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May 11, 2023

Will Melofchik NCOIL General Counsel 616 5<sup>th</sup> Avenue, Uni 106 Belmar, New Jersey 07719

Delivered via email: wmelofchik@ncoil.org

RE: NCOIL draft Biomarker Testing Insurance Coverage Model Act

Dear Will:

AHIP<sup>1</sup> appreciates the opportunity to provide comments on the October 18, 2022, NCOIL draft model, the *Biomarker Testing Insurance Coverage Model Act* ("draft Model Act").

In October 2022, NCOIL released a draft Model Act for consideration. The draft Model Act requires employers, employees, state Medicaid programs, and taxpayers ("purchasers of health care insurance coverage) to purchase biomarker testing that may not be clinically valid and provide clinical utility.

The draft Model requires purchasers of health care insurance coverage to pay for biomarker testing when the testing is "*supported by medical and scientific evidence*," which is defined to mean that the test is FDA approved, developed to inform pursuant to an FDA-approved drug, is covered by Medicare, **or** is supported by a national provider group or multi-stakeholder group. This means that the test does what it says it will do, but it does not mean that the test provides actionable information – to inform and improve treatment.

Beginning in July 2022, NOCIL members heard testimony from stakeholders on biomarker testing. Key take aways from that testimony include:

1. Legislation to mandate biomarker testing coverage is unnecessary as health insurance providers already do offer, and purchasers of health insurance coverage, including employers and states, are already purchasing biomarker testing coverage when such testing is clinically valid and provides clinical utility.

"[CA] Enrollees generally have coverage for biomarker testing that is supported by medical and scientific evidence and is determined medically necessary."<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit <u>www.ahip.org</u> to learn how working together, we are Guiding Greater Health.

<sup>&</sup>lt;sup>2</sup> https://33afce.p3cdn2.secureserver.net/wp-content/uploads/2023/03/SB-912 CHBRP Citron.pdf

The California Health Benefits Review Program reviewed a California Senate Bill (Senate Bill 912, which was similar to the NCOIL model) and found "[u]nder existing law, plans and policies are required to cover medically necessary diagnostic lab services and ongoing disease management services. Additionally, biomarker testing is broadly covered by California's EHB benchmark plan. "Broadly speaking, all enrollees with health insurance subject to [a proposed mandate in California] have coverage for biomarker testing that is supported by medical and scientific evidence and is determined medically necessary."<sup>3</sup>

Governor Newsom reiterated these concerns when he vetoed the bill: "While I appreciate the author's efforts to provide biomarker testing coverage, these services are already covered by Medi-Cal.<sup>4</sup>

"[w]hen biomarker tests are useful, and that is, when they provide accurate and actionable information for patients and providers, those tests are already covered. They may be covered due to existing law such as the ACA's EHB requirements or they may be covered under ERISA plans because they are medically necessary, they provide clinically useful information, and that information leads to better and more efficient care. Both employers and health insurers want better and more efficient care."<sup>5</sup>

2. Employers and public purchasers of health care, including your states' Medicaid programs, are concerned about the rising cost of health care and health insurance coverage. Broad coverage mandates, such as the draft Model Act, can be expensive and could lead to unnecessary care and additional costs for employers and employees.

"Let's talk for a minute about those costs and the cost of health insurance which stems directly from the higher cost of healthcare that is delivered. Those costs continue to grow. They've devoured the wages of working families putting more pressure on both workers and employers."<sup>6</sup>

"On the specific subject of mandating coverage for biomarker testing, ERIC believes that this mandate would likely increase costs, would drive waste in the healthcare system, and would further enrich the medical industrial complex without really benefiting patients."<sup>7</sup>

- <sup>5</sup> <u>https://33afce.p3cdn2.secureserver.net/wp-content/uploads/2023/02/NOLA-Health-Cmte-Minutes-11-17-22.pdf</u>
- <sup>6</sup> https://33afce.p3cdn2.secureserver.net/wp-content/uploads/2023/02/NOLA-Health-Cmte-Minutes-11-17-22.pdf

