

AMENDED IN SENATE APRIL 8, 2013

**SENATE BILL**

**No. 117**

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**Introduced by Senator ~~Rubio Hueso~~**

January 17, 2013

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An act to amend ~~Sections 116275, 116475, and 116590~~ *Section 2234.1* of, and to ~~add repeal~~ *Section 116276 to, 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 ~~drinking water.~~ health care.*

LEGISLATIVE COUNSEL'S DIGEST

SB 117, as amended, ~~Rubio Hueso. Drinking water: State Water Resources Control Board.~~ *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 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.*

~~Existing law, the California Safe Drinking Water Act, provides for the operation of public water systems, and imposes on the State Department of Public Health various responsibilities and duties. Existing law requires the department to conduct research, studies, and demonstration projects relating to the provision of a dependable, safe supply of drinking water, to adopt regulations to implement the California Safe Drinking Water Act, and to enforce provisions of the federal Safe Drinking Water Act.~~

~~This bill would transfer the various duties and responsibilities imposed on the department by the California Safe Drinking Water Act to the State Water Resources Control Board and make conforming changes.~~

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.

1     ~~(2)~~

2     (B) It is provided after the physician and surgeon has given the  
3 patient information concerning conventional treatment and  
4 describing the education, experience, and credentials of the  
5 physician and surgeon related to the alternative or complementary  
6 medicine that he or she practices.

7     ~~(3)~~

8     (C) In the case of alternative or complementary medicine, it  
9 does not cause a delay in, or discourage traditional diagnosis of,  
10 a condition of the patient.

11     ~~(4)~~

12     (D) It does not cause death or serious bodily injury to the patient.

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

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

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

29     *SEC. 2. Section 2257 of the Business and Professions Code is*  
30 *repealed.*

31     ~~2257. The violation of Section 109275 of the Health and Safety~~  
32 ~~Code, relating to informed consent for the treatment of breast~~  
33 ~~cancer, constitutes unprofessional conduct.~~

34     *SEC. 3. Section 109270 of the Health and Safety Code is*  
35 *amended to read:*

36     109270. The department shall:

37     (a) Prescribe reasonable regulations with respect to the  
38 administration of this article and Article 2 (commencing with  
39 Section 109300).

1 (b) Investigate violations of this article—~~and~~, Article 2  
2 (commencing with Section 109300), *and Article 2.5 (commencing*  
3 *with Section 109400)*, and report the violations to the appropriate  
4 enforcement authority.

5 (c) Secure the investigation and testing of the content, method  
6 of preparation, efficacy, or use of drugs, medicines, compounds,  
7 or devices proposed to be used, or used, by any individual, person,  
8 firm, association, or other entity in the state for the diagnosis,  
9 treatment, or cure of cancer, prescribe reasonable regulations with  
10 respect to the investigation and testing, and make findings of fact  
11 and recommendations upon completion of any such investigation  
12 and testing.

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

18 (e) Hold hearings—~~in~~ *with* respect ~~of~~ *to* those matters involving  
19 compliance with this article—~~and~~, Article 2 (commencing with  
20 Section 109300), *and Article 2.5 (commencing with Section*  
21 *109400)*, and subpoena witnesses and documents. Any or all  
22 hearings may be held before the Cancer Advisory Council. Any  
23 administrative action to be taken by the department as a result of  
24 the hearings shall be taken only after receipt of the  
25 recommendations of the council. Prior to issuance of a cease and  
26 desist order under Section 109345, a hearing shall be held. The  
27 person furnishing a sample *or manufacturer contact information*  
28 under Section 109295 shall be given due notice of the hearing and  
29 an opportunity to be heard.

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

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

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

36 109285. For the purposes of this article—~~and~~, Article 2  
37 (commencing with Section 109300), *and Article 2.5 (commencing*  
38 *with Section 109400)*, “cancer” means all malignant neoplasms  
39 regardless of the tissue of origin, including malignant lymphoma,  
40 Hodgkins disease, and leukemia.

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

3 109295. (a) On written request by the department, delivered  
4 personally or by mail, any individual, person, firm, association,  
5 or other entity engaged, or representing himself, *herself*, or itself,  
6 as engaged, in the diagnosis, treatment, alleviation, or cure of  
7 cancer shall ~~furnish~~ *do all of the following*:

8 (1) *Furnish* the department with the sample as the department  
9 may deem necessary for adequate testing of any drug, medicine,  
10 compound, or device used or prescribed by the individual, person,  
11 firm, association, or other entity in the diagnosis, treatment,  
12 alleviation, or cure of ~~cancer, and shall specify cancer~~. *The*  
13 *individual, person, firm, association, or other entity may*  
14 *alternatively furnish the department with the contact information*  
15 *of the manufacturer of the drug, medicine, compound, or device.*

16 (2) *Specify* the formula of any drug or compound and name all  
17 ingredients by their common or usual ~~names, and shall, upon like~~  
18 *names*.

