

AMENDED IN ASSEMBLY MARCH 11, 2024

CALIFORNIA LEGISLATURE—2023–24 REGULAR SESSION

**ASSEMBLY BILL**

**No. 3059**

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**Introduced by Assembly Member Weber**

February 16, 2024

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An act to amend ~~Sections 1367.005 and 1635.1 of Section 1635.1 of~~ *Section 1635.1 of*, and to add *Section 1367.624* to, 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

AB 3059, as amended, Weber. Human milk.

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~~

~~care; 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.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

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

- 1     SECTION 1. Section 1367.624 is added to the Health and
- 2     Safety Code, to read:
- 3     1367.624. A health care service plan contract, except for a
- 4     specialized health care service plan contract, that is issued,
- 5     amended, delivered, or renewed on or after January 1, 2025, shall
- 6     cover the same health benefits for human milk and human milk
- 7     derivatives covered under the Medi-Cal program as of 1988.
- 8     SEC. 2. Section 1635.1 of the Health and Safety Code is
- 9     amended to read:
- 10    1635.1. (a) Except as provided in subdivision (b), every tissue
- 11    bank operating in California on or after July 1, 1992, shall have a
- 12    current and valid tissue bank license issued or renewed by the
- 13    department pursuant to Section 1639.2 or 1639.3.
- 14    (b) This chapter does not apply to any of the following:
- 15    (1) The collection, processing, storage, or distribution of human
- 16    whole blood or its derivatives by blood banks licensed pursuant

1 to Chapter 4 (commencing with Section 1600) or any person  
2 exempt from licensure under that chapter.

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

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

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

18 (5) The collection, processing, storage, or distribution by an  
19 organ procurement organization (OPO), as defined in Section  
20 486.302 of Title 42 of the Code of Federal Regulations, if the OPO,  
21 at the time of collection, processing, storage, and distribution of  
22 the tissue, has been designated by the Secretary of Health and  
23 Human Services as an OPO and meets the requirements of Sections  
24 486.304 and 486.306 of Title 42 of the Code of Federal  
25 Regulations, as applicable.

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

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

34 (8) The storage of a human cell, tissue, or cellular- or  
35 tissue-based product (HCT/P), as defined by the federal Food and  
36 Drug Administration (FDA), that is either a medical device  
37 approved pursuant to Section 510 or 515 of the Federal Food,  
38 Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a  
39 biologic product approved under Section 351 of the federal Public  
40 Health Service Act (42 U.S.C. Sec. 262) by a licensed physician

1 or podiatrist acting within the scope and authority of their license  
2 and practicing in a lawful practice setting. The medical device or  
3 biologic product must have been obtained from a  
4 California-licensed tissue bank, been stored in strict accordance  
5 with the device's or product's package insert and any other  
6 manufacturer instructions, and used solely for the express purpose  
7 of direct implantation into or application on the practitioner's own  
8 patient. In order to be eligible for the exemption in this paragraph,  
9 the entity or organization where the physician or podiatrist who is  
10 eligible for the exemption is practicing shall notify the department,  
11 in writing, that the practitioner is licensed and meets the  
12 requirements of this paragraph. The notification shall include all  
13 of the following:

14 (A) A list of all practitioners to whom the notice applies.

15 (B) Acknowledgment that each listed practitioner uses the  
16 medical device or biologic product in the scope and authority of  
17 their license and practice for the purposes of direct patient care as  
18 described in this paragraph.

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

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

25 (9) The collection, processing, storage, or distribution of any  
26 organ, as defined in paragraph (2) of subdivision (c) of Section  
27 1635, within a single general acute care hospital, as defined in  
28 subdivision (a) of Section 1250, operating a Medicare-approved  
29 transplant program.

