

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 ~~board~~ *program administrator* to solicit

funds from various specified sources for purposes of the program and would require the ~~board, program administrator,~~ upon receipt ~~by the program administrator~~ 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 ~~and that there are disincentives~~ *burdens* faced by patients who
2 wish to participate in clinical trials and their ~~caregivers~~ *caregivers*,
3 *due to concerns that federal regulators would view the payments*
4 *made from those funds as prohibited inducements for patients to*
5 *receive the health care services provided during clinical 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 ~~from communities~~ that have
16 documented low levels of access to health services or participation
17 in clinical trials, face financial barriers to participation in clinical
18 trials, or have been identified as priorities for health services, to
19 participate in clinical trials by supporting ancillary costs to boost
20 participation rates among the research participant populations,
21 ensure these trials are widely accessible, improve the development
22 of therapies, and enhance innovation. *It is the intent of the*
23 *Legislature that this program eliminate barriers to the participation*
24 *of all patients, 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:

27

28 PART 7. CALIFORNIA CANCER CLINICAL TRIALS
29 PROGRAM
30

30

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 ~~paragraph~~
8 ~~(1)~~ of subdivision (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. ~~(a)~~ The university is hereby requested to do all of the
13 following:

14 ~~(1)~~

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

17 ~~(2)~~

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 ~~(A)~~

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

25 ~~(B)~~

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

31 ~~(C)~~

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

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

1 (5) *Members of the board shall serve without compensation. A*
2 *board member shall be reimbursed for any actual, necessary, and*
3 *reasonable expenses incurred in connection with his or her duties*
4 *as a board member.*

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

8 (B) *Notwithstanding subparagraph (A), the program*
9 *administrator shall use no more than 20 percent of the funds that*
10 *are made available for the program for administrative costs if the*
11 *program size and the funds that are received cover the costs of*
12 *administering the program.*

13 ~~(3)~~

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

19 ~~(4)~~

20 (d) *Publicize the availability of grants made available through*
21 *the program to organizations described in subdivision (a) of Section*
22 *101994.5.*

23 ~~(b) All persons appointed to the board shall have an interest in~~
24 ~~increasing and diversifying access to eligible cancer clinical trials~~
25 ~~and the ability and desire to solicit funds for the purpose of~~
26 ~~increasing and diversifying access to clinical trials as provided in~~
27 ~~this part.~~

28 ~~(e) Members of the board shall serve without compensation. A~~
29 ~~board member shall be reimbursed for any actual, necessary, and~~
30 ~~reasonable expenses incurred in connection with his or her duties~~
31 ~~as a board member.~~

32 ~~(d) (1) The board may adjust administrative costs available for~~
33 ~~use in the program based on the size of the program and the funds~~
34 ~~that are received.~~

35 ~~(2) Notwithstanding paragraph (1), the board shall use no more~~
36 ~~than 20 percent of the funds that are made available for the program~~
37 ~~for administrative costs if the program size and the funds that are~~
38 ~~received cover the costs of administering the program.~~

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 program, the university may pursue
2 any federal, state, or internal approvals, authorizations, or advice
3 it deems necessary to the university's participation.

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

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

8 101993. (a) ~~The board may program administrator, directly~~
9 ~~or through a university-affiliated foundation solicit funds on behalf~~
10 ~~of the program administrator foundation, may solicit funds~~ from
11 business, industry, foundations, research organizations, federal
12 government agencies, individuals, and other private sources for
13 the purpose of administering the program and awarding grants to
14 increase patient access to clinical trials targeting ~~cancer~~; *cancer*;
15 *consistent with guidelines established by the board.*

16 (b) ~~Only~~(1) *Subject to paragraph (2), only* funds from federal
17 or private sources may be used to administer the program or award
18 grants.

19 (2) *The university may use its own state source funds for*
20 *oversight and administration of the program, provided the*
21 *university is reimbursed from federal or private sources funds.*

22 101993.5. Any funds, personnel, facility, equipment, or other
23 resources that are allocated by the university to establish and
24 operate the program shall be reimbursed to the university, from
25 moneys donated to the fund, prior to distribution by the program
26 of any grants to any entity that is designated under subdivision (a)
27 of Section 101994.5.

