

AMENDED IN SENATE APRIL 30, 2013

AMENDED IN SENATE APRIL 8, 2013

**SENATE BILL**

**No. 117**

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**Introduced by Senator Hueso**

January 17, 2013

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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

SB 117, as amended, 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, *including, but not limited to, that the treatment is recommended or prescribed after informed consent is given and that the treatment recommended or prescribed meets the evidence-based medical standard, as specified.* 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 applicable licensing board. 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 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 (A) It is provided after informed consent and a good faith prior  
12 examination of the patient, and medical indication exists for the  
13 treatment or advice, or it is provided for health or well-being.  
14 (B) It is provided after the physician and surgeon has given the  
15 patient information concerning conventional treatment and  
16 describing the education, experience, and credentials of the  
17 physician and surgeon related to the alternative or complementary  
18 medicine that he or she practices.  
19 (C) In the case of alternative or complementary medicine, it  
20 does not cause a delay in, or discourage traditional diagnosis of,  
21 a condition of the patient.  
22 (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 SEC. 3. Section 109270 of the Health and Safety Code is  
20 amended to read:

21 109270. The department shall:

22 (a) Prescribe reasonable regulations with respect to the  
23 administration of this article and Article 2 (commencing with  
24 Section 109300).

25 (b) Investigate violations of this article, Article 2 (commencing  
26 with Section 109300), and Article 2.5 (commencing with Section  
27 109400), and report the violations to the appropriate enforcement  
28 authority.

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

37 (d) Adopt a regulation prohibiting the prescription,  
38 administration, sale or other distribution of any drug, substance,  
39 or device found to be harmful or of no value in the diagnosis,

1 prevention, or treatment of ~~cancer, except as authorized under~~  
2 ~~Article 2.5 (commencing with Section 109400):~~ *cancer*.

3 (e) Hold hearings with respect to those matters involving  
4 compliance with this article, Article 2 (commencing with Section  
5 109300), and Article 2.5 (commencing with Section 109400), and  
6 subpoena witnesses and documents. Any or all hearings may be  
7 held before the Cancer Advisory Council. Any administrative  
8 action to be taken by the department as a result of the hearings  
9 shall be taken only after receipt of the recommendations of the  
10 council. Prior to issuance of a cease and desist order under Section  
11 109345, a hearing shall be held. The person furnishing a sample  
12 or manufacturer contact information under Section 109295 shall  
13 be given due notice of the hearing and an opportunity to be heard.

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

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

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

20 109285. For the purposes of this article, Article 2 (commencing  
21 with Section 109300), and Article 2.5 (commencing with Section  
22 109400), “cancer” means all malignant neoplasms regardless of  
23 the tissue of origin, including malignant lymphoma, ~~Hodgkins~~  
24 *Hodgkin’s* disease, and leukemia.

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

27 109295. (a) On written request by the department, delivered  
28 personally or by mail, any individual, person, firm, association,  
29 or other entity engaged, or representing himself, herself, or itself,  
30 as engaged, in the diagnosis, treatment, alleviation, or cure of  
31 cancer shall do all of the following:

32 (1) Furnish the department with the sample as the department  
33 may deem necessary for adequate testing of any drug, medicine,  
34 compound, or device used or prescribed by the individual, person,  
35 firm, association, or other entity in the diagnosis, treatment,  
36 alleviation, or cure of cancer. The individual, person, firm,  
37 association, or other entity may alternatively furnish the department  
38 with the contact information of the manufacturer of the drug,  
39 medicine, compound, or device.

1 (2) Specify the formula of any drug or compound and name all  
2 ingredients by their common or usual names.

3 (3) Upon request of the department, furnish further necessary  
4 information as the department may request as to the composition  
5 and method of preparation of and the use that any drug, compound,  
6 or device is being put by the individual, person, firm, association,  
7 or other entity.

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

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

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

22 109300. The sale, offering for sale, holding for sale, delivering,  
23 giving away, prescribing, or administering of any drug, medicine,  
24 compound, or device to be used in the diagnosis, treatment,  
25 alleviation, or cure of cancer is unlawful and prohibited unless one  
26 of the following applies:

27 (a) An application with respect thereto has been approved under  
28 Section 505 of the federal Food, Drug, and Cosmetic Act.

29 (b) The use is consistent with Article 2.5 (commencing with  
30 Section 109400).

31 (c) There has been approved an application filed with the board  
32 setting forth all of the following:

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

37 (2) A full list of the articles used as components of the drug,  
38 medicine, compound, or ~~device~~; *device*.

39 (3) A full statement of the composition of the drug, medicine,  
40 compound, or ~~device~~; *device*.

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

6 (5) Such samples of the drug, medicine, compound, or device  
7 and of the articles used as components of the drug, medicine,  
8 compound, or device as the board may ~~require~~; and *require*.

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

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

13 109350. The department may direct that an individual, person,  
14 firm, association, or other entity shall cease and desist any further  
15 prescribing, recommending, or use of any drug, medicine,  
16 compound, or device for which no application has been approved  
17 under this article and Article 1 (commencing with Section 109250)  
18 unless its use is exempt under Section 109325 or 109330 or  
19 authorized under Article 2.5 (commencing with Section 109400).

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

22 109375. The director shall investigate possible violations of  
23 this article, Article 1 (commencing with Section 109250), and  
24 Article 2.5 (commencing with Section 109400), and report  
25 violations to the appropriate enforcement authority.

