



**BlueCross BlueShield  
Association**

An Association of Independent  
Blue Cross and Blue Shield Plans

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Assemblywoman Pamela Hunter  
711 East Genesee Street, 2nd Floor  
Syracuse, NY 13210-1540

Submitted electronically to William Melofchik ([wmelochik@ncoil.org](mailto:wmelochik@ncoil.org)).

**RE: Biomarker Testing Insurance Coverage Model Act Draft**

Dear Assemblywoman Hunter:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on the October 18, 2022, NCOIL draft model, the *Biomarker Testing Insurance Coverage Model Act* (“Model Act”).

BCBSA is a national federation of 34 independent, community-based and locally operated Blue Cross and Blue Shield companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

BCBSA embraces the promise of precision medicine as a key driver for optimal health and recognizes it as essential in shaping the future of health care. While we understand and support the drive to increase patient access to biomarker tests, we feel that the adoption of a model mandating coverage for such tests is unnecessary and inappropriate at this time.

Health plans cover biomarker tests after review of reliable scientific evidence and demonstration of clinical benefit from the results. When new, high-quality evidence is published demonstrating the clinical benefit of biomarker tests, health plans approve coverage policies accordingly. Timely updating is a routine part of Plans’ medical coverage policy process. For example, coverage of liquid biopsy testing (circulating tumor DNA testing) was expanded to include additional biomarkers and additional patient populations based on new scientific evidence.

We have specific concerns with the “medical and scientific evidence” standards used for coverage requirements as outlined in the Model Act.

- **Health Insurer and Medicaid Coverage Requirements:** The Model Act requires health insurers and Medicaid programs to cover biomarker testing when the test is “supported by medical and scientific evidence, including, but not limited to” the standards outlined below.

**Comment:** The term “supported by” can be loosely applied and broadly interpreted. If this Model Act is to be adopted, we recommend replacing “supported by” with “provides clinical utility as demonstrated by”. Additionally, the medical and scientific evidence standards should be fully defined to ensure specific requirements are met. Therefore, we recommend striking “but not limited to” before outlining the definition of “medical and scientific evidence”.

- **Sec. 3(a)(1): “labeled indications for a test approved or cleared by the Food and Drug Administration (FDA) or indicated tests for an FDA approved drug.”**

**Comment:** Plans routinely provide coverage for tests indicated for an FDA approved drug such as a companion diagnostic. However, most biomarker tests are laboratory developed tests, which are not regulated by the FDA. While laboratory processes are regulated by Clinical Laboratory Improvement Amendments (CLIA), there is no oversight regarding whether tests are diagnostically accurate or clinically useful.

- **Sec. 3(a)(2): “Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations.”**

**Comment:** MACs often lack rigorous evaluative capabilities. Further, local coverage determinations (LCDs) do not uniformly evaluate clinical evidence and result in coverage variance for similar items across states. The Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued a report titled [Local Coverage Determinations Create Inconsistency in Medicare Coverage](#), which found: (1) that presence of these LCDs was unrelated to the cost and utilization of items and service, (2) LCDs limited coverage for these items and services differently across States, and (3) LCDs defined similar clinical topics inconsistently.

- **Sec. 3(a)(3): “Nationally recognized clinical practice guidelines and consensus statements.”**

**Comment:** Clinical practice guidelines should be understood to meet the medical and scientific evidence threshold if they rely on systematic reviews that assess the available scientific studies in a prescribed fashion to minimize bias. This would permit conclusions as to whether a technology can lead to appropriate provision of medical care. However, consensus guidelines are opinion and are not informed by systematic reviews or reference to scientific studies in national peer-reviewed journals. We recommend removing consensus guidelines from the defined set of medical and scientific evidence standards that would trigger a coverage requirement under the Model Act.

In their report, [Clinical Practice Guidelines We Can Trust](#), the National Academy of Sciences discusses the recommended attributes of clinical practice guidelines (directly quoted below):

- “be based on a systematic review of the existing evidence;
- be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- consider important patient subgroups and patient preferences, as appropriate;
- be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations; and
- be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.”

This definition provides a clear distinction between the term “CPG” and other forms of clinical guidance derived from widely disparate development processes (e.g., consensus statements, expert advice, and appropriate use criteria). In sum, consensus statements do not necessarily meet these evidentiary thresholds and therefore should not be considered as meeting the “medical and scientific evidence” standards that would trigger a coverage mandate under the Model Act.

If implemented, the Model Act would significantly increase costs for health plans and state Medicaid programs. Ohio’s Legislative Budget Office (LBO) estimated the financial impact of a similar biomarker testing coverage bill, H.B. 608. In a [Fiscal Note & Local Impact Statement for H.B. 608](#), the LBO estimated that the costs to the state of such a bill could be roughly \$756,000 per year, costs to school districts could be roughly \$2.8 million per year, and the cost to other local governments could be roughly \$2.2 million per year.

Additionally, the Model Act would expose patients to financial hardship caused by unproven testing and resulting treatments. When patients receive tests for which the accuracy, risks, and benefits are unknown, it often leads to inappropriate downstream tests and treatments and initiates a chain of medical decisions. When the utility of the initial testing is not known, the chances of patients subsequently receiving the wrong medical care increases, including unnecessary follow-up tests, surgeries and ineffective medications. The costs of unvalidated biomarker testing mandates include not only the test itself, but also costs of the full cascade of follow-up care and its impact on patient morbidity and mortality. Finally, coverage mandates also can increase costs for patients, health plans, and state Medicaid programs by removing incentives for labs and test manufacturers to negotiate reasonable pricing.

For these reasons, BCBSA does not support the NCOIL draft Model Act and encourages NCOIL not to adopt it.

Thank you for your consideration of our comments. If you have any questions or need additional information, please contact Randi Chapman at [Randi.Chapman@bcbsa.com](mailto:Randi.Chapman@bcbsa.com).

Sincerely,

A handwritten signature in black ink that reads "Clay S. McClure". The signature is written in a cursive, flowing style.

Clay S. McClure  
Executive Director, State Affairs  
Blue Cross Blue Shield Association