

AMENDED IN ASSEMBLY MARCH 17, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1823**

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**Introduced by Assembly Member Bonilla**

February 8, 2016

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An act to add Part 7 (commencing with Section 101990) to Division 101 of the Health and Safety Code, relating to clinical trials.

LEGISLATIVE COUNSEL'S DIGEST

AB 1823, as amended, Bonilla. California Cancer Clinical Trials Program.

Existing law, the Inclusion of Women and Minorities in Clinical Research Act, requires a grantee, defined to include, but not be limited to, a college or university that conducts clinical research using state funds, to ensure that women and minority groups are included as subjects in each research project, except as provided. Existing law establishes the University of California.

This bill would provide for the establishment of the California Cancer Clinical Trials Program and *would* request that the University of California designate a nonprofit organization as the program administrator governed by a board of at least 5 members appointed by the president of the university. The bill would authorize the program administrator to solicit and receive funds from various specified sources for purposes of the program and would ~~authorize~~ *require* the board, upon receipt of at least \$500,000 in funding, to establish ~~program~~ *the Cancer Clinical Trials Grant Program* to increase patient access to eligible cancer clinical trials in underserved or disadvantaged communities and populations, as specified.

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. The Legislature finds and declares all of the  
2 following:

3 (a) According to Public Policy Institute of California's Future:  
4 Health Care report released in 2015, significant health disparities  
5 exist among socioeconomic, racial, ethnic, and regional groups in  
6 California. African Americans and persons with a high school  
7 education or less have significantly lower life expectancies than  
8 other groups of people, and individuals in some regions of the state  
9 or in particular communities face other significant health obstacles.

10 (b) The ability to translate medical findings from research to  
11 practice relies largely on having robust patient participation and  
12 a diverse participation pool. A low participation rate or a  
13 homogenous participant group prevents segments of the population  
14 from benefiting from advances achieved through clinical research  
15 and creates uncertainties over the applicability of research findings.  
16 Diverse patient participation in a clinical trial depends, in part, on  
17 whether a participant can afford ancillary costs like transportation,  
18 ~~child care~~, *child care*, or lodging during the course of his or her  
19 participation. A national study in 2015 found that patient  
20 households making less than \$50,000 annually were almost 30  
21 percent less likely to participate in clinical trials. This disparity  
22 threatens one of the most basic ethical underpinnings of clinical  
23 research, the requirement that the benefits of research be made  
24 available equitably among all eligible individuals.

25 (c) California is home to the following 10 National Cancer  
26 Institute-Designated Cancer Centers that perform cancer clinical  
27 trials research:

28 (1) University of California, ~~Irvine~~ *Irvine*, Chao Family  
29 Comprehensive Cancer Center.

30 (2) City of Hope Comprehensive Cancer Center.

31 (3) University of California, Los Angeles, Jonsson  
32 Comprehensive Cancer Center.

33 (4) Salk Institute Cancer Center.

34 (5) Sanford Burnham Prebys Medical Discovery Institute.

35 (6) Stanford Cancer Center.

1 (7) University of California, Davis, Comprehensive Cancer  
2 Center.

3 (8) University of California, San Diego, Moores Cancer Center.

4 (9) University of California, San Francisco, Helen Diller Family  
5 Comprehensive Cancer Center.

6 (10) University of Southern California, Norris Comprehensive  
7 Cancer Center.

8 (d) Cancer is the cause of almost one in four deaths in California.  
9 It is the second leading cause of death for Californians and the  
10 primary cause of death among Californian Asian/Pacific Islanders.  
11 A Californian will be diagnosed with cancer approximately every  
12 four minutes, and every ten minutes a Californian will die of  
13 cancer. African American Californians in particular face  
14 disproportionately higher rates of cancer incidence and mortality  
15 compared to other races and ethnicities.

16 (e) Addressing barriers faced by medically underserved and  
17 underrepresented individuals in cancer and other clinical trials and  
18 improving access to survivorship resources and services through  
19 partnerships with hospitals, regional and community cancer centers,  
20 and nonprofit organizations are some of the strategies  
21 recommended by the California Dialogue on Cancer, established  
22 in 2002 by California's Comprehensive Cancer Control Program  
23 to reduce the burden of cancer in California.

24 (f) According to the National Cancer Institute Cancer Clinical  
25 Trials Resource Guide, some of the barriers preventing individuals  
26 with cancer or at high risk of developing cancer from participating  
27 in clinical trials are direct and indirect financial and personal costs,  
28 including travel and child care expenses.

29 (g) It is the intent of the Legislature to enact legislation that  
30 would establish a program to enable willing patients of low to  
31 moderate income to participate in cancer and other clinical trials  
32 in order to boost participation rates, ensure these trials are widely  
33 accessible, improve the development of therapies, and enhance  
34 innovation.

35 SEC. 2. Part 7 (commencing with Section 101990) is added to  
36 Division 101 of the Health and Safety Code, to read:

1 PART 7. CALIFORNIA CANCER CLINICAL TRIALS  
2 PROGRAM

3  
4 101990. For purposes of this part, the following definitions  
5 apply:

6 (a) “Board” means the Board of Trustees of the California  
7 Cancer Clinical Trials Program.

