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HEALTH AND SAFETY CODE - HSC

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406] (*Division 104 added by Stats. 1995, Ch. 415, Sec. 6.)*

PART 4. DRUGS, DEVICES, AND COSMETICS [109250 - 109590] (*Part 4 added by Stats. 1995, Ch. 415, Sec. 6.)*

CHAPTER 4. Treatment of Cancer and Other Serious Diseases [109250 - 109505] (*Chapter 4 added by Stats. 1995, Ch. 415, Sec. 6.)*

ARTICLE 1. Intent and Definitions [109250 - 109295] (*Article 1 added by Stats. 1995, Ch. 415, Sec. 6.)*

109250. The effective diagnosis, care, treatment or cure of persons suffering from cancer is of paramount public importance. Vital statistics indicate that approximately 16 percent of the total deaths in the United States annually result from one or another of the forms of cancer. It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment that are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom.

Despite intensive campaigns of public education, there is a lack of adequate and accurate information among the public with respect to presently proven methods for the diagnosis, treatment, and cure of cancer. Various persons in this state have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment, or cure of cancer, whose representations are misleading to the public, with the result that large numbers of the public, relying on the representations, needlessly die of cancer, and substantial amounts of the savings of individuals and families relying on the representations are needlessly wasted.

It is, therefore, in the public interest that the public be afforded full and accurate knowledge as to the facilities and methods for the diagnosis, treatment, and cure of cancer available in this state and that to that end there be provided means for testing and investigating the value or lack thereof of alleged cancer remedies, devices, drugs, or compounds, and informing the public of the facts found, and protecting the public from misrepresentation in these matters.

The importance of continuing scientific research to determine the cause or cure of cancer is recognized, and the department shall administer this article and Article 2 (commencing with Section 109300) with due regard for the importance of bona fide scientific research and the clinical testing in hospitals, clinics, or similar institutions of new drugs or compounds.

(*Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.*)

109255. There is in the department a Cancer Advisory Council composed of nine physicians and surgeons licensed to practice medicine in, and residing in, this state, three persons who are not physicians and surgeons, two persons representing nonprofit cancer research institutes recognized by the National Cancer Institute, and the director of the department, who shall be an ex officio member. The members of the council shall be appointed by the Governor to serve for terms of four years. The Governor, in appointing the first members, shall appoint at least one member from the faculty of each of the schools teaching medicine and surgery and located in this state that are approved by the Medical Board of California. The Governor shall endeavor to maintain one member from the faculty of each school in making subsequent appointments.

(*Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.*)

109260. The members of the council, other than the director of the department, shall receive no compensation for their services, but shall be allowed their actual necessary traveling expenses incurred in the discharge of their duties.

Except as provided in Section 109390 the council is not required to conduct meetings open to the public in accordance with Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

(*Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.*)

109265. The council shall annually elect one of its members to serve as chairman. The council shall meet at least twice each year, and as often in addition as necessary, for the purpose of carrying out its duties.

109270. The department shall:

- (a) Prescribe reasonable regulations with respect to the administration of this article and Article 2 (commencing with Section 109300).
- (b) Investigate violations of this article and Article 2 (commencing with Section 109300), and report the violations to the appropriate enforcement authority.
- (c) Secure the investigation and testing of the content, method of preparation, efficacy, or use of drugs, medicines, compounds, or devices proposed to be used, or used, by any individual, person, firm, association, or other entity in the state for the diagnosis, treatment, or cure of cancer, prescribe reasonable regulations with respect to the investigation and testing, and make findings of fact and recommendations upon completion of any such investigation 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.
- (e) Hold hearings in respect of those matters involving compliance with this article and Article 2 (commencing with Section 109300) 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 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.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109275. (a) Upon a diagnosis of breast cancer, the physician and surgeon, meaning the primary provider who initially referred the patient for the screening or biopsy or, if different, the provider who has made the diagnosis of breast cancer and initially consulted with the patient about treatment, shall give the patient the written summary described in subdivision (c) and required by this section and shall note on the patient's chart that he or she has given the patient the written summary. The physician and surgeon may choose to provide the summary prior to the performance of a screening or biopsy for breast cancer upon a patient's request or at the discretion of the physician and surgeon in appropriate cases, including, but not limited to, instances when a patient has demonstrated risk factors, has a family history of breast cancer, or is otherwise susceptible.

