

AMENDED IN SENATE JUNE 16, 2015

AMENDED IN SENATE JUNE 1, 2015

AMENDED IN ASSEMBLY APRIL 28, 2015

AMENDED IN ASSEMBLY APRIL 13, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 159

Introduced by Assembly Member Calderon
(Coauthors: Assembly Members Brown, Daly, Lackey, Obernolte,
Olsen, and Waldron)
(Coauthors: Senators Allen, Anderson, and Stone)

January 21, 2015

An act to add Article 4.5 (commencing with Section 111548) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs and devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 159, as amended, Calderon. Investigational drugs, biological products, and devices.

Existing law, the federal Food, Drug, and Cosmetic Act, prohibits a person from introducing into interstate commerce any new drug unless the drug has been approved by the United States Food and Drug Administration (FDA). Existing law requires the sponsor of a new drug to submit to the FDA an investigational new drug application and to then conduct a series of clinical trials to establish the safety and efficacy of the drug in human populations and submit the results to the FDA in a new drug application.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. A violation of that law is a crime. The Sherman Food, Drug, and Cosmetic Law prohibits, among other things, the sale, delivery, or giving away of a new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the federal Food, Drug, and Cosmetic Act.

The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California and requires the board to take action against a licensee who is charged with unprofessional conduct. The Osteopathic Act provides for the licensure and regulation of osteopathic physicians and surgeons by the Osteopathic Medical Board of California and requires the board to enforce the Medical Practice Act with respect to its licensees.

This bill would permit a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with a serious or immediately life-threatening disease or condition, as specified. The bill would authorize, but not require, a health benefit plan, as defined, to provide coverage for any investigational drug, biological product, or device made available pursuant to these provisions. The bill would prohibit the Medical Board of California and the Osteopathic Medical Board of California from taking any disciplinary action against the license of a physician based solely on the physician's recommendation to an eligible patient regarding, or prescription for or treatment with, an investigational drug, biological product, or device if the recommendation or prescription is consistent with protocol approved by the physician's institutional review board or an accredited institutional review board, and would require the institutional review board to biannually report specified information to the State Department of Public Health, among others. The bill would prohibit a state agency from altering any recommendation made to the federal Centers for Medicare and Medicaid Services regarding a health care provider's certification to participate in the Medicare or Medicaid program based solely on the recommendation from an individual health care provider that a patient have access to an investigational drug, biological product, or device. ~~The bill would prohibit an official, employee, or agent of the state from blocking an eligible patient's access~~

to the investigational drug, biological product, or device pursuant to the bill's provisions.

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

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

1 SECTION 1. Article 4.5 (commencing with Section 111548)
2 is added to Chapter 6 of Part 5 of Division 104 of the Health and
3 Safety Code, to read:

4

5

Article 4.5. Right to Try Act

6

7 111548. This article shall be known and may be cited as the
8 Right to Try Act.

9 111548.1. For purposes of this article, unless the context
10 otherwise requires, the following definitions shall apply:

11 (a) "Consulting physician" means a physician and surgeon
12 licensed under the Medical Practice Act or an osteopathic physician
13 and surgeon licensed under the Osteopathic Act who performs all
14 of the following:

15 (A)

16 (1) Examines the qualified individual and his or her relevant
17 medical records.

18 (B)

19 (2) Confirms, in writing, the primary physician's diagnosis and
20 prognosis.

21 (C)

22 (3) Verifies, in the opinion of the consulting physician, that the
23 eligible patient is competent, acting voluntarily, and has made an
24 informed decision.

25 (b) "Eligible patient" means a person who meets all of the
26 following conditions:

27 (1) Has a serious or immediately life-threatening disease or
28 condition.

29 (2) Has considered all other treatment options currently approved
30 by the United States Food and Drug Administration.

31 (3) Has been unable to participate in a clinical trial for the
32 serious or immediately life-threatening disease or condition
33 identified in paragraph (1) within 100 miles of his or her home or

1 has not been accepted to that clinical trial within one week of
2 completion of the clinical trial application process.

3 (4) Has received a recommendation from his or her primary
4 physician and a consulting physician for an investigational drug,
5 biological product, or device.

