COMMERCE DEPARTMENT

Evaluation of HF XXXX: Point of Sale and Reporting Requirements for Pharmacy Benefit Managers and Health Insurers

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 would require pharmacy benefit managers (PBMs) and health insurers, also referred to in bill text as health carriers, to pass rebates and other compensation that they receive from drug manufacturers through to the consumers at the point-of-sale to reduce out-of-pocket (OOP) costs for prescription drugs. The mandate would also require PBMs and health carriers to submit data reports to the Commerce commissioner demonstrating their compliance with this mandate. If enacted, this requirement would begin on March 1, 2024, and continue thereafter.

Although some research suggests that PBMs may reduce costs for health plan issuers by negotiating lower prices for drugs, the degree to which these savings are passed down to consumers is not well understood. High OOP expenditures can lead to medication nonadherence and poor clinical outcomes, especially for historically underserved populations, while policies that reduce OOP pharmaceutical spending may improve adherence.

Some research shows that rebates can reduce drug costs paid by issuers and thereby reduce premiums paid by consumers. If rebates help to lower premiums by spreading the savings across all enrollees, then requiring PBMs to pass those rebates directly to consumers at the point-of-sale could concentrate the savings among enrollees whose drugs have rebates. The reviewed literature indicates that increased reporting requirements could increase the administrative fees charged by PBMs, resulting in potentially higher costs for health plans and consumers.

The literature is consistent about the lack of available PBM negotiation and rebate data, which makes it difficult to evaluate the impact of any proposed or enacted policy. Information about rebates, such as those occurring in PBM–manufacturer negotiations, are considered proprietary information. Therefore, no actuarial analysis was conducted for this proposed mandate.

The potential fiscal impact of this mandate is as follows:

- The State Employee Group Insurance Program (SEGIP) did not provide estimates of the fiscal impact of this legislation for the state. Therefore, the potential fiscal impact on SEGIP is unknown.
- Commerce has determined that this proposed mandate would likely not require defrayal under the Affordable Care Act because it provides a point-of-service rebate to enrollees filling prescription medications and does not constitute a new benefit.
- There is no estimated cost for public programs, as the state insurance mandate only applies to non-public, individual, fully insured small and large group 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 House File XXXX on point of sale and reporting requirements for pharmacy benefit managers and health insurers from the 92nd Legislature (2021–2022). The purpose of the evaluation is to provide the legislature with a detailed analysis of the potential impacts of any mandated health benefit proposal.

House File XXXX on point of sale and reporting requirements 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 potential 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

This House bill is sponsored by Representative Elkins and was introduced in the 92nd Legislature (2021–2022). If enacted, this bill would create new point-of-sale and reporting requirements for pharmacy benefit managers (PBMs) and health insurers (also referred to in bill text as health carriers). These parties would be required to pass all compensation for prescription drug benefits that they receive from drug manufacturers through to the consumers at the point-of-sale. Compensation can include, but is not limited to, direct or indirect benefits, rebates, discounts, credits, fees, grants, chargebacks, or other payments or benefits of any kind that PBMs and health carriers receive from drug manufacturers. This bill would also require PBMs and health carriers to submit data reports to the Commerce commissioner demonstrating compliance with such actions. If enacted, this requirement would begin on March 1, 2024, and continue thereafter.

Related Health Conditions

While no specific health conditions are mentioned in the proposed mandate, any health condition for which a patient is prescribed a drug that is covered by a pharmacy benefit plan could be considered an associated health condition.

Related State and Federal Laws

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

Federal Laws Relevant to This Proposed Mandate

Federal laws provide little precedent on the reporting of rebates from PBMs. In 2020, Centers for Medicare & Medicaid Services (CMS) updated transparency requirements under the ACA that apply to qualified health plans (QHPs). These updated requirements state that QHPs and the PBMs that serve them must report information on prescription drug benefits to the U.S. Department of Health and Human Services (HHS). CMS finalized regulations for this reporting at 45 CFR §156.295 and §184.50. Specifically, issuers of QHPs must submit prescription drug rebates, other price concessions, and spread pricing data.

Medicare Part D, which provides prescription drug benefits to enrollees through private plans and their PBM partners, does not require this type of reporting.

