

SUBJECT: Restructuring the Cancer Prevention and Research Institute of Texas

COMMITTEE: Public Health — committee substitute recommended

VOTE: 10 ayes — Kolkhorst, Naishtat, Collier, Cortez, S. Davis, Guerra, S. King, Laubenberg, J.D. Sheffield, Zedler

0 nays

1 absent — Coleman

SENATE VOTE: On final passage, April 3 — 31-0

WITNESSES: For — Sandra Castillo, Alamo Breast Cancer Foundation and the Young Survival Coalition; Carol Dallred, Texas Nurses Association; Dale Eastman, Alamo Breast Cancer Foundation; Paul Lammers, Mirna Therapeutics Inc.; Maria Linares, The Rose; Cathie Sublett, The Rose; Gary Thompson, Leukemia and Lymphoma Society; Terry Wilson-Gray, Bridge Breast Network; (*Registered, but did not testify:* Troy Alexander, Texas Medical Association; Nora Belcher, Texas e-Health Alliance; Carol Cannon; Kevin Cooper, Texas Nurse Practitioners; Teresa Devine, Blue Cross and Blue Shield of Texas; Anna Dragsbaek, The Immunization Partnership; James Gray, American Cancer Society Cancer Action Network; Shirley LaVergne; David Lofye, Livestrong Foundation; Matt Moore, Children’s Medical Center of Dallas; Jerry Worden, Alamo Breast Cancer Foundation)

Against — None

On — Kristen Doyle and Wayne Roberts, Cancer Prevention and Research Institute of Texas

BACKGROUND: Tex. Const., Art. III, sec. 67 authorizes the issuance of bonds to fund the Cancer Prevention and Research Institute of Texas. Health and Safety Code, ch. 102 establishes CPRIT, defines the institution’s duties, structure, and funding, and creates conflict-of-interest rules. The institution is led by an executive director who recommends certain grant applications for approval. The oversight committee may disregard the recommendation

with a two-thirds vote. A person has a substantial financial interest in an entity if the person is an employee, member, director, or officer of an entity, or if the person owns or controls more than 5 percent in the entity.

DIGEST:

CSSB 149 would make substantial changes to the structure, duties, and funding of the Cancer Prevention and Research Institute of Texas (CPRIT). It would also establish a code of conduct and additional conflict-of-interest rules.

Structure. The bill would modify the structure of institute, establish salary restrictions, and change the composition of the oversight committee.

Officers. The executive director position would be replaced by a chief executive officer (CEO) hired by the oversight committee. The CEO would need to have a demonstrated ability to lead and develop partnerships and coalitions. The CEO would hire chief scientific, operating, product development, and prevention officers who would report directly to the CEO and help further the institute's mission.

Salary. The institute could not supplement an employee's salary – including the CEO's salary – with gifts or grants given to the institute, but the chief scientific officer's salary could be supplemented from legislative appropriations or bond proceeds. The CEO's salary could only come from legislative appropriations.

Oversight committee. The terms of current members of the oversight committee would end immediately, and the governor, lieutenant governor and the speaker of the house of representatives would have to appoint new members to committee as soon as possible after the effective date.

The comptroller and the attorney general (or their designees) would be removed from the oversight committee, and no person with an interest in an entity receiving institute money could serve on the committee. The nine-member oversight committee would be made up of three members each appointed by the governor, lieutenant governor, and the speaker of the House of Representatives. Each must each appoint at least one person with extensive oncology or public health experience, and any oversight committee members appointed by those officials would serve at the pleasure of the appointing office.

The oversight committee would hire the CEO, annually set priorities for each grant program, and consider those priorities when awarding grants. The committee would also need to elect a presiding officer and an assistant presiding officer, and the bill would specify the term limits for these positions. The oversight committee would need to have responsibilities that are distinct from those of the CEO and institute employees. Members of the oversight committee would have to give the CEO verified financial statements.

