Medicaid program if such data is available;

(2) the Formulary Committee must review the drug, taking into account medical and clinical data and the information provided by the commissioner; and

(3) the Formulary Committee must hold a public forum and receive public comment for an additional 15 days.

The commissioner must provide a 15-day notice period before implementing the prior authorization.

(c) Except as provided in subdivision 13j, prior authorization shall not be required or utilized for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

(1) there is no generically equivalent drug available; and

(2) the drug was initially prescribed for the recipient prior to July 1, 2003; or

(3) the drug is part of the recipient's current course of treatment.

This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. Prior authorization shall automatically be granted for 60 days for brand name drugs prescribed for treatment of mental illness within 60 days of when a generically equivalent drug becomes available, provided that the brand name drug was part of the recipient's course of treatment at the time the generically equivalent drug became available.

(d) Prior authorization must not be required for liquid methadone if only one version of liquid methadone is available. If more than one version of liquid methadone is available, the commissioner shall ensure that at least one version of liquid methadone is available without prior authorization.

(e) Prior authorization may be required for an oral liquid form of a drug, except as described in paragraph (d). A prior authorization request under this paragraph must be automatically approved within 24 hours if the drug is being prescribed for a Food and Drug Administration-approved condition for a patient who utilizes an enteral tube for feedings or medication administration, even if the patient has current or prior claims for pills for that condition. If more than one version of the oral liquid form of a drug is available, the commissioner may select the version that is able to be approved for a Food and Drug Administration-approved condition for a patient who utilizes an enteral tube for feedings or medication administration. This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. The commissioner shall design and implement a streamlined prior authorization form for patients who utilize an enteral tube for feedings or medication administration and are prescribed an oral liquid form of a drug. The commissioner may require prior authorization for brand name drugs whenever a generically equivalent product is available, even if the prescriber specifically indicates "dispense as written-brand necessary" on the prescription as required by section 151.21, subdivision 2.

(f) Notwithstanding this subdivision, the commissioner may automatically require prior authorization, for a period not to exceed 180 days, for any drug that is approved by the United States Food and Drug Administration on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within the state. The Formulary Committee shall recommend to the commissioner general criteria to be used for the prior authorization of the drugs, but the committee is not required to review each individual drug. In order to continue prior authorizations for a drug after the 180-day period has expired, the commissioner must follow the provisions of this subdivision.

(g) Prior authorization under this subdivision shall comply with section 62Q.184.

(h) Any step therapy protocol requirements established by the commissioner must comply with ~~section~~ sections 62Q.1841 and 62Q.1842.

(i) Notwithstanding any law to the contrary, prior authorization or step therapy shall not be required or utilized for any class of drugs that is approved by the United States Food and Drug Administration for the treatment or prevention of HIV and AIDS.

EFFECTIVE DATE. This section is effective January 1, 2027, or upon federal approval, whichever is later.

Works Cited

1. Centers for Disease Control and Prevention. Diabetes basics. Diabetes. July 19, 2024. Accessed September 5, 2025. https://www.cdc.gov/diabetes/about/index.html

2. Donovan J, Nelson G. *Minnesota Health Care Quality Report: Results for Care Delivered in 2019*. MN Community Measurement; March 2021. https://mncmsecure.org/website/Reports/Community%20Reports/Health%20Care%20Quality%20Report/2020%20HCQR%20Chartbook%20FINAL.pdf