

ASSEMBLY BILL

No. 1278

Introduced by Assembly Member Hueso

February 22, 2013

An act to amend Section 2234.1 of, and to repeal Section 2257 of, the Business and Professions Code, and to amend Sections 109270, 109285, 109295, 109300, 109350, and 109375 of, and to add Article 2.5 (commencing with Section 109400) to Chapter 4 of Part 4 of Division 104 of, the Health and Safety Code, relating to health care.

LEGISLATIVE COUNSEL'S DIGEST

AB 1278, as introduced, Hueso. Integrative cancer treatment.

Existing law prohibits the sale, prescription, or administration of a drug, medicine, compound, or device to be used in the diagnosis, treatment, alleviation, or cure of cancer unless it has been approved by the federal Food and Drug Administration or by the State Department of Public Health, as specified, and makes a violation of that provision a misdemeanor. 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 act immunizes a physician and surgeon from discipline for providing advice or treatment that constitutes alternative or complementary medicine if the treatment or advice meets certain requirements. 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 prohibit a physician and surgeon, including an osteopathic physician and surgeon, from recommending, prescribing,

or providing integrative cancer treatment, as defined, to cancer patients unless certain requirements are met. The bill would specify that a failure of a physician and surgeon to comply with these requirements constitutes unprofessional conduct and cause for discipline by the individual's licensing entity. The bill would require the State Department of Public Health to investigate violations of these provisions and to hold hearings with respect to compliance with these provisions. The bill would make conforming changes to other related 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. Section 2234.1 of the Business and Professions
2 Code is amended to read:
3 2234.1. (a) A physician and surgeon shall not be subject to
4 discipline pursuant to subdivision (b), (c), or (d) of Section 2234
5 solely on the basis that the treatment or advice he or she rendered
6 to a patient is alternative or complementary medicine, including
7 the treatment of persistent Lyme Disease, if that treatment or advice
8 meets ~~all~~ *one* of the following requirements, *as applicable*:
9 (1) *The treatment or advice is for a condition other than cancer*
10 *and meets all of the following requirements:*
11 ~~(1)~~
12 (A) It is provided after informed consent and a good-faith prior
13 examination of the patient, and medical indication exists for the
14 treatment or advice, or it is provided for health or well-being.
15 ~~(2)~~
16 (B) It is provided after the physician and surgeon has given the
17 patient information concerning conventional treatment and
18 describing the education, experience, and credentials of the
19 physician and surgeon related to the alternative or complementary
20 medicine that he or she practices.
21 ~~(3)~~
22 (C) In the case of alternative or complementary medicine, it
23 does not cause a delay in, or discourage traditional diagnosis of,
24 a condition of the patient.
25 ~~(4)~~
26 (D) It does not cause death or serious bodily injury to the patient.

1 (2) *The treatment or advice is for cancer and is given in*
2 *compliance with Article 2.5 (commencing with Section 109400)*
3 *of Chapter 4 of Part 4 of Division 104 of the Health and Safety*
4 *Code.*

5 (b) For purposes of this section, “alternative or complementary
6 medicine,” means those health care methods of diagnosis,
7 treatment, or healing that are not generally used but that provide
8 a reasonable potential for therapeutic gain in a patient’s medical
9 condition that is not outweighed by the risk of the health care
10 method.

11 (c) Since the National Institute of Medicine has reported that it
12 can take up to 17 years for a new best practice to reach the average
13 physician and surgeon, it is prudent to give attention to new
14 developments not only in general medical care but in the actual
15 treatment of specific diseases, particularly those that are not yet
16 broadly recognized in California.

17 SEC. 2. Section 2257 of the Business and Professions Code is
18 repealed.

19 ~~2257. The violation of Section 109275 of the Health and Safety~~
20 ~~Code, relating to informed consent for the treatment of breast~~
21 ~~cancer, constitutes unprofessional conduct.~~

22 SEC. 3. Section 109270 of the Health and Safety Code is
23 amended to read:

24 109270. The department shall:

25 (a) Prescribe reasonable regulations with respect to the
26 administration of this article and Article 2 (commencing with
27 Section 109300).