The oversight committee would have to establish the research and prevention programs committees, and the CEO would have to appoint to the committee qualified patient advocates. The institute, oversight committee, and CEO would be responsible for developing rules and requirements for members of the research and prevention programs committees, as specified by the bill.

State auditor. This bill would not limit the authority of the state auditor.

Duties. The bill would modify grant award procedures, establish additional grant contract provisions, and require a compliance program. Generally, the institute would have to:

- continuously monitor contracts and agreements to ensure that each grant recipient complied with the terms and conditions of the contract;
- ensure that all grant proposals complied with established rules before they were submitted to the oversight committee for approval;
- establish procedures to document that the institute, employees, and committee members were complying with laws and establish rules regarding the peer review process and conflicts of interest;
- establish the Cancer Prevention and Research Institute of Texas Program Integration Committee composed of five officers, including the CEO as the presiding officer; and
- employ a chief compliance officer to help establish a compliance program, monitor and report to the oversight committee, confirm compliance of grant proposals, and ensure compliance of the program integration committee by attending and observing meetings.

Grants. The institute would have to maintain complete records of grant

applications and grant recipients, including the scores given to each applicant, financial and progress reports of each recipient, and any reviews done by the institute. Any electronic grant management system would be subject to a periodic audit, and the institute would have to fix any identified weaknesses in the system.

Grant award procedures. The research and prevention programs committee would have to score grant applications, make recommendations to the program integration committee, and explain why an application was recommended. The program integration committee would, by majority vote, decide whether to submit the applications to the oversight committee and document why they were recommended. The program integration committee would have to give priority to proposals that expedited product development (instead of commercialization) and addressed the goals of the Texas Cancer Plan. Grants would then need to be approved by a two-thirds vote of oversight committee, and the committee would have to document in the meeting minutes the reasons for not approving a recommendation, if applicable.

The institute's chief compliance officer would have to compare each grant application to a list of nonprofit donors that provide support to the institution. The institute could not award a grant to one of these donors or to an applicant that had given a gift or grant to the institute. The CEO would have to submit a written affidavit for each grant application, with all of the relevant information specified in the bill. Committee members and the CEO could not discuss the application until certain requirements were met.

Grant contract terms. Before awarding a grant, the oversight committee would have to establish a written contract with the recipient. The committee could terminate the contract and require repayment (of both principal and interest) if the recipient failed to meet the terms and conditions. The institute would have to adopt a policy on advance payments.

The contract would have to require matching funds equal to half the grant award and include certain information about the matching funds, as specified in the bill. The oversight committee would have to certify that the recipient had the necessary matching funds and would dedicate those funds to cancer research. The institute would have to adopt rules about how a grant recipient could fulfill the matching funds obligation. The bill

would specify minimum requirements for those rules, establish different ways to provide the matching funds, and describe the various funds that would and would not qualify for matching fund certification. The failure to provide matching fund certification could serve as grounds for termination of the contract. The bill would also establish procedural requirements for documentation and annual review of matching funds.

Grant evaluation. The bill would establish additional procedures for grant evaluation. It would require the institute to create reporting requirements and implement a report tracking system, among other things. The chief compliance officer would have to monitor compliance with the reporting requirements and notify the general counsel and oversight committee of any noncompliance. This would allow the institute to suspend or terminate a contract, but would not limit other available contract remedies.

Compliance program. The institute, under the direction of the chief compliance officer, would have to establish a compliance program to assess and ensure committee members and employees were in compliance with laws, rules, and policies. This would include compliance with ethics and standards of conduct, financial reporting, internal accounting controls, and auditing.

The institute could establish procedures, such as a telephone hotline, to allow private access to the compliance program, preserving the confidentiality and maintaining the anonymity of a person making a report or participating in an investigation. The bill would specify that certain information, such as identifying information, would be confidential and not subject to public disclosure, unless the individual consented. The bill would also specify to whom confidential information could be disclosed without consent, such as to a law enforcement agency, among others.

