SENATE BILL No. 912

Introduced by Senator Limón

February 2, 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 amend Section 14132 of the Welfare and Institutions Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 912, as introduced, 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. 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. State-mandated local program: yes.

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, including, but not limited to, any 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.

(c) When coverage of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is restricted for use by a health care service plan, the enrollee and their prescribing health care practitioner shall have access to clear, readily accessible, and convenient processes to request an exception. That process shall be made readily accessible on the health care service plan's internet website.

(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 three or four 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, including, but not limited to, any 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.

(c) When coverage of biomarker testing for the purpose of diagnosis, treatment, or ongoing monitoring of any medical condition is restricted for use by a health insurer, the insured and

their prescribing health care practitioner shall have access to clear, readily accessible, and convenient processes to request an exception. That process shall be made readily accessible on the health insurer's internet website.

(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 three or four cancer.

SEC. 3. Section 14132 of the Welfare and Institutions Code is amended to read:

14132. The following is the schedule of benefits under this chapter:

(a) *(1)* Outpatient services are covered ~~as follows:~~ *pursuant to paragraph (2).*

~~Physician,~~

(2) Physician, hospital or clinic outpatient, surgical center, respiratory care, optometric, chiropractic, psychology, podiatric, occupational therapy, physical therapy, speech therapy, audiology, acupuncture to the extent federal matching funds are provided for acupuncture, and services of persons rendering treatment by prayer or healing by spiritual means in the practice of any church or religious denomination insofar as these can be encompassed by federal participation under an approved plan, *are covered,* subject to utilization controls.

(b) (1) Inpatient hospital services, including, but not limited to, physician and podiatric services, physical therapy, and occupational therapy, are ~~covered~~ *covered,* subject to utilization controls.

(2) For a Medi-Cal fee-for-service beneficiary, emergency services and care that are necessary for the treatment of an emergency medical condition and medical care directly related to the emergency medical ~~condition.~~ *conditioned is covered.* This paragraph does not change the obligation of Medi-Cal managed care plans to provide emergency services and care. For the purposes of this paragraph, "emergency services and care" and "emergency medical condition" have the same meanings as those terms are defined in Section 1317.1 of the Health and Safety Code.

(c) Nursing facility services, subacute care services, and services provided by any category of intermediate care facility for the developmentally disabled, including podiatry, physician, nurse practitioner services, and prescribed drugs, as described in subdivision (d), are ~~covered~~ *covered,* subject to utilization controls.

Respiratory care, physical therapy, occupational therapy, speech therapy, and audiology services for patients in nursing facilities and any category of intermediate care facility for persons with developmental disabilities are ~~covered~~ *covered,* subject to utilization controls.

(d) (1) Purchase of prescribed drugs is ~~covered~~ *covered,* subject to the Medi-Cal List of Contract Drugs and utilization controls.

(2) Purchase of drugs used to treat erectile dysfunction or any off-label uses of those drugs are covered only to the extent that federal financial participation is available.

(3) (A) To the extent required by federal law, the purchase of outpatient prescribed drugs, for which the prescription is executed by a prescriber in written, nonelectronic form on or after April 1, 2008, is covered only when executed on a tamper resistant prescription form. The implementation of this paragraph shall conform to the guidance issued by the federal Centers for Medicare and Medicaid Services, but shall not conflict with state ~~statutes~~ *law* on the characteristics of tamper resistant prescriptions for controlled substances, including Section 11162.1 of the Health and Safety Code. The department shall provide providers and beneficiaries with as much flexibility in implementing these rules as allowed by the federal government. The department shall notify and consult with appropriate stakeholders in implementing, interpreting, or making specific this paragraph.

(B) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in subparagraph (A) by means of a provider bulletin or notice, policy letter, or other similar instructions without taking regulatory action.

(4) (A) (i) For the purposes of this paragraph, nonlegend has the same meaning as defined in subdivision (a) of Section 14105.45.

(ii) Nonlegend acetaminophen-containing products, including children's acetaminophen-containing products, selected by the department are covered benefits.

