COMMERCE DEPARTMENT

Evaluation of SF 3265: Requirements for Pharmacy Benefit Managers and Health Carriers Related to Clinician-Administered Drugs

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.

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Executive Summary

This proposed mandate addresses the practice of "white bagging," which occurs when clinician-administered drugs (i.e., drugs that must be administered by a health care provider in an outpatient setting) are filled by a pharmacy and then transported to a physician's office, hospital, or clinic for administration. This mandate would prohibit a pharmacy benefit manager (PBM) or plan from defining clinician-administered drugs as a pharmacy benefit and would allow health plan enrollees to obtain clinician-administered drugs from any authorized health care provider or pharmacy of their choice. In addition, the mandate would prohibit PBMs and plans from influencing the enrollee's choice of a provider or pharmacy by using financial incentives and require plans to provide equal coverage, cost sharing, and reimbursement for these drugs, regardless of whether the drug is administered by a preferred provider or pharmacy.

The public health impact of Senate File 3265 is not easily assessed. The literature in this field includes conflicting views on the practice of white bagging and reflects concern about the potential impact on clinical outcomes, patient safety, and access to medication. Increasing flexibility in the dispensing of clinician-administered drugs could limit delays associated with external specialty pharmacies. Based on an interpretation of the available literature, the increased competition associated with this mandate may encourage specialty pharmacies to adopt new and better practices if current practices are associated with treatment delays.

Literature on the impact of rising drug costs describes how PBMs may use their preferred specialty pharmacies to dispense clinician-administered drugs as a cost-containment strategy. Plans that use PBM specialty pharmacies often cover clinician-administered drugs as a pharmacy benefit rather than an outpatient clinical service. SF 3265's prohibition on defining clinician-administered drugs as a pharmacy benefit could reduce the cost of these drugs for enrollees, especially in plans where the pharmacy benefits have higher out-of-pocket maximums or deductibles than outpatient services. Utilization management, which PBMs and plans often impose on pharmacy benefits to control costs, has been shown to potentially increase the cost to consumers and may lead to delays in treatment, medical waste, and adverse clinical outcomes. Due to data and literature limitations for this topic, there may be additional factors, such as changes in drug pricing and the impact of competition among pharmacies, associated with this mandate's economic impact that cannot be explored in this report.

There was no actuarial analysis conducted for this proposed mandate because the mandate is broad and there are minimal data on the use of clinician-administered drugs or costs associated with third-party specialty pharmacies that dispense clinician-administered drugs.

The potential fiscal impact of this mandate is as follows:

- The State Employee Group Insurance Program has determined that the mandate would have no fiscal impact because clinician-administered drugs are covered under its medical benefit, not the pharmacy benefit, and the plan does not contract with pharmacies to administer drugs.
- Commerce has determined that this proposed mandate would likely not require defrayal under the Affordable Care Act because clinician-administered drugs are an existing benefit under the benchmark plan and EHB-compliant plans. The bill would alter cost-sharing and claims-processing requirements for health plans but does not add a new benefit.
- 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 3265 on requirements for pharmacy benefit managers and health carriers related to clinician-administered drugs from 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 3265 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 must 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 3265 is sponsored by Senators Koran and Klein and was introduced in the 92nd Legislature (2021–22) on February 17, 2022.

If enacted, this bill would prohibit a pharmacy benefit manager (PBM) or plan from defining clinician-administered drugs (i.e., drugs that must be administered by a health care provider in an outpatient setting) as a pharmacy benefit and would allow health plan enrollees to obtain clinician-administered drugs from any authorized health care provider or pharmacy of their choice. The mandate would also require a PBM or health carrier to provide equal coverage, cost sharing, and reimbursement for clinician-administered drugs regardless of whether the drugs are dispensed by a preferred/participating or nonpreferred/nonparticipating health care provider or pharmacy.

