SUBJECT: Creating the Dementia Prevention and Research Institute of Texas

COMMITTEE: Public Health — committee substitute recommended

VOTE: 9 ayes — VanDeaver, Campos, Bucy, Cunningham, Frank, Johnson, J. Jones, Schofield, Simmons

2 nays — Olcott, Shofner

2 absent — Collier, Pierson

SENATE VOTE: On final passage (March 5) — 29 - 2

WITNESSES: None (*The House companion to CSSB 5, HB 5 by Craddick, was considered in a public hearing on March 10*)

DIGEST: CSSB 5 would establish the Dementia Prevention and Research Institute of Texas (DPRIT) to:

- create and expedite innovation in research on dementia, Alzheimer's disease, Parkinson's disease, and related disorders to improve the health of state residents and enhance the state's research on these disorders, including the potential for a related medical or scientific breakthrough; and
- attract, create, or expand research capabilities of eligible higher education institutions and other entities by awarding grants related to these disorders.

DPRIT would be authorized to:

- award grants to further its purposes, including for research, associated costs, and prevention programs and strategies;
- collaborate with relevant state agencies, councils, and consortia to enhance health care and research for dementia, Alzheimer's disease, Parkinson's disease, and related disorders;

- employ staff as necessary; and
- contract with another state agency to share administrative costs.

DPRIT would be required to:

- establish standards and oversight bodies to ensure money authorized under the bill was used properly;
- monitor grant contracts authorized by the bill;
- ensure all grant proposals comply with the bill and rules adopted under the bill before being submitted;
- establish procedures to document compliance by the DPRIT, including employees and committee members, with all laws and rules governing peer review and conflicts of interests.

The DPRIT oversight committee created under the bill would be required to hire a chief executive officer that had demonstrated ability to lead and develop academic, commercial, and governmental partnerships and coalitions. DPRIT would have to employ a chief compliance officer, and the chief executive officer could hire any other officers as necessary.

The bill would require DPRIT to submit an annual report on its activities and other specified financial, compliance, and grant-related information to the governor, lieutenant governor, speaker of the House of Representatives, and standing committee of each legislative house with primary jurisdiction over DPRIT matters. The report would have to be posted on DPRIT's website.

DPRIT would be required to annually commission a certified public accounting firm to perform an independent financial audit of its activities and provide the audit to the comptroller. The comptroller would have to review and evaluate the audit, annually issue a report of that review, and make recommendations on DPRIT's financial practices and performance. DPRIT's oversight committee would be required to review the audit, the comptroller's report and recommendations, and DPRIT's financial activities.

DPRIT would be required to maintain complete records of each grant application submitted, each grant recipient's financial and progress reports, DPRIT's review of those reports, and the identity of each principal investor and owner of each grant recipient. DPRIT would have to keep each record for 15 years. DPRIT would have to have prepared periodic audits of any electronic grant management system used to maintain records and timely address any identified weaknesses.

DPRIT would be required to establish a compliance program under its chief compliance officer's direction to monitor compliance with the bill and rules adopted under the bill and for reporting incidents of noncompliance to the oversight committee. The bill would specify compliance-related duties, including attending and observing certain committee meetings, reporting on grant application recommendations, tracking and monitoring required reports by grant recipients, and establishing procedures for investigating allegations against applicable entities for fraud, waste, or abuse of state resources.

DPRIT would be subject to the Sunset Act and would sunset on September 1, 2035, unless continued by the Legislature.

Oversight committee. CSSB 5 would establish an oversight committee as DPRIT's governing body. The committee would be composed of three members each appointed by the governor, the lieutenant governor, and the speaker of the House of Representatives. Members would have to represent the state's geographic and cultural diversity. In making committee appointments, the governor, lieutenant governor, and speaker of the House would each have to appoint at least one person who was a physician or scientist with extensive experience working with dementia, Alzheimer's disease, Parkinson's disease, or related disorders. Appointments also would have to attempt to include persons affected by these disorders, or family members or caregivers of such persons. A person could not be an oversight committee member if the person or the person's spouse was employed by or participated in the management of an entity receiving money from DPRIT, owned or controlled interest in an entity receiving money, or used or received a substantial amount of goods,

services, or money from DPRIT. A member of the Cancer Research Institute of Texas Oversight Committee also would be excluded from serving on the DPRIT oversight committee.

