

AMENDED IN SENATE AUGUST 15, 2016

AMENDED IN ASSEMBLY MARCH 7, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1668**

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**Introduced by Assembly Member Calderon**

**(Coauthors: Assembly Members Alejo, Bonta, Brown, Campos, Chu, Dababneh, Daly, Frazier, Gatto, Gipson, Gonzalez, Gray, Hadley, Roger Hernández, Jones-Sawyer, Lackey, Linder, Low, McCarty, Medina, Obernolte, O'Donnell, Olsen, Rendon, Rodriguez, Salas, Mark Stone, Waldron, and Williams)**

(Coauthors: Senators Allen, Galgiani, Runner, and Stone)

January 15, 2016

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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 1668, 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department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the federal Food, Drug, and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 an 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 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.

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:

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Article 4.5. Right to Try Act

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

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

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

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

24 (1) Has an immediately life-threatening disease or condition.

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

27 (3) Has not been accepted to participate in the nearest clinical  
28 trial to his or her home for the immediately life-threatening disease  
29 or condition identified in paragraph (1) within one week of  
30 completion of the clinical trial application process, or, in the  
31 treating physician's medical judgment, it is unreasonable for the  
32 patient to participate in that clinical trial due to the patient's current  
33 condition and stage of disease.

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

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

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

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

18 (d) “Immediately life-threatening disease or condition” means  
19 a stage of disease in which there is a reasonable likelihood that  
20 death will occur within a matter of months.

21 (e) “Investigational drug, biological product, or device” means  
22 a drug, biological product, or device that has successfully  
23 completed phase one of a clinical trial approved by the United  
24 States Food and Drug Administration, but has not been approved  
25 for general use by the United States Food and Drug Administration  
26 and remains under investigation in a clinical trial approved by the  
27 United States Food and Drug Administration.

28 (f) “Primary physician” means a physician and surgeon licensed  
29 under the Medical Practice Act or an osteopathic physician and  
30 surgeon licensed under the Osteopathic Act.

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

33 (h) (1) “Written, informed consent” means a written document  
34 that has been approved by the primary physician’s institutional  
35 review board or an accredited independent institutional review  
36 board, is signed by an eligible patient, or his or her legally  
37 authorized representative when the patient lacks the capacity to  
38 consent, and attested to by the patient’s primary physician and a  
39 witness that, at a minimum, does all of the following:

1 (A) Explains the currently approved products and treatments  
2 for the immediately life-threatening disease or condition from  
3 which the patient suffers.

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

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

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

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

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

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

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

36 (2) Written, informed consent for purposes of this article shall  
37 be consistent with the informed consent requirements of the  
38 Protection of Human Subjects in Medical Experimentation Act  
39 (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 the coverage provided under  
15 Sections 1370.4 and 1370.6 of this code, Sections 10145.3 and  
16 10145.4 of the Insurance Code, or Sections 14087.11 and 14132.98  
17 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 the clinical trial for an investigational drug, biological  
26 product, or device is closed due to the lack of efficacy or for  
27 toxicity, the investigational drug, biological product, or device  
28 shall not be offered. If notice of closure of a clinical trial is given  
29 for an investigational drug, biological product, or device taken by  
30 a patient outside of a clinical trial, the manufacturer and the  
31 patient's primary physician shall notify the patient of the  
32 information from the safety committee of the clinical trial.

33 (e) If an eligible patient dies while being treated by an  
34 investigational drug, biological product, or device made available  
35 pursuant to this article, the patient's heirs *and health benefit plan,*  
36 *except to the extent the plan provided coverage pursuant to*  
37 *paragraph (2) of subdivision (c),* are not liable for any outstanding  
38 debt related to the treatment or lack of insurance for the treatment.

39 111548.3. (a) Notwithstanding any other law, a state regulatory  
40 board shall not revoke, fail to renew, or take any other disciplinary

1 action against a physician’s license based on the physician’s  
2 recommendation to an eligible patient regarding, or prescription  
3 for or treatment with, an investigational drug, biological product,  
4 or device if the recommendation or prescription is consistent with  
5 protocol approved by the physician’s institutional review board  
6 or an accredited independent institutional review board.

7 (b) The physician’s institutional review board or an accredited  
8 institutional review board shall biannually report the following  
9 information to the State Department of Public Health, the Medical  
10 Board of California, and the Osteopathic Medical Board of  
11 California:

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

14 (2) The status of the requests made.

15 (3) The duration of the treatment.

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

17 (5) The success or failure of the investigational drug, biological  
18 product, or device in treating the immediately life-threatening  
19 disease or condition from which the patient suffers.

20 (6) Any adverse event for each investigational drug, biological  
21 product, or device.

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

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

30 111548.5. This article does not create a private cause of action,  
31 and actions taken pursuant to this article shall not serve as a basis  
32 for a civil, criminal, or disciplinary claim or cause of action,  
33 including, but not limited to, product liability, medical negligence,  
34 or wrongful death, against a manufacturer of an investigational  
35 drug, biological product, or device, or against any other person or  
36 entity involved in the care of an eligible patient for harm done to  
37 the eligible patient or his or her heirs resulting from the  
38 investigational drug, biological product, or device, or the use or  
39 nonuse thereof, if the manufacturer or other person or entity has

- 1 complied with the terms of this article in relation to the eligible
- 2 patient, unless there was a failure to exercise reasonable care.

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