The proposed mandate would allow the administration of clinician-administered drugs by any authorized health care provider or pharmacy and does not *prohibit* what is commonly known as "white bagging" (i.e., distribution of a patient-specific medication from a pharmacy to a physician's office, hospital, or clinic for administration) but rather *requires* PBMs and health carriers to allow members to choose where to purchase medications without imposing incentives.

Related Health Conditions

The proposed mandate does not identify specific health conditions. Any health condition for which a patient requires a clinician-administered drug could be considered an associated health condition.

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

No federal health care statutes or regulations pertaining to white bagging of clinician-administered drugs were found in the review. However, two instances of applicable federal case law have been identified. In 2020, the U.S. Supreme Court ruled in the case of Rutledge v. Pharmaceutical Care Management Association that the Employee Retirement Income Security Act (ERISA) does not preempt

Arkansas state legislation and regulation of cost-control efforts as it relates to PBM business practices.[1] The U.S. Eighth Circuit Court of Appeals ruled the same for a case out of North Dakota in 2021.[2,3]

Minnesota State Laws Relevant to the Proposed Mandate

No Minnesota state health care laws or regulations pertaining to white bagging of clinician-administered drugs were found in this analysis.

State Comparison

Since 2021, three states have implemented legislation on white bagging:

- In Arkansas (A.C.A. § 23-99-1503), health insurance providers/PBMs are prohibited from imposing financial penalties, copayments, coinsurance, or deductibles for administered prescription medications beyond the ordinary terms.[4]
- In Louisiana (RS 22:1020.53) and Virginia (§ 38.2-3407.7), health insurance providers/PBMs are prohibited from imposing additional copayments, fees, or increased cost-sharing for covered services related to physician-administered drugs if received at a nonpreferred/nonparticipating provider or pharmacy and cannot influence an individual's choice of health care provider or pharmacy through monetary penalty.[5,6]

It is important to highlight that while these laws address the same topic, they are being implemented in different ways (relative to SF 3265) and may result in different outcomes and impacts. Along with Minnesota, at least 10 other states are considering bills related to white bagging of clinician-administered drugs in 2022.[7] While these laws pertain to specific states, the same rationale could apply to other states and PBM regulation.

Additionally, as identified in stakeholder comments, a similar bill prohibiting white bagging (HB 2305) was introduced in Missouri on January 6, 2022.[8] The Missouri Consolidated Health Care Plan (MCHCP)

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[1] Rutledge, Attorney General of Arkansas v. Pharmaceutical Care Management Association, No.18-540 (2020). https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf. Fuse Brown, C., & McCuskey, Y. (2020, December 17). The implications of Rutledge v. PCMA for state health care cost regulation. *Health Affairs.* https://www.healthaffairs.org/do/10.1377/forefront.20201216.909942/full/.

[2] Pharm. Care Mgmt. Ass'n. v. Wehbi, 2021 WL 5355916 (8th Cir. 2021). https://ecf.ca8.uscourts.gov/opndir/21/11/182926P.pdf

[3] *On reconsideration, Eighth Circuit concludes that ERISA does not preempt state law regulating PBMs*. (2022, January 12). Thomas Reuters. https://tax.thomsonreuters.com/blog/on-reconsideration-eighth-circuit-concludes-that-erisa-does-not-preempt-state-law-regulating-pbms/

[4] Ark. Code Ann. § 23-99-1503 (Lexis Advance through all acts of the Third Extraordinary Session [2022], including corrections and edits by the Arkansas Code Revision Commission).

[5] LA RS 22:1020.53 (2021). http://legis.la.gov/legis/Law.aspx?d=1240068

[6] Code of Virginia § 38.2-3407.7 Pharmacies; freedom of choice (2021). https://law.lis.virginia.gov/vacode/title38.2/chapter34/section38.2-3407.7/

[7] Other states considering legislation on white bagging include Arizona, California, Illinois, Maryland, Missouri, New York, Ohio, Oklahoma, and West Virginia.

