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**SB-535 Biomarker testing.** (2021-2022)

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**Senate Bill No. 535**

**CHAPTER 605**

An act to amend Section 1367.665 of the Health and Safety Code, and to amend Section 10123.20 of the Insurance Code, relating to health care coverage.

[ Approved by Governor October 06, 2021. Filed with Secretary of State October 06, 2021. ]

**LEGISLATIVE COUNSEL'S DIGEST**

SB 535, Limón. Biomarker testing.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires an individual or group health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after July 1, 2000, to provide coverage for all generally medically accepted cancer screening tests.

This bill would delete the references to individual or group health care service plan contracts and health insurance policies in those provisions. The bill would prohibit a health care service plan contract or health insurance policy issued, amended, delivered, or renewed on or after July 1, 2022, from requiring prior authorization for biomarker testing for an enrollee or insured with advanced or metastatic stage 3 or 4 cancer. The bill would also prohibit those health care service plans or health insurance policies from requiring prior authorization for biomarker testing for cancer progression or recurrence in the enrollee or insured with advanced or metastatic stage 3 or 4 cancer. The bill would provide that its provisions do not limit, prohibit, or modify an enrollee's or insured's rights to biomarker testing as part of an approved clinical trial, as specified. With respect to health care service plans, the bill would specifically apply the provisions relating to biomarker testing to Medi-Cal managed care plans, as specified. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

**THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:**

**SECTION 1.** Section 1367.665 of the Health and Safety Code is amended to read:

**1367.665.** (a) A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all terms and conditions that would otherwise apply.

(b) (1) A health care service plan contract, except for a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after July 1, 2022, shall not require prior authorization for either of the following:

(A) Biomarker testing for an enrollee with advanced or metastatic stage 3 or 4 cancer.

(B) Biomarker testing for cancer progression or recurrence in the enrollee with advanced or metastatic stage 3 or 4 cancer.

(2) This subdivision shall also apply to health care service plan contracts and Medi-Cal managed care plan contracts with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code.

(c) For purposes of this section, "biomarker test" means a diagnostic test, such as single or multigene, of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide patient treatment.

(d) Notwithstanding subdivision (b), this section does not prohibit a health care service plan from requiring prior authorization on biomarker testing that is not for an FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer.

(e) This section does not limit, prohibit, or modify an enrollee's rights to biomarker testing as part of an approved clinical trial under Section 1370.6.

**SEC. 2.** Section 10123.20 of the Insurance Code is amended to read:

**10123.20.** (a) A health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2000, shall be deemed to provide coverage for all generally medically accepted cancer screening tests, subject to all other terms and conditions that would otherwise apply.

(b) A health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2022, shall not require prior authorization for either of the following:

(1) Biomarker testing for an insured with advanced or metastatic stage 3 or 4 cancer.

(2) Biomarker testing of cancer progression or recurrence in the insured with advanced or metastatic stage 3 or 4 cancer.

(c) For purposes of this section, "biomarker test" means a diagnostic test, such as single or multigene, of the cancer patient's biospecimen, such as tissue, blood, or other bodily fluids, for DNA or RNA alterations, including phenotypic characteristics of a malignancy, to identify an individual with a subtype of cancer, in order to guide patient treatment.

(d) This section shall not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, or disability income insurance, except that for accident-only, specified disease, or hospital indemnity insurance, coverage for benefits under this section shall apply to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. This section shall not be construed as imposing a new benefit mandate on accident-only, specified disease, or hospital indemnity insurance.

(e) Notwithstanding subdivision (b), this section does not prohibit a health insurer from requiring prior authorization on biomarker testing that is not for an FDA-approved therapy for advanced or metastatic stage 3 or 4 cancer.

(f) This section does not limit, prohibit, or modify an insured's rights to biomarker testing as part of an approved clinical trial under Section 10145.4.

**SEC. 3.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.