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

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 ~~a nonprofit organization as~~ *an institute or office within the university to administer* the ~~program administrator~~ *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~~ *board* to solicit ~~and receive~~ 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:

SECTION 1. The Legislature finds and declares all of the following:

(a) According to *the 2016 report of the* Public Policy Institute of ~~California's Future: Health Care report released in 2015,~~ *California entitled California's Future: Health Care,* significant health disparities exist among socioeconomic, racial, ethnic, and regional groups in California. African Americans and persons with a high school education or less have significantly lower life expectancies than other groups of people, and individuals in some regions of the state or in particular communities face other significant health obstacles.

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

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

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

(2) City of Hope Comprehensive Cancer Center.

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

(4) Salk Institute Cancer Center.

(5) Sanford Burnham Prebys Medical Discovery Institute.

(6) Stanford Cancer ~~Center.~~ *Institute.*

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

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

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

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

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

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

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

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

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

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

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

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

PART 7. CALIFORNIA CANCER CLINICAL TRIALS PROGRAM

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

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

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

~~(b)~~

(c) "Fund" or "clinical trials fund" refers to a fund established by *or on behalf of* the ~~Program Administrator~~ *program administrator* to support the program.

~~(c)~~

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

~~(d)~~

(e) "Program administrator" means the ~~nonprofit organization~~ *institute or office* designated by the University of California pursuant to paragraph (1) of subdivision (a) of Section 101991.

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

~~(e)~~

(g) "University" means the University of California.

~~(f) "Eligible cancer clinical trial" means a clinical trial conducted in the state that targets cancer and is regulated by the federal Food and Drug Administration.~~

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

(1) Establish ~~and designate, or designate, a nonprofit organization, governed by the Nonprofit Public Benefit Corporation Law (Part 2 (commencing with Section 5110) of Division 2 of Title 1 of the Corporations Code)~~ *or designate an institute or office within the university* to administer the program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

101993. The ~~program administrator~~ *board* may *directly or through a university-affiliated foundation* solicit ~~and receive~~ funds *on behalf of the program administrator* from business, industry,

foundations, research organizations, government agencies, individuals, and other private and public sources for the purpose of administering the program *and awarding grants* to increase patient access to clinical trials targeting cancer.

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

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

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

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

(2) Nonprofit organizations ~~described in~~ *that are exempt from taxation under* Section 501(c) of the Internal Revenue Code *and* that do either of the following:

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

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

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

(1) Patient navigator services or programs.

(2) Education and community outreach.

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

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

~~(5)~~

(4) Counseling services for clinical trial participants.

~~(6)~~

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

~~(7)~~

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

(A) Airfare.

(B) Lodging.

(C) Rental automobile and fuel for the automobile.

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

(E) Meals.

(F) Dependent child care.

~~(8)~~

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

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

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

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

(1) An accounting of funds collected and expended.

(2) An evaluation of the program.

(3) Recommendations regarding the program.

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

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

~~(2)~~

(c) All moneys in the fund remaining after expenses are paid shall, prior to dissolution, be allocated to one or more organizations described in subdivision (a) of Section ~~101994.~~ *101994.5. Moneys remaining after the repayment required pursuant to Section 101993.5 shall be returned to the donors on a pro rata basis, or, at the donor's direction, redirected to one or more organizations that are described in subdivision (a) of Section 101994.5.*

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

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

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