

Assembly Bill No. 2915

CHAPTER 543

An act to add Article 1 (commencing with Section 104145) to Chapter 2 of Part 1 of Division 103 of the Health and Safety Code, and to repeal Section 9 of Chapter 661 of the Statutes of 1993, relating to public health.

[Approved by Governor September 14, 1996. Filed
with Secretary of State September 16, 1996.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2915, Friedman. Breast cancer research.

Existing law, in an uncodified statute (Sec. 9, Ch. 661, Stats. 1993, as amended by Sec. 2, Ch. 483, Stats. 1994), creates a Breast Cancer Research Program and requests the University of California to administer the program as a comprehensive grant and contract program to support research efforts into the cause, cure, treatment, earlier detection, and prevention of breast cancer. It states the intent of the Legislature that the University of California establish a Breast Cancer Research Council with specified membership and duties.

This bill would repeal these uncodified provisions of law and would reenact them, as amended, in a codified statute. It would revise provisions governing membership in the council and impose funding eligibility limitations on council members, among other things.

Existing law provides that revenues derived from a specified increase in cigarette taxes be deposited in the Breast Cancer Fund for allocation, upon appropriation by the Legislature, to one of 2 accounts. This provision provides that $\frac{1}{2}$ of the moneys in the fund be allocated to the Breast Cancer Research Account for research with respect to breast cancer, 90% of which is required to be allocated to the Breast Cancer Research Program discussed above.

This bill would require the State Auditor to conduct an audit of the Breast Cancer Research Program 1996-97 fiscal year grant award process. The bill also would require that the State Auditor review laws, rules, and regulations relevant to the Breast Cancer Research Program prior to the audit, make specified determinations in the audit, and report its findings to the Legislature.

The people of the State of California do enact as follows:

SECTION 1. Article 1 (commencing with Section 104145) is added to Chapter 2 of Part 1 of Division 103 of the Health and Safety Code, to read:

Article 1. The Breast Cancer Research Program

104145. (a) The Legislature hereby requests the University of California to establish and administer the Breast Cancer Research Program, which is created by this act, as a comprehensive grant and contract program to support research efforts into the cause, cure, treatment, earlier detection, and prevention of breast cancer. It is the intent of the Legislature that this program incorporate the principles and organizational elements specified in this act, including, but not limited to, a research program office with a director and other necessary staff, a Breast Cancer Research Council, and research review panels.

(b) For the purposes of this section:

(1) “Breast cancer research” includes, but is not limited to, research in the fields of biomedical science and engineering, the social, economic and behavioral sciences, epidemiology, technology development and translation, and public health.

(2) “Council” means the Breast Cancer Research Council.

(3) “Grantee” means any qualifying public, private, or nonprofit agency or individual, including, but not limited to, colleges, universities, hospitals, laboratories, research institutions, local health departments, voluntary health agencies, health maintenance organizations, corporations, students, fellows, entrepreneurs, and individuals conducting research in California.

(4) “Program” means the Breast Cancer Research Program.

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

(c) It is the intent of the Legislature that this program be administered pursuant to the following principles:

(1) The university shall work in close collaboration with the council and seek the consent of the council before taking an action different from the action recommended by the council.

(2) The council shall develop the strategic objectives and priorities of the program, actively participate in the overall management of the program, and make final recommendations on which research grants should be funded based on the research priorities established for the program and the technical merits of the proposals as determined by peer review panels.

(3) The program shall fund innovative and creative research, with a special emphasis on research that complements, rather than duplicates, the research funded by the federal government and other entities.

(4) The university and the council shall work in close collaboration with the Breast Cancer Early Detection Program.

(5) All research funds shall be awarded on the basis of the research priorities established for the program and the scientific merit of the proposed research, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality.



All investigators, regardless of affiliation, shall have equal access and opportunity to compete for program funds.

(6) The peer review process for the selection of research grants awarded under this program shall be generally modeled on that used by the National Institutes of Health in its grantmaking process.

