



Biotechnology Innovation Organization  
1201 New York Ave., NW  
Suite 1300  
Washington, DC, 20005  
202-962-9200

May 9, 2024

Minnesota Department of Health  
Via email to: [health.Rx@state.mn.us](mailto:health.Rx@state.mn.us)

**Re: Drugs of Substantial Public Interest: Draft Methodology for Public Comment**

Dear Minnesota Department of Health:

The Biotechnology Innovation Organization appreciates the opportunity to comment on the Minnesota Department of Health (MDH)'s proposed regulations regarding Drugs of Substantial Public Interest: Draft Methodology for Public Comment as required in statute by the Prescription Drug Price Transparency Act.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO has concerns that MDH's targeting of drugs to be included on the "substantial public interest list" are unclear and misses key contributing factors that shape the supply chain. Without an accurate context of the complexities of supply chain reimbursement dynamics, the substantial public interest list may result in a cache of information that could easily be misinterpreted and misapplied to policies that could hurt, not help patients in the long term. Therefore, we encourage MDH to include additional information in the reporting collected across the supply chain, as detailed in our comments below. BIO also encourages MDH to specify how it will maintain the confidentiality of sensitive information that will be collected by the Department, both information that will be made public and information that will be collected but withheld from public release. Lastly, BIO remains concerned that the requirements for identifying drugs of substantial public interest is overly broad, allowing for subjective anecdotal reporting without proper validation of responses and appropriate context.

**The requirements for identifying drugs of substantial public interest are overly broad and vague. MDH should provide greater detail how the received feedback will be utilized in determining the substantial public interest list.**

MDH states that in designating the substantial public interest list, the commissioner will consider information "relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state" and will consider drugs that are identified by the public and are of a "good fit" for the Act's reporting. These requirements

are extremely arbitrary and ambiguous and are beyond any stakeholder's control. The proposed methodology does not indicate how information will be deemed "relevant" or a "good fit" and how information identified by the public will be used in connection with the substantial public interest list. This could result in MDH being provided with vague feedback on specific drugs without any accompanying details or a background on why the individual is recommending those drugs for the substantial public interest list.

Allowing for public identification of these drugs is also highly subjective in nature. Two patients with the same exact insurance coverage, and copayment levels, may have very different experiences with affordability based upon their individual circumstances. Yet, there is no way of discerning these types of subjective responses and nothing in the draft requirements that would demonstrate how MDH would validate any of the claims reported by an individual. Accordingly, we urge MDH to carefully consider how the feedback received will be given appropriate context and utilized in determining the drugs of substantial public interest list. We request that MDH develop a detailed methodology that describes how MDH intends to evaluate the information received and validate the accuracy, relevance, and completeness of such information, including a description of any limitations associated with the sources utilized, such as what populations are included or excluded.

MDH also states that they may repeat a particular list of drugs over a period of time, with no additional detail as to the reasoning behind such action. BIO requests clarification if MDH intends to ask reporting entities to report on the same set of drugs at a later reporting period, or if MDH intends to repeat the application of the proposed methodology for the substantial public interest list but for different reporting periods.

As MDH continues to develop how these considerations will shape their approach, BIO requests that MDH continue to provide opportunities to comment, with a clear notice and comment period of at least 30 days, particularly if there are substantial changes in the process. We also recommend that manufacturers and other reporting entities have an opportunity to validate data submitted on the substantial public interest list and respond to any public feedback on the list to avoid confusion, disinformation, and/or bias. We also encourage MDH to work closely with manufacturers during the proposed five-step process for analyzing pharmacy claims to ensure current, accurate, and complete information is being utilized when making determinations for inclusion on the final list.

### **Analyzing claims within the state's APCD is not an accurate reflection of supply chain reimbursement dynamics.**

Within the draft methodology, MDH states that it will analyze pharmacy claims in the MN APCD that were incurred in the commercial market together with WAC prices. However, APCDs are not a true reflection of patient OOP costs, as it may not reflect secondary payer information or other concessions the plan may receive that is not adjudicated on a per-claim basis. As HHS itself notes "measures of total drug spending based on the APCD are likely to overstate total prescription drug spending because they do not contain information about manufacturer rebates provided to payers."<sup>1</sup> Additionally, the draft methodology is unclear whether data from other non-commercial payers will be analyzed.

Utilizing claims data also does not reflect current spending trends. APCDs typically report historic data submissions from the prior two years of paid claims. While new claims may be

---

<sup>1</sup> The Office of the Assistant Secretary for Planning and Evaluation (ASPE). "State All Payer Claims Databases: Identifying Challenges and Opportunities for Conducting Patient-Centered Outcomes Research and Multi-State Studies." October 2023.

submitted continuously, there is an inevitable lag in the historic claims that are submitted and reported through the APCD. Accordingly, drugs identified through the APCD would not accurately reflect current spending levels and encompass the continuously evolving dynamics within the supply chain.