Minnesota State Laws Relevant to This Proposed Mandate

Several state laws that aim to increase transparency of rebate practices through PBM reporting of rebate retention were identified in the policy analysis. In 2019, the Minnesota State Legislature passed a law requiring PBMs to report various rebate-related data (i.e., aggregate rebate, retained rebate, and spread pricing data) to the Commissioner of Commerce.[1] This proposed mandate builds on this law by specifying guidelines that PBMs must follow related to prescription drug benefits, information that PBMs must submit to show guidelines were met, and a time period for when information must be submitted to the Commissioner of Commerce. The current law does not provide the data that would be required to conduct an accurate analysis of the amounts consumers would receive at point-of-sale because available data do not reflect the flow of rebates from manufacturer negotiations or rebate use by health plans, nor do they include drug-level data.

State Comparison

In 2019, the state of Maine implemented a legislative package aimed at reducing the cost of prescription drugs. One of the bills passed into law, S.P. 466–L.D. 1504, specifically prohibits the retention of drug manufacturer rebates by PBMs and instead requires compensation to be passed directly to the consumers or health carriers at the point-of-sale "to reduce the out-of-pocket cost to the covered person/plan associated with a particular prescription drug."[2,3]

Additionally, since 2018, several states have implemented laws increasing transparency related to PBM rebate retention, specifically reporting requirements, as it is unclear how much of the rebates are passed through to plan enrollees to lower costs after PBMs negotiate with drug manufacturers.[4] In 2020, Georgia began requiring PBMs to report annual totals of rebates received from drug manufacturers that were not passed on to clients or health plans.[5] In addition, several states, including Arkansas, Delaware, New York, and Oklahoma, require PBMs to submit periodic (quarterly or annual) reports to the insurance commissioner or other administrative authorities.[6,7,8,9] These examples

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[1] Minnesota Legislature, Office of the Revisor of Statutes. Chapter 39, S.F.No. 278 (2019). https://www.revisor.mn.gov/laws/2019/0/Session+Law/Chapter/39/

[2] An Act To Protect Consumers from Unfair Practices Related to Pharmacy Benefits Management, ME SP 466 - LD 1504 (2019). https://legislature.maine.gov/bills/getPDF.asp?paper=SP0466&item=4&snum=129

[3] Prescription drug pricing; maximum allowable cost, 24-A ME Rev Stat § 4350 (2020). https://law.justia.com/codes/maine/2020/title-24-a/chapter-56-c/section-4350/

[4] Lanford, S., & Reck, J. (2021, June 14). *Legislative approaches to curbing drug costs targeted at PBMs.* National Academy for State Health Policy. https://www.nashp.org/pbm-laws-and-trends-over-time/

[5] An Act Relating to Regulation and Licensure of Pharmacy Benefit Managers, GA HB 323 (2019). https://www.legis.ga.gov/api/legislation/document/20192020/187577

[6] To Establish the 340b Drug Pricing Nondiscrimination Act, AK HB 1881 (2021). https://legiscan.com/AR/text/HB1881/id/2389437

[7] An Act to Amend Title 18 of the Delaware Code Relating to Pharmacy Benefits Managers, DE HB 219 (2021). https://legis.delaware.gov/json/BillDetail/GenerateHtmlDocumentSessionLaw?sessionLawId=78800&docTypeId=13&sessionLawName=chp256

[8] New York State Senate. Budget Bill, NY SB 7506B (2020). https://www.nysenate.gov/legislation/bills/2019/s7506

[9] Health insurance; modifying duties and prohibited acts of pharmacy benefit managers; authorizing Insurance Commissioner to take action on certain licenses. Emergency. OK SB 737 (2022). https://legiscan.com/OK/text/SB737/id/2571780

suggest that, like Minnesota, other states are seeking to increase the transparency of drug rebates and develop ways to ensure that savings from drug rebates are passed through more directly to consumers. Given the recent development and implementation of this legislation, there is no available analysis on how this legislation or other similar legislation has impacted individuals' choices for medications and other health care services.

Public Comments Summary

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

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

Stakeholder Engagement Analysis

For this proposed mandate, Commerce received four stakeholder comments. Two responses were not in support of the bill, and two expressed no opinion but provided facts and information. A stakeholder interview was conducted with one of the respondents for follow-up regarding the source of data provided in the RFI response.

