

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 ~~federal~~ *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new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the federal Food, Drug, and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 ~~terminal illnesses~~, *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, provided that the recommendation or prescription is consistent with medical standards of care. 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. In this article, unless the context otherwise requires,
10 the following definitions shall apply:

11 (a) “Eligible patient” means a person who meets all of the
12 following conditions:

13 (1) Has a ~~terminal illness~~; *serious or immediately*
14 *life-threatening disease or condition.*

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

17 (3) Has been unable to participate in a clinical trial for the
18 ~~terminal illness~~ *serious or immediately life-threatening disease or*
19 *condition* identified in paragraph (1) within 100 miles of his or her
20 home or has not been accepted to that clinical trial within one week
21 of completion of the clinical trial application process.

22 (4) Has received a recommendation from his or her physician
23 for an investigational drug, biological product, or device.

24 (5) Has given written informed consent for the use of the
25 investigational drug, biological product, or device, or if he or she
26 lacks the capacity to consent, his or her legally authorized
27 representative has given written informed consent on his or her
28 behalf.

29 (6) Has documentation from his or her physician attesting that
30 the patient has met the requirements of this subdivision.

31 (b) “Health benefit plan” means any plan or program that
32 provides, arranges, pays for, or reimburses the cost of health
33 benefits. “Health benefit plan” includes, but is not limited to, a
34 health care service plan contract issued by a health care service
35 plan, as defined in Section 1345 of this code, and a policy of health
36 insurance, as defined in Section 106 of the Insurance Code, issued
37 by a health insurer.

- 1 (c) (1) “Immediately life-threatening disease or condition”
 2 means a stage of disease in which there is a reasonable likelihood
 3 that death will occur within a matter of months or in which
 4 premature death is likely without early treatment.
- 5 (2) “Serious disease or condition” means a disease or condition
 6 associated with morbidity that has a substantial impact on
 7 day-to-day functioning.
- 8 (e)
- 9 (d) “Investigational drug, biological product, or device” means
 10 a drug, biological product, or device that has successfully
 11 completed phase one of a clinical trial approved by the United
 12 States Food and Drug Administration, but has not been approved
 13 for general use by the United States Food and Drug Administration
 14 and remains under investigation in a clinical trial approved by the
 15 United States Food and Drug Administration.
- 16 (d)
- 17 (e) “Physician” means a physician and surgeon licensed under
 18 the Medical Practice Act or an osteopathic physician and surgeon
 19 licensed under the Osteopathic Act.
- 20 (e)
- 21 (f) “State regulatory board” means the ~~California~~ Medical Board
 22 of California or the Osteopathic Medical Board of California.
- 23 (f) ~~“Terminal illness” means a disease that, without~~
 24 ~~life-sustaining procedures, will result in death in the near future~~
 25 ~~or a state of permanent unconsciousness from which recovery is~~
 26 ~~unlikely.~~
- 27 (g) (1) “Written, informed consent” means a written document
 28 that *has been approved by the physician’s institutional review*
 29 *board or an accredited independent institutional review board*, is
 30 signed by an eligible patient, or his or her legally authorized
 31 representative where the patient lacks the capacity to consent, and
 32 attested to by the patient’s physician and a witness that, at a
 33 minimum, does all of the following:
- 34 (1)
- 35 (A) Explains the currently approved products and treatments
 36 for the ~~terminal illness~~ *serious or immediately life-threatening*
 37 *disease or condition* from which the patient suffers.
- 38 (2)
- 39 (B) Attests to the fact that the patient, or where the patient lacks
 40 the capacity to consent, his or her legally authorized representative,

1 concurs with the patient’s physician in believing that all currently
2 approved and conventionally recognized treatments are unlikely
3 to prolong the patient’s life.

4 ~~(3)~~

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

7 ~~(4)~~

8 (D) Describes the potentially best and worst outcomes of using
9 the investigational drug, biological product, or device and describes
10 the most likely outcome. This description shall include the
11 possibility that new, unanticipated, different, or worse symptoms
12 might result and that death could be hastened by the proposed
13 treatment. The description shall be based on the physician’s
14 knowledge of the proposed treatment in conjunction with an
15 awareness of the patient’s condition.

16 ~~(5)~~

17 (E) Clearly states that the patient’s health benefit plan, if any,
18 and health care provider are not obligated to pay for the
19 investigational drug, biological product, or device or any care or
20 treatments consequent to use of the investigational drug, biological
21 product, or device.

22 ~~(6)~~

23 (F) Clearly states that the patient’s eligibility for hospice care
24 may be withdrawn if the patient begins curative treatment and that
25 care may be reinstated if the curative treatment ends and the patient
26 meets hospice eligibility requirements.

27 ~~(7)~~

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

30 ~~(8)~~

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

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

1 111548.2. (a) Notwithstanding Section 110280, 111520, or
2 111550, a manufacturer of an investigational drug, biological
3 product, or device may make available the manufacturer's
4 investigational drug, biological product, or device to an eligible
5 patient pursuant to this article. This article does not require that a
6 manufacturer make available an investigational drug, biological
7 product, or device to an eligible patient.

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

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

11 (2) Require an eligible patient to pay the costs of or associated
12 with the manufacture of the investigational drug, biological
13 product, or device.

14 (c) (1) This article does not expand or otherwise affect the
15 coverage provided under Sections 1370.4 and 1370.6 of this code,
16 Sections 10145.3 and 10145.4 of the Insurance Code, or Sections
17 14087.11 and 14132.98 of the Welfare and Institutions Code.

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

25 (d) If an eligible patient dies while being treated by an
26 investigational drug, biological product, or device made available
27 pursuant to this article, the patient's heirs are not liable for any
28 outstanding debt related to the treatment or lack of insurance for
29 the treatment.

30 111548.3. (a) Notwithstanding any other law, a state regulatory
31 board shall not revoke, fail to renew, or take any other disciplinary
32 action against a physician's license based solely on the physician's
33 recommendation to an eligible patient regarding, or prescription
34 for or treatment with, an investigational drug, biological product,
35 or device, provided that the recommendation or prescription is
36 consistent with medical standards of care.

37 (b) A state agency shall not alter any recommendation made to
38 the federal Centers for Medicare and Medicaid Services regarding
39 a health care provider's certification to participate in the Medicare
40 or Medicaid program based solely on the recommendation from

1 an individual health care provider that a patient have access to an
2 investigational drug, biological product, or device.

3 (c) An official, employee, or agent of this state shall not block
4 or attempt to block an eligible patient's access to an investigational
5 drug, biological product, or device pursuant to this article.
6 Counseling, advice, or a recommendation consistent with medical
7 standards of care from an individual licensed under Division 2
8 (commencing with Section 500) of the Business and Professions
9 Code shall not be considered a violation of this section.

10 (d) A violation of this section shall not be subject to Chapter
11 8 (commencing with Section 111825).

12 111548.5. This article does not create a private cause of action
13 against a manufacturer of an investigational drug, biological
14 product, or device, or against any other person or entity involved
15 in the care of an eligible patient using the investigational drug,
16 biological product, or device, for any harm done to the eligible
17 patient resulting from the investigational drug, biological product,
18 or device, so long as the manufacturer or other person or entity is
19 complying in good faith with the terms of this article, unless there
20 was a failure to exercise reasonable care.

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