28 (b) Investigate violations of this article—~~and, Article 2~~
29 ~~(commencing with Section 109300), and Article 2.5 (commencing~~
30 ~~with Section 109400), and report the violations to the appropriate~~
31 ~~enforcement authority.~~

32 (c) Secure the investigation and testing of the content, method
33 of preparation, efficacy, or use of drugs, medicines, compounds,
34 or devices proposed to be used, or used, by any individual, person,
35 firm, association, or other entity in the state for the diagnosis,
36 treatment, or cure of cancer, prescribe reasonable regulations with
37 respect to the investigation and testing, and make findings of fact
38 and recommendations upon completion of any such investigation
39 and testing.

(d) Adopt a regulation prohibiting the prescription, administration, sale or other distribution of any drug, substance, or device found to be harmful or of no value in the diagnosis, prevention, or treatment of cancer, *except as authorized under Article 2.5 (commencing with Section 109400)*.

(e) Hold hearings ~~in~~ *with respect to* those matters involving compliance with this article ~~and~~, Article 2 (commencing with Section 109300), *and Article 2.5 (commencing with Section 109400)*, and subpoena witnesses and documents. Any or all hearings may be held before the Cancer Advisory Council. Any administrative action to be taken by the department as a result of the hearings shall be taken only after receipt of the recommendations of the council. Prior to issuance of a cease and desist order under Section 109345, a hearing shall be held. The person furnishing a sample *or manufacturer contact information* under Section 109295 shall be given due notice of the hearing and an opportunity to be heard.

(f) Contract with independent scientific consultants for specialized services and advice.

In the exercise of the powers granted by this section, the department shall consult with the Cancer Advisory Council.

SEC. 4. Section 109285 of the Health and Safety Code is amended to read:

109285. For the purposes of this article ~~and~~, Article 2 (commencing with Section 109300), *and Article 2.5 (commencing with Section 109400)*, “cancer” means all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma, Hodgkins disease, and leukemia.

SEC. 5. Section 109295 of the Health and Safety Code is amended to read:

109295. (a) On written request by the department, delivered personally or by mail, any individual, person, firm, association, or other entity engaged, or representing himself, *herself*, or itself, as engaged, in the diagnosis, treatment, alleviation, or cure of cancer shall ~~furnish~~ *do all of the following*:

(1) *Furnish* the department with the sample as the department may deem necessary for adequate testing of any drug, medicine, compound, or device used or prescribed by the individual, person, firm, association, or other entity in the diagnosis, treatment, alleviation, or cure of ~~cancer, and shall specify cancer. The~~

1 *individual, person, firm, association, or other entity may*
2 *alternatively furnish the department with the contact information*
3 *of the manufacturer of the drug, medicine, compound, or device.*

4 (2) *Specify the formula of any drug or compound and name all*
5 *ingredients by their common or usual names, and shall, upon like*
6 *names.*

7 (3) *Upon request by of the department, furnish further necessary*
8 *information as it the department may request as to the composition*
9 *and method of preparation of and the use that any drug, compound,*
10 *or device is being put by the individual, person, firm, association,*
11 *or other entity. This*

12 (b) *This section shall apply to any individual, person, firm,*
13 *association, or other entity that renders health care or services to*
14 *individuals who have or believe they have cancer. This section*
15 *also applies to any individual, person, firm, association, or other*
16 *entity that by implication causes individuals to believe they have*
17 *cancer.*

18 ~~The~~

19 (c) *Upon the failure to either provide the sample or the*
20 *manufacturer's contact information, disclose the formula, or name*
21 *the ingredients as required by this section, it shall be conclusively*
22 *presumed that the drug, medicine, compound or device that is the*
23 *subject of the department's request has no value in the diagnosis,*
24 *treatment, alleviation, or cure of cancer.*

25 SEC. 6. Section 109300 of the Health and Safety Code is
26 amended to read:

27 109300. The sale, offering for sale, holding for sale, delivering,
28 giving away, prescribing, or administering of any drug, medicine,
29 compound, or device to be used in the diagnosis, treatment,
30 alleviation, or cure of cancer is unlawful and prohibited unless ~~(1)~~
31 ~~an~~ *one of the following applies:*

32 (a) *An application with respect thereto has been approved under*
33 *Section 505 of the federal Food, Drug, and Cosmetic Act, or (2)*
34 *there.*

35 (b) *The use is consistent with Article 2.5 (commencing with*
36 *Section 109400).*