One stakeholder stated that requiring PBMs and health carriers to provide drug rebates to members at the point-of-sale would distribute them to groups of people rather than to everyone. Specifically, this stakeholder said that point-of-sale rebates may only benefit health plan members who utilize drugs that are subject to rebates and that there would be a disproportionate increase in cost for members who either do not have prescription drug needs or are prescribed drugs that are not eligible for rebates. The disproportionate increase in cost would come in the form of increased premiums (estimated to be $40 per member per month), as health plans would no longer be able to use rebates

to reduce premiums. Without rebate revenue to offset premiums, a commercial health insurance stakeholder projected premiums to increase an average of 0.5% to 1.0%.[10]

Two stakeholders expressed concern that this bill would require implementing a new operational system for point-of-sale rebates that may result in significant operational costs, as no systems currently exist to calculate and remit point-of-sale rebates. Drug manufacturers pay rebates retrospectively based on the volume of prescriptions filled for a given drug on an annual basis. Stakeholders stated that the proprietary nature of rebates is a critical asset that PBMs use to effectively negotiate the lowest prices for drugs and that reporting requirements may undermine industry practices to negotiate savings for plans and consumers.

To support their feedback, one stakeholder referenced a 2019 report from HHS's Office of Inspector General that showed that PBM-negotiated rebates lead to lower prescription drug costs.[11] That same stakeholder referenced a 2016 Government Accountability Office study that showed that 99.6% of prescription drug rebates negotiated by PBMs on behalf of Medicare Part D participants were passed through to plan sponsors.[12]

One stakeholder commented that because the proposed health benefit mandates only apply to fully insured plans, they may have the potential to drive more employer groups to switch to self-insured coverage to avoid potential costs associated with benefit mandates. This stakeholder referenced a source that showed enrollment changes in self-insured and fully insured plans since 2011. This source indicates that, while enrollment 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 to indicate whether a causal relationship exists between the state insurance mandates and employer selection of self-insured plans given other variables that may account for changes in enrollment.[13,14]

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:

[10] An estimate provided by a stakeholder in the health care industry. This estimate captures the impact of shifting rebates to the individual member as well as the administrative costs of setting up systems to calculate point-of-sale rebates.
[11] U.S. Department of Health and Human Services, Office of Inspector General. (2019, September). *Rebates for brand-name drugs in Part D substantially reduced the growth in spending from 2011 to 2015* (OEI-03-19-00010). https://oig.hhs.gov/oei/reports/oei-03-19-00010.pdf
[12] Government Accounting Office. (2019, July). *Medicare Part D: Use of PBMs and efforts to manage drug expenditures and utilization* (GAO Report to Congressional Requesters). http://www.gao.gov/assets/gao-19-498.pdf
[13] 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
[14] 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.

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

Methodology for Analysis of Reviewed Literature

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

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

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

Public Health Impact

Research suggests PBMs may reduce costs for health plan issuers, to varying degrees, through negotiations with manufacturers and rebates that PBMs pass along to plans. However, it remains largely unknown the degree to which these savings are experienced by consumers.[15] With a series of nontransparent and complex transactions between PBMs, manufacturers, plans, and pharmacies, the resulting savings for consumers associated with rebates may only be expressed in savings through premiums.[16] However, with increases in cost-sharing across plan types and the increased number of

[15] Van Nuys, K. R. (2021). Estimation of the share of net expenditures on insulin captured by US manufacturers, wholesalers, pharmacy benefit managers, pharmacies, and health plans from 2014 to 2018. *JAMA Health Forum, 2*(11), e213409. https://doi.org/10.1001/jamahealthforum.2021.3409

[16] Schulman, K. A. (2018). The relationship between pharmacy benefit managers (PBMs) and the cost of therapies in the US pharmaceutical market: A policy primer for clinicians. *American Heart Journal, 206,* 113–122. https://doi.org/10.1016/j.ahj

high deductible plans on the market, savings may not be directly realized by consumers with medication needs.[17,18]

High copays and OOP expenditures are also associated with nonadherence to treatment and poor clinical outcomes. The association between medication adherence and cost is more significant for those in high deductible plans, as consumers are cost sensitive.[19,20] The negative impact of OOP costs on medication nonadherence is greater for historically underserved populations. One study suggested that policies to reduce OOP pharmaceutical spending may improve adherence in these historically underserved communities.[20]