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

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

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

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

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

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

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

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

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

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

23 *(12) The storage or distribution of pasteurized human milk that*  
24 *was obtained from a mothers' milk bank, as defined in Section*  
25 *14132.34 of the Welfare and Institutions Code, by a general acute*  
26 *care hospital.*

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

29 *10123.864. A health insurance policy, except a specialized*  
30 *health insurance policy, that is issued, amended, delivered, or*  
31 *renewed on or after January 1, 2025, shall cover the same health*  
32 *benefits for human milk and human milk derivatives covered under*  
33 *the Medi-Cal program as of 1988.*

34 *SEC. 4. No reimbursement is required by this act pursuant to*  
35 *Section 6 of Article XIII B of the California Constitution because*  
36 *the only costs that may be incurred by a local agency or school*  
37 *district will be incurred because this act creates a new crime or*  
38 *infraction, eliminates a crime or infraction, or changes the penalty*  
39 *for a crime or infraction, within the meaning of Section 17556 of*  
40 *the Government Code, or changes the definition of a crime within*

1 *the meaning of Section 6 of Article XIII B of the California*  
2 *Constitution.*

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

5 ~~1367.005. (a) An individual or small group health care service~~  
6 ~~plan contract issued, amended, or renewed on or after January 1,~~  
7 ~~2017, shall include, at a minimum, coverage for essential health~~  
8 ~~benefits pursuant to the federal Patient Protection and Affordable~~  
9 ~~Care Act (PPACA) and as outlined in this section. For purposes~~  
10 ~~of this section, “essential health benefits” means all of the~~  
11 ~~following:~~

12 ~~(1) Health benefits within the categories identified in Section~~  
13 ~~1302(b) of PPACA: ambulatory patient services, emergency~~  
14 ~~services, hospitalization, maternity and newborn care, mental health~~  
15 ~~and substance use disorder services, including behavioral health~~  
16 ~~treatment, prescription drugs, rehabilitative and habilitative services~~  
17 ~~and devices, laboratory services, preventive and wellness services~~  
18 ~~and chronic disease management, and pediatric services, including~~  
19 ~~oral and vision care.~~

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

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

29 ~~(ii) The health benefits mandated to be covered by the plan~~  
30 ~~pursuant to statutes enacted before December 31, 2011, as~~  
31 ~~described in the following sections: Sections 1367.002, 1367.06,~~  
32 ~~and 1367.35 (preventive services for children); Section 1367.25~~  
33 ~~(prescription drug coverage for contraceptives); Section 1367.45~~  
34 ~~(AIDS vaccine); Section 1367.46 (HIV testing); Section 1367.51~~  
35 ~~(diabetes); Section 1367.54 (alpha-fetoprotein testing); Section~~  
36 ~~1367.6 (breast cancer screening); Section 1367.61 (prosthetics for~~  
37 ~~laryngectomy); Section 1367.62 (maternity hospital stay); Section~~  
38 ~~1367.63 (reconstructive surgery); Section 1367.635 (mastectomies);~~  
39 ~~Section 1367.64 (prostate cancer); Section 1367.65~~  
40 ~~(mammography); Section 1367.66 (cervical cancer); Section~~

1 1367.665 (cancer screening tests); Section 1367.67 (osteoporosis);  
2 Section 1367.68 (surgical procedures for jaw bones); Section  
3 1367.71 (anesthesia for dental); Section 1367.9 (conditions  
4 attributable to diethylstilbestrol); Section 1368.2 (hospice care);  
5 Section 1370.6 (cancer clinical trials); Section 1371.5 (emergency  
6 response ambulance or ambulance transport services); subdivision  
7 (b) of Section 1373 (sterilization operations or procedures); Section  
8 1373.4 (inpatient hospital and ambulatory maternity); Section  
9 1374.56 (phenylketonuria); Section 1374.17 (organ transplants for  
10 HIV); Section 1374.72 (mental health parity); and Section 1374.73  
11 (autism/behavioral health treatment).

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

15 (iv) The health benefits covered by the plan that are not  
16 otherwise required to be covered under this chapter, to the extent  
17 required pursuant to Sections 1367.18, 1367.21, 1367.215, 1367.22,  
18 1367.24, and 1367.25, and Section 1300.67.24 of Title 28 of the  
19 California Code of Regulations.

