An act to amend Sections 1367.005 and 1635.1 of, and to add Section 1635.1 of, the Health and Safety Code, and to amend Section 10112.27 of, add Section 10123.864 to the Insurance Code, relating to human milk.

LEGISLATIVE COUNSEL’S DIGEST

Existing law licenses and regulates tissue banks and generally makes a violation of the requirements applicable to tissue banks a crime. Existing law exempts a “mothers’ milk bank,” as defined, from paying a licensing fee to be a tissue bank.

This bill would specify that a general acute care hospital is not required to have a license to operate a tissue bank to store or distribute pasteurized human milk that was obtained from a mothers’ milk bank.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, requires the Department of Managed Health Care to license and regulate health care service plans and makes a willful violation of the act a crime. Other existing law requires the Department of Insurance to regulate health insurers. Existing law requires an individual or small group health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2017, to include, at a minimum, coverage for essential health benefits pursuant to the federal Patient Protection and Affordable Care Act. Under existing law, essential health benefits include, among other things, certain maternity and newborn
health care service plans and health insurers, as specified, to provide certain health benefits and services, including, among others, maternity hospital stays, inpatient hospital and ambulatory maternity services, and maternal mental health programs.

This bill would specify that coverage of essential health benefits under a health care service plan or health insurance policy includes, with respect to maternity and newborn care, require a health care service plan contract or health insurance policy that is issued, amended, delivered, or renewed on or after January 1, 2025, to cover the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988.

Because a violation of the bill’s provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

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

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


The people of the State of California do enact as follows:

SECTION 1. Section 1367.624 is added to the Health and Safety Code, to read:

1367.624. 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 January 1, 2025, shall cover the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988.

SEC. 2. Section 1635.1 of the Health and Safety Code is amended to read:

1635.1. (a) Except as provided in subdivision (b), every tissue bank operating in California on or after July 1, 1992, shall have a current and valid tissue bank license issued or renewed by the department pursuant to Section 1639.2 or 1639.3.

(b) This chapter does not apply to any of the following:

(1) The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed pursuant
to Chapter 4 (commencing with Section 1600) or any person exempt from licensure under that chapter.

(2) The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.

(3) The collection of tissue by an individual physician and surgeon from their patient or the implantation of tissue by an individual physician and surgeon into their patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.

(4) The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.

(5) The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 486.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the tissue, has been designated by the Secretary of Health and Human Services as an OPO and meets the requirements of Sections 486.304 and 486.306 of Title 42 of the Code of Federal Regulations, as applicable.

(6) The storage of prepackaged, freeze-dried bone by a general acute care hospital.

(7) The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, if the freeze-dried bone and dermis have been obtained from a licensed tissue bank, are stored in strict accordance with a kit’s package insert and any other manufacturer instructions and guidelines, and are used for the express purpose of implantation into a patient.

(8) The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the federal Food and Drug Administration (FDA), that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician
or podiatrist acting within the scope and authority of their license
and practicing in a lawful practice setting. The medical device or
biologic product must have been obtained from a
California-licensed tissue bank, been stored in strict accordance
with the device’s or product’s package insert and any other
manufacturer instructions, and used solely for the express purpose
of direct implantation into or application on the practitioner’s own
patient. In order to be eligible for the exemption in this paragraph,
the entity or organization where the physician or podiatrist who is
eligible for the exemption is practicing shall notify the department,
in writing, that the practitioner is licensed and meets the
requirements of this paragraph. The notification shall include all
of the following:
(A) A list of all practitioners to whom the notice applies.
(B) Acknowledgment that each listed practitioner uses the
medical device or biologic product in the scope and authority of
their license and practice for the purposes of direct patient care as
described in this paragraph.
(C) A statement that each listed practitioner agrees to strictly
abide by the directions for storage in the device’s or product’s
package insert and any other manufacturer instructions and
guidelines.
(D) Acknowledgment by each practitioner that the medical
device or biologic product shall not be resold or distributed.
(9) The collection, processing, storage, or distribution of any
organ, as defined in paragraph (2) of subdivision (c) of Section
1635, within a single general acute care hospital, as defined in
subdivision (a) of Section 1250, operating a Medicare-approved
transplant program.
(10) The storage of allograft tissue by a person if all of the
following apply:
(A) The person, as defined in Section 1635, is a hospital, or an
outpatient setting regulated by the Medical Board of California
pursuant to Chapter 1.3 (commencing with Section 1248), including
an ambulatory surgical center.
(B) The person maintains a log that includes the date on which
the allograft tissue was received, the expiration date of the allograft
tissue, the date on which each allograft tissue is used for clinical
purposes, and the disposition of any allograft tissue samples that
remain unused at the time the allograft tissue expires.
(C) The allograft tissue meets all of the following:

(i) The allograft tissue was obtained from a tissue bank licensed by the state.

(ii) Each allograft tissue is individually boxed and labeled with a unique identification number and expiration date so that opening the shipping container will not disturb or otherwise alter any of the allograft tissue that is not being utilized.

(iii) The allograft tissue is intended for the express purpose of implantation into or application on a patient.

(iv) The allograft tissue is not intended for further distribution.

(v) The allograft tissue is registered with the FDA and designated to be maintained at ambient room temperature requiring no refrigeration.

(11) The storage or preparation for patient administration of tissue performed at a clinical trial site that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to the federal act.

(12) The storage or distribution of pasteurized human milk that was obtained from a mothers' milk bank, as defined in Section 14132.34 of the Welfare and Institutions Code, by a general acute care hospital.

SEC. 3. Section 10123.864 is added to the Insurance Code, to read:

10123.864. A health insurance policy, except a specialized health insurance policy, that is issued, amended, delivered, or renewed on or after January 1, 2025, shall cover the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988.

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.

SECTION 1. Section 1367.005 of the Health and Safety Code is amended to read:

1367.005. (a) An individual or small group health care service plan contract issued, amended, or renewed on or after January 1, 2017, shall include, at a minimum, coverage for essential health benefits pursuant to the federal Patient Protection and Affordable Care Act (PPACA) and as outlined in this section. For purposes of this section, “essential health benefits” means all of the following:

(1) Health benefits within the categories identified in Section 1302(b) of PPACA: ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care.

(2) (A) The health benefits covered by the Kaiser Foundation Health Plan Small Group HMO 30 plan (federal health product identification number 40513CA035) as this plan was offered during the first quarter of 2014, as follows, regardless of whether the benefits are specifically referenced in the evidence of coverage or plan contract for that plan:

(i) Medically necessary basic health care services, as defined in subdivision (b) of Section 1345 and Section 1300.67 of Title 28 of the California Code of Regulations.

(ii) The health benefits mandated to be covered by the plan pursuant to statutes enacted before December 31, 2011, as described in the following sections: Sections 1367.002, 1367.06, and 1367.35 (preventive services for children); Section 1367.25 (prescription drug coverage for contraceptives); Section 1367.45 (AIDS vaccine); Section 1367.46 (HIV testing); Section 1367.51 (diabetes); Section 1367.54 (alpha-fetoprotein testing); Section 1367.6 (breast cancer screening); Section 1367.61 (prosthetics for laryngectomy); Section 1367.62 (maternity hospital stay); Section 1367.63 (reconstructive surgery); Section 1367.635 (mastectomies); Section 1367.64 (prostate cancer); Section 1367.65 (mammography); Section 1367.66 (cervical cancer); Section
1367.665 (cancer screening tests); Section 1367.67 (osteoporosis);
Section 1367.68 (surgical procedures for jaw bones); Section
1367.71 (anesthesia for dental); Section 1367.9 (conditions
attributable to diethylstilbestrol); Section 1368.2 (hospice care);
Section 1370.6 (cancer clinical trials); Section 1371.5 (emergency
response ambulance or ambulance transport services); subdivision
(b) of Section 1373 (sterilization operations or procedures); Section
1373.4 (inpatient hospital and ambulatory maternity); Section
1374.56 (phenylketonuria); Section 1374.17 (organ transplants for
HIV); Section 1374.72 (mental health parity); and Section 1374.73
(autism/behavioral health treatment).