(iii) Nonlegend cough and cold products selected by the department are covered benefits.

(B) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in subparagraph (A)

by means of a provider bulletin or notice, policy letter, or other similar instruction without taking regulatory action.

(e) Outpatient dialysis services and home hemodialysis services, including physician services, medical supplies, drugs, and equipment required for dialysis, are covered, subject to utilization controls.

(f) Anesthesiologist services when provided as part of an outpatient medical procedure, nurse anesthetist services when rendered in an inpatient or outpatient setting under conditions set forth by the director, outpatient laboratory services, and x-ray services are covered, subject to utilization controls. This subdivision does not require prior authorization for anesthesiologist services provided as part of an outpatient medical procedure or for portable x-ray services in a nursing facility or any category of intermediate care facility for the developmentally disabled.

(g) Blood and blood derivatives are covered.

(h) (1) Emergency and essential diagnostic and restorative dental services, except for orthodontic, fixed bridgework, and partial dentures that are not necessary for balance of a complete artificial denture, are covered, subject to utilization controls. The utilization controls shall allow emergency and essential diagnostic and restorative dental services and prostheses that are necessary to prevent a significant disability or to replace previously furnished prostheses that are lost or destroyed due to circumstances beyond the beneficiary's control. Notwithstanding the foregoing, the director ~~may by regulation~~ *may, by regulation,* provide for certain fixed artificial dentures necessary for obtaining employment or for medical conditions that preclude the use of removable dental prostheses, and for orthodontic services in cleft palate deformities administered by the department's California Children's Services program.

(2) For persons 21 years of age or older, the services specified in paragraph (1) shall be provided subject to *all of* the following conditions:

(A) Periodontal treatment is not a benefit.

(B) Endodontic therapy is not a benefit except for vital pulpotomy.

(C) Laboratory processed crowns are not a benefit.

(D) Removable prosthetics shall be a benefit only for patients as a requirement for employment.

(E) The director may, by regulation, provide for the provision of fixed artificial dentures that are necessary for medical conditions that preclude the use of removable dental prostheses.

(F) Notwithstanding the conditions specified in subparagraphs (A) to (E), inclusive, the department may approve services for persons with special medical disorders subject to utilization review.

(3) Paragraph (2) shall become inoperative on July 1, 1995.

(i) Medical transportation is covered, subject to utilization controls.

(j) Home health care services are covered, subject to utilization controls.

(k) (1) Prosthetic and orthotic devices and eyeglasses are covered, subject to utilization controls. Utilization controls shall allow replacement of prosthetic and orthotic devices and eyeglasses necessary because of loss or destruction due to circumstances beyond the beneficiary's control. Frame styles for eyeglasses replaced pursuant to this subdivision shall not change more than once every two years, unless the department so directs.

(2) Orthopedic and conventional shoes are covered when provided by a prosthetic and orthotic supplier on the prescription of a physician and when at least one of the shoes will be attached to a prosthesis or brace, subject to utilization controls. Modification of stock conventional or orthopedic shoes when medically indicated is covered, subject to utilization controls. If there is a clearly established medical need that cannot be satisfied by the modification of stock conventional or orthopedic shoes, custom-made orthopedic shoes are covered, subject to utilization controls.

(3) Therapeutic shoes and inserts are covered when provided to a beneficiary with a diagnosis of diabetes, subject to utilization controls, to the extent that federal financial participation is available.

(*l*) Hearing aids are covered, subject to utilization controls. Utilization controls shall allow replacement of hearing aids necessary because of loss or destruction due to circumstances beyond the beneficiary's control.

(m) Durable medical equipment and medical supplies are covered, subject to utilization controls. The utilization controls shall allow the replacement of durable medical equipment and medical supplies when necessary because of loss or destruction

due to circumstances beyond the beneficiary's control. The utilization controls shall allow authorization of durable medical equipment needed to assist a disabled beneficiary in caring for a child for whom the disabled beneficiary is a parent, stepparent, foster parent, or legal guardian, subject to the availability of federal financial participation. The department shall adopt emergency regulations to define and establish criteria for assistive durable medical equipment in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

(n) Family planning services are covered, subject to utilization controls. However, for Medi-Cal managed care plans, utilization controls shall be subject to Section 1367.25 of the Health and Safety Code.