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

22 (B) If there are any conflicts or omissions in the plan identified  
23 in subparagraph (A) as compared with the requirements for health  
24 benefits under this chapter that were enacted prior to December  
25 31, 2011, the requirements of this chapter shall be controlling,  
26 except as otherwise specified in this section.

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

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

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

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

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

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

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

36 ~~(c) Except as provided in subdivision (d), this section does not~~  
37 ~~permit a health care service plan to make substitutions for the~~  
38 ~~benefits required to be covered under this section, regardless of~~  
39 ~~whether those substitutions are actuarially equivalent.~~



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

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

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

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

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

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

25 ~~(1) A specialized health care service plan contract.~~

26 ~~(2) A Medicare supplement plan.~~

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

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

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

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

38 ~~(m) A plan is not required to cover, under this section, changes~~  
39 ~~to health benefits that are the result of statutes enacted on or after~~  
40 ~~December 31, 2011.~~

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

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

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

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

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

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

32     ~~(1) “Habilitative services” means health care services and~~  
 33 ~~devices that help a person keep, learn, or improve skills and~~  
 34 ~~functioning for daily living. Examples include therapy for a child~~  
 35 ~~who is not walking or talking at the expected age. These services~~  
 36 ~~may include physical and occupational therapy, speech-language~~  
 37 ~~pathology, and other services for people with disabilities in a~~  
 38 ~~variety of inpatient or outpatient settings, or both. Habilitative~~  
 39 ~~services shall be covered under the same terms and conditions~~  
 40 ~~applied to rehabilitative services under the plan contract.~~

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

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

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

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

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

19     ~~1635.1. (a) Except as provided in subdivision (b), every tissue~~  
20 ~~bank operating in California on or after July 1, 1992, shall have a~~  
21 ~~current and valid tissue bank license issued or renewed by the~~  
22 ~~department pursuant to Section 1639.2 or 1639.3.~~

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

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

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

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

- 1     ~~(4) The collection, processing, storage, or distribution of fetal~~  
2 ~~tissue or tissue derived from a human embryo or fetus.~~
- 3     ~~(5) The collection, processing, storage, or distribution by an~~  
4 ~~organ procurement organization (OPO), as defined in Section~~  
5 ~~486.302 of Title 42 of the Code of Federal Regulations, if the OPO,~~  
6 ~~at the time of collection, processing, storage, and distribution of~~  
7 ~~the tissue, has been designated by the Secretary of Health and~~  
8 ~~Human Services as an OPO and meets the requirements of Sections~~  
9 ~~486.304 and 486.306 of Title 42 of the Code of Federal~~  
10 ~~Regulations, as applicable.~~
- 11     ~~(6) The storage of prepackaged, freeze-dried bone by a general~~  
12 ~~acute care hospital.~~
- 13     ~~(7) The storage of freeze-dried bone and dermis by any licensed~~  
14 ~~dentist practicing in a lawful practice setting, if the freeze-dried~~  
15 ~~bone and dermis have been obtained from a licensed tissue bank,~~  
16 ~~are stored in strict accordance with a kit's package insert and any~~  
17 ~~other manufacturer instructions and guidelines, and are used for~~  
18 ~~the express purpose of implantation into a patient.~~
- 19     ~~(8) The storage of a human cell, tissue, or cellular or~~  
20 ~~tissue-based product (HCT/P), as defined by the federal Food and~~  
21 ~~Drug Administration (FDA), that is either a medical device~~  
22 ~~approved pursuant to Section 510 or 515 of the Federal Food,~~  
23 ~~Drug, and Cosmetic Act (21 U.S.C. Sec. 360 et seq.) or that is a~~  
24 ~~biologic product approved under Section 351 of the federal Public~~  
25 ~~Health Service Act (42 U.S.C. Sec. 262) by a licensed physician~~  
26 ~~or podiatrist acting within the scope and authority of their license~~  
27 ~~and practicing in a lawful practice setting. The medical device or~~  
28 ~~biologic product must have been obtained from a~~  
29 ~~California-licensed tissue bank, been stored in strict accordance~~  
30 ~~with the device's or product's package insert and any other~~  
31 ~~manufacturer instructions, and used solely for the express purpose~~  
32 ~~of direct implantation into or application on the practitioner's own~~  
33 ~~patient. In order to be eligible for the exemption in this paragraph,~~  
34 ~~the entity or organization where the physician or podiatrist who is~~  
35 ~~eligible for the exemption is practicing shall notify the department,~~  
36 ~~in writing, that the practitioner is licensed and meets the~~  
37 ~~requirements of this paragraph. The notification shall include all~~  
38 ~~of the following:~~
- 39     ~~(A) A list of all practitioners to whom the notice applies.~~

