

AMENDED IN SENATE JULY 16, 2015

AMENDED IN SENATE JUNE 17, 2015

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1060**

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**Introduced by Assembly Member Bonilla**

February 26, 2015

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An act to add Chapter 2 (commencing with Section 101990) to Part 6 of Division 101 of the Health and Safety Code, relating to cancer, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 1060, as amended, Bonilla. Cancer clinical trials.

Existing law establishes the scope and function of the California Health and Human Services Agency, which includes departments charged with administering laws pertaining to public health and social services, among other things. Existing law also establishes the Inclusion of Women and Minorities in Clinical Research Act, which is designed to promote the inclusion of women and minority groups in clinical research, including clinical trials.

This bill would create the Cancer Clinical Trials Foundation in the Health and Human Services Agency, to be governed by a board of trustees. Members of the board would be appointed as specified. The bill would also create the Cancer Clinical Trials Fund, and would continuously appropriate this fund to the board, thereby making an appropriation. The bill would authorize the board to solicit and receive money, as specified. The bill would require the board, upon contribution of an unspecified amount of money to the fund, to establish the Cancer

Clinical Trials Grant Program, in order to increase patient access to cancer clinical trials in specified populations. The bill would require that grant money be used for designated purposes, and would also require grant recipients to report to the board. The bill would require the board to report to the Legislature, as specified. This bill would make related findings.

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

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

- 1 SECTION 1. The Legislature finds and declares the following:
- 2 (a) Almost 50 percent of clinical trial studies are not finished
- 3 in time due to low patient participation, recruitment and navigation
- 4 difficulties, and other barriers for patients. Due to economic and
- 5 socioeconomic circumstances and lack of patient knowledge,
- 6 clinical oncology trial participation and retention are both very
- 7 low as they relate to eligible participants.
- 8 (b) Overall, only 3 percent of eligible cancer patients participate
- 9 in clinical trials, and of those only 5 percent of trial participants
- 10 are from racial or ethnic minority communities.
- 11 (c) One barrier that prevents patients from participating in
- 12 federal Food and Drug Administration clinical trials is finances.
- 13 Patients of low to moderate income are often unable to bear the
- 14 burden of the ancillary costs of participating, such as airfare,
- 15 lodging, rental cars, and fuel.
- 16 (d) The American Medical Association conducted a study on
- 17 cancer trial participation. The study found that from 1996 to 2002,
- 18 of the 75,215 patients enrolled in the National Cancer Institute
- 19 trials for breast, lung, colorectal, and prostate cancers, only 3.1
- 20 percent were Hispanic, 9.2 percent were Black, and 1.9 percent
- 21 were Asian or Pacific Islanders, while 85.6 percent were White.
- 22 This lack of diversity is ~~alarming~~ *of concern* because of its impact
- 23 on researchers' ability to evaluate the effect of new treatments on
- 24 different populations. It also speaks to a lack of access to
- 25 potentially lifesaving trials for a large portion of the population.
- 26 (e) It is the intent of the Legislature to establish a program to
- 27 enable willing patients of low to moderate income to participate
- 28 in cancer clinical trials in order to boost participation rates, ensure

1 these trials are widely accessible, improve the development of  
2 cancer therapies, and enhance innovation.

3 SEC. 2. Chapter 2 (commencing with Section 101990) is added  
4 to Part 6 of Division 101 of the Health and Safety Code, to read:

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CHAPTER 2. CANCER CLINICAL TRIALS

7

8 101990. (a) "Board" means the Board of Trustees of the Cancer  
9 Clinical Trials Foundation.

10 (b) "Foundation" means the Cancer Clinical Trials Foundation.

11 (c) "Fund" means the Cancer Clinical Trials Fund.

12 101991. (a) The agency shall establish a nonprofit public  
13 benefit corporation, to be known as the Cancer Clinical Trials  
14 Foundation, that shall be governed by a board consisting of a total  
15 of five members. Three members shall be appointed by the  
16 Governor. Of these members, one shall be from a public cancer  
17 research institution, and one shall be from a private cancer research  
18 institution. One member shall be appointed by the Speaker of the  
19 Assembly. One member shall be appointed by the President pro  
20 Tempore of the Senate.

21 (b) The Governor shall appoint the president of the board from  
22 among those members appointed by the Governor, the Speaker of  
23 the Assembly, and the President pro Tempore of the Senate.