37 (c) *There has been approved an application filed with the board*
38 *setting forth all of the following:*

39 (a)

(1) Full reports of investigations that have been made to show whether or not the drug, medicine, compound, or device is safe for the use, and whether the drug, medicine, compound, or device is effective in the use;

(b)

(2) A full list of the articles used as components of the drug, medicine, compound, or device;

(c)

(3) A full statement of the composition of the drug, medicine, compound, or device;

(d)

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug, medicine, or compound or in the case of a device, a full statement of its composition, properties, and construction and the principle or principles of its operation;

(e)

(5) Such samples of the drug, medicine, compound, or device and of the articles used as components of the drug, medicine, compound, or device as the board may require; and

(f)

(6) Specimens of the labeling and advertising proposed to be used for the drug, medicine, compound, or device.

SEC. 7. Section 109350 of the Health and Safety Code is amended to read:

109350. The department may direct that ~~any~~ *an* individual, person, firm, association, or other entity shall cease and desist any further prescribing, recommending, or use of any drug, medicine, compound, or device for which no application has been approved under this article and Article 1 (commencing with Section 109250) unless its use is exempt under Section 109325 or 109330 *or authorized under Article 2.5 (commencing with Section 109400).*

SEC. 8. Section 109375 of the Health and Safety Code is amended to read:

109375. The director shall investigate possible violations of this article ~~and~~, Article 1 (commencing with Section 109250), *and Article 2.5 (commencing with Section 109400)*, and report violations to the appropriate enforcement authority.

1 SEC. 9. Article 2.5 (commencing with Section 109400) is
2 added to Chapter 4 of Part 4 of Division 104 of the Health and
3 Safety Code, to read:

4
5 Article 2.5. Integrative Cancer Treatment
6

7 109400. For purposes of this article:

8 (a) “Integrative cancer treatment” means the use of
9 evidence-based substances or therapies that are not the standard
10 of care for cancer treatment, for the purpose of reducing the size
11 of a cancer, slowing the progression of a cancer, or improving the
12 quality of life of a patient with cancer, by a physician and surgeon
13 practicing within his or her scope of practice.

14 (b) “Physician and surgeon” means a physician and surgeon
15 licensed pursuant to Section 2050 of the Business and Professions
16 Code or an osteopathic physician and surgeon licensed pursuant
17 to the Osteopathic Act.

18 (c) An individual “prescribes” a treatment when he or she orders
19 the treatment or a course of treatment.

20 (d) An individual “provides” a treatment when he or she actually
21 renders, administers, furnishes, or dispenses the treatment to the
22 patient.

23 109401. (a) Notwithstanding any other provision of law, a
24 physician and surgeon shall not recommend or prescribe integrative
25 cancer treatment for cancer patients unless the following
26 requirements are met, as applicable:

27 (1) The treatment is recommended or prescribed after informed
28 consent is given, as provided in Section 109402.

29 (2) The treatment recommended or prescribed meets the
30 evidence-based medical standard provided in Section 109403.

31 (3) The physician and surgeon prescribing the treatment
32 complies with the patient reevaluation requirements set forth in
33 Section 109404 after the treatment begins.

34 (4) The physician and surgeon prescribing the treatment
35 complies with all of the standards of care set forth in Section
36 109405.

37 (b) A physician and surgeon shall not provide integrative cancer
38 treatment for cancer patients unless the treatment is prescribed by
39 a physician and surgeon in compliance with subdivision (a).

109402. (a) For purposes of paragraph (1) of subdivision (a) of Section 109401, informed consent has been given if the patient signs a form stating either of the following:

(1) The name and telephone number of the physician and surgeon from whom the patient is receiving conventional cancer care and whether the patient has been informed of the type of cancer from which the patient suffers and his or her prognosis using conventional treatment options.

(2) That the patient has declined to be under the care of an oncologist or other physician and surgeon providing conventional cancer care.

(b) The form described in subdivision (a) shall include all of the following information:

(1) The type of care the patient will be receiving or that is being recommended is not the standard of care for treating cancer in California.

(2) The standard of care for treating cancer in California consists of radiation, chemotherapy, and surgery.

(3) The treatment that the physician and surgeon will be prescribing or recommending is not approved by the federal Food and Drug Administration for the treatment of cancer.