1 ~~(B) Acknowledgment that each listed practitioner uses the~~  
2 ~~medical device or biologic product in the scope and authority of~~  
3 ~~their license and practice for the purposes of direct patient care as~~  
4 ~~described in this paragraph.~~

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

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

11 ~~(9) The collection, processing, storage, or distribution of any~~  
12 ~~organ, as defined in paragraph (2) of subdivision (c) of Section~~  
13 ~~1635, within a single general acute care hospital, as defined in~~  
14 ~~subdivision (a) of Section 1250, operating a Medicare-approved~~  
15 ~~transplant program.~~

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

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

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

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

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

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

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

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

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

1     ~~(11) The storage or preparation for patient administration of~~  
 2 ~~tissue performed at a clinical trial site that is intended solely for~~  
 3 ~~investigational use by experts qualified by scientific training and~~  
 4 ~~experience to investigate the safety and effectiveness of drugs or~~  
 5 ~~devices if the investigation is conducted in accordance with the~~  
 6 ~~requirements of Section 505(i) of the federal Food, Drug, and~~  
 7 ~~Cosmetic Act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof~~  
 8 ~~(21 U.S.C. Sec. 360j(g)) and the regulations adopted pursuant to~~  
 9 ~~the federal act.~~

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

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

16     ~~10112.27. (a) An individual or small group health insurance~~  
 17 ~~policy issued, amended, or renewed on or after January 1, 2017,~~  
 18 ~~shall include, at a minimum, coverage for essential health benefits~~  
 19 ~~pursuant to the federal Patient Protection and Affordable Care Act~~  
 20 ~~(PPACA) and as outlined in this section. This section shall~~  
 21 ~~exclusively govern the benefits a health insurer must cover as~~  
 22 ~~essential health benefits. For purposes of this section, “essential~~  
 23 ~~health benefits” means all of the following:~~

24     ~~(1) Health benefits within the categories identified in Section~~  
 25 ~~1302(b) of PPACA: ambulatory patient services, emergency~~  
 26 ~~services, hospitalization, maternity and newborn care, mental health~~  
 27 ~~and substance use disorder services, including behavioral health~~  
 28 ~~treatment, prescription drugs, rehabilitative and habilitative services~~  
 29 ~~and devices, laboratory services, preventive and wellness services~~  
 30 ~~and chronic disease management, and pediatric services, including~~  
 31 ~~oral and vision care.~~

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

38     ~~(i) Medically necessary basic health care services, as defined~~  
 39 ~~in subdivision (b) of Section 1345 of the Health and Safety Code~~

1 and Section 1300.67 of Title 28 of the California Code of  
2 Regulations.