(7) An awardee shall be awarded grants for the full cost, both direct and indirect, of conducting the sponsored research consistent with those federal guidelines governing all federal research grants and contracts. All intellectual property assets developed under this program shall be treated in accordance with state and federal law.

(8) In establishing its research priorities, the council shall consider a broad range of cross-disciplinary breast cancer research, as defined in paragraph (1) of subdivision (b), including, but not limited to, research into the cause, cure, and prevention of breast cancer; translational and technological research, including research regarding the development and translation of technologies of earlier detection; research regarding the cultural, economic, and legal barriers to accessing the health care system for early detection and treatment of breast cancer; and research examining the link between breast cancer and environmental factors, including both natural and industrial chemicals, estrogen imitators, and electromagnetic fields.

(d) It is the intent of the Legislature that the university, as lead agency, do all of the following:

(1) Establish the Breast Cancer Research Council in accordance with the following:

(A) The council shall consist of at least 13 and no more than 15 members representing a range of expertise and experience, appointed by the President of the University of California. Individuals and organizations may submit nominations to the council, and the University of California shall solicit nominations from relevant organizations and individuals. The council shall be comprised of the following members:

(i) Four members from breast cancer survivor and breast cancer-related advocacy groups, including, but not limited to, the California Breast Cancer Organizations (CABCO).

(ii) Four members drawn from the ranks of scientists or clinicians, including one from an independent research university in California. The scientists shall have expertise covering the various fields of scientific endeavor, including, but not limited to, the fields of biomedical research and engineering, social, economic, and behavioral research, epidemiology, and public health.

(iii) Two members from nonprofit health organizations with a commitment to breast cancer research and control.

(iv) One member who is a practicing breast cancer medical specialist.

(v) Two members from private industry with a commitment to breast cancer research and control, including, but not limited to,



entrepreneurs, or persons from the science or high technology industry or persons from the health care sector.

(vi) One ex officio, nonvoting member from the Breast Cancer Early Detection Program.

(B) If the president appoints more than 13 members, it is the intent of the Legislature that the proportional representation remain substantially the same as set forth in subparagraph (A).

(C) Members shall serve without compensation, but may receive reimbursement for travel and other necessary expenses actually incurred in the performance of their official duties. Any member of the Breast Cancer Research Council shall be ineligible to apply for or receive funding for breast cancer research from the Breast Cancer Research Program during his or her term of service on the council, and for one cycle immediately following his or her term of service on the council, if the council member helped plan that subsequent cycle.

(D) Membership shall be staggered in such a way as to maintain a full council while ensuring a reasonable degree of continuity of expertise and consistency of direction.

(2) Provide overall coordination of the program.

(3) Provide staff assistance to the program and council.

(4) Develop administrative procedures relative to the solicitation, review, and awarding of grants to ensure an impartial, high quality peer review system.

(5) Recruit and supervise research review panels. The membership of these panels shall vary depending on the subject matter of the proposals and the review requirements, and shall draw on the most qualified individuals. The work of the review panels shall be administered pursuant to policies and procedures established for the implementation of the program. In order to avoid conflicts of interest and to ensure access to qualified reviewers, the university may utilize reviewers not only from California but also from outside the state. When serving on review panels, institutions, corporations, or individuals who have submitted grant applications for funding by this program shall be governed by conflict-of-interest provisions consistent with the National Institutes of Health Manual (Chapter 4510 (item h)), and any applicable conflict-of-interest provisions in state law.

(6) Provide for periodic program evaluation to ensure that research funded is consistent with program goals.

(7) Maintain a system of financial reporting and accountability.

(8) Provide for the systematic dissemination of research results to the public and the health care community, and provide for a mechanism to disseminate the most current research findings in the areas of cause, treatment, cure, earlier detection, and prevention of breast cancer, in order that these findings may be applied to the planning, implementation, and evaluation of the breast cancer-related programs of the State Department of Health Services,



including the Breast Cancer Early Detection Program authorized by this act.