(o) Inpatient intensive rehabilitation hospital services, including respiratory rehabilitation services, in a general acute care hospital are covered, subject to utilization controls, when either of the following criteria are met:

(1) A patient with a permanent disability or severe impairment requires an inpatient intensive rehabilitation hospital program as described in Section 14064 to develop function beyond the limited amount that would occur in the normal course of recovery.

(2) A patient with a chronic or progressive disease requires an inpatient intensive rehabilitation hospital program as described in Section 14064 to maintain the patient's present functional level as long as possible.

(p) (1) Adult day health care is covered in accordance with Chapter 8.7 (commencing with Section 14520).

(2) Commencing 30 days after the effective date of the act that added this paragraph, and notwithstanding the number of days previously approved through a treatment authorization request, adult day health care is covered for a maximum of three days per week.

(3) As provided in accordance with paragraph (4), adult day health care is covered for a maximum of five days per week.

(4) As of the date that the director makes the declaration described in subdivision (g) of Section 14525.1, paragraph (2) shall become inoperative and paragraph (3) shall become operative.

(q) (1) Application of fluoride, or other appropriate fluoride ~~treatment~~ *treatment*, as defined by the department, and other prophylaxis treatment for children 17 years of age and under are covered.

(2) All dental hygiene services provided by a registered dental hygienist, registered dental hygienist in extended functions, and registered dental hygienist in alternative practice licensed pursuant to Sections 1753, 1917, 1918, and 1922 of the Business and Professions Code may be covered as long as they are within the scope of Denti-Cal benefits and they are necessary services provided by a registered dental hygienist, registered dental hygienist in extended functions, or registered dental hygienist in alternative practice.

(r) (1) Paramedic services performed by a city, county, or special district, or pursuant to a contract with a city, county, or special district, and pursuant to a program established under former Article 3 (commencing with Section 1480) of Chapter 2.5 of Division 2 of the Health and Safety Code by a paramedic certified pursuant to that article, and consisting of defibrillation and those services specified in subdivision (3) of former Section ~~1482 of the article.~~ *1482 of the Health and Safety Code.*

(2) A provider enrolled under this subdivision shall satisfy all applicable statutory and regulatory requirements for becoming a Medi-Cal provider.

(3) This subdivision shall be implemented only to the extent funding is available under Section 14106.6.

(s) (1) In-home medical care services are covered when medically appropriate and subject to utilization controls, for a beneficiary who would otherwise require care for an extended period of time in an acute care hospital at a cost higher than in-home medical care services. The director shall have the authority under this section to contract with organizations qualified to provide in-home medical care services to those persons. These services may be provided to a patient placed in a shared or congregate living arrangement, if a home setting is not medically appropriate or available to the beneficiary.

(2) As used in this subdivision, "in-home medical care service" includes utility bills directly attributable to continuous, 24-hour operation of life-sustaining medical equipment, to the extent that federal financial participation is available.

(3) As used in this subdivision, in-home medical care services include, but are not limited to:

(A) Level-of-care and cost-of-care evaluations.

(B) Expenses, directly attributable to home care activities, for materials.

(C) Physician fees for home visits.

(D) Expenses directly attributable to home care activities for shelter and modification to shelter.

(E) Expenses directly attributable to additional costs of special diets, including tube feeding.

(F) Medically related personal services.

(G) Home nursing education.

(H) Emergency maintenance repair.

(I) Home health agency personnel benefits that permit coverage of care during periods when regular personnel are on vacation or using sick leave.

(J) All services needed to maintain antiseptic conditions at stoma or shunt sites on the body.

(K) Emergency and nonemergency medical transportation.

(L) Medical supplies.

(M) Medical equipment, including, but not limited to, scales, gurneys, and equipment racks suitable for paralyzed patients.

(N) Utility use directly attributable to the requirements of home care activities that are in addition to normal utility use.