(iii) Any other benefits mandated to be covered by the plan
pursuant to statutes enacted before December 31, 2011, as
described in those statutes.

(iv) The health benefits covered by the plan that are not
otherwise required to be covered under this chapter, to the extent
required pursuant to Sections 1367.18, 1367.21, 1367.215, 1367.22,
1367.24, and 1367.25, and Section 1300.67.24 of Title 28 of the
California Code of Regulations.

(v) Any other health benefits covered by the plan that are not
otherwise required to be covered under this chapter.

(B) If there are any conflicts or omissions in the plan identified
in subparagraph (A) as compared with the requirements for health
benefits under this chapter that were enacted prior to December
31, 2011, the requirements of this chapter shall be controlling;
except as otherwise specified in this section.

(C) Notwithstanding subparagraph (B) or any other provision
of this section, the home health services benefits covered under
the plan identified in subparagraph (A) shall be deemed to not be
in conflict with this chapter.

(D) For purposes of this section, the Paul Wellstone and Pete
Domenici Mental Health Parity and Addiction Equity Act of 2008
(Public Law 110-343) shall apply to a contract subject to this
section. Coverage of mental health and substance use disorder
services pursuant to this paragraph, along with any scope and
duration limits imposed on the benefits, shall be in compliance
with the Paul Wellstone and Pete Domenici Mental Health Parity
and Addiction Equity Act of 2008 (Public Law 110-343), and all
rules, regulations, or guidance issued pursuant to Section 2726 of
the federal Public Health Service Act (42 U.S.C. Sec. 300gg-26);
(3) With respect to habilitative services, in addition to any habilitative services and devices identified in paragraph (2), coverage shall also be provided as required by federal rules, regulations, and guidance issued pursuant to Section 1302(b) of PPACA. Habilitative services and devices shall be covered under the same terms and conditions applied to rehabilitative services and devices under the plan contract. Limits on habilitative and rehabilitative services and devices shall not be combined.

(4) With respect to pediatric vision care, the same health benefits for pediatric vision care covered under the Federal Employees Dental and Vision Insurance Program vision plan with the largest national enrollment as of the first quarter of 2014. The pediatric vision care benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any vision services covered under the plan identified in paragraph (2).

(5) With respect to pediatric oral care, the same health benefits for pediatric oral care covered under the dental benefit received by children under the Medi-Cal program as of 2014, including the provision of medically necessary orthodontic care provided pursuant to the federal Children’s Health Insurance Program Reauthorization Act of 2009. The pediatric oral care benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any dental or orthodontic services covered under the plan identified in paragraph (2).

(6) With respect to maternity and newborn care, the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988. The benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any maternity or newborn services covered under the plan identified in paragraph (2).

(b) Treatment limitations imposed on health benefits described in this section shall be no greater than the treatment limitations imposed by the corresponding plans identified in subdivision (a), subject to the requirements set forth in paragraph (2) of subdivision (a).

(c) Except as provided in subdivision (d), this section does not permit a health care service plan to make substitutions for the benefits required to be covered under this section, regardless of whether those substitutions are actuarially equivalent.
(d) To the extent permitted under Section 1302 of PPACA and any rules, regulations, or guidance issued pursuant to that section, and to the extent that substitution would not create an obligation for the state to defray costs for any individual, a plan may substitute its prescription drug formulary for the formulary provided under the plan identified in subdivision (a) if the coverage for prescription drugs complies with the sections referenced in clauses (ii) and (iv) of subparagraph (A) of paragraph (2) of subdivision (a) that apply to prescription drugs.

(e) A health care service plan, or its agent, solicitor, or representative, shall not issue, deliver, renew, offer, market, represent, or sell any product, contract, or discount arrangement as compliant with the essential health benefits requirement in federal law, unless it meets all of the requirements of this section.

(f) This section applies regardless of whether the plan contract is offered inside or outside the California Health Benefit Exchange created by Section 100500 of the Government Code.

(g) This section does not exempt a plan or a plan contract from meeting other applicable requirements of law.

