SB-306 Sexually transmitted disease: testing. (2021-2022)

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Senate Bill No. 306

CHAPTER 486

An act to amend Section 4076 of the Business and Professions Code, to amend Sections 120582, 120685, and 120917 of, and to add Section 1367.34 to, the Health and Safety Code, to add Section 10123.208 to the Insurance Code, and to amend Sections 14132 and 24007 of the Welfare and Institutions Code, relating to health care.

[Approved by Governor October 04, 2021. Filed with Secretary of State October 04, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

SB 306, Pan. Sexually transmitted disease: testing.

(1) Existing law authorizes a specified health care provider who diagnoses an STD, as specified, to prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners. The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime. The Pharmacy Law requires a pharmacist to dispense a prescription in a container that, among other things, is correctly labeled with the name of the patient or patients. Existing regulation requires a pharmacist to ensure that a patient receives written notice of their right to consult with a pharmacist, when the patient or the patient's agent is not present.

This bill would name the above practice "expedited partner therapy." The bill would require a health care provider to include "expedited partner therapy" or "EPT" on a prescription if the practitioner does not have the name of a patient's sexual partner, and would authorize a pharmacist to dispense an expedited partner therapy prescription and label the drug without an individual's name if the prescription includes "expedited partner therapy" or "EPT." The bill would specify that a health care provider is not liable in a medical malpractice action or professional disciplinary action, and that a pharmacist is not liable in a civil, criminal, or administrative action, if the health care provider's use of expedited partner therapy is in compliance with the law, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity. The bill would amend the Pharmacy Law to require a pharmacist to provide written notice that describes the right of an individual receiving expedited partner therapy to consult with a pharmacist about the medication and potential drug interactions. By expanding the scope of a crime, the bill would create a state-mandated local program.

(2) 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 a health care service plan contract or health insurance policy to provide coverage for reproductive and sexual health care services.

This bill would require health care service plans and insurers to provide coverage for home test kits for sexually transmitted diseases, as defined, and the laboratory costs for processing those kits, that are deemed medically necessary or appropriate and

ordered directly by a health care provider or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs. By expanding the definition of a crime, this bill would impose a state-mandated local program.

(3) Existing law requires every licensed physician and surgeon or other person engaged in prenatal care of a pregnant woman, or attending the woman at the time of delivery, to obtain or cause to be obtained a blood specimen of the woman to test for syphilis at the time of the first professional visit or within 10 days thereafter.

This bill would instead require every licensed health care professional engaged in providing prenatal care or attending a birthing patient at the time of delivery to provide syphilis screening and testing as outlined in the most recent guidelines published by the State Department of Public Health or other clinical guidelines.

(4) Under existing law, the State Department of Public Health licenses, registers, and regulates clinical laboratories and various clinical laboratory personnel. Existing law authorizes an HIV counselor who receives specified training and works in specified counseling and testing sites to perform HIV, hepatitis C virus (HCV), or combined HIV/HCV tests, including performing skin punctures for purposes of withdrawing blood for purposes of these tests, as specified. Under existing law, an HIV counselor must receive training directly from the Office of AIDS or work directly with HIV counseling staff that have been trained by the Office of AIDS or its agents.

This bill would authorize an HIV counselor to also perform specified sexually transmitted disease (STD) tests. The bill would require an HIV counselor to demonstrate sufficient knowledge of HIV, HCV, and STDs to provide appropriate counseling and referrals to patients and to demonstrate proficiency in administering rapid HIV, HCV, and STD tests before administering those tests. The bill would also allow HIV counselors to receive HIV counseling training through a training course that has been certified by the Office of AIDS and would authorize that department to determine which tests are to be included in trainings.

(5) 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. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing law prohibits a Medi-Cal managed care plan from restricting a beneficiary's choice of a qualified provider from whom the beneficiary may receive covered family planning services.

Under existing law, the Medi-Cal program administers the Family Planning, Access, Care, and Treatment (Family PACT) Program within the department to provide comprehensive clinical family planning services to a person with a family income at or below 200% of the federal poverty level. Existing law authorizes the department, subject to appropriation and draw down of federal matching funds, to provide reimbursement for sexually transmitted disease related services as part of the Family PACT Program.

The bill would, under specified conditions, include in the benefits for Medi-Cal and the Family PACT program home test kits for sexually transmitted diseases and the laboratory testing required to process those kits that are deemed medically necessary or appropriate and ordered directly by a health care provider or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

(6) 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. The Legislature finds and declares the following:

(a) The federal Centers for Disease Control and Prevention (CDC) estimates that 1 in 5 people in the United States have a sexually transmitted disease (STD). The CDC has also reported that STD rates have increased six years in a row. Nearly 340,000 Californians were infected with syphilis, chlamydia, or gonorrhea in 2018, which is an increase of 40 percent since 2013.

