HINMAN STRAUB PC
ATTORNEYS AT LAW

121 State Street
Albany, New York 12207-1693
Tel: 518-436-0751
Fax: 518-436-4751

June 6, 2023

RE: AN ACT to amend the insurance law and the social services law, in relation to requiring health insurance policies and Medicaid to cover biomarker testing for certain purposes.

S.1196-A (Persaud)
A.1673-A (Hunter)

MEMORANDUM IN OPPOSITION

Submitted on behalf of the Blue Cross and Blue Shield Plans

The New York State Conference of Blue Cross and Blue Shield Plans strongly opposes enactment of this bill, which would: (1) require health insurance and Medicaid coverage of biomarker testing, even when a less expensive and equally effective test is available; (2) establish a vague and overly broad standard for determining coverage requirements which, in light of the rapidly evolving science of biomarker testing, would be virtually impossible to comply with; and (3) impose significant costs to the State through requiring Medicaid coverage of biomarker testing and by establishing a new coverage mandate on qualified health plans ("QHPs"), which would have to be paid for by the State of New York. .

Specifically, this bill would require all health insurance plans and the Medicaid program to provide coverage for biomarker testing – "includ[ing] but [] not limited to single-analyte tests and multi-plex panel tests" – "for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition…"

I. This Bill Requires Coverage of Tests that Lack Clinical Utility, and Those for Which a Significantly Less Expensive Alternative is Available

When utilized appropriately, biomarker testing can be a vital clinical management tool. Practitioners may use such companion diagnostic ("CDx") tests to determine whether a particular (often biologic) therapy will benefit a patient's specific condition, and frequently rely on these assessments to identify the appropriate course of oncology treatments for cancer patients. As a result, health insurance plans routinely provide coverage of a diverse array of biomarker tests for which there is peer reviewed and scientifically established clinical utility. In fact, a study

commissioned by the American Cancer Society Cancer Action Network and LUNGevity Foundation found that "[t]he addition of new companion diagnostics is generally acted upon promptly by payers."[1]

However, as the report noted, "[t]he one exception is the very inconsistent coverage of FoundationOne CDx (F1CDx) across payers… the inclusion of multiple biomarkers in this panel that do not have established clinical utility continues to be a challenge." Unlike the biomarker tests covered by plans – which often rely on National Comprehensive Cancer Network ("NCCN") guidelines to identify tests that provide actionable results and improve patient care – F1CDx analyzes 324 genes, but is only approved for approximately 20 therapies.[2] Despite its limited clinical utility, the breadth of F1CDx is costly, nearly 3.5 times the average price of biomarker tests in general.[3] Nonetheless, as the F1CDx could satisfy the bill's requirement regarding "clinical utility" (i.e. "the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision"), coverage could be mandated under this legislation.

Further, by requiring that coverage of biomarker testing must "limit disruptions in care including the need for multiple biopsies or biospecimen samples," this bill would encourage use of such unnecessarily expensive CDxs. For example, an oncologist deciding whether to treat a breast cancer patient with Herceptin (trastuzumab) may select from a dozen biomarker tests cleared or approved by the U.S. Food and Drug Administration ("FDA") as a CDx for that course of treatment including. One such CDx, the automated INFORM HER2 Dual ISH DNA Probe Cocktail, can provide overnight results for $225.[4] However, if this bill were enacted, plans could be forced to cover the F1CDx test for 25 times the cost – the price of which would ultimately be borne by enrollees, as premiums increased to address the additional expenses.

II. <u>This Bill Establishes a Vague Standard for Coverage Requirements that is Impossible to Adhere to</u>

As the science of biomarker testing is constantly evolving, plans continuously undertake evidentiary assessments to determine clinical utility and resultant coverage standards. However, this bill would entirely undermine this critical process – as well as reliance on established clinical

---

[1] ADVI, "Payer Coverage Policies of Tumor Biomarker Testing," Commissioned By: American Cancer Society Cancer Action Network and LUNGevity Foundation, September 2020, *available at* https://www.fightcancer.org/sites/default/files/ACS%20CAN%20and%20LUNGevity_Payer%20Coverage%20Policies%20of%20Tumor%20Biomarker%20Testing.pdf.

[2] *Id.*

[3] Foundation Medicine, "Patient Information Guide," *available at* https://assets.ctfassets.net/vhribv12lmne/5BJHWaCe1Gwu8CaksomGS8/8169541f7d6a0ad110bcc0f228fbbe41/Patient_Information_Guide.pdf; *and* National Conference of State Legislators, "Biomarkers and Advancements in Cancer Care," December 21, 2021, *available at* https://www.ncsl.org/research/health/biomarkers-and-advancements-in-cancer-care.aspx.

[4] U.S. Food and Drug Administration, "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)," *available at* https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools; *and* Bob Carlson, MHA, "New Automated HER2 Test Promises Faster, More Accurate Testing," Biotechnol Healthc. 2011 Winter; 8(4): 32–33, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278128/#:~:text=Emch%20estimates%20the%20average%20list,(CPT%2088367%20and%2088368).

standards, such as NCCN guidelines – and instead require coverage of tests including, but not limited to, those supported by: (1) FDA approval, clearance or indication; (2) Centers for Medicare and Medicaid ("CMS") national coverage determinations; (3) Medicare administrative contractor local coverage determinations; and (4) "nationally recognized clinical practice guidelines" developed by independent organizations or medical professional societies. This would create a potentially limitless source of authorized resources, irrespective of the national acceptance or scientific credibility of such resource, which would be virtually impossible to catalogue. For example, the American Medical Association alone lists more than 125 national medical societies – which does not include state and local counterparts, or any (undefined) "independent organizations."

III. <u>This Bill Would Result in Enormous, Yet Undefined Costs to the State</u>

The Sponsor's Memorandum addresses this proposal's Fiscal Implications as: "Any cost of enacting this legislation is far overshadowed by ensuring that the course of treatment used in treating an individual patient's cancer is the most effective and cost-effective treatment." The above-discussed concerns regarding the limited clinical utility of unmitigated biomarker testing aside, due to its application to the State's Medicaid program, this bill would result in significant – yet undisclosed – costs related to coverage and administration. Further, pursuant to the Affordable Care Act ("ACA"), a state must "defray the cost" of any new coverage mandates on a QHP.[5] Therefore, New York would be liable for all costs incurred by a QHP providing coverage on the State's Health Exchange that are attributable to this bill.

For the foregoing reasons, the New York State Conference of Blue Cross and Blue Shield Plans urge that this bill not be enacted.

Respectfully submitted,

HINMAN STRAUB ADVISORS, LLC.
Legislative Counsel for the Blue Cross and Blue Shield Plans of New York

4853-9544-9099, v. 1

[5] 45 C.F.R. §155.170.