**The proposed methodology should include other key contributing factors in the supply chain.**

BIO appreciates MDH's consideration of price increases along the supply chain. However, the supply chain does not always mark-up drugs off the list price as suggested but may also receive significant rebates and discounts offered by manufacturers. Unfortunately, manufacturer rebates are often retained by intermediaries rather than passed down to patients. BIO has long advocated that pharmacy benefit managers and payers should pass through manufacturer rebates at the point of sale to lower patient out-of-pocket costs. As MDH considers supply chain dynamics, BIO encourages the state to assess how PBMs and payers contribute to significant price increases along the supply chain.

Appropriate context, such as patient's level of coverage through their insurance, or lack of insurance, and total out-of-pocket costs, is critical in understanding affordability concerns. Currently, most of the fields on the Public Input Standing Form are listed as optional, therefore stakeholders are likely to not include appropriate context. To accurately depict true patient OOP costs and provide necessary context for the substantial public interest list, BIO recommends that MDH include information regarding formularies, benefits, patient OOP costs, patient utilization/volume, and inflation and/or CPI-U within its proposed methodology. For instance, MDH could create a threshold for a certain number of claims/patients in order to be included in the substantial drug list. This contextual information is necessary to provide a more accurate reflection of systemic drug spending. For instance, a drug with low utilization, as well as a new drug, does not have enough claims to make generalizations about its pricing trajectory.

Additionally, MDH should also seek to identify discounts received by 340B providers, which can greatly lower the acquisition cost and therefore help identify more drugs that are marked up substantially by the supply chain. Hospitals eligible for 340B discounts impose substantial price markups between the reimbursement amount and acquisition price. A study by the New England Journal of Medicine found that price markups at 340B hospitals were 6.59 times as high as those in independent physician practices.<sup>2</sup> It is evident that these price markups have significant implications toward prices through the supply chain and should be accounted for within the proposed methodology.

**The proposed methodology does not provide sufficient safeguards to protect the confidentiality of sensitive information.**

The proposed methodology provides that data collected on drugs of substantial public interest will be made public via dashboards and downloadable files on MDH web pages; individual data elements identified as trade secret or not-public by reporting entities will be withheld from public release.

BIO recommends that MDH's reporting requirements should be based on information in the public domain, and specifically exempt confidential, proprietary, and any trade secret information that could cause financial harm to commercial entities. BIO also requests that

---

<sup>2</sup> Hospital Prices for Physician-Administered Drugs, New England Journal of Medicine, 390, 14, (1347-1348), (2024).

MDH implement a process for the protection of confidential, proprietary, and trade secret related information, particularly when submitted information impacts a multitude of commercial and/or reporting entities. This process should be consistent with the Minnesota Uniform Trade Secrets Act (Chapter 325C of the MN Revised Statutes) and the Federal Defend Trade Secrets Act of 2016 ([18 U.S.C. § 1836](#)). The process should include robust storage and access controls and safeguards to protect the confidentiality of sensitive information collected for the substantial public interest list. Confidentiality requirements are only as meaningful as the data privacy and security protections that are implemented to safeguard sensitive information against inadvertent or malicious improper disclosure.

**The proposal states that the 2022 commercial data will be used to inform the 2024 inaugural list of drugs, however this does not align with the time periods for data submitted by reporting entities.**

BIO requests clarification from MDH regarding potential inconsistencies between time periods for the data submitted by reporting entities and the data utilized to identify drugs of substantial public interest. As listed in the November 2023 "Form and Manner for Prescription Drug Data Sets", reporting entities were required to provide data for the 12-month period prior to the date of notification to report. As such, reported data will be mostly comprised of 2023 data sets. However, in this proposed rule, MDH proposes to develop the inaugural list of drugs using 2022 commercial data. Accordingly, this could create some inconsistencies between the time periods between the data submitted by reporting entities and the data utilized to identify drugs of public interest. We urge MDH not to proceed in publishing the inaugural list until MDH allows for public comment to address this issue and effectively resolve all timing inconsistencies.

**Considering whole drug product families may create confusion and arbitrary reporting.**

BIO requests that MDH reconsider the use of drug product families, as this will create confusion across manufacturer reporting and could result in arbitrary reporting. A manufacturer may be impacted by the pricing or other decisions of another manufacturer whose product may be grouped in the same drug product family. In addition, the proposed methodology of selecting drugs by family rather than individually could potentially cause certain drugs to be included on the substantial public interest list despite not meeting the statutory inclusion criteria under Minn. Stat. § 62J.84 Subd. 10.

\*\*\*

BIO appreciates the opportunity to provide feedback to MDH through this proposed methodology. We look forward to continuing to work with MDH to ensure that Minnesotans can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

/s/

Jack Geisser  
Senior Director,  
Healthcare Policy,  
Medicaid, and State Initiatives

/s/

Melody Calkins  
Senior Manager  
Healthcare Policy and Reimbursement