(O) Special drugs and medications.

(P) Home health agency supervision of visiting staff that is medically necessary, but not included in the home health agency rate.

(Q) Therapy services.

(R) Household appliances and household utensil costs directly attributable to home care activities.

(S) Modification of medical equipment for home use.

(T) Training and orientation for use of life-support systems, including, but not limited to, support of respiratory functions.

(U) Respiratory care practitioner services as defined in Sections 3702 and 3703 of the Business and Professions Code, subject to prescription by a physician and surgeon.

(4) A beneficiary receiving in-home medical care services is entitled to the full range of services within the Medi-Cal scope of benefits as defined by this section, subject to medical necessity

and applicable utilization control. Services provided pursuant to this subdivision, which are not otherwise included in the Medi-Cal schedule of benefits, shall be available only to the extent that federal financial participation for these services is available in accordance with a home- and community-based services waiver.

(t) Home- and community-based services approved by the United States Department of Health and Human Services are covered to the extent that federal financial participation is available for those services under the state plan or waivers granted in accordance with Section 1315 or 1396n of Title 42 of the United States Code. The director may seek waivers for any or all home- and community-based services approvable under Section 1315 or 1396n of Title 42 of the United States Code. Coverage for those services shall be limited by the terms, conditions, and duration of the federal waivers.

(u) *(1)* Comprehensive perinatal services, as provided through an agreement with a health care provider designated in Section 14134.5 and meeting the standards developed by the department pursuant to Section 14134.5, *are covered,* subject to utilization controls.

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(2) The department shall seek any federal waivers necessary to implement ~~the provisions of this subdivision.~~ *paragraph (1).* The provisions for which appropriate federal waivers cannot be obtained shall not be implemented. Provisions for which waivers are obtained or for which waivers are not required shall be implemented notwithstanding any inability to obtain federal waivers for the other provisions. ~~No provision of this~~ *This* subdivision shall ~~be implemented unless~~ *only be implemented if* matching funds from Subchapter XIX (commencing with Section 1396) of Chapter 7 of Title 42 of the United States Code are available.

(v) Early and periodic screening, diagnosis, and treatment for any individual under 21 years of age is covered, consistent with the requirements of Subchapter XIX (commencing with Section 1396) of Chapter 7 of Title 42 of the United States Code.

(w) Hospice service that is Medicare-certified hospice service is covered, subject to utilization controls. Coverage shall be available only to the extent that no additional net program costs are incurred.

(x) When a claim for treatment provided to a beneficiary includes both services that are authorized and reimbursable under this chapter and services that are not reimbursable under this chapter, that portion of the claim for the treatment and services authorized and reimbursable under this chapter shall be payable.

(y) Home- and community-based services approved by the United States Department of Health and Human Services for a beneficiary with a diagnosis of Acquired Immune Deficiency Syndrome (AIDS) or AIDS-related complex, who requires intermediate care or a higher level of care.

Services provided pursuant to a waiver obtained from the Secretary of the United States Department of Health and Human Services pursuant to this subdivision, and that are not otherwise included in the Medi-Cal schedule of benefits, shall be available only to the extent that federal financial participation for these services is available in accordance with the waiver, and subject to the terms, conditions, and duration of the waiver. These services shall be provided to a beneficiary in accordance with the client's needs as identified in the plan of care, and subject to medical necessity and applicable utilization control.

The director may, under this section, contract with organizations qualified to provide, directly or by subcontract, services provided for in this subdivision to an eligible beneficiary. Contracts or agreements entered into pursuant to this division shall not be subject to the Public Contract Code.

(z) Respiratory care when provided in organized health care systems as defined in Section 3701 of the Business and Professions Code, and as an in-home medical service as outlined in subdivision (s).

(aa) (1) There is hereby established in the department a program to provide comprehensive clinical family planning services to any person who has a family income at or below 200 percent of the federal poverty level, as revised annually, and who is eligible to receive these services pursuant to the waiver identified in paragraph (2). This program shall be known as the Family Planning, Access, Care, and Treatment (Family PACT) Program.