6 (5) Has given written informed consent for the use of the
7 investigational drug, biological product, or device, or, if he or she
8 lacks the capacity to consent, his or her legally authorized
9 representative has given written informed consent on his or her
10 behalf.

11 (6) Has documentation from his or her primary physician and
12 a consulting physician attesting that the patient has met the
13 requirements of this subdivision.

14 (c) “Health benefit plan” means a plan or program that provides,
15 arranges, pays for, or reimburses the cost of health benefits. “Health
16 benefit plan” includes, but is not limited to, a health care service
17 plan contract issued by a health care service plan, as defined in
18 Section 1345, and a policy of health insurance, as defined in
19 Section 106 of the Insurance Code, issued by a health insurer.

20 (d) (1) “Immediately life-threatening disease or condition”
21 means a stage of disease in which there is a reasonable likelihood
22 that death will occur within a matter of months or in which
23 premature death is likely without early treatment.

24 (2) “Serious disease or condition” means a disease or condition
25 associated with morbidity that has a substantial impact on
26 day-to-day functioning.

27 (e) “Investigational drug, biological product, or device” means
28 a drug, biological product, or device that has successfully
29 completed phase one of a clinical trial approved by the United
30 States Food and Drug Administration, but has not been approved
31 for general use by the United States Food and Drug Administration
32 and remains under investigation in a clinical trial approved by the
33 United States Food and Drug Administration.

34 (f) “Primary physician” means a physician and surgeon licensed
35 under the Medical Practice Act or an osteopathic physician and
36 surgeon licensed under the Osteopathic Act.

37 (g) “State regulatory board” means the Medical Board of
38 California or the Osteopathic Medical Board of California.

39 (h) (1) “Written, informed consent” means a written document
40 that has been approved by the primary physician’s institutional

1 review board or an accredited independent institutional review
2 board, is signed by an eligible patient, or his or her legally
3 authorized representative when the patient lacks the capacity to
4 consent, and attested to by the patient's primary physician and a
5 witness that, at a minimum, does all of the following:

6 (A) Explains the currently approved products and treatments
7 for the serious or immediately life-threatening disease or condition
8 from which the patient suffers.

9 (B) Attests to the fact that the patient, or when the patient lacks
10 the capacity to consent his or her legally authorized representative,
11 concurs with the patient's primary physician in believing that all
12 currently approved and conventionally recognized treatments are
13 unlikely to prolong the patient's life.

14 (C) Clearly identifies the specific proposed investigational drug,
15 biological product, or device that the patient is seeking to use.

16 (D) Describes the potentially best and worst outcomes of using
17 the investigational drug, biological product, or device and describes
18 the most likely outcome. This description shall include the
19 possibility that new, unanticipated, different, or worse symptoms
20 might result and that death could be hastened by the proposed
21 treatment. The description shall be based on the primary
22 physician's knowledge of the proposed treatment in conjunction
23 with an awareness of the patient's condition.

24 (E) Clearly states that the patient's health benefit plan, if any,
25 and health care provider are not obligated to pay for the
26 investigational drug, biological product, or device or any care or
27 treatments consequent to use of the investigational drug, biological
28 product, or device.

29 (F) Clearly states that the patient's eligibility for hospice care
30 may be withdrawn if the patient begins curative treatment and that
31 care may be reinstated if the curative treatment ends and the patient
32 meets hospice eligibility requirements.

33 (G) Clearly states that in-home health care may be denied if
34 treatment begins.

35 (H) States that the patient understands that he or she is liable
36 for all expenses consequent to the use of the investigational drug,
37 biological product, or device, and that this liability extends to the
38 patient's estate, except as otherwise provided in the patient's health
39 benefit plan or a contract between the patient and the manufacturer
40 of the drug, biological product, or device.

1 (2) Written, informed consent for purposes of this article shall
2 be consistent with the informed consent requirements of the
3 Protection of Human Subjects in Medical Experimentation Act
4 (Chapter 1.3 (commencing with Section 24170) of Division 20).

5 111548.2. (a) Notwithstanding Section 110280, 111520, or
6 111550, a manufacturer of an investigational drug, biological
7 product, or device may make available the manufacturer's
8 investigational drug, biological product, or device to an eligible
9 patient pursuant to this article. This article does not require that a
10 manufacturer make available an investigational drug, biological
11 product, or device to an eligible patient.

