



## DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

March 9, 2023

The Honorable Joseline A. Peña-Melnyk  
Chair, House Health and Government Operations Committee  
241 House Office Building  
Annapolis, MD 21401-1991

### **RE: HB 1217 – Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing - Letter of Concern**

Dear Chair Peña-Melnyk and Committee Members:

The Maryland Department of Health (MDH) respectfully submits this letter of concern for House Bill (HB) 1217 – Maryland Medical Assistance Program and Health Insurance – Required Coverage for Biomarker Testing. HB 1217 requires the Maryland Medicaid program to provide coverage for biomarker testing that is supported by medical and scientific evidence and to establish requirements for copayments, deductibles, coinsurance, and utilization review for testing.

MDH is in the process of implementing Medicaid coverage of biomarker testing to guide clinical management of individuals with cancer. MDH will cover biomarker tests for cancer-related care, when the tests are approved for use by the FDA, approved by Medicare, and meet specific National Comprehensive Cancer Network cancer guidelines. In addition, the companion drug/therapy must be FDA and Medicare approved.

Biomarker testing, however, may be used in the treatment and management of numerous other conditions including autoimmune diseases, cardiovascular disease, kidney disease, certain infectious diseases, and metabolic diseases. As drafted, HB 1217 will require MDH to cover biomarker testing for all possible diseases, not just those for purposes of directing cancer treatment. Many of these diseases are prevalent in the Medicaid population. As such, MDH anticipates a significant fiscal impact with an annual cost of upwards of \$600 million, subject to a blended federal match. Over the next five fiscal years, Medicaid anticipates total costs of \$3 billion (\$1.8 billion federal funds, \$1.2 billion state general funds).

Additionally, MDH notes that the timeliness standards associated with the prior authorization responses, as outlined in the bill, may not be feasible for MDH or a Managed Care Organization (MCO) to complete a sufficient review, and further, do not align with federal requirements. MDH timeliness standards for responding to prior authorizations for Medicaid/CHIP services requests align with CMS statute (42 CFR § 438.210). For standard authorization, a response must be provided as expeditiously as the enrollee's condition required and may not exceed 14 calendar days unless a justifiable extension is requested. Expedited decisions, for cases in which following the standard timeline could seriously jeopardize the patient's life or health, must be responded to as expeditiously as possible and no later than 72 hours after the receipt of the request. Prior authorization requests are reviewed within 24-48 hours on average.

If you need more information, please do not hesitate to contact Megan Peters, Acting Director of Governmental Affairs at [megan.peters@maryland.gov](mailto:megan.peters@maryland.gov) or (410) 260-3190.

Sincerely,

A handwritten signature in blue ink, appearing to read "LH Scott". The signature is fluid and cursive.

Laura Herrera Scott, M.D., M.P.H.  
Secretary