8 (b) “Fund” or “clinical trials fund” refers to a fund established  
9 by the Program Administrator to support the program.

10 (c) “Program” means the California Cancer Clinical Trials  
11 Program.

12 (d) “Program administrator” means the nonprofit organization  
13 designated by the University of California pursuant to paragraph  
14 (1) of subdivision (a) of Section 101991.

15 (e) “University” means the University of California.

16 (f) “Eligible cancer clinical trial” means a clinical trial conducted  
17 in the state that targets cancer and is regulated by the federal Food  
18 and Drug Administration.

19 101991. (a) The university is hereby requested to do all of the  
20 following:

21 (1) Establish and designate, or designate, a nonprofit  
22 organization, governed by the Nonprofit Public Benefit Corporation  
23 Law (Part 2 (commencing with Section 5110) of Division 2 of  
24 Title 1 of the Corporations Code) to administer the program.

25 (2) Establish a governing board of the program administrator  
26 consisting of at least five members, appointed by the president of  
27 the university to represent institutions and individuals performing,  
28 participating in, and supporting eligible cancer clinical trials in  
29 California.

30 (b) All persons appointed to the board shall have an interest in  
31 increasing and diversifying access to eligible cancer clinical trials  
32 and the ability and desire to solicit funds for the purpose of  
33 increasing and diversifying access to clinical trials as provided in  
34 this part.

35 (c) Members of the board shall serve without compensation. A  
36 board member shall be reimbursed for any actual, necessary, and  
37 reasonable expenses incurred in connection with his or her duties  
38 as a board member.

39 101992. (a) The university may participate in the program as  
40 the program administrator, a beneficiary, or both.

1 (b) Prior to establishing the board, the university may pursue  
2 any federal, state, or internal approvals, authorizations, or advice  
3 it deems necessary to the university's participation in the program.

4 (c) The university may decline to establish or participate in the  
5 program.

6 101993. The program administrator may solicit and receive  
7 funds from business, industry, foundations, research organizations,  
8 government agencies, individuals, and other private and public  
9 sources for the purpose of administering the program to increase  
10 patient access to clinical trials targeting cancer.

11 101993.5. Any money allocated by the university to establish  
12 and operate the program shall be reimbursed to the university,  
13 from moneys donated to the fund.

14 101994. (a) Upon receipt of at least five hundred thousand  
15 dollars (\$500,000) in funding for the program by the program  
16 administrator, the board shall establish the Cancer Clinical Trials  
17 Grant Program to increase patient access to eligible cancer clinical  
18 trials in underserved or disadvantaged communities and  
19 populations, including among women and patients from racial and  
20 ethnic minority communities and socioeconomically disadvantaged  
21 communities. The board shall determine the criteria to award grants  
22 to support cancer clinical trials. The board may award grants to  
23 any or all of the following:

24 (1) Public and private research institutions and hospitals that  
25 conduct eligible cancer clinical trials.

26 (2) Nonprofit organizations described in Section 501(c) of the  
27 Internal Revenue Code ~~and~~ *that* do either of the following:

28 (A) Specialize in direct patient support for improved clinical  
29 trial enrollment and retention.

30 (B) Engage in research on ~~health-disparities~~ *disparities and*  
31 *their relationship to clinical trial enrollment.*

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

35 (1) Patient navigator services or programs.

36 (2) Education and community outreach.

37 (3) Patient-friendly technical tools to assist patients in  
38 identifying available clinical trials.

39 (4) Translation and interpretation services of clinical trial  
40 information.

1 (5) Counseling services for clinical trial participants.

2 (6) Well-being services for clinical trial participants, including,  
3 but not limited to, physical therapy, pain management, stress  
4 management, and nutrition management.

5 (7) Payment of ancillary costs for patients and caregivers,  
6 including, but not limited to, all of the following during and  
7 related to participation in the clinical trial:

8 (A) Airfare.

9 (B) Lodging.

10 (C) Rental automobile and fuel for the automobile.

11 (D) Local public transportation by bus, train, or other public  
12 transportation.

13 (E) Meals.

14 (F) Dependent child care.

15 (8) Research on the effectiveness of these and other measures  
16 to increase patient access to clinical trials.

17 101995. (a) The board shall require grantees to submit any  
18 reports it deems necessary to ensure the appropriate use of funds  
19 consistent with the purposes of this part and the terms of any grant  
20 awards.

21 (b) The university may require the board to submit reports  
22 pertaining to the board's activities to the Regents of the University  
23 of California, including, but not limited to, the following  
24 information:

25 (1) An accounting of funds collected and expended.

26 (2) An evaluation of the program.

27 (e)

28 (3) Recommendations regarding the program.

29 101996. (a) (1) If the university determines at any time that  
30 the moneys in the fund are insufficient to establish or sustain the  
31 program, the university may terminate the program.

32 (2) All moneys in the fund remaining after expenses are paid  
33 shall, prior to dissolution, be allocated to one or more organizations  
34 described in subdivision (a) of Section 101994.

35 (b) If the ~~foundation~~ fund does not receive five hundred thousand  
36 dollars (\$500,000) or more by January 1, 2021, moneys remaining  
37 after the repayment required pursuant to ~~subdivision (a)~~ of Section  
38 101993.5 shall be returned to the donors on a pro rata basis.

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