(b) The failure of a physician and surgeon to inform a patient, by means of a standardized written summary developed by the department on the recommendation of the Cancer Advisory Council in accordance with subdivision (c), in layperson's language and in a language understood by the patient, of alternative efficacious methods of treatment that may be medically viable, including surgical, radiological, or chemotherapeutic treatments or combinations thereof, when the patient is being treated for any form of breast cancer, constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(c) (1) A standardized written summary in layperson's language and in a language understood by the patient shall be developed by the department with the recommendations of the Cancer Advisory Council, and shall be printed and made available by the Medical Board of California to physicians and surgeons, for the purposes of informing the patient of the advantages, disadvantages, risks, and descriptions of the procedures with regard to medically viable and efficacious alternative methods of treatment for breast cancer as required by subdivision (a).

(2) Commencing no later than January 1, 1995, and every three years thereafter, the department shall review the written summary and shall revise the written summary if the department determines that new or revised information should be included in the written summary, and shall provide a copy of the revised summary to the Medical Board of California.

(3) At the next revision of the standardized written summary required by this section, the department shall incorporate all of the following additional information:

(A) Information regarding methods of treatment for breast cancer that are in the investigational or clinical trial stage and are recognized for treatment by the Physician's Data Query of the National Cancer Institute.

(B) Available reference numbers, including, but not limited to, the "800" telephone numbers for the National Cancer Institute and the American Cancer Society, in order for breast cancer patients to obtain the most recent information.

(C) A discussion of breast reconstruction surgery, including, but not limited to, problems, benefits, and alternatives.

(D) Statistics on the incidence of breast cancer.

(d) The Medical Board of California shall establish a distribution system for the breast cancer treatment alternatives written summary, and shall provide a link to its Internet Web site that may be accessed by consumers interested in viewing and obtaining a copy of the summary.

(e) The department and the Medical Board of California shall each post the summary on its Internet Web site.

(Amended by Stats. 2006, Ch. 485, Sec. 1. Effective January 1, 2007.)

109276. In the first revision of the standardized written summary required under subdivision (c) of Section 109275 made following the effective date of the act that added this section, the State Department of Health Care Services shall incorporate information relating to breast cancer susceptibility gene (BRCA) mutations, in order to achieve increased genetic counseling and screening rates of individuals for whom BRCA test results can inform treatment decisions, consistent with evidence-based national recommendations.

(Added by Stats. 2017, Ch. 693, Sec. 2. (AB 1386) Effective January 1, 2018.)

109277. (a) Every person or entity who owns or operates a health facility or a clinic, or who is licensed as a physician and surgeon and rents or owns the premises where his or her practice is located, shall cause a sign or notice to be posted where a physician and surgeon performs breast cancer screening or biopsy as an outpatient service, or in a reasonably proximate area to where breast cancer screening or biopsy is performed. A sign or notice posted at the patient registration area of the health facility, clinic, or physician and surgeon's office shall constitute compliance with this section.

(b) The sign or notice shall read as follows:

"BE INFORMED"

"Upon a diagnosis of breast cancer, your physician and surgeon is required to provide you a written summary of alternative efficacious methods of treatment, pursuant to Section 109275 of the California Health and Safety Code. Your physician and surgeon may choose to provide the summary prior to the performance of a screening or biopsy for breast cancer at your request or at the physician and surgeon's discretion, when appropriate."

"The information about methods of treatment was developed by the State Department of Public Health to inform patients of the advantages, disadvantages, risks, and descriptions of procedures."

(c) The sign shall be not less than eight and one-half inches by 11 inches and shall be conspicuously displayed so as to be readable. The words "BE INFORMED" shall not be less than one-half inch in height and shall be centered on a single line with no other text. The message on the sign shall appear in English, Spanish, and Chinese.

(Amended by Stats. 2007, Ch. 483, Sec. 22. Effective January 1, 2008.)

109278. (a) The medical care provider primarily responsible for providing to a patient an annual gynecological examination shall provide to that patient during the annual examination a standardized summary in layperson's language and in a language understood by the patient containing a description of the symptoms and appropriate methods of diagnoses for gynecological cancers. Use of existing publications developed by nationally recognized cancer organizations is not precluded by this section.

