SB-912 Biomarker testing. (2021-2022)

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CALIFORNIA LEGISLATURE— 2021–2022 REGULAR SESSION

SENATE BILL NO. 912

Introduced by Senator Limón
(Coauthor: Senator Rubio)

February 02, 2022

An act to add Section 1367.667 to the Health and Safety Code, to add Section 10123.209 to the Insurance Code, and to add Section 14132.09 to the Welfare and Institutions Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 912, Limón. Biomarker testing.

(1) 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 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, and prohibits that contract or policy issued, amended, delivered, or renewed on or after July 1, 2022, from requiring prior authorization for biomarker testing for certain enrollees or insureds. Existing law applies the provisions relating to biomarker testing to Medi-Cal managed care plans, as prescribed.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after July 1, 2023, to provide coverage for biomarker testing, including whole genome sequencing, for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee’s or insured’s disease or condition if the test is supported by medical and scientific evidence, as prescribed. The bill would specify that it does not require a health care service plan or health

insurer to cover biomarker testing for screening purposes unless otherwise required by law. The bill would subject restricted use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of a medical condition to state and federal grievance and appeal processes. This bill would apply these provisions relating to biomarker testing to the Medi-Cal program, including 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.

(2) Existing law provides for the Medi-Cal program, administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services pursuant to a schedule of benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing law includes Rapid Whole Genome Sequencing as a covered benefit for any Medi-Cal beneficiary who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit.

Subject to the extent that federal financial participation is available and not otherwise jeopardized, and any necessary federal approvals have been obtained, this bill would expand the Medi-Cal schedule of benefits to include biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a Medi-Cal beneficiary's disease or condition if the test is supported by medical and scientific evidence, as prescribed. The bill would authorize the department to implement this provision by various means without taking regulatory action.

(3) 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

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

SECTION 1. Section 1367.667 is added to the Health and Safety Code, immediately following Section 1367.665, to read:

1367.667. (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, 2023, shall cover biomarker testing pursuant to this section. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition only if the test is supported by medical and scientific evidence. For purposes of this subdivision, "medical and scientific evidence" means one or more of the following:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

(2) A national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a Medicare Administrative Contractor.

(3) Nationally recognized clinical practice guidelines and consensus statements.

(b) A health care service plan that is subject to this section shall ensure that biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. This section does not require coverage of biomarker testing for screening purposes unless otherwise required by this chapter.

(c) Restricted use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is subject to grievance and appeal processes under state and federal law.

(d) This section shall apply to any health care service plan contract and Medi-Cal managed care plan contract 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.

(e) For purposes of this section, the following definitions apply:

(1) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a specific therapeutic intervention. A biomarker includes, but is not limited to, gene mutations or protein expression.

(2) "Biomarker testing" means the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests, and whole genome sequencing.

(3) “Consensus statements” means statements developed by an independent, multidisciplinary panel of experts who utilize a transparent methodology and reporting structure, and are subject to a conflict of interest policy. These statements are aimed at specific clinical circumstances and are based on the best available evidence to optimize 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 are subject to 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 costs of alternative care options, and those guidelines include recommendations intended to optimize clinical care.

(f) This section is subject to the provisions of Section 1367.665 as amended by Chapter 605 of the Statutes of 2021 for an enrollee with advanced or metastatic stage III or IV cancer.

SEC. 2. Section 10123.209 is added to the Insurance Code, to read:

10123.209. (a) A health insurance policy that is issued, amended, delivered, or renewed on or after July 1, 2023, shall include coverage for biomarker testing pursuant to this section. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured’s disease or condition only if the test is supported by medical and scientific evidence. For purposes of this subdivision, “medical and scientific evidence” means one or more of the following:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

(2) A national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a Medicare Administrative Contractor.

(3) Nationally recognized clinical practice guidelines and consensus statements.

(b) A health insurance policy that is subject to this section shall ensure that biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. This section shall not be construed to require coverage of biomarker testing for screening purposes unless otherwise required by this chapter.

(c) Restricted use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is subject to grievance and appeal processes under state and federal law.

(d) This section shall apply to an insurance policy issued, sold, renewed, or offered for health care services or coverage provided in the Medi-Cal program 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.

(e) 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 impose a new benefit mandate on accident-only, specified disease, or hospital indemnity insurance.

(f) For purposes of this section, the following definitions apply:

(1) “Biomarker” means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a specific therapeutic intervention. A biomarker includes, but is not limited to, gene mutations or protein expression.

(2) “Biomarker testing” means the analysis of an individual’s tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests, and whole genome sequencing.

(3) “Consensus statements” means statements developed by an independent, multidisciplinary panel of experts who utilize a transparent methodology and reporting structure, and are subject to a conflict of interest policy. These statements are aimed at specific clinical circumstances and are based on the best available evidence to optimize 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 are subject to 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 costs of alternative care options, and those guidelines include recommendations intended to optimize clinical care.

(g) This section is subject to the provisions of Section 10123.20 as amended by Chapter 605 of the Statutes of 2021 for an insured with advanced or metastatic stage III or IV cancer.

SEC. 3. Section 14132.09 is added to the Welfare and Institutions Code, to read:

14132.09. (a) By July 1, 2023, biomarker testing, as specified in this section, is a covered benefit, subject to utilization controls. Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a Medi-Cal beneficiary's disease or condition only if the test is supported by medical and scientific evidence. For purposes of this section, "medical and scientific evidence" means one or more of the following:

(1) A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

(2) A national coverage determination made by the federal Centers for Medicare and Medicaid Services or a local coverage determination made by a Medicare Administrative Contractor.

(3) Nationally recognized clinical practice guidelines and consensus statements.

(b) The department shall ensure that biomarker testing is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. This section does not require coverage of biomarker testing for screening purposes unless otherwise required by this chapter.

(c) Restricted use of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is subject to grievance and appeal processes under state and federal law.

(d) This section shall be implemented only to the extent that federal financial participation is available and not otherwise jeopardized, and any necessary federal approvals have been obtained.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking any further regulatory action.

(f) For purposes of this section, the following definitions apply:

(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. A biomarker includes, but is not limited to, gene mutations or protein expression.

(2) "Biomarker testing" is the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests, and whole genome sequencing.

(3) "Consensus statements" are statements developed by an independent, multidisciplinary panel of experts who utilize a transparent methodology and reporting structure, and are subject to a conflict of interest policy. These statements are aimed at specific clinical circumstances and are based on the best available evidence to optimize the outcomes of clinical care.

(4) "Nationally recognized clinical practice guidelines" are evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure, and are subject to 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 costs of alternative care options, and those guidelines include recommendations intended to optimize clinical care.

(g) This section is subject to the provisions of Section 1367.665 of the Health and Safety Code and Section 10123.20 of the Insurance Code as amended by Chapter 605 of the Statutes of 2021 for a Medi-Cal beneficiary with advanced or metastatic stage III or IV cancer.

SEC. 4. 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.