(h) This section does not prohibit a plan contract from covering additional benefits, including, but not limited to, spiritual care services that are tax deductible under Section 213 of the Internal Revenue Code.

(i) Subdivision (a) does not apply to any of the following:

(1) A specialized health care service plan contract.

(2) A Medicare supplement plan.

(3) A plan contract that qualifies as a grandfathered health plan under Section 1251 of PPACA or any rules, regulations, or guidance issued pursuant to that section.

(j) This section shall not be implemented in a manner that conflicts with a requirement of PPACA.

(k) An essential health benefit is required to be provided under this section only to the extent that federal law does not require the state to defray the costs of the benefit.

(l) This section does not obligate the state to incur costs for the coverage of benefits that are not essential health benefits as defined in this section.

(m) A plan is not required to cover, under this section, changes to health benefits that are the result of statutes enacted on or after December 31, 2011.
(n) (1) The department may adopt emergency regulations implementing this section. The department may, on a one-time basis, readopt any emergency regulation authorized by this section that is the same as, or substantially equivalent to, an emergency regulation previously adopted under this section.

(2) The initial adoption of emergency regulations implementing this section and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.

(3) The initial adoption of emergency regulations implementing this section made during the 2015–16 Regular Session of the Legislature and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.

(4) The director shall consult with the Insurance Commissioner to ensure consistency and uniformity in the development of regulations under this subdivision.

(5) This subdivision shall become inoperative on July 1, 2018.

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

(1) “Habilitative services” means health care services and devices that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology, and other services for people with disabilities in a variety of inpatient or outpatient settings, or both. Habilitative services shall be covered under the same terms and conditions applied to rehabilitative services under the plan contract.
(2) (A) “Health benefits,” unless otherwise required to be defined pursuant to federal rules, regulations, or guidance issued pursuant to Section 1302(b) of PPACA, means health care items or services for the diagnosis, cure, mitigation, treatment, or prevention of illness, injury, disease, or a health condition, including a behavioral health condition.

(B) “Health benefits” does not mean any cost-sharing requirements such as copayments, coinsurance, or deductibles.

(3) “PPACA” means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(4) “Small group health care service plan contract” means a group health care service plan contract issued to a small employer, as defined in Section 1357.500.

SEC. 2. Section 1635.1 of the Health and Safety Code is amended to read:

1635.1. (a) Except as provided in subdivision (b), every tissue bank operating in California on or after July 1, 1992, shall have a current and valid tissue bank license issued or renewed by the department pursuant to Section 1639.2 or 1639.3.

(b) This chapter does not apply to any of the following:

(1) The collection, processing, storage, or distribution of human whole blood or its derivatives by blood banks licensed pursuant to Chapter 4 (commencing with Section 1600) or any person exempt from licensure under that chapter.

(2) The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training, education, or for other medical or scientific research or investigation, when transplantation of the tissue is not intended or reasonably foreseeable.

(3) The collection of tissue by an individual physician and surgeon from their patient or the implantation of tissue by an individual physician and surgeon into their patient. This exemption shall not be interpreted to apply to any processing or storage of the tissue, except for the processing and storage of semen by an individual physician and surgeon when the semen was collected by that physician and surgeon from a semen donor or obtained by that physician and surgeon from a tissue bank licensed under this chapter.

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(4) The collection, processing, storage, or distribution of fetal tissue or tissue derived from a human embryo or fetus.

(5) The collection, processing, storage, or distribution by an organ procurement organization (OPO), as defined in Section 486.302 of Title 42 of the Code of Federal Regulations, if the OPO, at the time of collection, processing, storage, and distribution of the tissue, has been designated by the Secretary of Health and Human Services as an OPO and meets the requirements of Sections 486.304 and 486.306 of Title 42 of the Code of Federal Regulations, as applicable.

(6) The storage of prepackaged, freeze-dried bone by a general acute-care hospital.

(7) The storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, if the freeze-dried bone and dermis have been obtained from a licensed tissue bank, are stored in strict accordance with a kit’s package insert and any other manufacturer instructions and guidelines, and are used for the express purpose of implantation into a patient.