(2) The department shall seek a waiver in accordance with Section 1315 of Title 42 of the United States Code, or a state plan amendment adopted in accordance with Section 1396a(a)(10)(A)(ii)(XXI) of Title 42 of the United States Code,

which was added to Section 1396a of Title 42 of the United States Code by Section 2303(a)(2) of the federal Patient Protection and Affordable Care Act (PPACA) (Public Law 111-148), for a program to provide comprehensive clinical family planning services as described in paragraph (8). Under the waiver, the program shall be operated only in accordance with the waiver and the statutes and regulations in paragraph (4) and subject to the terms, conditions, and duration of the waiver. Under the state plan amendment, which shall replace the waiver and shall be known as the Family PACT successor state plan amendment, the program shall be operated only in accordance with this subdivision and the statutes and regulations in paragraph (4). The state shall use the standards and processes imposed by the state on January 1, 2007, including the application of an eligibility discount factor to the extent required by the federal Centers for Medicare and Medicaid Services, for purposes of determining eligibility as permitted under Section 1396a(a)(10)(A)(ii)(XXI) of Title 42 of the United States Code. To the extent that federal financial participation is available, the program shall continue to conduct education, outreach, enrollment, service delivery, and evaluation services as specified under the waiver. The services shall be provided under the program only if the waiver and, when applicable, the successor state plan amendment are approved by the federal Centers for Medicare and Medicaid Services and only to the extent that federal financial participation is available for the services. This section does not prohibit the department from seeking the Family PACT successor state plan amendment during the operation of the waiver.

(3) Solely for the purposes of the waiver or Family PACT successor state plan amendment and notwithstanding any other law, the collection and use of an individual's social security number shall be necessary only to the extent required by federal law.

(4) Sections 14105.3 to 14105.39, inclusive, 14107.11, 24005, and 24013, and any regulations adopted under these statutes shall apply to the program provided for under this subdivision. No other law under the Medi-Cal program or the State-Only Family Planning Program shall apply to the program provided for under this subdivision.

(5) 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, without taking regulatory action,

the provisions of the waiver after its approval by the federal Centers for Medicare and Medicaid Services and the provisions of this section by means of an all-county letter or similar instruction to providers. Thereafter, the department shall adopt regulations to implement this section and the approved waiver in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Beginning six months after the effective date of the act adding this subdivision, the department shall provide a status report to the Legislature on a semiannual basis until regulations have been adopted.

(6) If the Department of Finance determines that the program operated under the authority of the waiver described in paragraph (2) or the Family PACT successor state plan amendment is no longer cost effective, this subdivision shall become inoperative on the first day of the first month following the issuance of a 30-day notification of that determination in writing by the Department of Finance to the chairperson in each house that considers appropriations, the chairpersons of the committees, and the appropriate subcommittees in each house that considers the State Budget, and the Chairperson of the Joint Legislative Budget Committee.

(7) If this subdivision ceases to be operative, all persons who have received or are eligible to receive comprehensive clinical family planning services pursuant to the waiver described in paragraph (2) shall receive family planning services under the Medi-Cal program pursuant to subdivision (n) if they are otherwise eligible for Medi-Cal with no share of cost, or shall receive comprehensive clinical family planning services under the program established in Division 24 (commencing with Section 24000) either if they are eligible for Medi-Cal with a share of cost or if they are otherwise eligible under Section 24003.

(8) For purposes of this subdivision, “comprehensive clinical family planning services” means the process of establishing objectives for the number and spacing of children, and selecting the means by which those objectives may be achieved. These means include a broad range of acceptable and effective methods and services to limit or enhance fertility, including contraceptive methods, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies, natural family planning,

abstinence methods, and basic, limited fertility management. Comprehensive clinical family planning services include, but are not limited to, preconception counseling, maternal and fetal health counseling, general reproductive health care, including diagnosis and treatment of infections and conditions, including cancer, that threaten reproductive capability, medical family planning treatment and procedures, including supplies and followup, and informational, counseling, and educational services. Comprehensive clinical family planning services shall not include abortion, pregnancy testing solely for the purposes of referral for abortion or services ancillary to abortions, or pregnancy care that is not incident to the diagnosis of pregnancy. Comprehensive clinical family planning services shall be subject to utilization control and include all of the following:

(A) Family planning related services and male and female sterilization. Family planning services for men and women shall include emergency services and services for complications directly related to the contraceptive method, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies, and followup, consultation, and referral services, as indicated, which may require treatment authorization requests.

