Strategy template:
healthcare_205_establ_Rx_affordabilitycommission

Priority Strategy title: Establish Rx affordability commission

Strategy Catalogue unique identifier(s): 205
Original submitting organization(s)/agency(ies): Minnesota Senate/Sen. Klein
Drafting organization/agency: Minnesota Department of Health
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1. This priority strategy addresses the following aspect of the Commission’s charge (select only the one that represents the best fit):
   - Transform the health and human services system.
   - Increase administrative efficiencies and improve program simplification within health and human services public programs.
   - Identify evidence-based strategies for addressing the significant cost drivers of State spending on health and human services.
   - Reduce waste in administrative and service spending in health and human service
   - Advance health equity across geographies, racial and ethnic groups

2. Please describe the populations impacted by this strategy:
This strategy is intended to benefit all Minnesota commercial purchasers of prescription drugs, including individuals, by establishing upper limits for reimbursements paid to pharmacies for selected drugs, and ultimately across the prescription supply chain serving Minnesota residents.

Depending on the number of drugs considered under this strategy, it has the potential to indirectly affect premiums in Minnesota’s fully insured market and costs faced by self-insured employers.

This strategy is not designed to directly affect Minnesota’s Medical Assistance reimbursements, given that they are regulated by federal law and benefit from existing rebate arrangements. Employer plans subject to the Employee Retirement Income Security Act of 1974 (ERISA) and Part D plans will not bound by the upper reimbursement limits.

3. Problem statement
   a. What is the primary problem this strategy is expected to mitigate or resolve relative to the focus area?
   Amidst high and increasing prescription drug prices, a sizeable group of Minnesotans face high costs associated with prescription drug treatment, which can result in high out of pocket costs for those individuals, increased premiums for all beneficiaries on affected health plans, as well as foregone care and worsened health outcomes. For those that filled prescriptions, approximately 135,000 Minnesotans paid more than $1,000 out of pocket in prescription drug

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1 Modeled after Senator Jensen’s proposed SF353, the Prescription Drug Affordability Act.
pharmacy costs in 2013; and 1,075 commercially insured Minnesotans paid over $5,000 or more out of pocket. Yet, some Minnesotans find they must forego filling a prescription due to cost, which is now at levels observed during the economic recession from ten years ago (9.1 percent in 2017); not filling prescription is associated with worse health and wellbeing. For example, Minnesotans with a chronic condition who did not fill a prescription due to cost reported an average of 4.4 additional mentally unhealthy days per month and 3.9 additional physically unhealthy days than their counterparts who did not report challenges with filling a prescription.  

Establishing upper reimbursement limits for select prescription drugs has the potential to generate savings (over the long term) to individuals using prescription drugs, as well as individuals and employers contributing to health insurance premiums.

b. What is the secondary problem(s) the strategy is expected to mitigate or resolve relative to the focus area and/or other focus areas?

Because of the high and increasing cost of prescription drugs, the share of Minnesotans reporting forgoing a prescription therapy because of cost is substantial. This can have an impact on the health of individuals and the well-being of individuals and families, especially if the foregone care results in the worsening of an underlying condition, lost work and wages, or reduced quality of life.

4. Priority Strategy description
a. What is the strategy?
To establish a Prescription Drug Affordability Commission to:
1. Assess, for certain drugs, whether the wholesale acquisition cost (WAC) would lead to affordability challenges for the state health care system or high out-of-pocket costs for patients.
2. Establish an upper reimbursement limit to apply, as permitted, to all purchases and payer reimbursement for drugs dispensed or administered to individuals in the state through a range of means.
3. Through analysis, identify potential instances of price gouging for referral to the Minnesota Attorney General.
4. Perform certain activities related to ensuring compliance with requirements for upper reimbursement limits.

b. What steps are required to implement the strategy?
Establishing Infrastructure
- Enact enabling legislation;
- Appoint members of the affordability review commission;
- Appoint members of a technical advisory council that would support the technical and analytic activities of the commission;
- Hire staff to support the commission and the operation of its activities, including to work with the technical advisory council;
- Enter into contractual arrangements to access pricing information, establish needed data systems, and acquire needed technical expertise;
- Establish a process for reporting by manufacturers, including timelines, content and data submission requirements, and enforcement; and

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2 MDH Health Economics Program Analysis of the All Payer Claims Database; updated data is not currently available.
3 MDH Health Economics Program analysis of 2013 and 2017 Minnesota Health Access Survey data.
- Enact legislation giving the Attorney General authority to pursue suspected cases of price gouging.

Affordability Review Process
- Analyze available data on WAC, including data submitted by manufacturers to identify drugs meeting the review criteria;
- As authorized, select potentially a subset of all drugs meeting the requirement that the commission believes it is able to conduct a review on with available resources and in a reasonable length of time;
- Conduct public meetings during the review and otherwise seek feedback from the interested public, including patient advocacy organizations;
- Conduct review of selected drugs selected and, as appropriate, establish upper reimbursement limits; and
- Publish findings accessible to all affected entities across the supply chain and interested stakeholders.