(8) The storage of a human cell, tissue, or cellular- or tissue-based product (HCT/P), as defined by the federal Food and Drug Administration (FDA), that is either a medical device approved pursuant to Section 510 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a biologic product approved under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262) by a licensed physician or podiatrist acting within the scope and authority of their license and practicing in a lawful practice setting. The medical device or biologic product must have been obtained from a California-licensed tissue bank, been stored in strict accordance with the device’s or product’s package insert and any other manufacturer instructions, and used solely for the express purpose of direct implantation into or application on the practitioner’s own patient. In order to be eligible for the exemption in this paragraph, the entity or organization where the physician or podiatrist who is eligible for the exemption is practicing shall notify the department, in writing, that the practitioner is licensed and meets the requirements of this paragraph. The notification shall include all of the following:

(A) A list of all practitioners to whom the notice applies.
(B) Acknowledgment that each listed practitioner uses the
medical device or biologic product in the scope and authority of
their license and practice for the purposes of direct patient care as
described in this paragraph.

(C) A statement that each listed practitioner agrees to strictly
abide by the directions for storage in the device’s or product’s
package insert and any other manufacturer instructions and
guidelines.

(D) Acknowledgment by each practitioner that the medical
device or biologic product shall not be resold or distributed.

(9) The collection, processing, storage, or distribution of any
organ, as defined in paragraph (2) of subdivision (c) of Section
1635, within a single general acute care hospital, as defined in
subdivision (a) of Section 1250, operating a Medicare-approved
transplant program:

(10) The storage of allograft tissue by a person if all of the
following apply:

(A) The person, as defined in Section 1635, is a hospital, or an
outpatient setting regulated by the Medical Board of California
pursuant to Chapter 1.3 (commencing with Section 1248), including
an ambulatory surgical center.

(B) The person maintains a log that includes the date on which
the allograft tissue was received, the expiration date of the allograft
tissue, the date on which each allograft tissue is used for clinical
purposes, and the disposition of any allograft tissue samples that
remain unused at the time the allograft tissue expires.

(C) The allograft tissue meets all of the following:

(i) The allograft tissue was obtained from a tissue bank licensed
by the state.

(ii) Each allograft tissue is individually boxed and labeled with
a unique identification number and expiration date so that opening
the shipping container will not disturb or otherwise alter any of
the allograft tissue that is not being utilized.

(iii) The allograft tissue is intended for the express purpose of
implantation into or application on a patient.

(iv) The allograft tissue is not intended for further distribution.

(v) The allograft tissue is registered with the FDA and
designated to be maintained at ambient room temperature requiring
no refrigeration.
(11) The storage or preparation for patient administration of tissue performed at a clinical trial site that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Sec. 360(j)(g)) and the regulations adopted pursuant to the federal act.

(12) The storage or distribution of pasteurized human milk that was obtained from a mothers' milk bank, as defined in Section 14132.34 of the Welfare and Institutions Code, by a general acute care hospital.

SEC. 3. Section 10112.27 of the Insurance Code is amended to read:

10112.27. (a) An individual or small group health insurance policy issued, amended, or renewed on or after January 1, 2017, shall include, at a minimum, coverage for essential health benefits pursuant to the federal Patient Protection and Affordable Care Act (PPACA) and as outlined in this section. This section shall exclusively govern the benefits a health insurer must cover as essential health benefits. For purposes of this section, “essential health benefits” means all of the following:

(1) Health benefits within the categories identified in Section 1302(b) of PPACA: ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care.

(2) (A) The health benefits covered by the Kaiser Foundation Health Plan Small Group HMO 30 plan (federal health product identification number 40513CA035) as this plan was offered during the first quarter of 2014, as follows, regardless of whether the benefits are specifically referenced in the plan contract or evidence of coverage for that plan:

(i) Medically necessary basic health care services, as defined in subdivision (b) of Section 1345 of the Health and Safety Code
and Section 1300.67 of Title 28 of the California Code of Regulations.