19 (3) *Upon request by* of the department, furnish further necessary  
20 information as ~~it~~ *the department* may request as to the composition  
21 and method of preparation of and the use that any drug, compound,  
22 or device is being put by the individual, person, firm, association,  
23 or other entity. ~~This~~

24 (b) *This* section shall apply to any individual, person, firm,  
25 association, or other entity that renders health care or services to  
26 individuals who have or believe they have cancer. This section  
27 also applies to any individual, person, firm, association, or other  
28 entity that by implication causes individuals to believe they have  
29 cancer.

30 ~~The~~

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

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

39 109300. The sale, offering for sale, holding for sale, delivering,  
40 giving away, prescribing, or administering of any drug, medicine,

1 compound, or device to be used in the diagnosis, treatment,  
 2 alleviation, or cure of cancer is unlawful and prohibited unless ~~(1)~~  
 3 ~~an~~ *one of the following applies:*

4 (a) An application with respect thereto has been approved under  
 5 Section 505 of the federal Food, Drug, and Cosmetic Act, ~~or (2)~~  
 6 ~~there.~~

7 (b) *The use is consistent with Article 2.5 (commencing with*  
 8 *Section 109400).*

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

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

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

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

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

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

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

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

37 109350. The department may direct that ~~any~~ *an* individual,  
 38 person, firm, association, or other entity shall cease and desist any  
 39 further prescribing, recommending, or use of any drug, medicine,  
 40 compound, or device for which no application has been approved

1 under this article and Article 1 (commencing with Section 109250)  
2 unless its use is exempt under Section 109325 or 109330 *or*  
3 *authorized under Article 2.5 (commencing with Section 109400).*

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

6 109375. The director shall investigate possible violations of  
7 this article ~~and~~, Article 1 (commencing with Section 109250), *and*  
8 *Article 2.5 (commencing with Section 109400), and report*  
9 *violations to the appropriate enforcement authority.*

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

13

14

*Article 2.5. Integrative Cancer Treatment*

15

16 109400. *For purposes of this article:*

17 (a) *“Integrative cancer treatment” means the use of a*  
18 *combination of evidence-based substances or therapies for the*  
19 *purpose of reducing the size of a cancer, slowing the progression*  
20 *of a cancer, or improving the quality of life of a patient with*  
21 *cancer, by a physician and surgeon practicing within his or her*  
22 *scope of practice.*

23 (b) *“Physician and surgeon” means a physician and surgeon*  
24 *licensed pursuant to Section 2050 of the Business and Professions*  
25 *Code or an osteopathic physician and surgeon licensed pursuant*  
26 *to the Osteopathic Act.*

27 109401. (a) *Notwithstanding any other provision of law, a*  
28 *physician and surgeon shall not recommend or prescribe*  
29 *integrative cancer treatment for cancer patients unless the*  
30 *following requirements are met, as applicable:*

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

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

35 (3) *The physician and surgeon prescribing the treatment*  
36 *complies with the patient reevaluation requirements set forth in*  
37 *Section 109404 after the treatment begins.*

38 (4) *The physician and surgeon prescribing the treatment*  
39 *complies with all of the standards of care set forth in Section*  
40 *109405.*

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

4 109402. (a) For purposes of paragraph (1) of subdivision (a)  
5 of Section 109401, informed consent has been given if the patient  
6 signs a form stating either of the following:

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

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

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

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

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

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

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

28 (5) The following written statements:

29  
30 *THE STATE DEPARTMENT OF PUBLIC HEALTH AND THE*  
31 *PHYSICIAN PRESCRIBING YOUR INTEGRATIVE CANCER*  
32 *CARE RECOGNIZE THE IMPORTANCE OF USING*  
33 *CONVENTIONAL CANCER TREATMENTS, INCLUDING*  
34 *RADIATION, CHEMOTHERAPY, AND SURGERY. IT IS HIGHLY*  
35 *RECOMMENDED THAT YOU SEE AN ONCOLOGIST OR*  
36 *ANOTHER PHYSICIAN TO PROVIDE YOU WITH*  
37 *CONVENTIONAL CANCER CARE.*

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

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

*(a) The treatment is recognized by the Physician’s Data Query of the National Cancer Institute.*

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

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

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

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

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

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

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

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

*(1) Information regarding the treatment prescribed, including 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 his or her licensing board. That person shall not be  
24 subject to Section 109335 or 109370.

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**All matter omitted in this version of the bill  
appears in the bill as introduced in the  
Senate, January 17, 2013. (JR11)**