All 50 states have enacted policies that regulate PBMs and fall into one of these five categories: pricing and reimbursement, pharmacy operations, pharmacy network, licensure and registration, and reporting requirements.[17] However, while states may set their own rules for PBM practices, they are also challenged to evaluate the effects of those rules as PBMs claim that much of their data are proprietary. Mattingly et al. reflect on the importance of new and existing policies to be evaluated through objective processes, minimizing the use of reports developed by or for PBM and health plan advocacy groups.[17] Improving the availability of objective, high-quality analysis of PBM practices is highlighted as a key factor in improving the robustness and accuracy of evaluation reports for policy-making.[17,18,19,21,22]

Economic Impact

Despite the limited data available on rebates, some research shows that rebates may be associated with lower drug costs paid by issuers.[23] However, there are discrepancies in PBMs' reporting on the percentage of savings passed on to health plans and payers and the actual savings that plans and payers report.[19] If rebates are associated with lower premiums for consumers (based on cost savings by plans), then requirements for PBMs to pass rebates directly to consumers at the point-of-sale could change the savings calculation. With health plan designs that retain rebates and reflect savings through lowered premiums, the shift of rebates from issuers directly to consumers receiving medication alters

[17] Mattingly, T. J. (2022). State-level policy efforts to regulate pharmacy benefit managers (PBMs). *Research in Social and Administrative Pharmacy, 18*(11), 3995–4002. https://doi.org/10.1016/j.sapharm.2022.07.045
[18] Seeley, E., & Kesselheim, A. S. (2019). *Pharmacy benefit managers: Practices, controversies, and what lies ahead* [Issue brief]. Commonwealth Fund.
[19] Royce, T. J. (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
[20] Reynolds, E. L. (2020). Association of out-of-pocket costs on adherence to common neurologic medications. *Neurology, 94*(13), e1415–e1426. https://doi.org/10.1212/wnl.0000000000009039
[21] Van Nuys, K. R. (2021). Estimation of the share of net expenditures on insulin captured by US manufacturers, wholesalers, pharmacy benefit managers, pharmacies, and health plans from 2014 to 2018. *JAMA Health Forum, 2*(11), e213409. https://doi.org/10.1001/jamahealthforum.2021.3409
[22] Brot-Goldberg, Z., Che, C., & Handel, B. (2022, April). *Pharmacy benefit managers and vertical relationships in drug supply: State of current research* (NBER Working Paper No. w29959). SSRN. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4092288
[23] Schulman, K. A. (2018). The relationship between pharmacy benefit managers (PBMs) and the cost of therapies in the US pharmaceutical market: A policy primer for clinicians. *American Heart Journal, 206,* 113–122. https://doi.org/10.1016/j.ahj

the current strategies that plans use to reduce costs for all enrollees. Furthermore, mandates that increase reporting requirements and altered rebate distribution may increase the administrative fees charged by PBMs, resulting in potentially higher costs for health plans and consumers.[24]

Given the limited data available on rebates and proprietary negotiations between PBMs, drug manufacturers, and health plans, the mechanisms through which savings are passed to consumers are unclear.[25,26,27,28] Lower premiums may be one way that rebates benefit consumers, but data on OOP costs suggest that savings from rebates are not shared proportionately by all enrollees. Furthermore, recent models do not show whether increased OOP costs borne by consumers are offset by lower premiums.[29,30] With the cost of specialty medications, particularly oncology drugs, growing at a faster rate than the cost in other drug classes, rising OOP costs may be most apparent for consumers requiring specialty medications.[25] It may be the case that these medications are associated with higher rebates as a percentage of drug list price and utilization.

The discrepancy between consumer OOP costs and negotiated reimbursement between pharmacies and PBMs suggests that savings from rebates are not passed along to the consumer at the point of purchase.[30] Many insurance plan designs require high deductibles and coinsurance, so that passing rebates directly to consumers may reduce OOP expenditures for those with high-cost-sharing and high-deductible plans for drugs.[26] With the lack of transparency around manufacturer and PBM rebate negotiations, [25,26] the evaluation of reviewed literature is unable to gauge the degree to which savings felt by individuals receiving rebates directly would outweigh costs associated with unknown market behavior along the drug supply chain that might result from requirements for passing rebates directly to consumers.

