November 3, 2022

Minnesota Department of Commerce
Insurance Division
85 7th Place East, Suite
(Submitted electronically to andrew.kleinendorst@state.mn.us)

Re: Mandated Health Benefit Proposal Evaluations, Public Comment Period
SF 990 – Mandating coverage of multiple biologic products (OPPOSE)
HF 4899 – Mandating coverage for biomarker testing (SUPPORT)

Dear Mr. Kleinendorst,

On behalf of the Alliance for Safe Biologic Medicines (ASBM), we are writing to offer comment on two mandated health benefit bills under consideration by the Department of Commerce.

ASBM is an organization of diverse healthcare stakeholders representing patients, physicians, pharmacists, manufacturers of both originator and biosimilar products, researchers, and others working together to ensure patient safety is at the forefront of biosimilars policy discussions. ASBM believes in promoting the use of biosimilars with the goal of offering new therapeutic options and reducing healthcare costs for patients.

SF 990 – Mandating coverage of multiple biologic products (OPPOSE)

It is our view that HF 1516/SF 990 while intended to promote competition and lower prices, may result in unintended negative consequences- such as actually increasing, rather than lowering, drug costs for Minnesota patients.

For example, In Subd. 2; section (b) the bill language states:

> (b) If a pharmacy benefit manager or health carrier elects coverage of a product listed in paragraph (a), clauses (1) to (3), it must also elect equivalent coverage for all of the products listed in paragraph (a), clauses (1) to (3).

Clauses (1) to (3) refer to reference products, biosimilars, and interchangeable biosimilars, respectively.

Under current law, manufacturers must compete on net price to win a preferred formulary spot. This is accomplished through negotiated discounts, rebates, and other price concessions that often bring the net cost down far below the "list price" or Wholesale Acquisition Cost (WAC). This bill would remove these incentives for manufacturers to compete on net cost.

In effect, this bill requires a pharmacy benefit manager or health carrier that covers ANY biologic product in a given class, to reimburse ALL products in that class, regardless of its actual cost to the payer. The availability of biosimilars currently places downward pressure on net prices by forcing reference product manufacturers to discount their products heavily in order to compete. By requiring health plans to cover all approved products in a class (regardless of net cost), *it effectively creates an incentive for all manufacturers to raise their prices.*

We believe that this bill will place upward rather than downward pressure on prices overall and result in increasing patient costs over time as these costs are inevitably passed on to patients.
The bill's directive (Sec. 4) that the Commissioner of Health monitor and report on its effects on net costs at the end of 2023 is a tacit acknowledgement that such unintended effects on net expenditures are anticipated.

Prior to advancing any legislation, we have repeatedly urged the legislature to further study this important issue, including how these potential changes to Minnesota Statutes chapter 62W may result in increasing costs to both healthcare payers and patients, and to work with various stakeholders such as ASBM to promote policies that advance innovation while reducing overall treatment costs.

While we strongly support legislation that is written with the goal of realizing cost savings through competition between multiple biologic products, we believe that HF 1516/SF 990 undermines this objective by removing current incentives to compete on price and will ultimately reduce rather than promote affordability of biologics. **For this reason, we strongly urge the Department of Commerce to oppose SF 990.**

HF 4899 – Mandating coverage for biomarker testing (SUPPORT)

ASBM supports HF 4899, which would require health insurers in Minnesota to increase patient access to biomarker testing. Patients with serious and chronic conditions such as cancer or rheumatoid arthritis, must often try multiple treatments before finding the one that works best for them. Biomarker testing helps ensure that patients receive the right treatment for them in a timely manner.

For example, precision medicine is dramatically improving cancer outcomes by using information about a person's own genes or proteins (biomarkers) to prevent, diagnose, or treat disease. When used in the treatment of cancer, precision medicine incorporates specific information about a person's cancer to inform diagnosis, prognosis, therapy selection, and to monitor how well therapy is working.

Advances in biomarker testing and cancer treatments now allow for targeted cancer therapies that can improve patient survival and quality of life. Testing patients for specific biomarkers is integral to precision medicine in cancer care, but despite evidence pointing to the benefits, testing rates lag behind clinical guideline recommendations. Research shows that there are socioeconomic inequalities in biomarker testing and targeted therapy utilization across cancer types.

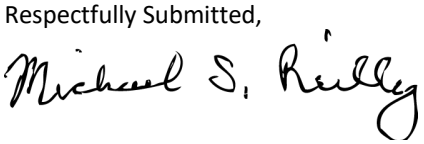
- 60% of oncology drugs launched in the past 5 years require or recommend biomarker testing prior to use.
- 66% of oncology providers reported that insurance coverage is a significant or moderate barrier to appropriate biomarker testing for their patients.
- Many underserved communities are not benefitting from the latest advancements in biomarker testing: patients who are older, Black, uninsured, or Medicaid-insured are less likely to be tested for guideline-indicated biomarkers. Without action, this could increase existing disparities in cancer outcomes by race, ethnicity, income, and geography.

The benefits of biomarker testing are not limited to cancer. Biomarker tests are now becoming available which are relevant to the fields of rheumatology, gastroenterology, and other areas. These include a biomarker test which can determine whether or not a patient is among the significant portion of patients (estimates range between 40%-67%) that do not respond to TNF inhibitors, commonly used to treat rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and other conditions. A biomarker test can help avoid the lost time, worsened health, and unnecessary costs associated with the trial-and-error approach of using first-line biologic or biosimilars unlikely to help a particular patient.

But health care coverage for biomarker testing too often fails to keep pace with these scientific advancements. HF 4899 will work to remedy this by requiring health plans in Minnesota to cover biomarker testing when supported by medical and scientific evidence, including nationally-recognized clinical practice guidelines and FDA approval.

Timely access to appropriate biomarker testing helps achieve better health outcomes, improves quality of life for patients, and reduces costs to our health system. **For these reasons, we strongly urge the Department of Commerce to support HF4899.**

Respectfully Submitted,



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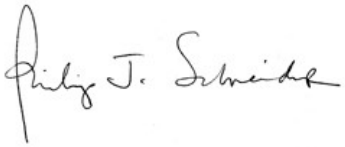

Philip J. Schneider, MS, FASHP
Advisory Board Chair, Alliance for Safe Biologic Medicines

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