The bill would establish the grounds and procedures for removing a member from the committee. Members would serve staggered six-year terms. The committee would be required to biennially elect a presiding officer and assistant presiding officer, and would be authorized to elect additional officers. Committee members would not be entitled to compensation but would be entitled to reimbursement for necessary expenses incurred in performing official duties.

The committee would have to hold a public meeting at least quarterly, with appropriate notice and a formal public comment period. The committee would be authorized to conduct a closed meeting to discuss issues related to securities or other revenue-sharing obligations or an ongoing compliance investigation.

The committee would be required to annually set grant program priorities and consider those priorities in awarding grants. The committee also would have to adopt a code of conduct related to certain conflicts of interest applicable to each oversight committee member, program integration committee member, and DPRIT employee.

CSSB 5 would provide for the initial appointment of oversight committee members to specified staggered terms by December 31, 2025, and the committee could not act until a majority of members had taken office.

Other committees. CSSB 5 would require the DPRIT oversight committee to create a peer review committee composed of experts in fields related to dementia, Alzheimer's disease, Parkinson's disease, or related disorders, and trained patient advocates who met certain qualifications. Peer review committee members could not serve on the governing board of an entity receiving a DPRIT grant. The oversight committee also would be authorized to create additional ad hoc advisory committees composed of experts.

DPRIT would be required to establish a program integration committee composed of the chief executive officer, three senior employees responsible for program policy and oversight, and the executive commissioner of the Health and Human Services Commission or the executive commissioner's designee.

The bill also would establish a higher education advisory committee composed of one member each appointed by the chancellor or president of The University of Texas System, the Texas A&M University System, the Texas Tech University System, the University of Houston System, the Texas State University System, the University of North Texas System, Baylor College of Medicine, and Rice University.

Dementia Prevention and Research Fund. CSSB 5 would establish the Dementia Prevention and Research Fund as a special fund in the treasury outside the general revenue fund, to be administered by DPRIT. The fund could be used only for purposes authorized under the Texas Constitution, including the award of grants for research or prevention of dementia, Alzheimer's disease, Parkinson's disease, and related disorders, grants for or purchase of research facilities, and the operation of DPRIT.
A grant recipient could use the money for research consistent with the bill's purposes and in accordance with a contract between the recipient and DPRIT. Authorized expenses would include honoraria, travel, conference expenses, supplies, operating expenses, contracted research and development, capital equipment, and facility construction or renovation.

A grant recipient awarded money for research could not spend more than 5 percent of the money on indirect costs. No more than 5 percent of the total amount of grant money awarded in a fiscal year could be used during that year for facility purchase, construction, remodel, or renovation. No more than 10 percent of total grant money awarded in a fiscal year could be used during that year for prevention projects and strategies to mitigate the incidence of dementia, Alzheimer's disease, Parkinson's disease, or related disorders.

Conflicts of interest. CSSB 5 would require the oversight committee to adopt conflict-of-interest rules, based on standards applicable to members of scientific review committees of the National Institutes of Health, to govern oversight committee members, program integration committee members, peer review committee members, and DPRIT employees.

Committee members and DPRIT employees who had a conflict of interest regarding an application for review or other action would have to disclose the conflict and recuse themselves from participation in reviewing the application according to procedures specified by the bill. They also could not access information regarding the matter to be decided. Members or employees would have a conflict of interest if they or a person related to them within the second degree of affinity or consanguinity had a professional or financial interest, as defined by the bill, in an entity awarded a grant or applying for a grant from the institute.

