

AMENDED IN SENATE AUGUST 2, 2016

AMENDED IN SENATE JUNE 23, 2016

AMENDED IN ASSEMBLY MAY 27, 2016

AMENDED IN ASSEMBLY APRIL 12, 2016

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  
(Principal coauthor: Assembly Member Waldron)**

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 establish or designate an institute or office within the university to administer the program, which would be 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 funds from various specified sources for purposes of the program and would require the program administrator, upon receipt of at least \$500,000 in funding, to establish 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 the 2016 report of the Public Policy Institute  
4 of California entitled California’s Future: Health Care, significant  
5 health disparities exist among socioeconomic, racial, ethnic, and  
6 regional groups in California. African Americans and persons with  
7 a high school education or less have significantly lower life  
8 expectancies than other groups of people, and individuals in some  
9 regions of the state or in particular communities face other  
10 significant health obstacles.

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

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

- 1 (1) University of California, Irvine, Chao Family Comprehensive  
2 Cancer Center.
- 3 (2) City of Hope Comprehensive Cancer Center.
- 4 (3) University of California, Los Angeles, Jonsson  
5 Comprehensive Cancer Center.
- 6 (4) Salk Institute Cancer Center.
- 7 (5) Sanford Burnham Prebys Medical Discovery Institute.
- 8 (6) Stanford Cancer Institute.
- 9 (7) University of California, Davis, Comprehensive Cancer  
10 Center.
- 11 (8) University of California, San Diego, Moores Cancer Center.
- 12 (9) University of California, San Francisco, Helen Diller Family  
13 Comprehensive Cancer Center.
- 14 (10) University of Southern California, Norris Comprehensive  
15 Cancer Center.
- 16 (d) Cancer is the cause of almost one in four deaths in California.  
17 It is the second leading cause of death for Californians and the  
18 primary cause of death among Californian Asian/Pacific Islanders.  
19 A Californian will be diagnosed with cancer approximately every  
20 four minutes, and every 10 minutes a Californian will die of cancer.  
21 African American Californians in particular face disproportionately  
22 higher rates of cancer incidence and mortality compared to other  
23 races and ethnicities.
- 24 (e) Addressing barriers faced by medically underserved and  
25 underrepresented individuals in cancer and other clinical trials and  
26 improving access to survivorship resources and services through  
27 partnerships with hospitals, regional and community cancer centers,  
28 and nonprofit organizations are some of the strategies  
29 recommended by the California Dialogue on Cancer, established  
30 in 2002 by California's Comprehensive Cancer Control Program  
31 to reduce the burden of cancer in California.
- 32 (f) According to the National Cancer Institute Cancer Clinical  
33 Trials Resource Guide, some of the barriers preventing individuals  
34 with cancer or at high risk of developing cancer from participating  
35 in clinical trials are direct and indirect financial and personal costs,  
36 including travel and child care expenses.
- 37 (g) It is the finding of the Legislature that some corporations,  
38 individuals, public and private foundations, health care providers,  
39 and other stakeholders are hesitant to contribute to, or accept funds  
40 from, programs that are organized to alleviate financial burdens

1 faced by patients who wish to participate in clinical trials and their  
2 caregivers, due to concerns that federal regulators would view the  
3 payments made from those funds as prohibited inducements for  
4 patients to receive the health care services provided during clinical  
5 trials.

6 (h) It is the intent of the Legislature to enact legislation that  
7 would establish a program to authorize business, industry, public  
8 and private foundations, individuals, and other stakeholders to  
9 donate to the program described in this act, as well as to other  
10 nonprofit corporations and public charities that specialize in the  
11 enrollment, retention, and increased participation of patients in  
12 cancer clinical trials.

13 (i) It is the intent of the Legislature to enact legislation that  
14 would establish a program to better enable donors willing to assist  
15 clinical research participants that have documented low levels of  
16 access to health services or participation in clinical trials, face  
17 financial barriers to participation in clinical trials, or have been  
18 identified as priorities for health services, to participate in clinical  
19 trials by supporting ancillary costs to boost participation rates  
20 among the research participant populations, ensure these trials are  
21 widely accessible, improve the development of therapies, and  
22 enhance innovation. It is the intent of the Legislature that this  
23 program eliminate barriers to the participation of all patients,  
24 regardless of socioeconomic status, in clinical trials.

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

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28 PART 7. CALIFORNIA CANCER CLINICAL TRIALS  
29 PROGRAM  
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31 101990. For purposes of this part, the following definitions  
32 shall apply:

33 (a) "Board" means the Board of Trustees of the California  
34 Cancer Clinical Trials Program.

35 (b) "Eligible cancer clinical trial" means a clinical trial, as  
36 defined in Section 300gg-8(d) of Title 42 of the United States  
37 Code, that is conducted in the state, that targets cancer, and that  
38 is regulated by the United States Food and Drug Administration.

1 (c) “Fund” or “clinical trials fund” refers to a fund established  
2 by or on behalf of the program administrator to support the  
3 program.

4 (d) “Program” means the California Cancer Clinical Trials  
5 Program.

6 (e) “Program administrator” means the institute or office  
7 designated by the University of California pursuant to subdivision  
8 (a) of Section 101991.

9 (f) “Program grant recipient” means an organization that receives  
10 support from the fund to carry out the purposes of this part.

11 (g) “University” means the University of California.  
12 101991. The university is hereby requested to do all of the  
13 following:

14 (a) Establish or designate an institute or office within the  
15 university to administer the program.

