

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 to solicit funds from various specified sources for purposes of the program and would require the board, 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:

29 (1) University of California, Irvine, Chao Family Comprehensive
30 Cancer Center.

31 (2) City of Hope Comprehensive Cancer Center.

1 (3) University of California, Los Angeles, Jonsson
2 Comprehensive Cancer Center.

3 (4) Salk Institute Cancer Center.

4 (5) Sanford Burnham Prebys Medical Discovery Institute.

5 (6) Stanford Cancer Institute.

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

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

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

11 (10) University of Southern California, Norris Comprehensive
12 Cancer Center.

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

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

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

34 (g) It is the finding of the Legislature that some corporations,
35 individuals, public and private foundations, and other stakeholders
36 are hesitant to contribute to, or accept funds from, programs that
37 are organized to alleviate financial burdens, and that there are
38 disincentives faced by patients who wish to participate in clinical
39 trials and their caregivers.

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

8 (i) It is the intent of the Legislature to enact legislation that
 9 would establish a program to better enable donors willing to assist
 10 clinical research participants from communities that have
 11 documented low levels of access to health services or participation
 12 in clinical trials, face financial barriers to participation in clinical
 13 trials, or have been identified as priorities for health services, to
 14 participate in clinical trials by supporting ancillary costs to boost
 15 participation rates among the research participant populations,
 16 ensure these trials are widely accessible, improve the development
 17 of therapies, and enhance innovation.

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

20

21 PART 7. CALIFORNIA CANCER CLINICAL TRIALS
 22 PROGRAM

23

24 101990. For purposes of this part, the following definitions
 25 shall apply:

26 (a) "Board" means the Board of Trustees of the California
 27 Cancer Clinical Trials Program.

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

32 (c) "Fund" or "clinical trials fund" refers to a fund established
 33 by or on behalf of the program administrator to support the
 34 program.

35 (d) "Program" means the California Cancer Clinical Trials
 36 Program.

37 (e) "Program administrator" means the institute or office
 38 designated by the University of California pursuant to paragraph
 39 (1) of subdivision (a) of Section 101991.

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

3 (g) “University” means the University of California.

4 101991. (a) The university is hereby requested to do all of the
5 following:

6 (1) Establish or designate an institute or office within the
7 university to administer the program.

8 (2) Establish the board, to consist of at least five members,
9 appointed by the president of the university to represent institutions
10 and individuals performing, participating in, and supporting eligible
11 cancer clinical trials in California.

12 (A) The members shall have varying backgrounds to promote
13 the purposes of this part.

14 (B) The board shall be qualified through the experience,
15 expertise, and diversity of its members in the design,
16 implementation, and support of clinical trials, and through studying
17 and addressing socioeconomic, ethnic or racial, regional, and other
18 barriers to participation and interventions to remove those barriers.

19 (C) Efforts shall be made to include representatives of a range
20 of public and private research institutions, health care providers,
21 health care foundations, and patient advocacy organizations.

22 (3) Publicize to National Cancer Institute-Designated Cancer
23 Centers, community organizations, hospitals, hospital associations,
24 industry, health care foundations, and government agencies, the
25 opportunity to submit nominations for board membership to the
26 president of the university.

27 (4) Publicize the availability of grants made available through
28 the program to organizations described in subdivision (a) of Section
29 101994.5.

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.

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

4 (2) Notwithstanding paragraph (1), the board shall use no more
5 than 20 percent of the funds that are made available for the program
6 for administrative costs if the program size and the funds that are
7 received cover the costs of administering the program.

8 101992. (a) The university may participate in the program as
9 the program administrator, a beneficiary, or both.

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

13 (c) The university may decline to establish or participate in the
14 program.

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

17 101993. (a) The board may directly or through a
18 university-affiliated foundation solicit funds on behalf of the
19 program administrator from business, industry, foundations,
20 research organizations, *federal* government agencies, individuals,
21 and other private ~~and public~~ sources for the purpose of
22 administering the program and awarding grants to increase patient
23 access to clinical trials targeting cancer.

24 (b) *Only funds from federal or private sources may be used to*
25 *administer the program or award grants.*

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

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

1 101994.5. (a) The board shall determine the criteria to award
2 and administer grants to support cancer clinical trials. The board
3 may award grants to any or all of the following:

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

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

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

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

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

16 (1) Patient navigator services or programs.

17 (2) Education and community outreach.

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

20 (4) Counseling services for clinical trial participants.

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

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

27 (A) Airfare.

28 (B) Lodging.

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

30 (D) Local public transportation by bus, train, or other public
31 transportation.

32 (E) Meals.

33 (F) Dependent child care.

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

36 (c) When determining program grant recipients pursuant to
37 subdivision (a), the board is encouraged to grant special
38 consideration to public or nonprofit applicants that provide patient
39 services related to cancer clinical trials that address health
40 disparities or that possess two or more years' experience in the

1 improvement of enrollment, retention, or participation in cancer
2 clinical trial participation with an emphasis on underserved
3 populations.

4 101995. (a) The board shall require grantees to submit any
5 reports it deems necessary to ensure the appropriate use of funds
6 consistent with the purposes of this part and the terms of any grant
7 awards.

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

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

13 (2) An evaluation of the program.

14 (3) Recommendations regarding the program.

15 101996. (a) If the university determines at any time that the
16 moneys in the fund are insufficient to establish or sustain the
17 program, the university may terminate the program.

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

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

33 101997. Nothing in this part shall preclude the university from
34 establishing or operating one or more similar programs to facilitate
35 participation in any clinical trials, as defined in Section 300gg-8(d)
36 of Title 42 of the United States Code.

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