(4) The care that the patient will be receiving or that is being recommended is not mutually exclusive of the patient receiving conventional cancer treatment.

(5) The following written statements:

THE STATE DEPARTMENT OF PUBLIC HEALTH AND THE PHYSICIAN PRESCRIBING YOUR INTEGRATIVE CANCER CARE RECOGNIZE THE IMPORTANCE OF USING CONVENTIONAL CANCER TREATMENTS, INCLUDING RADIATION, CHEMOTHERAPY, AND SURGERY. IT IS HIGHLY RECOMMENDED THAT YOU SEE AN ONCOLOGIST OR ANOTHER PHYSICIAN TO PROVIDE YOU WITH CONVENTIONAL CANCER CARE.

ANY AND ALL MEDICAL TREATMENTS INVOLVE SOME DEGREE OF RISK OF INJURY UP TO AND INCLUDING DEATH.

1 109403. For purposes of paragraph (2) of subdivision (a) of
2 Section 109401, a treatment meets the evidence-based medical
3 standard for integrative cancer treatment if all of the following
4 requirements are met:

5 (a) In the opinion of the physician and surgeon recommending
6 or prescribing the treatment, the treatment has the potential to
7 reduce the size of a cancer, slow the progression of a cancer, or
8 improve the quality of life of a patient with cancer, based on
9 reasonable evidence from peer-reviewed scientific medical journals.

10 (b) In the opinion of the physician and surgeon recommending
11 or prescribing the treatment, the expected benefits of the treatment
12 substantially outweigh the expected harm from the treatment, as
13 derived from peer-reviewed scientific or medical journals.

14 (c) The treatment, when properly provided, does not cause death
15 or bodily injury to the patient.

16 109404. For purposes of paragraph (3) of subdivision (a) of
17 Section 109401, a physician and surgeon prescribing integrative
18 cancer treatment complies with the patient reevaluation
19 requirements if all of the following conditions are satisfied:

20 (a) The patient is informed regarding the measurable results
21 achieved within the timeframe established pursuant to paragraph
22 (2) of subdivision (a) of Section 109405 and at regular and
23 appropriate intervals during the treatment plan.

24 (b) The physician and surgeon reevaluates treatment when
25 progress stalls or reverse,s in the opinion of the physician and
26 surgeon or the patient, or as evidenced by objective evaluations.

27 (c) The patient is informed about and agrees to any proposed
28 change or changes in treatment, including, but not limited to, the
29 risks and benefits of the proposed change or changes, the costs
30 associated with the proposed change or changes, and the timeframe
31 within which the proposed change or changes will be reevaluated.

32 109405. For purposes of paragraph (4) of subdivision (a) of
33 Section 109401, a physician and surgeon complies with all of the
34 standards of care in prescribing integrative cancer treatment under
35 this article if all of the following requirements are met:

36 (a) The physician and surgeon provides the patient with all of
37 the following when prescribing the treatment:

38 (1) Information regarding the treatment prescribed, including
39 its usefulness in treating cancer.

1 (2) A timeframe and plan for reevaluating the treatment using
2 standard and conventional means in order to assess treatment
3 efficacy.

4 (3) A cost estimate for the prescribed treatment.

5 (b) The physician and surgeon ensures that relevant, generally
6 accepted tests are administered to confirm the effectiveness and
7 progress of the treatment.

8 (c) The physician and surgeon, prior to prescribing or changing
9 the treatment, makes a good faith effort to obtain from the patient
10 all relevant charts, records, and laboratory results relating to the
11 patient's conventional cancer care.

12 (d) At the request of the patient, the physician and surgeon
13 makes a good faith effort to coordinate the care of the patient with
14 the physician and surgeon providing conventional cancer care to
15 the patient.

16 (e) At the request of the patient, the physician and surgeon
17 provides a synopsis of any treatment rendered pursuant to this
18 article to the physician and surgeon providing conventional cancer
19 care to the patient, including subjective and objective assessments
20 of the patient's state of health and response to that treatment.

21 109406. The failure of a physician and surgeon to comply with
22 this article constitutes unprofessional conduct and cause for
23 discipline by that individual's licensing entity. That person shall
24 not be subject to Section 109335 or 109370.