[8] MO 101st General Assembly, 2nd Regular Session, House Bill 2305 (2022). Creates provisions relating to insurance coverage of pharmacy services. https://house.mo.gov/Bill.aspx?bill=HB2305&year=2022&code=R

estimated this bill could have a fiscal impact greater than $18 million, as it would eliminate MCHCP's ability to use pharmacy and provider management programs, which could increase drug and administration costs.[9]

A report performed by the Massachusetts Health Policy Commission provided recommendations to the Massachusetts legislature based on a review of third-party specialty pharmacy use for clinician-administered drugs. Based on the public, economic, and fiscal impact evaluation performed by the state, they recommended policymakers consider minimum safety standard requirements for third-party pharmacies in dispensing clinician-administered drugs, neutral payment policies only for drugs subject to white bagging, actions to promote public transparency and oversight of the "full drug distribution chain," as well as other policies and actions related to third-party specialty pharmacy use for clinician-administered drugs.[10,11,12]

Public Comments Summary

To assess the public health, economic, and fiscal impact of SF 3265, 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.

[9] HB 2305, 101st General Assembly, 2nd Regular Session (2022). Creates provisions relating to insurance coverage of pharmacy services. https://house.mo.gov/billtracking/bills221/fiscal/fispdf/4950H.01I.ORG.pdf

[10] Medications in Massachusetts included Remicade (autoimmune diseases), Sandostatin LAR (cancer), Gammagard Liquid (Alzheimer's), and Xgeva/Prolia (cancer).

[11] Health Policy Commission. (2019). *Review of third-party specialty pharmacy use for clinician-administered drugs.* https://www.mass.gov/doc/review-of-third-party-specialty-pharmacy-use-for-clinician-administered-drugs/download

[12] Source provided by MDH.

Stakeholder Engagement Analysis

For this proposed mandate, Commerce received 10 stakeholder comments. Four stakeholders were not in support of the mandate and suggested that it would increase health care costs for Minnesotans, three were in support and suggested it would lower health care costs for Minnesotans, and three expressed no opinion but mentioned cost implications and factual advantages and disadvantages of the bill. The types of stakeholder groups that submitted responses included health care providers and physicians, state and commercial health insurance providers, PBMs, and industry organizations. Stakeholder interviews were conducted with three of the respondents.

Unfavorable Feedback

Stakeholders opposed to this proposed mandate believe that white bagging improves access to drugs, decreases costs for prescriptions, increases transparency of costs through real-time claims billing rather than a buy-and-bill strategy, and improves the communication between providers and pharmacies.

PBM and health carrier stakeholders expressed concern that the proposed mandate would undermine access to affordable drugs for Minnesotans by raising costs in the administration of pharmacy benefits for a health plan. If administration costs increased, it would in turn raise costs for employers, SEGIP, and the state's Medicaid population. More specifically, small business stakeholders expressed concern the bill would limit their ability to control costs and offer competitive health benefits to employees. These stakeholders cited a national survey that noted that in 2020 (prior to COVID-19), 51% of small businesses reported the cost of health insurance as a critical problem for sustainable development.[13] Small business stakeholders stressed that the cost of health insurance has increased and stated that they have been priced out of the fully insured market.

PBM and health carrier stakeholders also noted that specialty drug prices are high and are increasing, along with hospital and physician markups and fees. They cited several articles documenting markups and fees, one of which said that markups were on average 3–7 times higher than Medicare average sale prices in 2021.[14] These stakeholders believe that using specialty pharmacies saves patients money and makes premiums more affordable. Other commenters noted that providers and hospitals have a conflict of interest and that their support of this mandate is profit driven and based on buy-and-bill practices.