28 101994. Upon the program administrator's receipt of at least
29 five hundred thousand dollars (\$500,000) in funding for the
30 program, ~~the board~~ *program administrator* shall establish the fund
31 and the Cancer Clinical Trials Grant Program to increase patient
32 access to eligible cancer clinical trials in underserved or
33 disadvantaged communities and populations, including among
34 women and patients from racial and ethnic minority communities
35 and socioeconomically disadvantaged communities.

36 101994.5. (a) The board shall determine the criteria to award
37 and administer grants to support ~~cancer clinical trials~~; *program*
38 *grant recipients*. The board may award grants to any or all of the
39 following:

- 1 (1) Public and private research institutions and hospitals that
2 conduct eligible cancer clinical trials.
- 3 (2) Nonprofit organizations that are exempt from taxation under
4 Section 501(c) of the Internal Revenue Code and that do either of
5 the following:
- 6 (A) Specialize in direct patient support for improved clinical
7 trial enrollment and retention.
- 8 (B) Engage in research on health disparities and their
9 relationship to clinical trial enrollment.
- 10 (b) Grants awarded pursuant to subdivision (a) shall be used for
11 activities to increase patient access to eligible cancer clinical trials,
12 including, but not limited to, any of the following:
- 13 (1) Patient navigator services or programs.
- 14 (2) Education and community outreach.
- 15 (3) Patient-friendly technical tools to assist patients in
16 identifying available clinical trials.
- 17 (4) Counseling services for clinical trial participants.
- 18 (5) Well-being services for clinical trial participants, including,
19 but not limited to, physical therapy, pain management, stress
20 management, and nutrition management.
- 21 (6) Payment of ancillary costs for patients and caregivers,
22 including, but not limited to, all of the following during and related
23 to participation in the clinical trial:
- 24 (A) Airfare.
- 25 (B) Lodging.
- 26 (C) Rental automobile and fuel for the automobile.
- 27 (D) Local public transportation by bus, train, or other public
28 transportation.
- 29 (E) Meals.
- 30 (F) Dependent child care.
- 31 (7) Research on the effectiveness of these and other measures
32 to increase patient access to clinical trials.
- 33 (c) When determining program grant recipients pursuant to
34 subdivision (a), the board is encouraged to grant special
35 consideration to public or nonprofit applicants that provide patient
36 services related to cancer clinical trials that address health
37 disparities or that possess two or more years' experience in the
38 improvement of enrollment, retention, or participation in cancer
39 clinical trial participation with an emphasis on underserved
40 populations.

1 101995. (a) ~~The board~~ *program administrator* shall require
2 grantees to submit any reports it deems necessary to ensure the
3 appropriate use of funds consistent with the purposes of this part
4 and the terms of any grant awards.

5 (b) The university may require the board to submit reports
6 pertaining to the program's and the board's activities to the Regents
7 of the University of California, including, but not limited to, the
8 following information:

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

10 (2) An evaluation of the program.

11 (3) Recommendations regarding the program.

12 101996. (a) If the university determines at any time that the
13 moneys in the fund are insufficient to establish or sustain the
14 program, the university may terminate the program.

15 (b) If the fund does not receive five hundred thousand dollars
16 (\$500,000) or more by January 1, 2021, or, if at any time, the ~~board~~
17 *program administrator* determines that the 20 percent limit on
18 administrative costs set forth in ~~paragraph (2) of subdivision (d)~~
19 *subparagraph (B) of paragraph (6) of subdivision (b)* of Section
20 101991 is inadequate to support the cost of administering the
21 program authorized pursuant to this part, ~~moneys remaining after~~
22 ~~the repayment required pursuant to Section 101993.5 shall be~~
23 ~~returned to the donors on a pro rata basis.~~ *the program*
24 *administrator may elect to dissolve the program.*

25 (c) All moneys in the fund remaining after expenses are paid
26 shall, prior to dissolution, be allocated to one or more organizations
27 described in subdivision (a) of Section 101994.5. ~~Moneys~~
28 ~~remaining after the repayment required pursuant to Section~~
29 ~~101993.5 shall be returned to the donors on a pro rata basis, or, at~~
30 ~~the donor's direction, redirected to one or more organizations that~~
31 ~~are described in subdivision (a) of Section 101994.5.~~

32 101997. ~~Nothing in this part shall~~ *This part does not* preclude
33 the university from establishing or operating one or more similar
34 programs to facilitate participation in any clinical trials, as defined
35 in Section 300gg-8(d) of Title 42 of the United States Code.

O