Date of Hearing: April 19, 2016

ASSEMBLY COMMITTEE ON HIGHER EDUCATION
Jose Medina, Chair
AB 1823 (Bonilla) – As Amended April 12, 2016

[Note: This bill was heard by the Assembly Health Committee on March 15, 2016, and approved by a vote of 17-0.]

SUBJECT: California Cancer Clinical Trials Program

SUMMARY: Requests the University of California (UC) establish and designate a nonprofit public benefit corporation to solicit and receive funds from business, industry, foundations, and other sources for the Cancer Clinical Trials Program (Program) to increase patient access to clinical trials. Specifically, **this bill**:

1) Finds and declares all of the following:

   a) According to the 2016 report of the Public Policy Institute of 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: University of California, Irvine, Chao Family Comprehensive Cancer Center; City of Hope Comprehensive Cancer Center; University of California, Los Angeles, Jonsson Comprehensive Cancer Center; Salk Institute Cancer Center; Sanford Burnham Prebys Medical Discovery Institute; Stanford Cancer Institute; University of California, Davis, Comprehensive Cancer Center; University of California, San Diego, Moores Cancer Center; University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center; 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 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 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.

2) Requests UC 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 UC president to represent institutions and individuals performing, participating in, and supporting eligible cancer clinical trials in California. Requires the members of the board to have, among other requirements, varying backgrounds to promote the purpose of the Program.

3) Provides that, prior to establishing the board, UC may pursue any federal, state, or international approvals, authorizations or advice necessary for participation in the Program. Provides that the board may use no more than 20% of funds for administrative costs of the Program.

4) Provides that the board may solicit and receive funds from public and private sources and that money expended by UC to establish and operate the Program shall be reimbursed from donated moneys. Provides that UC may terminate the Program if it is determined unviable.

5) Provides that upon receipt of at least $500,000 the board shall establish the Program to provide grants to any or all of the following:

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

   b) Nonprofit organizations that specialize in direct patient support for improved clinical trial enrollment and retention or engage in research on health disparities and their relationship to clinical trial enrollment.

6) Provides that grants awarded shall be used for activities to increase patient access to eligible cancer clinical trials, including, but not limited to, any of the following:

   a) Patient navigator services or programs;

   b) Education and community outreach;

   c) Patient-friendly technical tools to assist patients in identifying available clinical trials;

   d) Counseling services for clinical trial participants;

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

   f) Provide payments for patients and caregivers may include costs related to participation in the trial, including airfare, lodging, meals, transportation, etc; and,

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

7) Provides that when determining program grant recipients 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.

8) Provides that 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.

9) Provides that UC may require the board to submit reports, as specified, pertaining to the board's activities to the UC Regents.

10) Provides that if UC determines at any time that the moneys in the fund are insufficient to establish or sustain the program, UC may terminate the program; all moneys in the fund remaining after expenses are paid shall, prior to dissolution, be allocated to one or more grant organizations.

11) Provides that if the fund does not receive $500,000 or more by January 1, 2021, or, if at any time, the board determines that the 20% limit on administrative costs is inadequate to support the cost of administering the Program, moneys remaining after the repayment shall be returned to the donors on a pro rata basis.

EXISTING LAW: Establishes UC as a public trust and confers the full powers of the UC upon the UC Regents. The Constitution establishes that the UC is subject to legislative control only to the degree necessary to ensure the security of its funds and compliance with the terms of its endowments. Judicial decisions have held that there are three additional areas in which there may be limited legislative intrusion into university operations: authority over the appropriation of state moneys; exercise of the general police power to provide for the public health, safety and welfare; and, legislation on matters of general statewide concern not involving internal university affairs. (Constitution of California, Article IX, Section 9)

FISCAL EFFECT: Unknown.

COMMENTS: *Purpose of this bill.* According to the author, this bill seeks to remedy the problem of low patient participation in FDA-approved cancer clinical trials. More importantly, there are a disproportionately low number of patients in underrepresented communities including African Americans, Latinos/Hispanics, Asians and Pacific Islanders, and American Indians. The author asserts this problem will be addressed by creating a privately funded state grant program to help patients pay for the ancillary costs associated with participation in these trials. Some of the barriers to patient participation in clinical trials include the following: lack of awareness of the available clinical trials, mistrust of research and the medical system, and loss of income. Clinical trials do not pay these ancillary costs associated with participation in a clinical trial such as transportation, hotel stays, and companion traveling expenses. The costs fall onto the clinical trial participant who may be unable to pay and therefore, unable to enroll in the trial.

Background. According to the Assembly Health Committee analysis, the National Cancer Institute notes over 30,000 patients are enrolled in cancer clinical trials annually. It is estimated that only about 3-5% of the 10.1 million adults with cancer in the U.S. participate in cancer trials, however. A 2011 study published in the journal Annals of Surgery, based on data from the California Cancer Registry, found that less than one percent of cancer patients in California enroll in clinical trials.

Black patients, those older than 65, those with early stage cancer or with gastrointestinal or lung cancers were less likely to enroll than average. In 2004, the SELECT prostate cancer prevention trial completed recruiting over 35,000 men of whom 21% were minorities. According to a 2014 study in the journal Cancer, less than 5% of trial participants are non-white and less than 2% of clinical cancer research studies focus on non-white ethnic or racial groups.

Clinical trials are a critical step in the discovery of new prevention, diagnostic, and treatment methods for cancer. Racial and ethnic minorities, older adults, rural residents, and individuals of low socioeconomic status are underrepresented among participants in cancer-related trials. Without adequate representation of these populations in clinical trials, researchers cannot learn about potential differences among groups, and cannot ensure the generalization of results. In addition, participation in clinical trials increases access to state-of-the-art cancer care, a critical survival factor in many minority and underrepresented populations that suffer disproportionately from cancer.

Committee staff notes that, according to information provided by UC, clinical trials conducted by UC generally have higher participation than the national average from underrepresented minority populations. Figures can range in the 13%-16% participation rate.

Previous legislation. AB 1060 (Bonilla) of 2015, was similar to this bill. It was vetoed by Governor Brown, citing, in 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. This bill responds to the Governor's veto message by moving administrative responsibility from HHS to the UC."

Requested amendments. The University of Southern California (USC) has expressed concerns on the appointments structure for the Program board. Specifically, USC notes the USC Norris Comprehensive Cancer Center focuses on testing new therapies for cancer, optimizing existing treatments, discovering prevention methods and developing ways to improve quality of life. USC notes the center is one of the nation's 41 comprehensive cancer centers. According to USC, the board appointment structure should be amended to provide more qualifiers to ensure those with sufficient expertise in cancer treatment serve on the board.

REGISTERED SUPPORT / OPPOSITION:

Support

Association of California Healthcare Districts
Association of Northern California Oncologists
California Academy of PA's
California Chronic Care Coalition
California Immigrant Policy Center
City of Hope
Health Access California
Lazarex Cancer Foundation
Pharmaceutical Researchers and Manufacturers of America
Susan G. Komen California Collaborative
University of California

Opposition

None on File

Analysis Prepared by: Laura Metune / HIGHER ED. / (916) 319-3960