

AMENDED IN SENATE AUGUST 31, 2015

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

Introduced by Assembly Member Bonilla

February 26, 2015

An act to add *and repeal* 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: *cancer*.

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~~ *bill, until January 1, 2022*, would ~~create~~ *establish* 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~~. *to be used to administer a grant*

program. The bill would limit the amount the agency may spend to establish the foundation to \$300,000 of appropriated funds, to be repaid by January 1, 2021, but would otherwise prohibit General Fund moneys from being used for the foundation. The bill would authorize the board to solicit and receive money, as ~~specified~~, specified, and would authorize the agency to apply for federal funds for this purpose. The bill would require the board, upon contribution of ~~an unspecified amount of money~~ at least \$500,000 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~~-no. 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 of concern because of its impact on

1 researchers' ability to evaluate the effect of new treatments on
2 different populations. It also speaks to a lack of access to
3 potentially lifesaving trials for a large portion of the population.

4 (e) It is the intent of the Legislature to establish a program to
5 enable willing patients of low to moderate income to participate
6 in cancer clinical trials in order to boost participation rates, ensure
7 these trials are widely accessible, improve the development of
8 cancer therapies, and enhance innovation.

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

11
12 CHAPTER 2. CANCER CLINICAL TRIALS

13
14 101990. (a) "Board" means the Board of Trustees of the Cancer
15 Clinical Trials Foundation.

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

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

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

27 (b) *All persons appointed to the board shall have an interest in*
28 *increasing access to cancer clinical trials and the ability and desire*
29 *to solicit funds for the purpose of increasing access to clinical*
30 *trials as provided in this chapter.*

31 ~~(b)~~

32 (c) The Governor shall appoint the president of the board from
33 among those members appointed by the Governor, the Speaker of
34 the Assembly, and the President pro Tempore of the Senate.

35 ~~(c)~~

36 (d) The foundation, or an authorized representative thereof,
37 shall apply for tax exempt status under Section 501(c)(3) of the
38 Internal Revenue Code.

39 ~~(d)~~

1 (e) Members of the board shall serve without compensation but
2 shall be reimbursed for any actual and necessary expenses incurred
3 in connection with their duties as members of the board.

4 (e)

5 (f) The foundation shall be subject to the Nonprofit Public
6 Benefit Corporation Law (Part 2 (commencing with Section 5110)
7 of Division 2 of Title 2 of the Corporations Code).

8 (f)

9 (g) The California Health and Human Services Agency shall
10 determine which department in the agency shall administer the
11 foundation.

12 101992. (a) Of the members of the board first appointed by
13 the Governor pursuant to Section 101991, one member shall be
14 appointed to serve a two-year term, one member shall be appointed
15 to serve a three-year term, and one member shall be appointed to
16 serve a four-year term.

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

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

23 101993. (a) There is hereby created *in the State Treasury* the
24 Cancer Clinical Trials Fund. ~~Notwithstanding Section 13340 of~~
25 ~~the Government Code, all money~~ *Moneys* in the fund ~~is~~
26 ~~continuously appropriated to the board without regard to fiscal~~
27 ~~years, shall be used~~ for the administration and support of the
28 program created pursuant to this ~~chapter.~~ *chapter upon*
29 *appropriation of the Legislature.*

30 (b) The Cancer Clinical Trials Foundation may solicit and
31 receive funds from business, industry, foundations, and other
32 private and public sources for the purpose of administering the
33 Cancer Clinical Trials Grant Program to increase patient access
34 to cancer clinical trials.

35 (c) *The agency may apply for federal funds for the foundation.*

36 (e)

37 (d) The board shall use no more than 20 percent of funds made
38 available for the Cancer Clinical Trials Grant Program for
39 administrative costs.

1 101993.5. (a) *The agency may not spend more than three*
2 *hundred thousand dollars (\$300,000) of moneys appropriated to*
3 *the agency to establish the foundation.*

4 (b) *Any money used to establish the foundation shall be paid*
5 *back to the agency on or before January 1, 2021, from moneys*
6 *donated to the Cancer Clinical Trials Fund.*

7 (c) *After the initial investment authorized by subdivision (a),*
8 *no General Fund moneys shall be used to operate the foundation.*

9 101994. (a) ~~Upon contribution of an unspecified amount of~~
10 ~~moneys at least five hundred thousand dollars (\$500,000) to the~~
11 ~~foundation, the board shall establish the Cancer Clinical Trials~~
12 ~~Grant Program to increase patient access to cancer clinical trials~~
13 ~~in underserved or disadvantaged communities and populations,~~
14 ~~including among women and patients from racial and ethnic~~
15 ~~minority communities. The board shall determine the criteria to~~
16 ~~award grants, and may award grants to either or both of the~~
17 ~~following:~~

18 (1) ~~Public and private research institutions and hospitals that~~
19 ~~conduct cancer clinical trials approved by the federal Food and~~
20 ~~Drug Administration.~~

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

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

28 (1) ~~Patient navigator services or programs.~~

29 (2) ~~Education and community outreach.~~

30 (3) ~~Patient-friendly technical tools to assist patients in~~
31 ~~identifying available clinical trials.~~

32 (4) ~~Translation and interpretation services of clinical trial~~
33 ~~information.~~

34 (5) ~~Counseling services for clinical trial participants.~~

35 (6) ~~Well-being services for clinical trial participants, including,~~
36 ~~but not limited to, physical therapy, pain management, stress~~
37 ~~management, and nutrition management.~~

38 (7) ~~Payment of ancillary costs for patients and caregivers,~~
39 ~~including, but not limited to:~~

40 (A) ~~Airfare during the clinical trial.~~

- 1 (B) Lodging during the clinical trial.
- 2 (C) Rental cars during the clinical trial.
- 3 (D) Fuel during the clinical trial.
- 4 (E) Local transportation via bus, train, or other public
- 5 transportation during the clinical trial.
- 6 (F) Meals during the clinical trial.
- 7 (G) Child care costs during the clinical trial.

8 *(c) If the foundation does not receive five hundred thousand*
 9 *dollars (\$500,000) or more by January 1, 2021, moneys remaining*
 10 *after the repayment required pursuant to subdivision (b) of Section*
 11 *101993.5 shall be returned to the donors on a pro rata basis.*

12 *(d) If the grant program is established pursuant to this section,*
 13 *all moneys in the fund shall be awarded by grant prior to the repeal*
 14 *of this chapter.*

15 101995. (a) Grant recipients shall report to the board to ensure
 16 the appropriate use of funds within one year of receiving a grant.

17 (b) (1) The board shall report to the Legislature to ensure the
 18 appropriate use of the funds. The report shall include accountability
 19 measures, including, but not limited to, a description of how the
 20 funds were used, an evaluation of the grant program, and
 21 recommendations for the program. This report shall be submitted
 22 by January 1, 2020.

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

26 *101996. This chapter shall remain in effect only until January*
 27 *1, 2022, and as of that date is repealed, unless a later enacted*
 28 *statute, that is enacted before January 1, 2022, deletes or extends*
 29 *that date.*