Conflict-of-interest rules. The institute's oversight committee would have to adopt conflict-of-interest rules to govern the oversight, program integration, research and prevention programs committees, as well as institute employees.

Recusal. Anyone governed by the conflict-of-interest rules would need to recuse themselves if they were closely related to, or had a professional or financial interest in, a grant applicant or recipient. An institute employee could not have an office in a facility owned by a grant applicant or recipient. The bill would define the situations in which an individual had a

professional or financial interest that would require recusal, and the oversight committee could adopt additional conflict-of-interest rules.

Disclosure. Anyone governed by the institute's conflict-of-interest rules would need to provide written notice to certain officers about a potential conflict with a grant applicant and recuse themselves from the review of the application and could not have access to application information.

There would be additional disclosure requirements for committee members. Members of the oversight, program integration, and research and prevention programs' committees would also need to recuse themselves from any discussions, deliberations, and votes on the applications. Members of the oversight and program integration committees would have to disclose the conflict in an open meeting of the oversight committee. Members of the research and prevention programs would have to disclose a professional or financial conflict and recuse themselves for any matter before their committee.

Reported conflicts. Any committee member or employee who reported a potential conflict, impropriety, or self-dealing of another individual would be in compliance with the bill's rules, but members and employees would be also subject to other applicable laws and rules. A violation of the conflict-of-interest rules would warrant removal from the grant review process.

Waiver. The oversight committee would have to adopt rules regarding the waiver of conflict-of-interest rules in exceptional circumstances, and any committee member or employee could request a waiver. The waiver rules would have to meet specific requirements detailed in the bill, including reporting, documentation, and approval requirements.

Unreported conflicts. If a committee member or employee became aware of an unreported conflict of interest, the person would have to immediately notify the CEO. The CEO would have to notify the presiding officer of the oversight committee and the general counsel to determine the nature and extent of the conflict. A grant applicant could request an investigation into a potentially unreported conflict by giving the CEO a written request with all the relevant facts within 30 days of the final funding recommendations for the applicable grant cycle.

If the institute's general counsel was notified about a potentially

unreported conflict, they would have to investigate and provide the CEO and presiding officer of the oversight committee with an opinion on the matter. The opinion would have to include a statement of the facts, a determination about whether a conflict, impropriety, or self-dealing existed, and, if so, the appropriate course of action. If the matter involved the presiding officer of the oversight committee, the general counsel would report to the next ranking member not involved in the matter. The bill would specify procedures by which the CEO or presiding officer of the oversight committee would order recusal based on the general counsel's opinion.

The CEO or presiding officer would have to make a final determination about the potentially unreported conflict, impropriety, or self-dealing. The determination would have to include information about actions taken to address the issue, including the reconsideration of an application or the referral to another committee for review. The bill would establish additional procedures, such as notice requirements, about these determinations. An unreported conflict by an individual could not be used to invalidate a grant application, unless specifically decided by a CEO or presiding officer.

Code of conduct. The oversight committee would have to adopt a code of conduct applicable to the members of the oversight and program integration committees and institute employees. The bill would specify the minimum requirements for the code of conduct. It would have to prohibit accepting or soliciting gifts, disclosing confidential information, and serving on the board of directors of grant recipients, among other things. A member of the research and prevention programs committees could not serve on the board of directors of a similar organization affiliated with a grant recipient.

Reports. By January 31 of each year, the institute would have to submit to certain government authorities and post online a report of its activities, grant awards, grants in progress, research accomplishments, and future program directions. Among other things, the report would need to include a statement about the compliance program's activities, any proposed legislation or recommendations, and any conflict-of-interest waivers granted in the preceding year.

Funding. The bill would modify the institute's funding mechanisms and establish that certain records were public information.

Cancer prevention and research fund. The cancer prevention and research fund would not include patent, royalty, and licenses fees and other incomes received from grant contracts. The legislatively appropriated funds could not include proceeds from the issuance of bonds authorized by the Texas Constitution, but the fund could include debt service on bonds.