(B) All United States Department of Agriculture, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies that are in keeping with current standards of practice and from which the individual may choose.

(C) Culturally and linguistically appropriate health education and counseling services, including informed consent, that include all of the following:

(i) Psychosocial and medical aspects of contraception.

(ii) Sexuality.

(iii) Fertility.

(iv) Pregnancy.

(v) Parenthood.

(vi) Infertility.

(vii) Reproductive health care.

(viii) Preconception and nutrition counseling.

(ix) Prevention and treatment of sexually transmitted infection.

(x) Use of contraceptive methods, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies.

(xi) Possible contraceptive consequences and followup.

(xii) Interpersonal communication and negotiation of relationships to assist individuals and couples in effective contraceptive method use and planning families.

(D) A comprehensive health history, updated at the next periodic visit (between 11 and 24 months after initial examination) that includes a complete obstetrical history, gynecological history, contraceptive history, personal medical history, health risk factors, and family health history, including genetic or hereditary conditions.

(E) A complete physical examination on initial and subsequent periodic visits.

(F) Services, drugs, devices, and supplies deemed by the federal Centers for Medicare and Medicaid Services to be appropriate for inclusion in the program.

(G) (i) Home test kits for sexually transmitted diseases, including any laboratory costs of processing the kit, that are deemed medically necessary or appropriate and ordered directly by an enrolled Medi-Cal or Family PACT clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

(ii) For purposes of this subparagraph, "home test kit" means a product used for a test recommended by the federal Centers for Disease Control and Prevention guidelines or the United States Preventive Services Task Force that has been CLIA-waived, FDA-cleared or -approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting.

(iii) Reimbursement under this subparagraph shall be contingent upon the addition of codes specific to home test kits in the Current Procedural Terminology or Healthcare Common Procedure Coding System to comply with Health Insurance Portability and Accountability Act requirements. The home test kit shall be sent by the enrolled Family PACT provider to a Medi-Cal-enrolled laboratory with fee based on Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule.

(9) In order to maximize the availability of federal financial participation under this subdivision, the director shall have the

discretion to implement the Family PACT successor state plan amendment retroactively to July 1, 2010.

(ab) (1) Purchase of prescribed enteral nutrition products is covered, subject to the Medi-Cal list of enteral nutrition products and utilization controls.

(2) Purchase of enteral nutrition products is limited to those products to be administered through a feeding tube, including, but not limited to, a gastric, nasogastric, or jejunostomy tube. A beneficiary under the Early and Periodic Screening, Diagnostic, and Treatment Program shall be exempt from this paragraph.

(3) Notwithstanding paragraph (2), the department may deem an enteral nutrition product, not administered through a feeding tube, including, but not limited to, a gastric, nasogastric, or jejunostomy tube, a benefit for patients with diagnoses, including, but not limited to, malabsorption and inborn errors of metabolism, if the product has been shown to be neither investigational nor experimental when used as part of a therapeutic regimen to prevent serious disability or death.

(4) 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 the amendments to this subdivision made by the act that added this paragraph by means of all-county letters, provider bulletins, or similar instructions, without taking regulatory action.

(5) The amendments made to this subdivision by the act that added this paragraph shall be implemented June 1, 2011, or on the first day of the first calendar month following 60 days after the date the department secures all necessary federal approvals to implement this section, whichever is later.

(ac) Diabetic testing supplies are covered when provided by a pharmacy, subject to utilization controls.

(ad) (1) Nonmedical transportation is covered, subject to utilization controls and permissible time and distance standards, for a beneficiary to obtain covered Medi-Cal services.

