TO THE HONORABLE SENATE:

The Committee on Health and Welfare to which was referred Senate Bill No. 154 entitled "An act relating to health insurance coverage for biomarker testing" respectfully reports that it has considered the same and recommends that the bill be amended by striking out all after the enacting clause and inserting in lieu thereof the following:

Sec. 1. HEALTH INSURANCE AND MEDICAID COVERAGE FOR BIOMARKER TESTING; DEPARTMENT OF FINANCIAL REGULATION; AGENCY OF HUMAN SERVICES; REPORTS

(a) As used in this section:

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

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

(3) "Consensus statements" means statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy. These statements are aimed at specific clinical circumstances and the statements are based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

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

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

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

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

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

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

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

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

(2) On or before January 15, 2027, the Agency of Human Services shall report to the House Committee on Health Care and the Senate Committee on Health and Welfare regarding the approvals that would be needed from the Centers for Medicare and Medicaid in order for Vermont Medicaid to cover biomarker testing as set forth in subsection (b) of this section and the costs to

the Medicaid program if Vermont were to enact legislation requiring that coverage.

Sec. 2. 33 V.S.A. § 1806 is amended to read:

§ 1806. QUALIFIED HEALTH BENEFIT PLANS

* * *

(e)(1) A health insurer offering a qualified health benefit plan shall comply with the following insurance and consumer information requirements:

* * *

(2) A health insurer offering a qualified health benefit plan shall comply with all other insurance requirements for health insurers as provided in 8 V.S.A. chapter 107 and as specified by rule by the Commissioner of Financial Regulation and shall pay a $5.00 per person, per month fee to the Department of Financial Regulation for each enrollee in the insurer's qualified health benefit plans.

* * *

Sec. 3. EFFECTIVE DATE

This act shall take effect on passage.

(Committee vote: _____)

_____

Senator _____

FOR THE COMMITTEE