24 (c) *The foundation, or an authorized representative thereof,*  
25 *shall apply for tax exempt status under Section 501(c)(3) of the*  
26 *Internal Revenue Code.*

27 (e)

28 (d) Members of the board shall serve without compensation but  
29 shall be reimbursed for any actual and necessary expenses incurred  
30 in connection with their duties as members of the board.

31 (d)

32 (e) The foundation shall be subject to the Nonprofit Public  
33 Benefit Corporation Law (Part 2 (commencing with Section 5110)  
34 of Division 2 of Title 2 of the Corporations Code), ~~except that if~~  
35 ~~there is a conflict with this chapter and the Nonprofit Public Benefit~~  
36 ~~Corporation Law, this chapter shall prevail.~~ *Code).*

37 (e)

38 (f) The California Health and Human Services Agency shall  
39 determine which department in the agency shall administer the  
40 foundation.

1 101992. (a) Of the members of the board first appointed by  
2 the Governor pursuant to Section 101991, one member shall be  
3 appointed to serve a two-year term, one member shall be appointed  
4 to serve a three-year term, and one member shall be appointed to  
5 serve a four-year term.

6 (b) Of the members of the board first appointed by the Speaker  
7 of the Assembly and the President pro Tempore of the Senate  
8 pursuant to Section 101991, each member shall be appointed to  
9 serve a four-year term.

10 (c) Upon the expiration of the initial appointments for the board,  
11 each member shall be appointed to serve a four-year term.

12 101993. (a) There is hereby created the Cancer Clinical Trials  
13 Fund. Notwithstanding Section 13340 of the Government Code,  
14 all money in the fund is continuously appropriated to the board  
15 without regard to fiscal years, for the administration and support  
16 of the program created pursuant to this chapter.

17 (b) The Cancer Clinical Trials Foundation may solicit and  
18 receive funds from business, industry, foundations, and other  
19 private and public sources for the purpose of administering the  
20 Cancer Clinical Trials Grant Program to increase patient access  
21 to cancer clinical trials.

22 (c) The board shall use no more than 20 percent of funds made  
23 available for the Cancer Clinical Trials Grant Program for  
24 administrative costs.

25 101994. (a) Upon contribution of an unspecified amount of  
26 moneys to the foundation, the board shall establish the Cancer  
27 Clinical Trials Grant Program to increase patient access to cancer  
28 clinical trials in underserved or disadvantaged communities and  
29 populations, including among women and patients from racial and  
30 ethnic minority communities. The board shall determine the criteria  
31 to award grants, and may award grants to either or both of the  
32 following:

33 (1) Public and private research institutions and hospitals that  
34 conduct cancer clinical trials approved by the federal Food and  
35 Drug Administration.

36 (2) Nonprofit organizations described in Section 501(c)(3) of  
37 the Internal Revenue Code of 1954 that are exempt from income  
38 tax under Section 501(a) of that code and that specialize in direct  
39 patient support for improved clinical trial enrollment and retention.

1 (b) Grants awarded pursuant to subdivision (a) shall be used for  
2 activities to increase patient access to cancer clinical trials,  
3 including, but not limited to, any of the following:

- 4 (1) Patient navigator services or programs.
- 5 (2) Education and community outreach.
- 6 (3) Patient-friendly technical tools to assist patients in  
7 identifying available clinical trials.
- 8 (4) Translation and interpretation services of clinical trial  
9 information.

10 (5) Counseling services for clinical trial participants.  
11 (6) Well-being services for clinical trial participants, including,  
12 but not limited to, physical therapy, pain management, stress  
13 management, and nutrition management.

14 (7) Payment of ancillary costs for patients and caregivers,  
15 including, but not limited to:

- 16 (A) Airfare during the clinical trial.
- 17 (B) Lodging during the clinical trial.
- 18 (C) Rental cars during the clinical trial.
- 19 (D) Fuel during the clinical trial.
- 20 (E) Local transportation via bus, train, or other public  
21 transportation during the clinical trial.
- 22 (F) Meals during the clinical trial.
- 23 (G) Child care costs during the clinical trial.

24 101995. (a) Grant recipients shall report to the board to ensure  
25 the appropriate use of funds within one year of receiving a grant.

26 (b) (1) The board shall report to the Legislature to ensure the  
27 appropriate use of the funds. The report shall include accountability  
28 measures, including, but not limited to, a description of how the  
29 funds were used, an evaluation of the grant program, and  
30 recommendations for the program. This report shall be submitted  
31 by January 1, 2020.

32 (2) The requirement for submitting a report imposed under  
33 paragraph (1) is inoperative on January, 1, 2024, pursuant to  
34 Section 10231.5 of the Government Code.