
SENATE COMMITTEE ON EDUCATION

Senator Carol Liu, Chair
2015 - 2016 Regular

Bill No: AB 1823
Author: Bonilla
Version: June 23, 2016
Urgency: No
Consultant: Kathleen Chavira
Hearing Date: June 29, 2016
Fiscal: Yes

Subject: California Cancer Clinical Trials Program

SUMMARY

This bill requests the University of California (UC) to establish a board representing institutions and individuals performing, participating in and supporting eligible cancer clinical trials in California to solicit and receive funds from federal or private sources for the California Cancer Clinical Trials Program, as specified, to provide grants to increase patient access to eligible cancer clinical trials in underserved or disadvantaged communities, as specified.

BACKGROUND

The California Constitution establishes the UC, a public trust to be administered by the Regents of the UC and grants the Regents full powers of organization and government, subject only to such legislative control as may be necessary to insure security of its funds, compliance with the terms of its endowments, statutory requirements around competitive bidding and contracts, sales of property and the purchase of materials, goods and services. (Article IX, Section (9)(a) of the California Constitution)

ANALYSIS

This bill establishes the California Cancer Clinical Trials Program. It:

- 1) Requests the UC to:
 - a) Establish or designate an institute or office with the university to administer the program.
 - b) Establish the Board of Trustees of the California Cancer Clinical Trials Program, as specified, to represent institutions and individuals performing, participating in and supporting eligible cancer clinical trials in California.
 - c) Publicize the opportunity to submit nomination for board membership.
 - d) Publicize the availability of grants that are available through the Program to organizations, as specified.

- 2) Establishes requirements for the board of the program. It:
 - a) Requires that appointees to the board have an interest ability and desire to solicit funds for purpose of increasing and diversifying access to clinical trials.
 - b) Requires that board members serve without compensation but be reimbursed for expenses, as specified.
- 3) Provides for the use of funds for administrative costs by authorizing adjustment of these costs based on the size of the program and funds received and caps the amount allowed for these costs at 20 percent of funds received cover the costs of administration.
- 4) Authorizes the University of California (UC) to:
 - a) Participate as the program administrator, a beneficiary, or both.
 - b) Pursue any approvals, authorizations, or advice it deems necessary prior to establishing the program.
 - c) Decline to establish or participate in the program.
 - d) Terminate the program if it is determined not viable.
- 5) Authorizes the program administrator to solicit funds, as specified, for the purposes of program administration or awarding grant awards, limits funds for administration to those received from federal or private sources and authorizes the UC to use state source funds for administration and oversight of the program, provided the UC is reimbursed from these sources, and makes implementation of the program contingent upon the receipt of at least \$500,000 in funding for this purpose.
- 6) Requires reimbursement for any resources allocated by the UC for purposes of the program prior to the distribution of any grants.
- 7) Requires the board to determine criteria to award and administer grants, outlines those entities authorized to be granted awards, encourages consideration of groups that meet specified criteria and outlines the uses of grant awards.
- 8) Authorizes the program administrator to require reporting by grantees, as specified.
- 9) Authorizes the UC to terminate the program if it determines funds are insufficient to establish/sustain it, authorizes the program administrator to dissolve the program if \$500,000 is not received by January 1, 2021, or if the administrative cap of 20 percent is determined to be inadequate.

- 10) Requires that money remaining in the fund after payment of expenses be allocated to an organization that meets the qualifications of a grant recipient as outlined in the bill.
- 11) Clarifies that nothing in the bill's provisions precludes the UC from establishing or operating other similar programs under specified federal regulations.

STAFF COMMENTS

- 1) ***Need for the bill.*** According to the author, this bill seeks to remedy the problem of low patient participation in FDA-approved cancer clinical trials. More importantly, it is an effort to address the disproportionately low number of patients from underrepresented communities including African Americans, Latinos/Hispanics, Asians and Pacific Islanders, and American Indians. The author contends that nationwide, only 3 percent of eligible cancer patients participate in clinical trials and of those, only 5 percent are from these underrepresented communities. According to the author, barriers to participation include a lack of awareness, mistrust of research and the medical system, loss of income, and transportation and lodging costs. These ancillary costs of participation fall onto the clinical trial participant who may be unable to pay, and therefore unable to enroll in the trial.

This bill proposes to address this issue by creating a privately funded grant program through the University of California (UC) to assist patients in paying for the ancillary costs associated with participation in these trials.

- 2) ***Impact on UC and state funds?*** This bill requires that funds for program administration and grant awards come from federal and private sources. It also authorizes the UC to use state source funds for administration and oversight of the program, provided the UC is reimbursed from federal or private sources. According to the author, the UC has already expended state funds for purposes of gaining permission from federal regulators and engaging in other administrative activity to establish the program and these provisions are intended to authorize reimbursement of the funds used for these purposes. There is no intent to use state funds for any ongoing administrative or oversight expenses.

Staff recommends the bill be amended on page 7 lines 19-21 to clarify that these provisions apply to “start-up” oversight and administration costs only.

Staff notes that the bill authorizes up to 20 percent of funds to be used for administrative costs. State funded programs typically authorize up to 5 percent of funding for these costs. The 20 percent figure combines all administrative costs (direct, indirect, and administrative) into one. According to the UC, administrative costs for research programs typically run greater than 20 percent and this cap would be among the lowest in the state for research program administration.

Staff also notes that the UC is authorized to establish, decline to establish or participate, or terminate the program. According to the author, the intent of the bill and for the program is that, once established, the program will operate

exclusively on private or federal funds. If the program does not collect sufficient funding to continue operation of the program using private or federal funds, the University is under no obligation to continue program operations. The language in the bill is explicit about the UC's ability to determine whether or not to establish or terminate the program, to ensure the University will not be compelled to expend state-sourced dollars in operation of the program.

- 3) **Prior legislation.** AB 1060 (Bonilla, 2015) proposed establishment of the Cancer Clinical Trials Foundation in the Health and Human Services Agency, to be governed by a board of trustees, to administer a grant program substantively similar to that proposed by this bill. AB 1060 was vetoed in October 2015, by the Governor whose message read, in pertinent part:

"Numerous private organizations already perform this fundraising function. While I support eliminating barriers to take part in clinical trials, I am hesitant to place this new burden on the Health and Human Services Agency which is managing a huge expansion of our health care system."

SUPPORT

Association of California Healthcare Districts
Susan G. Komen California Collaborative

OPPOSITION

None received.

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