(b) For the purposes of this section, "medical care provider" means a health care professional licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code or pursuant to an initiative act referred to in that division providing medical care within his or her lawful scope of practice.

(Added by Stats. 1997, Ch. 754, Sec. 2. Effective January 1, 1998.)

109280. (a) A standardized written summary in layperson's language and in a language understood by patients shall be approved by the department. The department may approve the use of an existing publication from a recognized cancer authority as the written summary. Commencing on January 1, 2003, and every three years thereafter, the department shall review its approval of the use of an existing publication from a recognized cancer authority as the written summary to ensure that the approved written summary comprises timely, new, and revised information regarding prostate cancer treatment options as the department determines is necessary. The written summary shall be printed or made available by the Medical Board of California to physicians and surgeons, concerning the advantages, disadvantages, risks, and descriptions of procedures with regard to medically viable and efficacious alternative methods of treatment of prostate cancer. Physicians and surgeons are urged to make the summary available to patients when appropriate.

(b) The department and the Medical Board of California shall each post this summary on its Internet Web site for public use.

(c) If the department updates this summary, it shall send the updated summary to the Medical Board of California and both the department and the Medical Board of California shall each post this updated summary on its Internet Web site.

(Amended by Stats. 2007, Ch. 130, Sec. 171. Effective January 1, 2008.)

109282. (a) Every person or entity who owns or operates a health facility or a clinic, or who is licensed as a physician and surgeon and rents or owns the premises where his or her practice is located, shall cause a sign or notice to be posted where prostate cancer screening or treatment is performed by any physician and surgeon, or in a reasonably proximate area to where prostate cancer screening or treatment is performed. A sign or notice posted at the patient registration area of the health facility, clinic, or physician and surgeon's office shall constitute compliance with this section.

(b) The sign or notice shall read as follows:

"BE INFORMED"

"If you are a patient being treated for any form of prostate cancer, or prior to performance of a biopsy for prostate cancer, your physician and surgeon is urged to provide you a written summary of alternative efficacious methods of treatment, pursuant to Section 109280 of the California Health and Safety Code."

"The information about methods of treatment was developed by the State Department of Public Health to inform patients of the advantages, disadvantages, risks, and descriptions of procedures."

(c) The sign shall be not less than eight and one-half inches by 11 inches and shall be conspicuously displayed so as to be readable. The words "BE INFORMED" shall not be less than one-half inch in height and shall be centered on a single line with no other text. The message on the sign shall appear in English, Spanish, and Chinese.

(d) Subject to future, regular production and replacement schedules from the implementation of the act adding this subdivision, these signs and notices shall include the Internet Web site address of the State Department of Public Health and the Medical Board of California, and a notice regarding the availability of updated prostate cancer summaries on these Web sites.

(Amended by Stats. 2006, Ch. 241, Sec. 33. Effective January 1, 2007. Operative July 1, 2007, by Sec. 37 of Ch. 241.)

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

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109290. No person may undertake to treat or alleviate cancer by use of drugs, surgery, or radiation unless the person holds a license issued under a law of this state expressly authorizing the diagnosis and treatment of disease by use of drugs, surgery, or radiation.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109295. On written request by the department, delivered personally or by mail, any individual, person, firm, association, or other entity engaged, or representing himself, or itself, as engaged, in the diagnosis, treatment, alleviation, or cure of cancer shall 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 the formula of any drug or compound and name all ingredients by their common or usual names, and shall, upon like request by the department, furnish further necessary information as it may request as to the composition and method of preparation of and the use that any drug, compound, or device is being put by the individual, person, firm, association, or other entity. This section shall apply to any individual, person, firm, association, or other entity that renders health care or services to individuals who have or believe they have cancer. This section also applies to any individual, person, firm, association, or other entity that by implication causes individuals to believe they have cancer.

The failure to either provide the sample, disclose the formula, or name the ingredients as required by this section shall be conclusively presumed that the drug, medicine, compound or device that is the subject of the department's request has no value in the diagnosis, treatment, alleviation, or cure of cancer.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)