

AMENDED IN SENATE AUGUST 19, 2016
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

**Introduced by Assembly Member Bonilla
(Principal coauthor: Assembly Member Waldron)**

February 8, 2016

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.

1 (c) California is home to the following 10 National Cancer
2 Institute-Designated Cancer Centers that perform cancer clinical
3 trials research:

4 (1) University of California, Irvine, Chao Family Comprehensive
5 Cancer Center.

6 (2) City of Hope Comprehensive Cancer Center.

7 (3) University of California, Los Angeles, Jonsson
8 Comprehensive Cancer Center.

9 (4) Salk Institute Cancer Center.

10 (5) Sanford Burnham Prebys Medical Discovery Institute.

11 (6) Stanford Cancer Institute.

12 (7) University of California, Davis, Comprehensive Cancer
13 Center.

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

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

17 (10) University of Southern California, Norris Comprehensive
18 Cancer Center.

19 (d) Cancer is the cause of almost one in four deaths in California.
20 It is the second leading cause of death for Californians and the
21 primary cause of death among Californian Asian/Pacific Islanders.
22 A Californian will be diagnosed with cancer approximately every
23 four minutes, and every 10 minutes a Californian will die of cancer.
24 African American Californians in particular face disproportionately
25 higher rates of cancer incidence and mortality compared to other
26 races and ethnicities.

27 (e) Addressing barriers faced by medically underserved and
28 underrepresented individuals in cancer and other clinical trials and
29 improving access to survivorship resources and services through
30 partnerships with hospitals, regional and community cancer centers,
31 and nonprofit organizations are some of the strategies
32 recommended by the California Dialogue on Cancer, established
33 in 2002 by California's Comprehensive Cancer Control Program
34 to reduce the burden of cancer in California.

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

1 (g) It is the finding of the Legislature that some corporations,
 2 individuals, public and private foundations, health care providers,
 3 and other stakeholders are hesitant to contribute to, or accept funds
 4 from, programs that are organized to alleviate financial burdens
 5 faced by patients who wish to participate in clinical trials and their
 6 caregivers, due to concerns that federal regulators would view the
 7 payments made from those funds as prohibited inducements for
 8 patients to receive the health care services provided during clinical
 9 trials.

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

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

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

31

32 PART 7. CALIFORNIA CANCER CLINICAL TRIALS
 33 PROGRAM

34

35 101990. For purposes of this part, the following definitions
 36 shall apply:

37 (a) "Board" means the Board of Trustees of the California
 38 Cancer Clinical Trials Program.

39 (b) "Eligible cancer clinical trial" means a clinical trial, as
 40 defined in Section 300gg-8(d) of Title 42 of the United States

1 Code, that is conducted in the state, that targets cancer, and that
2 is regulated by the United States Food and Drug Administration.

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

6 (d) “Program” means the California Cancer Clinical Trials
7 Program.

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

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

13 (g) “University” means the University of California.
14 101991. The university is hereby requested to do all of the
15 following:

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

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

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

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

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

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

37 (5) Members of the board shall serve without compensation. A
38 board member shall be reimbursed for any actual, necessary, and
39 reasonable expenses incurred in connection with his or her duties
40 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.~~ *costs.*

9 (C) *Notwithstanding subparagraph (B), in the first year of the*
10 *program, the program administrator may use more than 20 percent*
11 *of the funds for administrative costs, in order to fund the costs of*
12 *establishing the program.*

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

18 (d) Publicize the availability of grants made available through
19 the program to organizations described in subdivision (a) of Section
20 101994.5.

21 101992. (a) The university may participate in the program as
22 the program administrator, a beneficiary, or both.

23 (b) Prior to establishing the program, the university may pursue
24 any federal, state, or internal approvals, authorizations, or advice
25 it deems necessary to the university’s participation.

26 (c) The university may decline to establish or participate in the
27 program.

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

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

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

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

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

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

19 101994.5. (a) The board shall determine the criteria to award
20 and administer grants to support program grant recipients. The
21 board may award grants to any or all of the following:

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

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

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

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

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

34 (1) Patient navigator services or programs.

35 (2) Education and community outreach.

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

38 (4) Counseling services for clinical trial participants.

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

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

7 (A) Airfare.

8 (B) Lodging.

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

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

12 (E) Meals.

13 (F) Dependent child care.

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

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

24 101995. (a) The program administrator shall require grantees
25 to submit any reports it deems necessary to ensure the appropriate
26 use of funds consistent with the purposes of this part and the terms
27 of any grant awards.

28 (b) The university may require the board to submit reports
29 pertaining to the program's and the board's activities to the Regents
30 of the University of California, including, but not limited to, the
31 following information:

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

33 (2) An evaluation of the program.

34 (3) Recommendations regarding the program.

35 101996. (a) If the university determines at any time that the
36 moneys in the fund are insufficient to establish or sustain the
37 program, the university may terminate the program.

38 (b) If the fund does not receive five hundred thousand dollars
39 (\$500,000) or more by January 1, 2021, or, if at any time, the
40 program administrator determines that the 20 percent limit on

1 administrative costs set forth in subparagraph (B) of paragraph (6)
2 of subdivision (b) of Section 101991 is inadequate to support the
3 cost of administering the program authorized pursuant to this part,
4 the program administrator may elect to dissolve the program.

5 (c) All moneys in the fund remaining after expenses are paid
6 shall, prior to dissolution, be allocated to one or more organizations
7 described in subdivision (a) of Section 101994.5.

8 101997. This part does not preclude the university from
9 establishing or operating one or more similar programs to facilitate
10 participation in any clinical trials, as defined in Section 300gg-8(d)
11 of Title 42 of the United States Code.

O