(b) The COVID-19 pandemic has exacerbated rates of STDs in California and across the country that were already skyrocketing to epidemic proportions prior to the public health emergency.

(c) Although the STD epidemic has reached communities across the state, California youth, people of color, and gay, bisexual, and transgender people are disproportionately impacted.

(d) Statewide data indicate that over one-half of all STDs in the state are experienced by California youth 15 to 24, inclusive, years of age.

(e) Currently, African American young women are 500 percent more likely to contract gonorrhea and chlamydia than their White counterparts.

(f) These disparities are expected to worsen during the COVID-19 pandemic. Studies conducted by the CDC suggest a range of factors linked to social determinants of health likely contribute to STD rate disparities, including inequitable access to safe, culturally competent, quality health care, mental health, and substance use treatment services, as well as high rates of incarceration, lack of access to economic mobility and education opportunities, adequate housing, racial segregation, and racism.

(g) A new, antibiotic-resistant strain of gonorrhea began to spread across the country during the COVID-19 crisis, a sign that the epidemic has been neglected for a long period of time.

(h) The California Department of Public Health also noted a sharp rise in disseminated gonococcal infections, a severe complication of untreated gonorrhea that spreads across the body through the bloodstream that is likely the result of people not seeking testing and treatment during the pandemic.

(i) Untreated STDs can lead to serious long-term health consequences. The CDC estimates that untreated STDs cause at least 24,000 women in the United States each year to become infertile.

(j) STDs increase both the transmission and acquisition of human immunodeficiency virus (HIV), particularly among bisexual and gay men.

(k) The human papillomavirus (HPV) can lead to increased risk of developing cancer. The number of HPV-related cancers in men dramatically increased in 2016.

(l) Untreated syphilis can also result in devastating and negative maternal child health outcomes, including infant death. The CDC estimates that of the pregnant women who acquire syphilis up to four years before delivery, 80 percent will transmit the infection to the fetus and 40 percent may result in stillbirth or death.

(m) The CDC estimated that new STD infections acquired in 2018 totaled nearly $16 billion in direct lifetime medical costs nationwide. Chlamydia, gonorrhea, and syphilis combined accounted for more than $1 billion of the total cost. Sexually acquired HIV and HPV were the most costly due to lifetime treatment for HIV at $13.7 billion and treatment for HPV-related cancers at $755 million.

(n) Approximately $1 billion is spent annually in California on health costs associated with STDs.

(o) California has the second highest syphilis rate in the nation. While 90 percent of all male syphilis cases in 2013 were among bisexual and gay men, the epidemic has spread among women. Between 2008 and 2018, the syphilis rate among women of reproductive age increased by 743 percent.

(p) California ranks fifth among states in congenital syphilis rates. In 2018, approximately 329 babies were born with congenital syphilis across the state and there were 20 stillbirths associated with the disease. More than 100 babies were born with congenital syphilis in Los Angeles County in 2020 during the COVID-19 pandemic.

(q) The scope of the STD epidemic requires a bold response. California must take a comprehensive and robust approach to strengthen our public health infrastructure, ensure access to STD coverage, and care for all Californians, during the pandemic and beyond.

SEC. 2. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section

3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in a commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within the scope of practice.

(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.

(f) Notwithstanding subdivision (a) or any other law, a pharmacist may dispense a drug prescribed pursuant to Section 120582 of the Health and Safety Code and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words "expedited partner therapy" or the letters "EPT."

(g) A pharmacist who prescribes, dispenses, furnishes, or otherwise renders EPT, as authorized in subdivision (f), shall not be liable in, and shall not be subject to, a civil, criminal, or administrative action, sanction, or penalty for rendering EPT, if the use of EPT is in compliance with this section, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

(h) A pharmacist who provides EPT under this section shall provide written notification that describes the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions.

SEC. 3. Section 1367.34 is added to the Health and Safety Code, to read:

1367.34. (a) (1) Every health care service plan contract issued, amended, renewed, or delivered on or after January 1, 2022, shall provide coverage for home test kits for sexually transmitted diseases (STD), including any laboratory costs of processing the kit, that are deemed medically necessary or appropriate and ordered directly by a clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

(2) A commercial health care plan is required to cover the services outlined in paragraph (1) when ordered for an enrollee by an in-network provider.

(b) For purposes of this section, "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.

(c) This section shall not apply to health care service plans contracting 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. For those health care service plans, the Medi-Cal requirements contained in subdivision (af) of Section 14132 of the Welfare and Institutions Code shall apply.