(2) (A) (i) Nonmedical transportation includes, at a minimum, round trip transportation for a beneficiary to obtain covered Medi-Cal services by passenger car, taxicab, or any other form of public or private conveyance, and mileage reimbursement when conveyance is in a private vehicle arranged by the beneficiary and

not through a transportation broker, bus passes, taxi vouchers, or train tickets.

(ii) Nonmedical transportation does not include the transportation of a sick, injured, invalid, convalescent, infirm, or otherwise incapacitated beneficiary by ambulance, litter van, or wheelchair van licensed, operated, and equipped in accordance with state and local statutes, ordinances, or regulations.

(B) Nonmedical transportation shall be provided for a beneficiary who can attest in a manner to be specified by the department that other currently available resources have been reasonably exhausted. For a beneficiary enrolled in a managed care plan, nonmedical transportation shall be provided by the beneficiary's managed care plan. For a Medi-Cal fee-for-service beneficiary, the department shall provide nonmedical transportation when those services are not available to the beneficiary under Sections 14132.44 and 14132.47.

(3) Nonmedical transportation shall be provided in a form and manner that is accessible, in terms of physical and geographic accessibility, for the beneficiary and consistent with applicable state and federal disability rights laws.

(4) It is the intent of the Legislature in enacting this subdivision to affirm the requirement under Section 431.53 of Title 42 of the Code of Federal Regulations, in which the department is required to provide necessary transportation, including nonmedical transportation, for recipients to and from covered services. This subdivision shall not be interpreted to add a new benefit to the Medi-Cal program.

(5) The department shall seek any federal approvals that may be required to implement this subdivision, including, but not limited to, approval of revisions to the existing state plan that the department determines are necessary to implement this subdivision.

(6) This subdivision 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.

(7) Prior to the effective date of any necessary federal approvals, nonmedical transportation was not a Medi-Cal managed care benefit with the exception of when provided as an Early and Periodic Screening, Diagnostic, and Treatment service.

(8) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department, without taking any further regulatory action, shall implement, interpret, or make specific this subdivision by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions until the time regulations are adopted. By July 1, 2018, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing January 1, 2018, and notwithstanding Section 10231.5 of the Government Code, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

(9) This subdivision shall not be implemented until July 1, 2017.

(ae) (1) No sooner than January 1, 2022, Rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, is 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.

(2) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department, without taking any further regulatory action, shall implement, interpret, or make specific this subdivision by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions until the time regulations are adopted.

(3) This subdivision shall be implemented only to the extent that any necessary federal approvals are obtained, and federal financial participation is available and not otherwise jeopardized.

(af) (1) Home test kits for sexually transmitted diseases that are deemed medically necessary or appropriate and ordered directly by an enrolled Medi-Cal clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

(2) For purposes of this subdivision, “home test kit” means a product used for a test recommended by the federal Centers for Disease Control and Prevention guidelines or the United States Preventive Services Task Force that has been CLIA-waived, FDA-cleared or -approved, or developed by a laboratory in

accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting.

(3) Reimbursement under this subparagraph shall be contingent upon the addition of codes specific to home test kits in the Current Procedural Terminology or Healthcare Common Procedure Coding System to comply with Health Insurance Portability and Accountability Act requirements. The home test kit shall be sent by the enrolled Medi-Cal provider to a Medi-Cal-enrolled laboratory with fee based on Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule.

(4) This subdivision 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.

(5) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the ~~State Department of Health Care Services~~ *department* may implement this subdivision by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking any further regulatory action.

(ag) (1) By July 1, 2023, biomarker testing, as specified in this subdivision, 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, including, but not limited to, any of the following:

(A) 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.

(B) 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.

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

(2) 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.

(3) A Medi-Cal beneficiary and their prescribing health care practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to the biomarker testing benefit. That process shall be made readily accessible on the department's internet website.

(4) This subdivision 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.

(5) 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 subdivision by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking any further regulatory action.

(6) For purposes of this subdivision, the following definitions apply:

(A) "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.

(B) "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.

(C) "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.

(D) "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.

(7) This subdivision 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 three or four 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.

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