Sinking fund. The bill would establish the cancer prevention and research interest and fund as a general revenue dedicated account. It would consist of patent, royalty, and licenses fees, other income received from grant contracts and earned interest on investments of fund money. The fund could only be used to pay for debt service on bonds authorized by the Texas Constitution, as determined the Legislature's General Appropriations Act.

Open records. The records of a nonprofit organization created to support the institute would be public information. The institute would have to post online records related to any gift, grant, or other consideration given to the institute, committee member, or employee. The post would need to include the donor name, gift amount, and date of donation.

Effective dates. The oversight committee would have to establish a compliance program and adopt rules to implement the bill as soon as possible. The bill would only apply to a grant application submitted on or after the effective date. By December 1, 2013, the oversight committee would have to employ a CEO and chief compliance officer. By January 1, 2014, the committee members and employees would have to comply with the bill's qualification requirements.

This bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2013.

**SUPPORTERS
SAY:**

CSSB 149 would enable CPRIT to ethically and effectively continue its mission by restructuring the institute's leadership and peer review process, requiring matching funds from grant recipients, establishing a compliance program, and strengthening conflict-of-interest prohibitions.

In 2007, Texas voters approved a constitutional amendment to establish the Cancer Prevention and Research Institute of Texas (CPRIT) and authorize the issuance of \$3 billion in bonds to fund cancer research and

prevention programs and services. In 2012, allegations arose about potentially improper grants, conflicts of interest, and favoritism, prompting criminal investigations and legislative inquiries. A recent report from the state auditor noted that CPRIT's inadequate transparency and accountability of grant management processes reduced its ability to properly award and effectively monitor its grants. The report revealed that three grants — totaling \$56 million — were approved without proper peer review. One of the recipients, a start-up company, was given \$11 million without adequate reviews of their business or scientific plans.

Despite the controversy, the institute serves a worthy mission. Due in part to the creation of CPRIT, Texas provides more cancer research funds than any other state. These funds have enabled health care providers and researchers to conduct groundbreaking studies, recruit and train new physicians and scientists, and diagnose and treat more cancer patients. One organization estimates that a CPRIT grant allowed them to increase mammogram screenings by 400 percent.

CPRIT is enabling important cancer research and helping increase access to services, and the bill would allow the institute to continue to fulfill its mission in a transparent, responsible manner. It would ensure that grants are awarded to established companies well prepared to conduct cancer research or offer services by requiring grant recipients to provide substantial matching funds. It would also establish stricter peer review procedures for grant applications and more thorough reporting requirements for grant recipients.

In addition, the bill would implement a system of checks and balances designed to prevent bias, favoritism, and self-dealing. The bill would strengthen the oversight committee, add a code of conduct, and establish stricter conflict-of-interest rules which would prevent and deter impropriety by committee members and employees. By establishing new requirements for committee members and employees, as well as grant applicants and recipients, the bill would ensure that grants were awarded in an ethical, accountable manner.

By changing the funding mechanisms, the bill would also push the institute to become self-sufficient, relieving any future burden on Texas taxpayers.

OPPONENTS
SAY:

CSSB 149 should not extend the life of CPRIT. Although the bill could prevent some impropriety and self-dealing, it would not entirely stop abuse of the system. The institute has in place existing conflict-of-interest prohibitions and peer review processes that did not prevent improper grants from being awarded to a variety of inappropriate recipients. As the recent fiasco has shown, offering large grants of money will always be tainted by politics. Texas should dismantle the institute to prevent further abuse of public funds.

OTHER
OPPONENTS
SAY:

CSSB 149 could go further to prevent the institute from becoming embroiled in controversy. CPRIT should sever ties with any supporting nonprofit organizations to prevent additional doubts about transparency and accountability.

NOTES:

Compared with the Senate engrossed version, the committee substitute requires a code of conduct. It specifies ways that a grant recipient can meet the matching fund requirement. It also modifies the chief compliance officer's duties, the institute's reporting requirements, and the composition of and qualifications for the oversight committee.