March 7, 2025

Senator Alice Mann
95 University Avenue W.
Minnesota Senate Bldg.
Room 3225
St. Paul, MN 55155

Dear Senator Mann,

The Association for Accessible Medicines (AAM) and its Biosimilars Council are writing to express concerns regarding Senate File 1876. While we appreciate the intent to improve drug affordability and access, we believe certain provisions could unintentionally disrupt well-functioning aspects of the current drug market. Given the complexities of drug coverage and distribution, we respectfully request you consider the following suggestions as the bill progresses.

AAM represents manufacturers of finished generic pharmaceuticals and biosimilars, manufacturers of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. AAM is committed to ensuring access to safe, quality, and effective medicines. The Biosimilars Council is a leading resource for information on biosimilars, which offer more affordable alternatives to brand-name biologic medicines.

Recommendation: Delete lines 2.14 and 2.20 from Subd. 2, which state, "(2) the wholesale acquisition cost of any other equivalent generic drug."

These provisions require a pharmacy benefit manager (PBM) or health carrier to include in its drug formulary the brand or any equivalent generic drug with the lowest wholesale acquisition cost (WAC). To comply with Subd. 2 (a)(2) and (b)(2) a comparison between the WAC price of competing generic drugs would have to be conducted by the PBM or health carrier. This requirement will not increase patient savings or increase access to lower-cost drugs as intended.

Generic payment rates are effectively managed through Maximum Allowable Cost (MAC) pricing. PBMs and health carriers set MAC prices to reimburse pharmacies for dispensing generic drugs, regardless of the manufacturer. Pharmacies are allowed to select the product, typically based on the lowest available cost, from any manufacturer or distributor. This system fosters competition among generic manufacturers, driving prices down to the benefit of patients. Requiring WAC comparisons would add an unnecessary layer of complexity without a clear benefit.

Recommendation: On line 3.4, delete "or generic drug with the lowest wholesale acquisition cost".

The same concerns stemming from Subd. 2. are contained in this provision. The requirement that a new version of a generic drug be compared with a version already on formulary is unnecessary. The formulary designed by the PBM or health carrier will cover any generic version of the equivalent brand drug regardless of which manufacturer produces it. The new and existing versions of the generic drug compete for market share, which is typically determined by the lowest available cost. This competition results in the deflation of generic drug prices to the benefit of patients.

Recommendation: Delete the first sentence in Subd. 4 (a) and Subd. 4 (b) starting on lines 3.14 and 3.23.

These similar provisions require a PBM or health carrier to structure its formulary to give preference to the generic or biosimilar drug or its reference brand drug with the lowest out-of-pocket (OOP) cost to the patient. This does not consider that variability in patient costs are determined by the coverage or plan design, not manufacturer price. The OOP is not determined until a drug product is added to a formulary and which tier the product is placed.

Recommendation: Substitute language in Subd. 4 (a) and (b) limitations on the use of utilization management tools.

Currently, the bill would prohibit the use of prior authorization or step therapy on the drug product with the lowest WAC price. AAM suggests this be changed to prohibit utilization management tools being used on any drug product with a lower WAC than the brand reference product. This will grant pharmacies and others within the supply chain to select appropriate drug products that present a lower cost for patients.

Additional areas of concern: Subd. 2 (c), (d) and Subd. 3 (b) require further study.

The provisions in Subd. 2 (c) and (d) require additional consideration due to differences in the sale and distribution between small molecule and biologic drugs. AAM is currently engaging our members and hope to have additional recommendations as the bill moves through the legislative process. However, AAM suggests you consider requiring "at least one" biosimilar with a lower WAC price than the reference brand drug be preferred on the formulary. WAC prices are transitory and may be changed more often than the formulary they are placed on.

Similar concerns are raised with Subd. 3 (b). Though the marketplace for biologics and biosimilars do not follow the same MAC process for distribution, requiring the lowest priced biosimilar or its reference product that becomes available will cause inconsistent changes to a formulary. The WAC price for a biosimilar can change rapidly to react to competition in the marketplace. Biosimilars and their reference brand biologic drugs are more often utilized at a health care facility than dispensed directly to a patient at a pharmacy counter. Prescribers must write each prescription for a particular biosimilar so having a formulary change every time a WAC is adjusted lower will cause unnecessary confusion.

In conclusion, AAM believes these recommendations will help ensure that Senate File 1876 achieves its goals without unintended consequences for the generic and biosimilar drug markets. AAM looks forward to working with you on this important issue as it moves through the legislative process, and we appreciate you considering our perspective. Please contact me at brett.michelin@accessiblemeds.org should you have any questions regarding these recommendations or additional concerns raised in this letter.

Sincerely,

Brett Michelin
Senior Director, State Government Affairs