AMENDED IN SENATE JUNE 19, 2015

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has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the federal Food, Drug, and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

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

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

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

Article 4.5. Right to Try Act

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

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

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

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

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

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

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

(1) Has ~~a serious or~~ *an* immediately life-threatening disease or condition.

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

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

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

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

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

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

(d) ~~(1)~~ "Immediately life-threatening disease or condition" means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of ~~months or in which premature death is likely without early treatment.~~ *months.*

~~(2) "Serious disease or condition" means a disease or condition associated with morbidity that has a substantial impact on day-to-day functioning.~~

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

(f) "Primary physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act.

(g) "State regulatory board" means the Medical Board of California or the Osteopathic Medical Board of California.

(h) (1) "Written, informed consent" means a written document that has been approved by the primary physician's institutional review board or an accredited independent institutional review board, is signed by an eligible patient, or his or her legally

authorized representative when the patient lacks the capacity to consent, and attested to by the patient's primary physician and a witness that, at a minimum, does all of the following:

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

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

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

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

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

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

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

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

(2) Written, informed consent for purposes of this article shall be consistent with the informed consent requirements of the

Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

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

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

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

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

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

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

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

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

111548.3. (a) Notwithstanding any other law, a state regulatory board shall not revoke, fail to renew, or take any other disciplinary action against a physician's license 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 independent institutional review board.

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

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

(2) The status of the requests made.

(3) The duration of the treatment.

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

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

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

(c) A state agency shall not alter 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.

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

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

nonuse thereof, if the manufacturer or other person or entity has complied with the terms of this article in relation to the eligible patient, unless there was a failure to exercise reasonable care.

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