(9) Develop policies and procedures to facilitate the translation of research results into commercial, alternate technological, and other applications wherever appropriate and consistent with state and federal law.

(10) Transmit annually on or before each December 31, a report to the Legislature on grants made, grants in progress, program accomplishments, and future program directions. Each report shall include, but not be limited to, the following information:

(A) The number and dollar amounts of research grants, including the amount allocated to indirect costs.

(B) The subject of research grants.

(C) The relationship between federal and state funding for breast cancer research.

(D) The relationship between each project and the overall strategy of the research program.

(E) A summary of research findings including discussion of promising new areas.

(F) The institutions and campuses receiving grant awards.

In addition, the first annual report shall include an evaluation and recommendations concerning the desirability and feasibility of requiring for-profit grantees to compensate the state in the event that a grant results in the development of a profit-making product. This evaluation shall include, but not be limited to, the costs and benefits of requiring a for-profit grantee to repay the grant, to provide the product at cost to Medi-Cal and other state programs serving low-income breast cancer patients, and to pay the state a percentage of the royalties derived from the product.

(e) It is the intent of the Legislature that no more than 5 percent of the allocation to the university be used for the purposes of administration of this program.

(f) It is the intent of the Legislature that the responsibilities of the council shall include, but not be limited to, the following:

(1) Development and review of the strategic objectives and research priorities of the program.

(2) Delineation of resource allocation across the various priorities established for the program.

(3) Participation in periodic program and financial review, including the report transmitted pursuant to paragraph (10) of subdivision (d).

(4) Development and review of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program.

(5) Development of appropriate linkages to nonacademic entities, including, but not limited to, voluntary organizations, health



care delivery systems, industry, government agencies, research entrepreneurs, and public officials.

(6) Development and review of criteria and standards for granting awards.

(7) Oversight and review of the request for applications (RFA).

(8) Review of research review panel reports and recommendations for grant awards.

(9) Making of final recommendations on which grants are to be awarded.

(10) Development and review of oversight mechanisms for the dissemination of research results.

(11) Development and review of policies and liaison programs to facilitate the translation of research results into commercial, alternate technological, or other applications wherever appropriate.

(12) Establishment of its own internal rules of operation.

(13) Participation in the identification and recruitment of breast cancer advocates and survivors, clinicians, scientists, and persons from the science, high technology, or health care sector with relevant expertise for possible participation in a peer review panel. The council may propose to assign a member of the council to sit as a nonvoting member of the peer review panels.

(g) (1) The State Auditor shall conduct an audit of the Breast Cancer Research Program 1996–97 fiscal year grant award process. Prior to conducting the audit, the State Auditor shall review laws, rules, and regulations relevant to the Breast Cancer Research Program. The audit by the State Auditor shall make the following determinations:

(A) Whether the Breast Cancer Research Program has adequate controls to ensure that the program is administered in a manner designed to minimize any potential conflicts that may arise from the university's dual role as program administrator and grant recipient.

(B) Whether the Breast Cancer Research Program has adequate controls to safeguard the program's funds and assets, and whether those controls are operating as intended.

(2) The State Auditor shall conduct its audit and report its findings to the Legislature on or before January 1, 1998.

(3) The program shall retain documents received and prepared in connection with grant applications or awards until the State Auditor has completed its audit. The university, the State Auditor, and their respective employees shall maintain these documents in a manner that will protect these documents from public disclosure.

(4) Nothing in this subdivision shall be construed to prevent the university from making publicly available, after awards for a cycle of funding have been publicly announced, those applicants receiving funding for that cycle from the Breast Cancer Research Program, the names and affiliations of the peer reviewers of each study section, an abstract of grant awards, the amount of funding received from the



program, and any other information the university released in prior grant award cycles.

(5) The actual and reasonable costs incurred by the audit shall be paid by the State Auditor.

SEC. 2. Section 9 of Chapter 661 of the Statutes of 1993, as amended by Section 2 of Chapter 483 of the Statutes of 1994, is repealed.