3 (ii) The health benefits mandated to be covered by the plan  
4 pursuant to statutes enacted before December 31, 2011, as  
5 described in the following sections of the Health and Safety Code:  
6 Sections 1367.002, 1367.06, and 1367.35 (preventive services for  
7 children); Section 1367.25 (prescription drug coverage for  
8 contraceptives); Section 1367.45 (AIDS vaccine); Section 1367.46  
9 (HIV testing); Section 1367.51 (diabetes); Section 1367.54  
10 (alpha-fetoprotein testing); Section 1367.6 (breast cancer  
11 screening); Section 1367.61 (prosthetics for laryngectomy); Section  
12 1367.62 (maternity hospital stay); Section 1367.63 (reconstructive  
13 surgery); Section 1367.635 (mastectomies); Section 1367.64  
14 (prostate cancer); Section 1367.65 (mammography); Section  
15 1367.66 (cervical cancer); Section 1367.665 (cancer screening  
16 tests); Section 1367.67 (osteoporosis); Section 1367.68 (surgical  
17 procedures for jaw bones); Section 1367.71 (anesthesia for dental);  
18 Section 1367.9 (conditions attributable to diethylstilbestrol);  
19 Section 1368.2 (hospice care); Section 1370.6 (cancer clinical  
20 trials); Section 1371.5 (emergency response ambulance or  
21 ambulance transport services); subdivision (b) of Section 1373  
22 (sterilization operations or procedures); Section 1373.4 (inpatient  
23 hospital and ambulatory maternity); Section 1374.56  
24 (phenylketonuria); Section 1374.17 (organ transplants for HIV);  
25 Section 1374.72 (mental health parity); and Section 1374.73  
26 (autism/behavioral health treatment).

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

30 (iv) The health benefits covered by the plan that are not  
31 otherwise required to be covered under Chapter 2.2 (commencing  
32 with Section 1340) of Division 2 of the Health and Safety Code,  
33 to the extent otherwise required pursuant to Sections 1367.18,  
34 1367.21, 1367.215, 1367.22, 1367.24, and 1367.25 of the Health  
35 and Safety Code, and Section 1300.67.24 of Title 28 of the  
36 California Code of Regulations.

37 (v) Any other health benefits covered by the plan that are not  
38 otherwise required to be covered under Chapter 2.2 (commencing  
39 with Section 1340) of Division 2 of the Health and Safety Code.

1 ~~(B) If there are any conflicts or omissions in the plan identified~~  
2 ~~in subparagraph (A) as compared with the requirements for health~~  
3 ~~benefits under Chapter 2.2 (commencing with Section 1340) of~~  
4 ~~Division 2 of the Health and Safety Code that were enacted before~~  
5 ~~December 31, 2011, the requirements of Chapter 2.2 (commencing~~  
6 ~~with Section 1340) of Division 2 of the Health and Safety Code~~  
7 ~~shall control, except as otherwise specified in this section.~~

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

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

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

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

38 ~~(5) With respect to pediatric oral care, the same health benefits~~  
39 ~~for pediatric oral care covered under the dental benefit received~~  
40 ~~by children under the Medi-Cal program as of 2014, including the~~



1 ~~provision of medically necessary orthodontic care provided~~  
2 ~~pursuant to the federal Children's Health Insurance Program~~  
3 ~~Reauthorization Act of 2009. The pediatric oral care benefits~~  
4 ~~covered pursuant to this paragraph shall be in addition to, and shall~~  
5 ~~not replace, any dental or orthodontic services covered under the~~  
6 ~~plan identified in paragraph (2).~~

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

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

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

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

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

38 ~~(f) This section applies regardless of whether the policy is~~  
39 ~~offered inside or outside the California Health Benefit Exchange~~  
40 ~~created by Section 100500 of the Government Code.~~

1 ~~(g) This section does not exempt a health insurer or a health~~  
2 ~~insurance policy from meeting other applicable requirements of~~  
3 ~~law.~~

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

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

9 ~~(1) A policy that provides excepted benefits as described in~~  
10 ~~Sections 2722 and 2791 of the federal Public Health Service Act~~  
11 ~~(42 U.S.C. Sec. 300gg-21; 42 U.S.C. Sec. 300gg-91).~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9     ~~SEC. 4. No reimbursement is required by this act pursuant to~~  
10 ~~Section 6 of Article XIII B of the California Constitution because~~  
11 ~~the only costs that may be incurred by a local agency or school~~  
12 ~~district will be incurred because this act creates a new crime or~~  
13 ~~infraction, eliminates a crime or infraction, or changes the penalty~~  
14 ~~for a crime or infraction, within the meaning of Section 17556 of~~  
15 ~~the Government Code, or changes the definition of a crime within~~  
16 ~~the meaning of Section 6 of Article XIII B of the California~~  
17 ~~Constitution.~~