[13] Wade, H., & Heritage, A. (2020, July). *Small business problems priorities.* NFIB. https://assets.nfib.com/nfibcom/NFIB-Problems-and-Priorities-2020.pdf

[14] Herman, B. (2019, February 15). *Hospitals are making a lot of money on outpatient drugs*. Axios. https://www.axios.com/2019/02/15/hospital-charges-outpatient-drug-prices-markups.

Additionally, PBM and health carrier stakeholders estimated that savings could be $117 million if white bagging is doubled in Medicaid and commercial insurance plans over the next 10 years, citing a series of sources.[15,16,17,18,19,20,21,22,23]

A commercial health insurance carrier stated that the proposed mandate would limit the ability of health plans to effectively negotiate savings on behalf of members, would encourage the use of out-of-network or nonparticipating pharmacies, would limit plan design options that increase the value of members' health care dollars, and would allow hospitals and providers to buy and bill for clinician-administered drugs at any marked-up rate.

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 simultaneously. The source does not provide data indicating whether a causal relationship exists between the state insurance mandates and employer selection of self-insured plans given other variables that may account for changes in enrollment.[24,25]

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[15] U.S. Census. State population totals and components of change: 2010–2019. https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html

[16] U.S. Census, Health insurance in the United States: Number and percentage of people without health insurance coverage by state: 2017 to 2018. Table generated from https://www.census.gov/data.html. Stakeholder calculations.

[17] Table II.B.2.b.(1): Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and state. AHRQ Medical Expenditure Panel Survey. https://meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2016/tiib2b1.htm

[18] 2020 Employer Health Benefits Survey. Kaiser Family Foundation. https://www.kff.org/health-costs/report/2019-employer-health-benefits-survey/

[19] Marketplace enrollment [Table]. Kaiser Family Foundation. https://www.kff.org/health-reform/state-indicator/marketplace-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[20] Medicare Advantage/Part D contract and enrollment data: Monthly enrollment by state. Kaiser Family Foundation. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-State

[21] Medicaid enrollment: Monthly Medicaid and CHIP application, eligibility determination, and enrollment reports (Medicaid.gov). https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html

[22] Medicaid gross spending for drugs by delivery system and brand or generic status (MACPAC.gov). https://www.macpac.gov/publication/medicaid-gross-spending-for-drugs-by-delivery-system-and-brand-or-generic-status/

[23] Dual eligibles as a percent of total Medicare beneficiaries. Kaiser Family Foundation. https://www.kff.org/medicaid/state-indicator/duals-as-a-of-medicare-beneficiaries/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[24] 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

[25] 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.

In stakeholder feedback, no cost estimates were provided. A commercial health insurer stated that they are not able to estimate the fiscal impact of the mandate. However, other stakeholders referred to a similar bill prohibiting white bagging in Missouri that estimates that the fiscal impact on MCHCP, a Missouri health plan that covers state employees and retirees, could be greater than $18 million (see the State Comparison section above for more details). Based on the data provided in Missouri's fiscal note, which primarily utilized purported savings provided by PBMs, Missouri's analysis may not be relevant for evaluating the fiscal impact for Minnesota.

Favorable Feedback

Stakeholders in favor of the bill indicated that white bagging is a cost-shifting tactic used by PBMs and health carriers and does not reflect the savings reported by PBMs and health carriers. Proponents of the mandate flagged the considerable administrative costs associated with use of external pharmacies and the costs associated with waste from incorrect or delayed dosing. One stakeholder cited a Vizient Survey that found health systems are spending $310 million annually on labor requirements to manage the additional workload associated with white bagging and have spent an estimated $114 million on additional resources required to manage the excess coordination of patient and provider needs associated with white bagging.[26] Stakeholders claimed that instances of waste resulting from white bagging can lead to considerable surprise costs to patients when a dose needs to be changed or a delay causes a medication to pass its use-by date. One stakeholder challenged the feasibility and ease of use of the exceptions practices of health plans, noting that access, availability, and transparency challenges resulted in increased administrative time for providers.