<sup>&</sup>lt;sup>3</sup> <u>http://analyses.chbrp.com/document/view.php?id=1668</u>

<sup>&</sup>lt;sup>4</sup> <u>https://www.gov.ca.gov/wp-content/uploads/2022/09/SB-912-VETO.pdf?emrc=49097a</u>

<sup>&</sup>lt;sup>77</sup> <u>https://33afce.p3cdn2.secureserver.net/wp-content/uploads/2023/02/NOLA-Health-Cmte-Minutes-11-17-22.pdf</u>

"..the Model proposed would broadly require insurance to cover biomarker testing when the testing is supported by medical and scientific evidence which is defined to mean that the test is FDA-approved, developed to inform pursuit into an FDA- approved drug, is covered by Medicare or supported by a national provider group or multistakeholder group. Basically, this means that the test works. It doesn't mean that the test is actually useful."<sup>8</sup>

"The CA analysis projected that if the mandate was enacted [which was similar to the draft Model Act] the primary change would be the test will be conducted more often when they weren't really called for. They described this as test use for screening purposes rather than tests that would be due to indications and lead the clinical responses. They projected that the use of biomarker testing would increase at about a \$1,000 a pop but that it wouldn't likely improve health. Reading between the lines they anticipated that providers would start ordering more of these tests in order to obtain information that wasn't actually useful or actionable."<sup>9</sup>

"And I can't imagine mandating that insurance pay for those tests which would result in many more of those tests being delivered especially knowing how it might affect patients. Employers don't support mandates for this kind of reason. If a treatment service or product is going to improve health and especially if it's going to bring value by improving health and lowering cost of course we want to cover it but broad mandates often don't distinguish and recommendations from a provider group or a consensus group don't necessarily meet these objectives nor does attest mean FDA-approved."<sup>10</sup>

"Mandates could lead to waste in the healthcare system and when we waste money on one treatment that money is no longer available to spend on useful and needed treatment for this particular patient or for others."<sup>11</sup>

As the purchaser of Medicaid health care coverage, Governor Newsom reiterated, when he vetoed SB 912, stated: "...biomarker testing is valuable when it can inform a condition's diagnosis and treatment, but this bill would require Medi-Cal to cover unnecessary testing that may not inform the best treatment to care for the beneficiary. This bill would establish broad and contradictory coverage requirements that go beyond the Department's evidence-based policies, which would unnecessarily increase costs without increasing the quality of coverage. I believe the Department should retain its current flexibility to establish evidence-based policies in light of the dynamic and changing nature of medicine.<sup>12</sup>

<sup>&</sup>lt;sup>8</sup> <u>https://33afce.p3cdn2.secureserver.net/wp-content/uploads/2023/02/NOLA-Health-Cmte-Minutes-11-17-22.pdf</u>

<sup>&</sup>lt;sup>9</sup> https://33afce.p3cdn2.secureserver.net/wp-content/uploads/2023/02/NOLA-Health-Cmte-Minutes-11-17-22.pdf

<sup>&</sup>lt;sup>10</sup> <u>https://33afce.p3cdn2.secureserver.net/wp-content/uploads/2023/02/NOLA-Health-Cmte-Minutes-11-17-22.pdf</u>

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<sup>&</sup>lt;sup>12</sup> <u>https://www.gov.ca.gov/wp-content/uploads/2022/09/SB-912-VETO.pdf?emrc=49097a</u>

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Over the past two years, NCOIL policymakers have consistently raised concerns with access to affordable health care and health insurance coverage. Given affordability concerns and the high rate of biomarker coverage today, AHIP questions the need for NCOIL action and respectfully recommends a no vote on the draft Model Act.

Thank you for the opportunity to highlight the key areas of stakeholder testimony. AHIP continues to stand ready to partner together in making health care more affordable and accessible for all Americans.

Sincerely,

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