SEC. 4. Section 120582 of the Health and Safety Code is amended to read:

120582. (a) Notwithstanding any other law, a physician and surgeon who diagnoses a sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection, as determined by the department, or recommended in the most recent federal Centers for Disease Control and Prevention guidelines for the prevention or treatment of sexually transmitted diseases, in an individual patient may prescribe, dispense, furnish, or otherwise provide, including in a standing order, prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners. This practice shall be known as expedited partner therapy (EPT). The department may adopt regulations to implement this section.

(b) Notwithstanding any other law, a nurse practitioner pursuant to Section 2836.1 of the Business and Professions Code, a certified nurse-midwife pursuant to Section 2746.51 of the Business and Professions Code, and a physician assistant pursuant to Section 3502.1 of the Business and Professions Code may include EPT in their practice by dispensing, furnishing, or otherwise providing, including through a standing order, prescription antibiotic drugs to the sexual partner or partners of a patient with a diagnosed sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection, as determined by the department, or recommended in the most recent federal Centers for Disease Control and Prevention guidelines for the prevention or treatment of sexually transmitted diseases, without examination of the patient's sexual partner or partners.

(c) If a health care provider does not have the name of a patient's sexual partner for a drug prescribed pursuant to subdivision (a) or (b), the prescription shall include the words "expedited partner therapy" or the letters "EPT."

(d) A health care provider shall not be liable in a medical malpractice action or professional disciplinary action if the health care provider's use of EPT is in compliance with this section, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

(e) Medi-Cal coverage of expedited partner therapy pursuant to this section shall be implemented only to the extent that the State Department of Health Care Services obtains any necessary federal approvals and federal financial participation is available and not jeopardized.

SEC. 5. Section 120685 of the Health and Safety Code is amended to read:

120685. (a) Every licensed health care professional engaged in providing prenatal care or attending a birthing patient at the time of delivery, shall provide syphilis screening and testing as outlined in the most recent guidelines published by the State Department of Public Health.

(b) This section does not limit a local health jurisdiction's ability to provide additional recommendations or guidelines for syphilis screening and testing, nor does it limit the ability of a health care professional to follow other existing clinical guidelines for syphilis screening and testing recommendations, including guidelines issued by local health authorities, as long as, at minimum, the health care professional complies with subdivision (a).

SEC. 6. Section 120917 of the Health and Safety Code is amended to read:

120917. (a) An HIV counselor who meets the requirements of subdivision (f) may do all of the following:

(1) Perform any HIV, hepatitis C virus (HCV), or other sexually transmitted disease (STD) test that is classified as waived under the federal Clinical Laboratory Improvement Act (CLIA) (42 U.S.C. Sec. 263a et seq.) if all of the following conditions exist:

(A) The performance of the HIV, HCV, or STD test meets the requirements of CLIA and, subject to subparagraph (D), Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.

(B) The HIV counselor has been trained and demonstrates proficiency in administering the HIV, HCV, or STD test.

(C) The HIV counselor demonstrates sufficient knowledge of HIV, HCV, or STDs to provide appropriate counseling and referrals to patients for the test they are performing.

(D) Notwithstanding Section 1246 of the Business and Professions Code, an HIV counselor may perform skin punctures for the purpose of withdrawing blood for an HIV, HCV, or STD test, upon specific authorization from a licensed physician and surgeon, provided that the person meets all of the following requirements:

(i) The HIV counselor works under the direction of a licensed physician and surgeon.

(ii) The HIV counselor has been trained in administering rapid HIV, HCV, or STD tests and in universal infection control precautions, consistent with best infection control practices established by the Division of Occupational Safety and Health in the Department of Industrial Relations and the federal Centers for Disease Control and Prevention. The HIV counselor shall not administer a rapid HIV, HCV, or STD test until they demonstrate proficiency in administering the test.

(E) The person performing the HIV, HCV, or STD test meets the requirements for the performance of waived laboratory testing pursuant to subdivision (a) of Section 1206.5 of the Business and Professions Code. For purposes of this subdivision and subdivision (a) of Section 1206.5 of the Business and Professions Code, an HIV counselor who meets the requirements of subdivision (f) shall be “other health care personnel providing direct patient care” as referred to in paragraph (14) of subdivision (a) of Section 1206.5 of the Business and Professions Code.

(F) The patient is informed that the preliminary result of the test is indicative of the likelihood of HIV infection, HCV exposure, or other STD exposure and that the result may need to be confirmed by an additional more specific test, or, if approved by the federal Centers for Disease Control and Prevention for that purpose, a second different rapid HIV, HCV, or STD test. This subdivision does not allow an HIV counselor to perform an HIV, HCV, or STD test that is not classified as waived under the CLIA.