One stakeholder provided external research showing the ability of hospital system specialty pharmacies to potentially reduce out-of-pocket (OOP) spending by consumers and reduce overall expenditures for care. This stakeholder stated that the use of external specialty pharmacies likely increases OOP costs for patients because pharmacy benefits may not have caps on OOP expenses.

Stakeholders noted that external specialty pharmacies introduce treatment risks and safety concerns and can delay the delivery of care. Examples include incorrect medication doses, medications shipped to incorrect locations, and long wait times before administration of a drug can begin. Citing the Vizient Survey, one stakeholder mentioned that 66% of patients reported receiving the incorrect dose or medication, as when treatment updates made the product delivered obsolete.[26] Overall, 92% of patients in this survey reported experiencing care issues due to problems with medications received through specialty pharmacy services. Another stakeholder provided a study showing that the use of external pharmacies resulted in dispensing times that were 5 times higher than those of integrated

[26] Vizient. (2021). *Survey on the patient care impact and additional expense of white/brown bagging.* https://www.senate.mn/committees/2021-2022/3095_Committee_on_Health_and_Human_Services_Finance_and_Policy/Vizient%20white%20bagging%20report%202021.pdf

hospital specialty pharmacies.[27] Stakeholders flagged access challenges, particularly for community hospitals, where underserved populations may be especially impacted by delays and confrontations with external pharmacy management.

Some stakeholders noted that SF 3265 would provide flexibility for plans and providers to determine the appropriate approach for patient care based on the needs of the patient, the medications involved, and the context. There may be instances where white bagging may be more cost effective when providing care, such as for small rural clinics or for the treatment of rare diseases. Some stakeholders noted that the proposed mandate does not prohibit white bagging but rather seeks to reduce barriers to accessing or providing the highest quality of care based on patients' individual needs.

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

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

[27]Zuckerman, A. D., Whelchel, K., Kozlicki, M., Simonyan, A. R., Donovan, J. L., Gazda, N. P., Mourani, J., Smith, A. M., Young, L., Ortega, M., & Kelley, T. N. (2022). Health-system specialty pharmacy role and outcomes: A review of current literature. *American Journal of Health-System Pharmacy*, *79*(21), 1906–1918. https://doi.org/10.1093/ajhp/zxac212

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

The public health impact of SF 3265 is not easily assessed. The literature in this field includes conflicting views on the practice of white bagging and reflects concern regarding clinical outcomes, patient safety, and access to medication. Parties that challenge requirements to use PBM specialty pharmacies to dispense clinician-administered drugs raise concerns about potentially unsafe storage, transportation, and handoff of drugs that may impact their safety and integrity prior to administration. Given the fragile and perishable nature of many specialty medications, the use of third-party pharmacies for medication transportation may have health consequences.[28,29,30]

Qualitative studies assessing the experience of providers and practices, particularly those specializing in oncology, raise concerns about barriers to safe and timely treatment when engaging with specialty pharmacies.[28] In oncology, it is common to test patients the day of treatment to assess the appropriateness of dose for infusion treatment, and oncologists have voiced a concern that the inflexibility associated with medications sourced from third-party pharmacies can cause delays in treatment. Delays in treatment in oncology are associated with adverse clinical outcomes.[28,31,32,33]

However, outside of provider surveys, there is limited documentation on the magnitude of delays associated with the practice of white bagging. Based on our evaluation of the literature, this mandate may reduce existing delays by increasing flexibility for medical dispensing to overcome delays associated with external specialty pharmacies or by driving the use of new practices associated with specialty pharmacies through increased competition. SF 3265 may help to resolve the current challenges associated with specialty pharmacies by driving the improvement of delivery and flexibility in a system that requires "earning" the business as a preferred source for dispensing clinician-administered medications.