The bill also would specify procedures for:

- the oversight committee to grant a waiver of conflict-of-interest requirements under exceptional circumstances;
- DPRIT's general counsel to investigate unreported potential conflicts of interest; and
- DPRIT's chief executive officer or the oversight committee's presiding officer to make a final determination regarding an unreported conflict of interest or other impropriety or self-dealing.

Grant award procedure. CSSB 5 would require DPRIT to establish a peer review process to evaluate and recommend all grants awarded by the oversight committee under the bill. The oversight committee would be required to adopt rules for the grant award procedure. The rules would have to require the peer review committee to score grant applications and make recommendations to the program integration and oversight committees regarding awarding grants, including a prioritized list ranking grant applications and explanatory information. The rules also would have to require the program integration committee to submit to the oversight

committee a list of applications approved by majority vote for recommendation that included documentation on considered factors, was based on the list submitted by the peer review committee, and prioritized proposals according to criteria specified by the bill.

A peer review committee member could not attempt to use the member's official position to influence a decision to approve or award a grant or contract to the member's employer. A program integration committee member could not discuss a recommendation with an oversight committee member unless the program integration committee had submitted its list of approved recommendations.

Each grant award recommendation would have to be approved by two-thirds of oversight committee members present and voting. Disapproval of a grant award recommendation would require an explanatory statement to be included in the meeting minutes. The oversight committee could not award more than $300 million in grants in a fiscal year, and could not award a grant to an applicant who had made a gift or grant to DPRIT, an oversight committee member, or a DPRIT employee on or after January 1, 2026.

The oversight committee would be authorized to approve grants for a multiyear project and would have to specify the total amount approved for such projects. The total amount would be considered to have been awarded in the fiscal year the peer review committee approved the project. DPRIT would be required to disburse only the money as needed to be spent in each fiscal year.

Before disbursing grant money under the bill, DPRIT would have to execute a written contract with the recipient, including terms specified in the bill for grant repayment under certain circumstances, intellectual property rights, matching funds, spending timelines, and deliverables.

Before DPRIT disbursed money, the recipient would be required to certify that the recipient had available an unexpended amount of money equal to half of the grant amount dedicated to the research specified in the grant

proposal. CSSB 5 would require DPRIT to adopt rules regarding a grant recipient's obligations according to minimum standards for certifying matching money as specified in the bill.

The oversight committee would have to establish standards requiring all grant awards to be subject to an intellectual property agreement that allowed the state to collect royalties, income, and other benefits realized as a result of projects undertaken with money awarded under CSSB 5. The committee also would have to establish standards to ensure that grant recipients purchased goods and services from in-state suppliers as reasonably possible, and from historically underutilized businesses as defined by state law.

As a condition of awarding a grant, the oversight committee would have to require that the recipient submit to regular inspection reviews of the grant project by DPRIT employees to ensure contract compliance and ongoing progress. The chief executive officer would be required to report at least annually to the oversight committee on the progress and continued merit of projects awarded grants by DPRIT.

Public information. Under CSSB 5, a grant applicant's name and address, the amount requested in a grant proposal, the type of research to be addressed by a proposal, and any other information DPRIT designated with a grant applicant's consent would be public information and could be disclosed under the Public Information Act.

To protect the actual or potential value of information submitted to DPRIT by a grant applicant or recipient, the following information would be confidential and not subject to disclosure under the Public Information Act or any other law:

- all other information contained in a grant application, peer review evaluation, award contract, or progress report relating to a product, device, or process, the application or use thereof, and all technological and scientific information developed by the applicant or recipient; and

- the plans, specifications, blueprints, and designs, including related proprietary information, of a scientific research and development facility.

The following information also would be confidential and not subject to disclosure under the Public Information Act, unless the information related to an individual who consented to disclosure:

- information that revealed the identity of an individual who reported fraud, waste, or abuse of state resources to the DPRIT compliance program office, sought guidance from the office, or participated in an investigation under the program;
- information that revealed the identity of an individual who was alleged to have, or might have planned, initiated, or participated in activities specified in a report submitted to the office if, after completing an investigation, the office determined the report to be unsubstantiated or without merit; and
- other information collected or produced in a compliance program investigation if releasing the information would interfere with an ongoing investigation.