Compliance, Enforcement and Ongoing Operations
- Conduct compliance activities related to reporting by manufacturers and adherence to payment limits;
- Report incidents of suspected price gouging to the Attorney General; and
- Report annually to the Legislature and the public on prescription drug price trends, statistics on drug price notifications submitted by manufacturers to the review commission, and any affordability reviews findings.

i. Who will need to take them?
Activities by the commission could be performed by a broad set of actors, depending on factors related to costs, independence, access to price data, and available expertise, including:
- Commission chair, staff, and members;
- Technical advisory council members;
- State agency staff;
- Vendors such as the Institute for Clinical and Economic Review (ICER) with expertise in cost-effectiveness analysis;
- The Minnesota Attorney General (related to enforcement and pursuing price gouging incidents); and
- The Minnesota Legislature.

ii. When will they need to be taken?
The timing of implementation would be tied to legislative effective dates and would, presumably, begin with the designation of a chair to the Commission and the nomination of members.

iii. How long will implementation take?
Similar legislation being debated across the country assumed the establishment of reimbursement limits within approximately two years after the passage of legislation.

iv. What will be the associated systems impacts?
N/A

v. What will be the associated resource requirements?
Resource needs for implementation would be highly dependent on the structure of the commission’s work, how it chooses to execute it (e.g., contracts vs. staff research), how many drugs meet the criteria for review and are selected for review, how many reviews will result in the establishment of upper reimbursement limits, and how rigorous the enforcement of reimbursement limits will be.
vi. What will be the implementation challenges? Does the strategy create an administrative burden or additional costs for the State or for any external stakeholder(s)?

- **Scope and Capacity** – We estimate that possibly 1,000 drugs per year would fall within the purview of the prescription drug affordability commission. Thus, the time and resources needed to perform the evaluation charged to the commission would be substantial, limiting the commission to taking action on only a handful of drugs per year based on clearly defined criteria that would need to be developed by the commission.

- **Litigation** – Evidence from states that have pursued similar or related legislation suggests manufacturers and representatives of their trade group will take vigorous legal actions to challenge any legislation and potentially aspects of implementation. This will require legal support, including from the Attorney General.

- **Compliance and Enforcement** – Although the commission may articulate a reimbursement limit, it is possible that entities in the supply chain may assume they are not bound by it. This presents operational challenges around how the State will assess and be aware of compliance, as well as how the State will approach enforcement.

- **Assignment of Responsibilities** – There is limited public information concerning cost-effectiveness analysis of prescription drugs, which makes it challenging for payers to assess the value of a drug relative to alternative drug therapies or non-drug therapies. While certain third-party entities are beginning to produce cost- and therapeutic effectiveness analyses that could be of use to implementation of this strategy, the commission would need to find ways to conduct this highly complex, technically demanding work, including by assessing the rigor of industry-produced analyses and studies, and considering patient testimony on access, affordability and preferences.

c. How will the strategy mitigate or resolve the primary problem it is addressing?

By limiting reimbursement levels and establishing them consistent with therapeutic values of prescription therapy, individuals would be expected to experience lower costs related to prescription drugs, either directly when paying for a prescription or indirectly via lower overall premiums for coverage that includes prescription benefits. This would be a result of entities across the supply chain complying with state law and doing so because incentives to reimburse in excess of these levels or demanding reimbursements above those levels have been removed from transactions.

d. What are possible unintended consequences this strategy could have?

Past criticisms of approaches like affordability commissions (also referred to as prescription drug affordability boards [PDABs]) have pointed to the potential for reduced access to selected prescription drugs, based on the theory that manufacturers will be reluctant to sell their products in an environment of reduced reimbursement. However, it is implausible that manufacturers will cede the whole Minnesota market because, even at lower reimbursement levels, they will generate revenue that will be above expenses from research and development, production, and marketing.4

5. Expected results and supporting evidence

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a. **What are the expected results, and when will their impact be experienced?**

By reducing reimbursement levels for select drugs consistent with the therapeutic value of a drug, spending by individuals and payers on the drugs subject to these levels will, over time, decline or stabilize. Moreover, recognizing state-level initiatives, manufacturers might have incentives to establish reimbursement levels more consistent with likely outcomes of a review and produce useful public information for cost- and therapeutic effectiveness considerations. The impact will be experienced with the first establishment of an upper reimbursement level; to be felt in substantial ways across prescription drug spending, upper reimbursement levels for a number of drugs would have to be in force.

i. **What is the anticipated fiscal impact to the State in the next biennium (select one)?**

- ☒ New costs
- □ Budget neutral
- □ Cost savings

ii. **If new costs are anticipated, what is the scope of the new costs (select one)?**

- □ Small: $1 to $999,999
- ☒ Medium: $1 million to $9,999,999
- □ Large: Greater than $10 million

iii. **Will any state investment be required?**

Yes, upfront and on-going resources would be needed to effectively implement this strategy as described and generate a meaningful impact on prescription drug cost and resulting spending.

iv. **What will be the programmatic and population impacts?**

Implementation of this strategy will result in lower costs for all Minnesota patients who are not Medicaid beneficiaries or employees of commercial firms governed by ERISA legislation and prescribed one of the drugs for which upper reimbursement limits are established. The strategy has the potential to constrain premium growth related to the use of rising prescription drugs; the process will also create significant increased transparency on the costs and value of selected drugs.

v. **What are the key results of the equity review?**

Does the strategy consider the impact on populations that experience high costs associated with prescription drugs?

How does the strategy reduce institutional and structural barriers?

Establish an equitable mechanism in the development of the commission and in the implementation process

How will the commission reduce inequities and disproportionality that impact populations experiencing poor health outcomes?

Establish equity criteria in the selection of prescription drugs

Further equity considerations:

What could be the equity implications when adapting this strategy to Minnesota’s health and human service system?
Make decisions to prioritize drugs based on usage and necessity for each population group.

b. What evidence supports the strategy’s effectiveness, if any?
   Nationally, it remains too early to assess the impact of state-level action to set upper price limits on selected, high cost prescription drugs. Prescription drug affordability review legislation was passed in Maryland5 and Maine6 in 2019. Internationally, there is substantial evidence that the use of centralized, national reimbursement limits, or centralized negotiation with drug manufacturers, results in lower pharmaceutical prices.7