Talking Points on the Biomarker Testing Bills - HB1074/SB689

The biomarker testing bills, as currently written, will significantly increase health care costs and premiums, affecting both consumers and employers and further present significant challenges across the system, including financial strain, administrative complexity, and the risk of coverage gaps and disparities.

While biomarker testing holds promise for improving diagnosis and treatment in certain cases, these bills may not represent the most effective or efficient approach to promote the ongoing inclusion of clinically beneficial biomarker testing into coverage.

- **Background and Lack of Specificity:**
  - These bills exhibit a broad and vague definition of biomarker testing without specifying which biomarker tests are necessary or appropriate. Biomarker testing is an evolving medical area with an estimate of more than 175000 tests.[1]
  - Biomarker tests are in different stages of development. Some tests are and will be more useful in changing clinical outcomes than others. Considering all biomarker testing as equal in quality and efficacy will increase health costs without clear benefits for patients.

- **Quality and Safety**
  - Laboratory standards: These bills do not include standards for laboratories that produce biomarkers. Laboratory standards addressing validity and reliability of testing must be included in any legislation associated with biomarker tests to ensure that patients receive accurate and reliable information. Acting on inaccurate testing results will potentially lead to poor clinical outcomes. Acting on inaccurate testing information will in a best-case scenario lead to increased medical costs without corresponding health improvement. At the federal level, the Food and Drug Administration (FDA) has finalized regulations to oversee laboratory-developed tests, over concerns about reliability and patient safety.

- **Efficacy**
  - The FDA does not consider the ability of tests to improve clinical outcomes when it issues the approval of a biomarker test. The FDA does not compare a new biomarker test to existing methods of diagnosis/treatment to determine if a new test is more reliable or efficacious or of equal quality to existing methodology. CMS coverage determinations do not equate to clinical efficacy as local determinations often vary. Consensus statements are opinion not medical fact based.
  - Approving coverage of biomarker tests based only on FDA approval, CMS coverage and/or clinical guidelines/consensus statements will lead to unnecessary, expensive. and potentially harmful medical care. The ACA requires coverage of biomarker testing that currently meets the highest standards of medical evidence.

[1] Concert Genetics assigns a code for every genetic testing product on the market (called a Genetic Testing Unit, or GTU). This does not include all biomarker tests but just the genetic ones. Their most recent estimate is that there are over 175,000 genetic testing products currently on the market. Concert. GTU Test Identifier. www.concert.co/gtu-test-identifier.

- **Cost Impact and Feasibility:** The CHIA review of these bills concluded that mandating coverage for biomarker testing by fully insured health plans would lead to a notable financial impact resulting up to $35 million annually and the five-year total expenditure could surpass $168 million.
    - The CHIA MBR review considered analysis 1300 procedure codes for their cost analysis concluding a high price tag of $35 million annually. Additionally, the cost estimate did not incorporate any potential administrative impacts associated with the bill's requirement for shortened prior authorization time frames
    - Such a substantial cost increase may not be justified given the uncertainty surrounding the efficacy of many biomarker tests and the limited clinical evidence available for their use.
    - Lack of specificity in the bill could lead to unnecessary testing, potentially driving up healthcare costs without clear benefits to patients.
- **Administrative Challenges:**
    - Many biomarker tests currently do not have specific codes, many are billed with nonspecific codes or codes with require manual claims intervention which is costly. Non-Specific coding requires medical record documentation to support medical necessity. The medical knowledge needed to interpret the clinical value of biomarkers for individual patients requires highly specialized clinical knowledge. Many commercial insurance carriers rely on vendors with clinical expertise in laboratory standards, biomarker testing and clinical interpretation for assistance. Medicaid plans and state systems are not currently equipped to handle the coding issues associated with coverage of all biomarker testing, potentially leading to coverage gaps and disparities in access to biomarker testing, particularly for underrepresented minorities which further hampers the intent of the bill.
    - These bills will not have the ability to impact Medicare coverage or self-insured plans. Requiring lower standards for biomarker coverage for the fully insured commercial market will lead to further administrative fragmentation of the marketplace and increased costs for small employers and consumers.
    - Timing of prior authorization: Biomarker tests are not emergency medical care. At their best, the results for biomarker tests supply additional information to inform clinical decision making. They are not a substitute for clinical decision making. Requiring biomarker tests to adhere to the same rapid approval timelines as emergency care may not be appropriate or necessary given their non-urgent nature.

- **Equity and Effectiveness:** A recent JAMA article highlights that state biomarker testing laws have shown limited efficacy in addressing disparities in care, particularly among communities most susceptible to such inequities. Furthermore, laws primarily focused on insurance coverage fail to address underlying causes of healthcare inequities, such as social determinants of health, potential biases among healthcare providers in offering testing, or the financial accessibility of testing.[2] While it is acknowledged that health plans under the Affordable Care Act (ACA) cover preventative screenings and tests for their members with zero copays, it's crucial to note that even with zero copay tests, disparities persist in testing rates among minority populations.

[2] Lin GA, Coffman JM, Phillips KA. The State of State Biomarker Testing Insurance Coverage Laws. *JAMA.* Published online May 13, 2024. doi:10.1001/jama.2024.6058