(2) Notwithstanding Section 1246.5 of the Business and Professions Code, order and report HIV, HCV, or STD test results from tests performed pursuant to paragraph (1) to patients without authorization from a licensed health care professional or the health care professional’s authorized representative. Patients with indeterminate or positive test results from tests performed pursuant to paragraph (1) shall be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.

(b) An HIV counselor who has been certified pursuant to subdivision (b) of Section 120871 prior to September 1, 2009, and who will administer rapid HIV, HCV, or STD skin puncture tests shall obtain training required by clause (ii) of subparagraph (B) of paragraph (1) of subdivision (a) prior to September 1, 2011. The HIV counselor shall not, unless also certified as a limited phlebotomist technician, perform a skin puncture pursuant to this section until after completing the training required by that clause.

(c) An HIV counselor who has been certified pursuant to subdivision (f) prior to January 1, 2022, and who will administer rapid STD tests, shall obtain training required by subparagraph (B) of paragraph (1) of subdivision (a). The HIV counselor shall not, unless also certified as a limited phlebotomist technician, perform STD tests pursuant to this section until after completing the training required by that clause.

(d) An HIV counselor who meets the requirements of this section with respect to performing any HIV, HCV, or STD test that is classified as waived under the CLIA may not perform any other test unless that person meets the statutory and regulatory requirements for performing that other test.

(e) This section does not certify an HIV counselor as a phlebotomy technician or a limited phlebotomy technician, or fulfill any requirements for certification as a phlebotomy technician or a limited phlebotomy technician, unless the HIV counselor has otherwise satisfied the certification requirements imposed pursuant to Section 1246 of the Business and Professions Code.

(f) (1) An HIV counselor shall meet one of the following criteria:

(A) Is trained by the Office of AIDS and working in an HIV counseling and testing site funded by the department through a local health jurisdiction, or its agents.

(B) Is working in an HIV counseling and testing site that meets both of the following criteria:

(i) Utilizes HIV counseling staff who are trained by the Office of AIDS or its agents.

(ii) Has a quality assurance plan approved by the local health department in the jurisdiction where the site is located and has HIV counseling and testing staff who comply with the quality assurance requirements specified in Section 1230 of Article 1 of Group 9 of Subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations.

(C) Has completed a training course that has been approved by the Office of AIDS.

(2) (A) The Office of AIDS or its agents may charge a fee for training HIV counseling staff.

(B) The local health department may charge a fee for the quality assurance plan approval.

(3) The Office of AIDS may determine which HIV, HCV, and STD tests are to be included in the training for HIV counseling staff. This determination may be modified by the department at any time, in consultation with appropriate local public health stakeholders. Both the establishment and modification of this determination shall be exempt from the requirements 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).

SEC. 7. Section 10123.208 is added to the Insurance Code, to read:

10123.208. (a) A health insurance policy issued, amended, renewed, or delivered on or after January 1, 2022, excluding specialized health insurance policies, shall provide coverage for home test kits for sexually transmitted diseases (STD), including any laboratory costs of processing the kit, that are deemed medically necessary or appropriate and ordered directly by an in-network clinician, or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

(b) For purposes of this section, “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.

SEC. 8. Section 14132 of the Welfare and Institutions Code is amended to read:

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

(a) Outpatient services are covered as follows:

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, 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 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. 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 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 subject to utilization controls.

(d) (1) Purchase of prescribed drugs is 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 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 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 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 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.

(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) 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, subject to utilization controls.

The department shall seek any federal waivers necessary to implement the provisions of this subdivision. 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 subdivision shall be implemented unless 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 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.

SEC. 9. Section 24007 of the Welfare and Institutions Code is amended to read:

24007. (a) The department shall determine the scope of benefits for the program, which shall include, but is not limited to, the following:

(1) Family planning related services and male and female sterilization. Family planning services for men and women include emergency and complication services directly related to the contraceptive method and followup, consultation, and referral services, as indicated, that may require treatment authorization requests.

(2) All United States Department of Health and Human Services, Federal Drug Administration-approved birth control methods, devices, and supplies that are in keeping with current standards of practice and from which the individual may choose.

(3) Culturally and linguistically appropriate health education and counseling services, including informed consent; psychosocial and medical aspects of contraception, sexuality, fertility, pregnancy, and parenthood; infertility; reproductive health care; preconceptual and nutrition counseling; prevention and treatment of sexually transmitted infection; use of contraceptive methods, devices, and supplies; possible contraceptive consequences and followup; interpersonal communication and negotiation of relationships to assist individuals and couples in effective contraceptive method use and planning families.

(4) 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.

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

(6) (A) 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 Family PACT clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

(B) For purposes of this paragraph, “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.

(C) 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.

(D) This paragraph 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.

(b) Benefits under this program shall be effective in 30 days after notice to providers, but not sooner than January 1, 1997.

SEC. 10. 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.