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[28] Royce, T. J., Schenkel, C., Kirkwood, K., Levit, L., Levit, K., & Kircher, S. (2020). Impact of pharmacy benefit managers on oncology practices and patients. *JCO Oncology Practice, 16*(5), 276–284. https://doi.org/10.1200/jop.19.00606

[29] Patel, B. N., & Audet, P. R. (2014). A review of approaches for the management of specialty pharmaceuticals in the United States. *PharmacoEconomics, 32*(11), 1105–1114. https://doi.org/10.1007/s40273-014-0196-0

[30] Drettwan, J. J., & Kjos, A. L. (2019). An ethical analysis of pharmacy benefit manager (PBM) practices. *Pharmacy, 7*(2), 65. https://doi.org/10.3390/pharmacy7020065Hanna

[31] Vizient. (2021). *Survey on the patient care impact and additional expense of white/brown bagging.* https://www.senate.mn/committees/2021-2022/3095_Committee_on_Health_and_Human_Services_Finance_and_Policy/Vizient%20white%20bagging%20report%202021.pdf

[32] Zhou, C., & Zhang, Y. (2012). The vast majority of Medicare Part D beneficiaries still don't choose the cheapest plans that meet their medication needs. *Health Affairs, 31*(10), 2259–2265. https://doi.org/10.1377/hlthaff.2012.0087

[33] Hanna, T. P., King, W. D., Thibodeau, S., Jalink, M., Paulin, G. A., Harvey-Jones, E., O'Sullivan, D. E., Booth, C. M., Sullivan, R., & Aggarwal, A. (2020). Mortality due to cancer treatment delay: Systematic review and meta-analysis. *BMJ,* m4087.

Economic Impact

Available literature consistently notes the rising cost of medications, particularly clinician-administered medications, and the resulting burden on payers, health systems, and patients.[34,35,36] Prices for hospital-sourced clinician-administered medications are reported to be higher than those from PBMs' specialty pharmacies.[35] Higher prices may be more common in hospital systems than outpatient provider settings, where clinician-administered drugs may come from a variety of pharmacies.[37] Literature on the impact of rising drug costs cites the use of PBM-preferred external pharmacies for the dispensing of specialty drugs as one strategy used by issuers to address this rising cost.[29,34,36] Some literature suggests that the use of PBMs may mitigate the burden of rising drug costs for issuers,[34,37,38] while other research shows that drug utilization management prices and the costs borne by issuers and patients contribute to adverse clinical outcomes.[31,36]

However, the literature is unclear on whether the value PBMs create through proprietary negotiations with drug manufacturers results in reduced cost sharing or lower premiums.[34] Studies on consumer plan selection, namely, for plans associated with Medicare, indicate that consumers often make choices that do not reflect known medication use. Consumers may prioritize higher premium plans with lower deductibles, where their OOP medication costs are equal across plans. Plan designs with PBM specialty pharmacies shift the coverage of clinician-administered drugs to an individual's pharmacy benefit. The bill's provision to restrict this pharmacy benefit practice could reduce the cost of clinician-administered drugs if the plan design has high OOP maximums or separate deductibles for pharmacy benefits.

However, other research suggests that allowing providers and enrollees to choose the pharmacy for clinician-administered drugs could increase premiums and that any reductions in OOP expenses may be offset by higher plan premiums.[32,37] Given the potential for high OOP costs associated with pharmacy benefits, this may allow consumers to have flexibility in selecting a medication source that reflects their plan's design.[31]

The higher costs of clinician-administered medications provided by hospital pharmacies may reflect additional clinical quality and safety measures as well as coordination and quality control management.[37,38] Utilization management, which is common for pharmacy benefits, has been shown