The proprietary nature of negotiations between PBMs and manufacturer and issuers may provide an opportunity to reduce drug costs. Requirements to shift all or some of rebates to consumers at the point-of-sale could result in reduced rebates to payers and in higher premiums associated with

[24] Reynolds, E. L. (2020). Association of out-of-pocket costs on adherence to common neurologic medications. *Neurology, 94*(13), e1415–e1426. https://doi.org/10.1212/wnl.0000000000009039
[25] Royce, T. J. (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
[26] Schulman, K. A. (2018). The relationship between pharmacy benefit managers (PBMs) and the cost of therapies in the US pharmaceutical market: A policy primer for clinicians. *American Heart Journal, 206*, 113–122. https://doi.org/10.1016/j.ahj
[27] Mattingly, T. J. (2022). State-level policy efforts to regulate pharmacy benefit managers (PBMs). *Research in Social and Administrative Pharmacy, 18*(11), 3995–4002. https://doi.org/10.1016/j.sapharm.2022.07.045
[28] Seeley, E., & Kesselheim, A. S. (2019). *Pharmacy benefit managers: Practices, controversies, and what lies ahead* [Issue brief]. Commonwealth Fund.
[29] Brot-Goldberg, Z., Che, C., & Handel, B. (2022, April). *Pharmacy benefit managers and vertical relationships in drug supply: State of current research* (NBER Working Paper No. w29959). SSRN. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4092288
[30] Van Nuys, K. R. (2021). Estimation of the share of net expenditures on insulin captured by US manufacturers, wholesalers, pharmacy benefit managers, pharmacies, and health plans from 2014 to 2018. *JAMA Health Forum, 2*(11), e213409. https://doi.org/10.1001/jamahealthforum.2021.3409

increased spending from plans.[31] However, the degree to which PBM and manufacturer negotiations impact trends in drug pricing suggests that rebate negotiations may play a role in rising drug prices and in an overall increase in net expenditures by consumers and payers.[32]

PBM Market Concentration and Vertical Integration. The potential savings for plans and payers associated with rebates, together with the degree to which point-of-sale regulations may alter the savings available to health plans, may be related to PBM market concentration and vertical integration.[33] The literature does indicate a potential role for PBMs in market efficiency for drugs, but this is mediated by the concentration of PBMs and market negotiations. One study noted that consolidation may reduce the extent to which PBMs create market efficiencies in drug pricing.[34] With economic models demonstrating a considerable increase in the negotiating power of PBMs, the impact of the recent trend of mergers and increased vertical integration on current business practices of PBMs is unknown.[31]

Limitations

The literature is consistent about the lack of available PBM negotiation and rebate data, which makes it difficult to evaluate the impact of any proposed or enacted policy. [31,33,35] Empirical, objective studies do not capture proprietary rebate data that are needed to assess the potential downstream savings to issuers and/or consumers from PBM practices.[33] There are limited data to suggest that rebates may reduce premiums or OOP costs for consumers.[36,37] However, it is unclear whether any enacted policies have resulted in savings for health care systems or consumers or whether these policies improve health outcomes or the quality of care.[36]

More data are needed to understand the critical relationships and directionalities of the supply chain and conduct thorough economic impact evaluations, particularly to predict market behavior. Robust economic impact evaluations will require two critical pieces of data—drug-specific rebate information and contract terms between PBMs and health plans—to effectively evaluate drug pricing, the market,

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[31] Royce, T. J. (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

[32] Schulman, K. A. (2018). The relationship between pharmacy benefit managers (PBMs) and the cost of therapies in the US pharmaceutical market: A policy primer for clinicians. *American Heart Journal, 206*, 113–122. https://doi.org/10.1016/j.ahj

[33] Brot-Goldberg, Z., Che, C., & Handel, B. (2022, April). *Pharmacy benefit managers and vertical relationships in drug supply: State of current research* (NBER Working Paper No. w29959). SSRN. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4092288

[34] Conti, R. F. (2021). Common agent or double agent? Pharmacy benefit managers in the prescription drug market. *SSRN Electronic Journal.* https://doi.org/10.2139/ssrn.3

[35] Seeley, E., & Kesselheim, A. S. (2019). *Pharmacy benefit managers: Practices, controversies, and what lies ahead* [Issue brief]. Commonwealth Fund.