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

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Article 2.5. Integrative Cancer Treatment

32 109400. For purposes of this article:

33 (a) “Integrative cancer treatment” means the use of a  
34 combination of evidence-based substances or therapies for the  
35 purpose of reducing the size of a cancer, slowing the progression  
36 of a cancer, or improving the quality of life of a patient with cancer,  
37 by a physician and surgeon practicing within his or her scope of  
38 practice.

39 (b) “Physician and surgeon” means a physician and surgeon  
40 licensed pursuant to Section 2050 of the Business and Professions

1 Code or an osteopathic physician and surgeon licensed pursuant  
2 to the Osteopathic Act.

3 109401. (a) Notwithstanding any other provision of law, a  
4 physician and surgeon shall not recommend or prescribe integrative  
5 cancer treatment for cancer patients unless the following  
6 requirements are met, as applicable:

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

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

11 (3) The physician and surgeon prescribing the treatment  
12 complies with the patient reevaluation requirements set forth in  
13 Section 109404 after the treatment begins.

14 (4) The physician and surgeon prescribing the treatment  
15 complies with all of the standards of care set forth in Section  
16 109405.

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

20 109402. (a) For purposes of paragraph (1) of subdivision (a)  
21 of Section 109401, informed consent has been given if the patient  
22 signs a form stating either of the following:

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

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

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

33 (1) The type of care the patient will be receiving or that is being  
34 recommended is not, in whole or in part, the conventional treatment  
35 for treating cancer in California.

36 (2) The conventional treatment for treating cancer in California  
37 consists of radiation, chemotherapy, and surgery.

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

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

4 (5) The following written statements:

5  
6 THE STATE DEPARTMENT OF PUBLIC HEALTH AND  
7 THE PHYSICIAN PRESCRIBING YOUR INTEGRATIVE  
8 CANCER CARE RECOGNIZE THE IMPORTANCE OF USING  
9 CONVENTIONAL CANCER TREATMENTS, INCLUDING  
10 RADIATION, CHEMOTHERAPY, AND SURGERY. IT IS  
11 HIGHLY RECOMMENDED THAT YOU SEE AN  
12 ONCOLOGIST OR ANOTHER PHYSICIAN TO PROVIDE  
13 YOU WITH CONVENTIONAL CANCER CARE.

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

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19 109403. For purposes of paragraph (2) of subdivision (a) of  
20 Section 109401, a treatment meets the evidence-based medical  
21 standard for integrative cancer treatment if ~~one~~ *either* of the  
22 following requirements is met:

23 (a) The treatment is recognized by the Physician's Data Query  
24 of the National Cancer Institute *and has been reported to reduce*  
25 *the size of a cancer, slow the progression of a cancer, or improve*  
26 *the quality of life of a patient with cancer.*

27 ~~(b) The treatment has been published in at least three~~  
28 ~~peer-reviewed scientific medical journals.~~

29 ~~(c) The treatment has been reported in at least three~~  
30 ~~peer-reviewed articles published in complementary and alternative~~  
31 ~~medicine journals to have the potential of reducing the size of a~~  
32 ~~cancer, slowing the progression of a cancer, or improving the~~  
33 ~~quality of life of a patient with cancer.~~

34 *(b) The treatment has been reported to reduce the size of a*  
35 *cancer, slow the progression of a cancer, or improve the quality*  
36 *of life of a patient with cancer in peer-reviewed literature,*  
37 *peer-reviewed biomedical compendia, and other peer-reviewed*  
38 *medical literature that all meet the criteria for indexing of the*  
39 *National Institutes of Health's National Library of Medicine.*

1 109404. For purposes of paragraph (3) of subdivision (a) of  
2 Section 109401, a physician and surgeon prescribing integrative  
3 cancer treatment complies with the patient reevaluation  
4 requirements if all of the following conditions are satisfied:

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

9 (b) The physician and surgeon reevaluates treatment when  
10 progress stalls or reverses, in the opinion of the physician and  
11 surgeon or the patient, or as evidenced by objective evaluations.

12 (c) The patient is informed about and agrees to any proposed  
13 change or changes in treatment, including, but not limited to, the  
14 risks and benefits of the proposed change or changes, the costs  
15 associated with the proposed change or changes, and the timeframe  
16 within which the proposed change or changes will be reevaluated.

17 109405. For purposes of paragraph (4) of subdivision (a) of  
18 Section 109401, a physician and surgeon complies with all of the  
19 standards of care in prescribing integrative cancer treatment under  
20 this article if all of the following requirements are met:

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

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

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

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

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

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

36 (d) At the request of the patient, the physician and surgeon  
37 makes a good faith effort to coordinate the care of the patient with  
38 the physician and surgeon providing conventional cancer care to  
39 the patient.

1 (e) At the request of the patient, the physician and surgeon  
2 provides a synopsis of any treatment rendered pursuant to this  
3 article to the physician and surgeon providing conventional cancer  
4 care to the patient, including subjective and objective assessments  
5 of the patient’s state of health and response to that treatment.

6 109406. The failure of a physician and surgeon to comply with  
7 this article constitutes unprofessional conduct and cause for  
8 discipline by his or her licensing board. That person shall not be  
9 subject to Section 109335 or 109370.

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