Information made confidential or excepted from public disclosure could be made available to a law enforcement agency or prosecutor, a governmental agency responsible for investigating a matter specified in a compliance report, or a committee member or DPRIT employee responsible for a compliance program investigation or an investigation review.

DPRIT would be required to post on its website records pertaining to any gift, grant, or other consideration provided to DPRIT, an employee, or an oversight committee member, in the employee's or member's official capacity. The information posted would have to include each donor's name and the amount and date of the donation.

Effective date. CSSB 5 would take effect December 1, 2025, but only if the proposed constitutional amendment CSSJR 3 took effect. If that

amendment was not approved by voters, the bill would have no effect.

SUPPORTERS SAY:

By creating the Dementia Prevention and Research Institute of Texas, CSSB 5 would help make Texas the leader in combating dementia, Alzheimer's disease, and other degenerative neurological disorders. The bill would make a major investment in research focused on the prevention and treatment of such diseases, improving the health and quality of life of millions of Texans and benefiting the state's economy. The impact of dementia and related diseases is growing due to a rapidly aging population and increased life expectancy, and the need for increased investment in research, prevention, and treatment is urgent. Dementia is a leading cause of death in the U.S., and Texas ranks high among other states in Alzheimer's cases and deaths. Additionally, lack of neurological medical care is especially acute in some regions of the state, which limits access to critical care.

CSSB 5 would accelerate innovation in dementia research by providing grants through DPRIT, which would be modeled in certain respects after the Cancer Prevention and Research Institute of Texas (CPRIT), the state's institute for funding cancer research. CPRIT has successfully attracted excellent cancer researchers and doctors to Texas and provided a significant economic return on the state's investment. DPRIT also would help attract top research talent to the state and create high-quality jobs, as well as provide royalty payments to the state from funded projects. By advancing efforts to mitigate the causes and effects of dementia, DPRIT could help relieve caregiving costs in the state, which can burden families for many years. DPRIT also would augment current research efforts by facilitating collaboration among medical and scientific experts.

Texas' business-friendly regulatory environment provides advantages that ideally position the state to take on the challenge of combating dementia and become a major center of biomedical research. While some have questioned the place of government in funding such research, Texas' current budget surplus presents a unique opportunity to improve the lives of millions in Texas and beyond. Additionally, DPRIT could facilitate types of research, such as projects focused on prevention, that might not

be pursued by private entities alone, since they may not be especially profitable. CSSB 5 also provides strong protections against conflicts of interest to ensure the integrity of the state's investment.

CRITICS SAY:

While combatting dementia is a worthwhile goal, CSSB 5 would create an open-ended, long term financial risk for taxpayers outside of the proper scope of government, and there are other appropriate priorities for public funds. Private industry, nonprofits, and universities are capable of addressing the problem without government involvement in research. CSSB 5 also would create a new state bureaucracy without sufficient accountability measures.

CSSB 5 would model DPRIT on CPRIT, which itself has had problems with a lack of accountability in the use of public money. DPRIT could be more problematic, as dementia research is broader and more ambiguous in scope than cancer research, and because DPRIT would involve more bureaucratic layers and political appointees, it could increase inefficiency and the potential for favoritism.

OTHER CRITICS SAY:

CSSB 5 should provide more guardrails and limits on the types of research funded through DPRIT, including by prioritizing research on the causes of dementia while taking account of lifestyle and the effects of drugs taken by patients. The bill should protect against commercialized and invasive device research that could harm vulnerable elderly Texans.

The bill would allow for conflict of interest requirements to be waived in certain circumstances, and it is unclear how many waivers would be granted, which could raise concerns about transparency. The bill should do more to provide a buffer between pharmaceutical companies operating for profit and state business.

NOTES:

According to the Legislative Budget Board, the bill would have an impact of $0 to general revenue related funds through the biennium. DPRIT would be funded initially with a transfer of $3 billion from the general revenue fund as provided by CSSJR 3.