

1 S.154

2 An act relating to health insurance coverage for biomarker testing

3 It is hereby enacted by the General Assembly of the State of Vermont:

4 Sec. 1. HEALTH INSURANCE AND MEDICAID COVERAGE FOR

5 BIOMARKER TESTING; DEPARTMENT OF FINANCIAL

6 REGULATION; AGENCY OF HUMAN SERVICES; REPORTS

7 (a) As used in this section:

8 (1) “Biomarker” means a characteristic that is objectively measured and  
9 evaluated as an indicator of normal biological processes, pathogenic processes,  
10 or pharmacologic responses to a specific therapeutic intervention, including  
11 known gene-drug interactions for medications being considered for use or  
12 already being administered. Biomarkers include gene mutations,  
13 characteristics of genes, and protein expression.

14 (2) “Biomarker testing” means the analysis of a patient’s tissue, blood,  
15 or other biospecimen for the presence of a biomarker. Biomarker testing  
16 includes single-analyte tests; multiplex panel tests; protein expression analysis;  
17 and whole exome, whole genome, and whole transcriptome sequencing.

18 (3) “Consensus statements” means statements developed by an  
19 independent, multidisciplinary panel of experts utilizing a transparent  
20 methodology and reporting structure and with a conflict of interest policy.  
21 These statements are aimed at specific clinical circumstances and the

1 statements are based on the best available evidence for the purpose of  
2 optimizing the outcomes of clinical care.

3 (4) “Nationally recognized clinical practice guidelines” means evidence-  
4 based clinical practice guidelines developed by independent organizations or  
5 medical professional societies utilizing a transparent methodology and  
6 reporting structure and with a conflict of interest policy. Clinical practice  
7 guidelines establish standards of care informed by a systematic review of  
8 evidence and an assessment of the benefits and risks of alternative care options  
9 and include recommendations intended to optimize patient care.

10 (b) The Department of Financial Regulation and Agency of Human  
11 Services shall analyze the costs associated with requiring health insurance  
12 coverage and Medicaid coverage, respectively, for biomarker testing for the  
13 purposes of diagnosis, treatment, appropriate management, and ongoing  
14 monitoring of a patient’s disease or condition when the test is supported by  
15 medical and scientific evidence, including:

16 (1) labeled indications for a test approved or cleared by the U.S. Food  
17 and Drug Administration (FDA);

18 (2) indicated tests for an FDA-approved drug;

19 (3) warnings and precautions on FDA-approved drug labels;

1           (4) Centers for Medicare and Medicaid Services national coverage  
2           determinations or Medicare Administrative Contractor local coverage  
3           determinations; or

4           (5) nationally recognized clinical practice guidelines and consensus  
5           statements.

6           (c)(1) On or before January 15, 2027, the Department of Financial  
7           Regulation shall report to the House Committee on Health Care and the Senate  
8           Committees on Health and Welfare and on Finance on the estimated amount  
9           that health insurance premiums would increase if Vermont were to enact  
10           legislation requiring health insurance coverage of biomarker testing as set forth  
11           in subsection (b) of this section, including the amounts of the State's financial  
12           obligations for defrayal of premium increases for qualified health benefit plans  
13           pursuant to 45 C.F.R. § 155.170 and for premium increases in the State  
14           Employees' Health Benefit Plan.

15           (2) On or before January 15, 2027, the Agency of Human Services shall  
16           report to the House Committee on Health Care and the Senate Committee on  
17           Health and Welfare regarding the approvals that would be needed from the  
18           Centers for Medicare and Medicaid in order for Vermont Medicaid to cover  
19           biomarker testing as set forth in subsection (b) of this section and the costs to  
20           the Medicaid program if Vermont were to enact legislation requiring that  
21           coverage.

- 1      Sec. 2. EFFECTIVE DATE
- 2      This act shall take effect on passage.