16 (b) Establish the board, to consist of at least five members,  
17 appointed by the president of the university to represent institutions  
18 and individuals performing, participating in, and supporting eligible  
19 cancer clinical trials in California.

20 (1) The members shall have varying backgrounds to promote  
21 the purposes of this part.

22 (2) The board shall be qualified through the experience,  
23 expertise, and diversity of its members in the design,  
24 implementation, and support of clinical trials, and through studying  
25 and addressing socioeconomic, ethnic or racial, regional, and other  
26 barriers to participation and interventions to remove those barriers.

27 (3) Efforts shall be made to include representatives of a range  
28 of public and private research institutions, health care providers,  
29 health care foundations, and patient advocacy organizations.

30 (4) 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 (5) 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.

1 (6) (A) The program administrator may adjust administrative  
2 costs available for use in the program based on the size of the  
3 program and the funds that are received.

4 (B) Notwithstanding subparagraph (A), the program  
5 administrator shall use no more than 20 percent of the funds that  
6 are made available for the program for administrative costs if the  
7 program size and the funds that are received cover the costs of  
8 administering the program.

9 (c) Publicize to National Cancer Institute-Designated Cancer  
10 Centers, community organizations, hospitals, hospital associations,  
11 industry, health care foundations, and government agencies, the  
12 opportunity to submit nominations for board membership to the  
13 president of the university.

14 (d) Publicize the availability of grants made available through  
15 the program to organizations described in subdivision (a) of Section  
16 101994.5.

17 101992. (a) The university may participate in the program as  
18 the program administrator, a beneficiary, or both.

19 (b) Prior to establishing the program, the university may pursue  
20 any federal, state, or internal approvals, authorizations, or advice  
21 it deems necessary to the university's participation.

22 (c) The university may decline to establish or participate in the  
23 program.

24 (d) The university may terminate the program if it determines  
25 that the program is not viable.

26 101993. (a) The program administrator, directly or through a  
27 university-affiliated foundation, may solicit funds from business,  
28 industry, foundations, research organizations, federal government  
29 agencies, individuals, and other private sources for the purpose of  
30 administering the program and awarding grants to increase patient  
31 access to clinical trials targeting cancer, consistent with guidelines  
32 established by the board.

33 (b) (1) Subject to paragraph (2), only funds from federal or  
34 private sources may be used to administer the program or award  
35 grants.

36 (2) The university may use its own state source funds for  
37 oversight and administration of the ~~program~~, *program relating to*  
38 *the initial start-up costs of the program only*, provided the  
39 university is reimbursed from federal or private sources funds.

1 101993.5. Any funds, personnel, facility, equipment, or other  
2 resources that are allocated by the university to establish and  
3 operate the program shall be reimbursed to the university, from  
4 moneys donated to the fund, prior to distribution by the program  
5 of any grants to any entity that is designated under subdivision (a)  
6 of Section 101994.5.

7 101994. Upon the program administrator's receipt of at least  
8 five hundred thousand dollars (\$500,000) in funding for the  
9 program, the program administrator shall establish the fund and  
10 the Cancer Clinical Trials Grant Program to increase patient access  
11 to eligible cancer clinical trials in underserved or disadvantaged  
12 communities and populations, including among women and patients  
13 from racial and ethnic minority communities and  
14 socioeconomically disadvantaged communities.

15 101994.5. (a) The board shall determine the criteria to award  
16 and administer grants to support program grant recipients. The  
17 board may award grants to any or all of the following:

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

20 (2) Nonprofit organizations that are exempt from taxation under  
21 Section 501(c) of the Internal Revenue Code and that do either of  
22 the following:

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

25 (B) Engage in research on health disparities and their  
26 relationship to clinical trial enrollment.

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

30 (1) Patient navigator services or programs.

31 (2) Education and community outreach.

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

34 (4) Counseling services for clinical trial participants.

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

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

- 1 (A) Airfare.
- 2 (B) Lodging.
- 3 (C) Rental automobile and fuel for the automobile.
- 4 (D) Local public transportation by bus, train, or other public
- 5 transportation.
- 6 (E) Meals.
- 7 (F) Dependent child care.
- 8 (7) Research on the effectiveness of these and other measures
- 9 to increase patient access to clinical trials.

10 (c) When determining program grant recipients pursuant to  
11 subdivision (a), the board is encouraged to grant special  
12 consideration to public or nonprofit applicants that provide patient  
13 services related to cancer clinical trials that address health  
14 disparities or that possess two or more years' experience in the  
15 improvement of enrollment, retention, or participation in cancer  
16 clinical trial participation with an emphasis on underserved  
17 populations.

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

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

- 26 (1) An accounting of funds collected and expended.
- 27 (2) An evaluation of the program.
- 28 (3) Recommendations regarding the program.

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

32 (b) If the fund does not receive five hundred thousand dollars  
33 (\$500,000) or more by January 1, 2021, or, if at any time, the  
34 program administrator determines that the 20 percent limit on  
35 administrative costs set forth in subparagraph (B) of paragraph (6)  
36 of subdivision (b) of Section 101991 is inadequate to support the  
37 cost of administering the program authorized pursuant to this part,  
38 the program administrator may elect to dissolve the program.

1 (c) All moneys in the fund remaining after expenses are paid  
2 shall, prior to dissolution, be allocated to one or more organizations  
3 described in subdivision (a) of Section 101994.5.  
4 101997. This part does not preclude the university from  
5 establishing or operating one or more similar programs to facilitate  
6 participation in any clinical trials, as defined in Section 300gg-8(d)  
7 of Title 42 of the United States Code.

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