(ii) The health benefits mandated to be covered by the plan pursuant to statutes enacted before December 31, 2011, as described in the following sections of the Health and Safety Code: Sections 1367.002, 1367.06, and 1367.35 (preventive services for children); Section 1367.25 (prescription drug coverage for contraceptives); Section 1367.45 (AIDS vaccine); Section 1367.46 (HIV testing); Section 1367.51 (diabetes); Section 1367.54 (alpha-fetoprotein testing); Section 1367.6 (breast cancer screening); Section 1367.61 (prosthetics for laryngectomy); Section 1367.62 (maternity hospital stay); Section 1367.63 (reconstructive surgery); Section 1367.635 (mastectomies); Section 1367.64 (prostate cancer); Section 1367.65 (mammography); Section 1367.66 (cervical cancer); Section 1367.665 (cancer screening tests); Section 1367.67 (osteoporosis); Section 1367.68 (surgical procedures for jaw bones); Section 1367.71 (anesthesia for dental); Section 1367.9 (conditions attributable to diethylstilbestrol); Section 1368.2 (hospice care); Section 1370.6 (cancer clinical trials); Section 1371.5 (emergency response ambulance service); subdivision (b) of Section 1373 (sterilization operations or procedures); Section 1373.4 (inpatient hospital and ambulatory maternity); Section 1374.56 (phenylketonuria); Section 1374.17 (organ transplants for HIV); Section 1374.72 (mental health parity); and Section 1374.73 (autism/behavioral health treatment).

(iii) Any other benefits mandated to be covered by the plan pursuant to statutes enacted before December 31, 2011, as described in those statutes.

(iv) The health benefits covered by the plan that are not otherwise required to be covered under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code, to the extent otherwise required pursuant to Sections 1367.18, 1367.21, 1367.215, 1367.22, 1367.24, and 1367.25 of the Health and Safety Code, and Section 1300.67.24 of Title 28 of the California Code of Regulations.

(v) Any other health benefits covered by the plan that are not otherwise required to be covered under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.
(B) If there are any conflicts or omissions in the plan identified in subparagraph (A) as compared with the requirements for health benefits under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code that were enacted before December 31, 2011, the requirements of Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code shall control, except as otherwise specified in this section.

(C) Notwithstanding subparagraph (B) or any other provision of this section, the home health services benefits covered under the plan identified in subparagraph (A) shall not be in conflict with Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(D) For purposes of this section, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343) shall apply to a policy subject to this section. Coverage of mental health and substance use disorder services pursuant to this paragraph, along with any scope and duration limits imposed on the benefits, shall be in compliance with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343), and all rules, regulations, and guidance issued pursuant to Section 2726 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-26).

(3) With respect to habilitative services, in addition to any habilitative services and devices identified in paragraph (2), coverage shall also be provided as required by federal rules, regulations, or guidance issued pursuant to Section 1302(b) of PPACA. Habilitative services and devices shall be covered under the same terms and conditions applied to rehabilitative services and devices under the policy. Limits on habilitative and rehabilitative services and devices shall not be combined.

(4) With respect to pediatric vision care, the same health benefits for pediatric vision care covered under the Federal Employees Dental and Vision Insurance Program vision plan with the largest national enrollment as of the first quarter of 2014. The pediatric vision care services covered pursuant to this paragraph shall be in addition to, and shall not replace, any vision services covered under the plan identified in paragraph (2).

(5) With respect to pediatric oral care, the same health benefits for pediatric oral care covered under the dental benefit received by children under the Medi-Cal program as of 2014, including the
provision of medically necessary orthodontic care provided pursuant to the federal Children's Health Insurance Program Reauthorization Act of 2009. The pediatric oral care benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any dental or orthodontic services covered under the plan identified in paragraph (2).

(6) With respect to maternity and newborn care, the same health benefits for human milk and human milk derivatives covered under the Medi-Cal program as of 1988. The benefits covered pursuant to this paragraph shall be in addition to, and shall not replace, any maternity or newborn services covered under the plan identified in paragraph (2).

