March 24, 2025

Chair Melissa Wiklund
95 University Avenue W.
Minnesota Senate Bldg., Room 2107
St. Paul, MN 55155

Dear Chair Wiklund:

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 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 allow 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

Brett Michelin
Senior Director, State Government Affairs
Association for Accessible Medicines