[34] Conti, R., Frandsen, B. R., Powell, M., & Rebitzer, J. B. (2021). Common agent or double agent? Pharmacy benefit managers in the prescription drug market. *SSRN Electronic Journal.* https://doi.org/10.2139/ssrn.3859111
[35] Jacobs, M. S., & Johnson, K. A. (2012). Curbing the costly trend: exploring the need for a progressive approach to the management of specialty pharmaceuticals under the medical benefit. *American health & drug benefits*, *5*(5), 280–289.
[36] Howell, S., Yin, P. T., & Robinson, J. C. (2021). Quantifying the economic burden of drug utilization management on payers, manufacturers, physicians, and patients. *Health Affairs, 40*(8), 1206–1214. https://doi.org/10.1377/hlthaff.2021.00036
[37] Robinson, J. C., Whaley, C. M., & Brown, T. T. (2021). Price differences to insurers for infused cancer drugs in hospital outpatient departments and physician offices: Study examines differences in prices insurers pay for cancer drugs in hospital outpatient clinics compared with physician offices. *Health Affairs*, *40*(9), 1395–1401.
[38] Anderson, K. E., Alexander, G. C., Ma, C., Dy, S. M., & Sen, A. P. (2022). Medicare Advantage coverage restrictions for the costliest physician-administered drugs. *American Journal of Managed Care, 28*(7), e255–e262. https://doi.org/10.37765/ajmc.2022.89184

to increase the cost to consumers and cause delays in treatment, medical waste, and adverse clinical outcomes associated with access barriers to medication.[36] One study estimated that, despite strategies to reduce costs, sourcing medications through specialty pharmacies may result in prices that are 17% higher than hospital-sourced medications.[35]

This review did not identify literature that addresses the impact of increased medication-dispensing competition on drug pricing. Therefore, it is unclear whether white bagging is associated with higher drug list prices[34] or whether the use of PBMs is critical for market efficiency for drug pricing.[36] However, given the relatively higher costs of dispensing clinician-administered medications through hospital pharmacies, the bill's equal reimbursement requirement may reduce the cost differential between dispensing locations. Competition between hospitals, the health system, and specialty pharmacies could create downward pressure on drug prices, but given the spread between drug prices and reimbursement, this may not result in savings for individuals.[35] Due to limitations in the data, as noted below, there may be additional factors associated with this mandate's economic impact.

Limitations

Given the emerging nature of this topic, limited objective research is available to assess the public health and economic impacts of SF 3265. The literature consistently acknowledges the challenges associated with assessing the mechanisms by which drug pricing and patients' OOP costs are affected by the market behaviors of plans, PBMs, and pharmacies. Due to the opaque nature of drug pricing and of the proprietary rebate negotiations between PBMs and drug manufacturers, economic impacts are not easily conceptualized.[36] Much of the relevant literature on this topic comes from consultant or industry-specific sources that do not provide information on the data used for their analysis.[34] As a result, most of the research requires assumptions that significantly impact the usability and/or generalizability of the results.

Actuarial Analysis[39]

There was no actuarial analysis conducted for this proposed mandate. This proposed mandate would prohibit a health plan from covering clinician-administered drugs only as a pharmacy benefit and give providers the ability to obtain the drugs directly, with both the medication and the administration covered as medical benefits. This mandate does not specify any specific drugs or health conditions and would apply to any health condition for which a patient receives a physician-administered drug. Because the mandate is broad, and because there are minimal data available quantifying the prevalence of or costs associated with the practice of white bagging, the ability to perform any actuarial analysis on the impact of this mandate is limited.

[39] 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.

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 estimated cost to public programs.

- This mandate is estimated to have no fiscal impact on 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 estimated fiscal impact. Because the SEGIP Advantage Health Plan's clinician-administered drugs are covered under the medical benefit, not the pharmacy benefit, and SEGIP's health administrators do not contract with pharmacies to administer drugs, this legislation is estimated to have no fiscal impact on the SEGIP Advantage Health Plan.

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.[40] 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.[41]

Commerce has determined that SF 3265 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. The mandate merely alters cost sharing and claims-processing requirements for health plans but does not add a new benefit. Based on Commerce's precedent for such types of bills, there would be no defrayal requirement associated with passage of this bill.