12 (b) A manufacturer may do both of the following:

13 (1) Provide an investigational drug, biological product, or device
14 to an eligible patient without receiving compensation.

15 (2) Require an eligible patient to pay the costs of or associated
16 with the manufacture of the investigational drug, biological
17 product, or device.

18 (c) (1) This article does not expand ~~or otherwise affect~~ the
19 coverage provided under Sections 1370.4 and 1370.6 of this code,
20 Sections 10145.3 and 10145.4 of the Insurance Code, or Sections
21 14087.11 and 14132.98 of the Welfare and Institutions Code.

22 (2) This article does not require a health benefit plan to provide
23 coverage for the cost of any investigational drug, biological
24 product, or device, or the costs of services related to the use of an
25 investigational drug, biological product, or device under this article.
26 A health benefit plan may provide coverage for an investigational
27 drug, biological product, or device made available pursuant to this
28 section.

29 (d) If the clinical trial for an investigational drug, biological
30 product, or device is closed due to the lack of efficacy or for
31 toxicity, the investigational drug, biological product, or device
32 shall not be offered. If notice *of closure of a clinical trial* is given
33 for an investigational drug, biological product, or device taken by
34 a patient outside of a clinical trial, the manufacturer and the
35 patient's primary physician shall notify the patient of the
36 information from the safety committee of the clinical trial.

37 (e) If an eligible patient dies while being treated by an
38 investigational drug, biological product, or device made available
39 pursuant to this article, the patient's heirs are not liable for any

1 outstanding debt related to the treatment or lack of insurance for
2 the treatment.

3 111548.3. (a) Notwithstanding any other law, a state regulatory
4 board shall not revoke, fail to renew, or take any other disciplinary
5 action against a physician's license based solely on the physician's
6 recommendation to an eligible patient regarding, or prescription
7 for or treatment with, an investigational drug, biological product,
8 or device if the recommendation or prescription is consistent with
9 protocol approved by the physician's institutional review board
10 or an accredited independent institutional review board.

11 (b) The physician's institutional review board or an accredited
12 institutional review board shall biannually report the following
13 information to the State Department of Public Health, the Medical
14 Board of California, and the Osteopathic Medical Board of
15 California:

16 (1) The number of requests made for an investigational drug,
17 biological product, or device.

18 (2) The status of the requests made.

19 (3) The duration of the treatment.

20 (4) The costs of the treatment paid by eligible patients.

21 (5) *The success or failure of the investigational drug, biological*
22 *product, or device in treating the serious or immediately*
23 *life-threatening disease or condition from which the patient suffers.*

24 (6) *Any adverse event for each investigational drug, biological*
25 *product, or device.*

26 (c) A state agency shall not alter any recommendation made to
27 the federal Centers for Medicare and Medicaid Services regarding
28 a health care provider's certification to participate in the Medicare
29 or Medicaid program based solely on the recommendation from
30 an individual health care provider that a patient have access to an
31 investigational drug, biological product, or device.

32 ~~(d) An official, employee, or agent of this state shall not block~~
33 ~~or attempt to block an eligible patient's access to an investigational~~
34 ~~drug, biological product, or device pursuant to this article.~~
35 ~~Counseling, advice, or a recommendation consistent with medical~~
36 ~~standards of care from an individual licensed under Division 2~~
37 ~~(commencing with Section 500) of the Business and Professions~~
38 ~~Code shall not be considered a violation of this section.~~

39 ~~(e)~~

1 (d) A violation of this section shall not be subject to Chapter
2 8 (commencing with Section 111825).
3 111548.5. This article does not create a private cause of action,
4 and actions taken pursuant to this article shall not serve as a basis
5 for a civil, criminal, or disciplinary claim or cause of action,
6 including, but not limited to, product liability, medical negligence,
7 or wrongful death, against a manufacturer of an investigational
8 drug, biological product, or device, or against any other person or
9 entity involved in the care of an eligible patient for harm done to
10 the eligible patient or his or her heirs resulting from the
11 investigational drug, biological product, or device, or the use or
12 nonuse thereof, if the manufacturer or other person or entity has
13 complied with the terms of this article in relation to the eligible
14 patient, unless there was a failure to exercise reasonable care.