HEALTH AND SAFETY CODE - HSC

DIVISION 101. ADMINISTRATION OF PUBLIC HEALTH [100100 - 101997] *(Division 101 added by Stats. 1995, Ch. 415, Sec. 3.)*

PART 7. California Cancer Clinical Trials Program [101990 - 101997] *(Part 7 added by Stats. 2016, Ch. 661, Sec. 2.)*

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.

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

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

(e) “Program administrator” means the institute or office designated by the University of California pursuant to 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.

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

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)

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

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

(b) Establish 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.

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

(2) 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.

(3) 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.

(4) 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.

(5) 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.

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

(B) Notwithstanding subparagraph (A), the program administrator shall use no more than 20 percent of the funds that are made available for the program for administrative costs.

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

(c) 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.

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

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)

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

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

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)

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

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

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

(Amended by Stats. 2017, Ch. 561, Sec. 126. (AB 1516) Effective January 1, 2018.)

101993.5. Any 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, prior to distribution by the program of any grants to any entity that is designated under subdivision (a) of Section 101994.5.

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)

101994. Upon the program administrator's receipt of at least five hundred thousand dollars ($500,000) in funding for the program, the program administrator 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.

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)

101994.5. (a) The board shall determine the criteria to award and administer grants to support program grant recipients. 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 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) Counseling services for clinical trial participants.

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

(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.

(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.

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)

101995. (a) The program administrator 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.

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)

101996. (a) 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 program administrator determines that the 20-percent limit on administrative costs set forth in subparagraph (B) of paragraph (6) of subdivision (b) of Section 101991 is inadequate to support the cost of administering the program authorized pursuant to this part, the program administrator may elect to dissolve the program.

(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 101994.5.

(Amended by Stats. 2017, Ch. 561, Sec. 127. (AB 1516) Effective January 1, 2018.)

101997. This part does not 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.

(Added by Stats. 2016, Ch. 661, Sec. 2. (AB 1823) Effective January 1, 2017.)