[40] See 45 CFR § 155.170(a)(2).
[41] 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.

Appendix A: Bill Text

A bill for an act relating to health; establishing requirements for pharmacy benefit managers and health carriers related to clinician-administered drugs; proposing coding for new law in Minnesota Statutes, chapter 62W.

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

Section 1.

[62W.15] CLINICIAN-ADMINISTERED DRUGS.

Subdivision 1.

Definitions.

(a) For purposes of this section, the following definitions apply.

(b) "Affiliated pharmacy" means a pharmacy in which a pharmacy benefit manager or health carrier has an ownership interest either directly or indirectly, or through an affiliate or subsidiary.

(c) "Clinician-administered drug" means an outpatient prescription drug other than a vaccine that:

(1) cannot reasonably be self-administered by the patient to whom the drug is prescribed or by an individual assisting the patient with self-administration; and

(2) is typically administered:

(i) by a health care provider authorized to administer the drug, including when acting under a physician's delegation and supervision; and

(ii) in a physician's office, hospital outpatient infusion center, or other clinical setting.

Subd. 2.

Prohibition on requiring coverage as a pharmacy benefit.

A pharmacy benefit manager or health carrier shall not require that a clinician-administered drug or the administration of a clinician-administered drug be covered as a pharmacy benefit.

Subd. 3.

Enrollee choice.

A pharmacy benefit manager or health carrier:

(1) shall permit an enrollee to obtain a clinician-administered drug from a health care provider authorized to administer the drug, or a pharmacy;

(2) shall not interfere with the enrollee's right to obtain a clinician-administered drug from their provider or pharmacy of choice, and shall not offer financial or other incentives to influence the enrollee's choice of a provider or pharmacy;

(3) shall not require clinician-administered drugs to be dispensed by a pharmacy selected by the pharmacy benefit manager or health carrier; and

(4) shall not limit or exclude coverage for a clinician-administered drug when it is not dispensed by a pharmacy selected by the pharmacy benefit manager or health carrier, if the drug would otherwise be covered.

Subd. 4.

Cost-sharing and reimbursement.

A pharmacy benefit manager or health carrier:

(1) may impose coverage or benefit limitations on an enrollee who obtains a clinician-administered drug from a health care provider authorized to administer the drug, or a pharmacy, only if these limitations would also be imposed were the drug to be obtained from an affiliated pharmacy or a pharmacy selected by the pharmacy benefit manager or health carrier;

(2) may impose cost-sharing requirements on an enrollee who obtains a clinician-administered drug from a health care provider authorized to administer the drug, or a pharmacy, only if these requirements would also be imposed were the drug to be obtained from an affiliated pharmacy or a pharmacy selected by the pharmacy benefit manager or health carrier; and

(3) shall not reimburse a health care provider or pharmacy for clinician-administered drugs and their administration, at an amount that is lower than would be applied to an affiliated pharmacy or pharmacy selected by the pharmacy benefit manager or health carrier.

Subd. 5.

Other requirements.

A pharmacy benefit manager or health carrier:

(1) shall not require or encourage the dispensing of a clinician-administered drug to an enrollee in a manner that is inconsistent with the supply chain security controls and chain of distribution set by the federal Drug Supply Chain Security Act, United States Code, title 21, section 360eee, et seq.;

(2) shall not require a specialty pharmacy to dispense a clinician-administered medication directly to a patient with the intention that the patient will transport the medication to a health care provider for administration; and

(3) may offer, but shall not require:

(i) the use of a home infusion pharmacy to dispense or administer clinician-administered drugs to enrollees; and

(ii) the use of an infusion site external to the enrollee's provider office or clinic.

Appendix B: Key Search Terms for Literature Scan

Clinician-administered drugs

Drug distribution

Medication distribution

Patient-specific medication

Pharmacy benefit

Physician-administered drugs

Specialty pharmacy

White bagging

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