[36] Mattingly, T. J. (2022). State-level policy efforts to regulate pharmacy benefit managers (PBMs). *Research in Social and Administrative Pharmacy, 18*(11), 3995–4002. https://doi.org/10.1016/j.sapharm.2022.07.045

[37] Van Nuys, K. R. (2021). Estimation of the share of net expenditures on insulin captured by US manufacturers, wholesalers, pharmacy benefit managers, pharmacies, and health plans from 2014 to 2018. *JAMA Health Forum, 2*(11), e213409. https://doi.org/10.1001/jamahealthforum.2021.3409

and end user costs. [38] It is not clear from this review whether this proposed mandate's reporting requirements would improve transparency for data required for impact evaluation.

In addition, much of the available data regarding the potential economic impact of policies regulating PBM practices are based on public programs (such as Medicare and Medicaid) and may not reflect the nuances of all commercial plans.[38,39] Some research relies on data that are more than 20 years old, which may not reflect the current cost savings associated with PBM practices or formulary design.[40]

Actuarial Analysis[41]

There was no actuarial analysis conducted for this proposed mandate. This proposed mandate would create new point-of-sale and reporting requirements for PBMs and health carriers, with the goal of reducing OOP costs for beneficiaries. The reduction in point-of-sale costs would be driven by a requirement that PBMs and health carriers must pass on all compensation, rebates, discounts, and credits from drug manufacturers directly to the covered beneficiaries. The lack of reporting requirements and available data precludes any quantitative actuarial analysis.

Fiscal Impact

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

- SEGIP did not provide estimates of the fiscal cost of this legislation for the state.
- There are no defrayal costs assessed by Commerce.
- There is no estimated fiscal impact for public programs.

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 QHP 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 QHP issuers on behalf of the enrollee.

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[38] Seeley, E., & Kesselheim, A. S. (2019). *Pharmacy benefit managers: Practices, controversies, and what lies ahead* [Issue brief]. Commonwealth Fund.

[39] Dusetzina, S. B. (2017). Association of prescription drug price rebates in Medicare Part D with patient out-of-pocket and federal spending. *JAMA Internal Medicine, 177*(8), 1185. https://doi.org/10.1001/jamainternmed

[40] Brot-Goldberg, Z., Che, C., & Handel, B. (2022, April). *Pharmacy benefit managers and vertical relationships in drug supply: State of current research* (NBER Working Paper No. w29959). SSRN. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4092288

[41] 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.

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.[42] States must identify the state-required benefits that are in addition to EHBs, and QHP 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.[43]

Commerce has determined that this bill would not constitute a benefit mandate as defined under the ACA, as it does not relate to any new requirement for specific care, treatment, or services. This bill would provide a new point-of-service rebate to enrollees filling prescription medications. Based on Commerce's precedent for such types of bills, there would be no defrayal requirement associated with passage of this bill.

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.

[42] See 45 CFR §155.170(a)(2).
[43] See 45 CFR §155.170(a)(3) and §155.170(c).

Appendix A. Bill Text

A bill for an act 1.2 relating to health; requiring PBMs and health carriers to use prescription drug rebates and other compensation to benefit covered persons; proposing coding for new law in Minn. Stat. chapter 62W.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: Section 1. [62W.15] RESPONSIBILITY TO USE COMPENSATION FOR BENEFIT OF COVERED PERSONS.

Subdivision 1. Compensation used to reduce point of sale costs. (a) A pharmacy benefit manager or health carrier must remit all compensation received from a drug manufacturer related to its prescription drug benefit directly to the covered person associated with a particular prescription drug, at the point of sale, to reduce the covered person's out-of-pocket cost for that prescription drug. (b) "Compensation" means any direct or indirect financial benefit, including but not limited to rebates, discounts, credits, fees, grants, chargebacks, or other payments or benefits of any kind.

Subd. 2. Report on compliance. Beginning March 1, 2024, and each March 1 thereafter, a pharmacy benefit manager or health carrier shall file with the commissioner a report, in the form and manner specified by the commissioner, demonstrating how the pharmacy benefit manager or health carrier has complied with this section.

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

Appendix B. Key Search Terms for Literature Scan

Drug manufacturers

Formularies

Health insurers

Out-of-pocket prescription drug costs

Outpatient drugs

Pharmacy benefit managers

Pharmacy networks

COMMERCE DEPARTMENT

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