(b) Treatment limitations imposed on health benefits described in this section shall be no greater than the treatment limitations imposed by the corresponding plans identified in subdivision (a), subject to the requirements set forth in paragraph (2) of subdivision (a).

(c) Except as provided in subdivision (d), this section does not permit a health insurer to make substitutions for the benefits required to be covered under this section, regardless of whether those substitutions are actuarially equivalent.

(d) To the extent permitted under Section 1302 of PPACA and any rules, regulations, or guidance issued pursuant to that section, and to the extent that substitution would not create an obligation for the state to defray costs for any individual, an insurer may substitute its prescription drug formulary for the formulary provided under the plan identified in subdivision (a) if the coverage for prescription drugs complies with the sections referenced in clauses (ii) and (iv) of subparagraph (A) of paragraph (2) of subdivision (a).

(e) A health insurer, or its agent, producer, or representative, shall not issue, deliver, renew, offer, market, represent, or sell any product, policy, or discount arrangement as compliant with the essential health benefits requirement in federal law, unless it meets all of the requirements of this section. This subdivision shall be enforced in the same manner as Section 790.03, including through the means specified in Sections 790.035 and 790.05.

(f) This section applies regardless of whether the policy is offered inside or outside the California Health Benefit Exchange created by Section 100500 of the Government Code.
(g) This section does not exempt a health insurer or a health insurance policy from meeting other applicable requirements of law.

(h) This section does not prohibit a policy from covering additional benefits, including, but not limited to, spiritual care services that are tax deductible under Section 213 of the Internal Revenue Code.

(i) Subdivision (a) does not apply to any of the following:

(1) A policy that provides excepted benefits as described in Sections 2722 and 2791 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-21; 42 U.S.C. Sec. 300gg-91).

(2) A policy that qualifies as a grandfathered health plan under Section 1251 of PPACA or any binding rules, regulations, or guidance issued pursuant to that section.

(j) This section shall not be implemented in a manner that conflicts with a requirement of PPACA.

(k) An essential health benefit is required to be provided under this section only to the extent that federal law does not require the state to defray the costs of the benefit.

(l) This section does not obligate the state to incur costs for the coverage of benefits that are not essential health benefits as defined in this section.

(m) An insurer is not required to cover, under this section, changes to health benefits that are the result of statutes enacted on or after December 31, 2011.

(n) (1) The commissioner may adopt emergency regulations implementing this section. The commissioner, on a one-time basis, may readopt any emergency regulation authorized by this section that is the same as, or substantially equivalent to, an emergency regulation previously adopted under this section.

(2) The initial adoption of emergency regulations implementing this section and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.
(3) The initial adoption of emergency regulations implementing this section made during the 2015–16 Regular Session of the Legislature and the readoption of emergency regulations authorized by this subdivision shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readoption of emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and each shall remain in effect for no more than 180 days, by which time final regulations may be adopted.

(4) The commissioner shall consult with the Director of the Department of Managed Health Care to ensure consistency and uniformity in the development of regulations under this subdivision.

(5) This subdivision shall become inoperative on July 1, 2018.

(o) This section does not impose on health insurance policies the cost-sharing or network limitations of the plans identified in subdivision (a) except to the extent otherwise required to comply with this code, including this section, and as otherwise applicable to all health insurance policies offered to individuals and small groups.

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

(1) "Habilitation services" means health care services and devices that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology, and other services for people with disabilities in a variety of inpatient or outpatient settings, or both. Habilitation services shall be covered under the same terms and conditions applied to rehabilitative services under the policy.

(2) (A) "Health benefits," unless otherwise required to be defined pursuant to federal rules, regulations, or guidance issued pursuant to Section 1302(b) of PPACA, means health care items or services for the diagnosis, cure, mitigation, treatment, or prevention of illness, injury, disease, or a health condition, including a behavioral health condition.

(B) "Health benefits" does not mean any cost-sharing requirements such as copayments, coinsurance, or deductibles.
(3) “PPACA” means the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.

(4) “Small-group health-insurance policy” means a group health insurance policy issued to a small employer, as defined in subdivision (q) of Section 10753.

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.