BILL ANALYSIS

C.S.H.B. 4990
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Health Care Reform, Select
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Texas continually strives to discover groundbreaking strategies to increase health care access and affordability. One of the largest drivers of rising health care costs is prescription drug pricing and anticompetitive practices in the market on the part of pharmacy benefit managers. Without action taken by the legislature to address this issue, costs will continue to go unfettered. C.S.H.B. 4990 seeks to reduce the cost of prescription drugs for taxpayers, employers, and consumers through the establishment of the Texas Pharmaceutical Initiative. Through this initiative, the bill provides for the establishment of a statewide pharmacy benefit manager focused on price transparency and providing savings, not only to the state, but also ultimately to consumers. Under the leadership of the initiative, Texas will develop manufacturing partnerships to produce and distribute both generic and specialty prescription drugs, making essential medications affordable and accessible to more patients. To further bolster these efforts, the legislation allows for the initiative to invest in the provision of health care cost and claims analytic services to support each of its important functions. Finally, C.S.H.B. 4990 creates the Texas pharmaceutical initiative fund in order to secure public and private resources to bring this project to fruition and provide ongoing financial support.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 of this bill.

ANALYSIS

C.S.H.B. 4990 amends the Government Code to establish the Texas Pharmaceutical Initiative to provide cost-effective access to prescription drugs and other medical supplies for employees, dependents, and retirees of public higher education systems and institutions, members of the Employees Retirement System of Texas (ERS) or the Teacher Retirement System of Texas (TRS), persons confined by the Texas Department of Criminal Justice (TDCJ) or the Texas Juvenile Justice Department (TJJD), Medicaid recipients, and CHIP enrollees. The bill authorizes a state entity that provides health benefit plan coverage to such individuals to elect to provide access to prescription drugs and other medical supplies under the initiative as the entity determines appropriate.

C.S.H.B. 4990 establishes that the initiative is governed by a board that is administratively attached to the Health and Human Services Commission (HHSC) and is composed of the following members:

- the executive commissioner of HHSC or the executive commissioner's designee;

- the executive director of ERS or the executive director's designee;
- the executive director of TRS or the executive director's designee;
- three members appointed by the governor;
- one member appointed by the governor from a list of three names submitted by the lieutenant governor;
- one member appointed by the governor from a list of three names submitted by the speaker of the house of representatives; and
- the chancellor of The University of Texas System, or the chancellor's designee, who serves in an ex-officio capacity.

The bill establishes that board members serve staggered six-year terms and a vacancy is filled in the same manner as the original appointment. The bill requires the governor to designate the board's presiding officer. Board members serve without compensation but may be reimbursed for travel and other actual and reasonable expenses incurred in the performance of the member's duties on the board.

C.S.H.B. 4990 requires the board to do the following:

- develop and implement the initiative and related programs established by the bill;
- establish procedures and policies for the administration of the initiative;
- establish procedures to document compliance by board members and personnel with applicable laws governing conflicts of interest;
- ensure that a program or entity created under the bill meets any applicable licensing or accreditation requirements under state or federal law; and
- recommend rules necessary to implement the bill's provisions for adoption by the executive commissioner of HHSC.

C.S.H.B. 4990 authorizes the board to do the following to carry out the bill's purposes:

- execute contracts and other instruments and conduct all activities the board determines necessary for those purposes;
- authorize one or more board members to execute contracts and other instruments on the board's behalf;
- establish a committee or other similar entity to exercise powers delegated by the board and exercise any other administrative duties or powers as the board considers necessary;
- employ an executive director and necessary personnel to provide administrative support; and
- award grants to public or private persons to implement the initiative.

The bill further authorizes the board to refrain from establishing a program or entity under the bill's provisions if the board determines that establishment is not feasible with current resources or considering other state-funded programs. The bill requires a contract or agreement executed under the bill's provisions to comply with the Professional Services Procurement Act, if applicable.

C.S.H.B. 4990 requires the board to contract for a statewide pharmacy benefit manager (PBM), as provided under applicable provisions of the State Purchasing and General Services Act, to provide cost-effective prescription drugs through the establishment of a pharmacy network to state entities served by the initiative. The bill requires the PBM to provide pricing transparency, a pass-through of all rebates and fees, and fair and equitable pricing to a pharmacy that participates in the PBM's pharmacy network. The bill requires the PBM to contract with appropriate persons to do the following:

- provide an evidence-based benefit design, a prior authorization process, and a new drug review process; and
- partner with suppliers, pharmaceutical manufacturers, and group purchasing organizations for competitive acquisition of prescription drugs and medical supplies.

C.S.H.B. 4990 requires the board to establish and implement a central service center and an associated network of satellite distribution facilities to provide prescription drugs and medical

supplies to individuals specified by the bill for state entities that elect to participate in the initiative. The bill requires the center to meet the following criteria:

- be constructed to withstand extreme weather conditions, natural disasters, and power outages;
- be capable of providing disaster preparedness and response resources statewide; and
- include a mail order pharmacy and specialty pharmacy.

The bill authorizes such a pharmacy to assess delivery and handling fees on persons receiving prescription drugs from the pharmacy and authorizes the center to assess an inventory storage charge, transaction fees, or other fees on persons obtaining prescription drugs and medical supplies from the center to support the center's distribution and other operational costs, including overhead and margin.

C.S.H.B. 4990 requires the board to establish a pharmaceutical advanced preparation facility to serve as an outsourcing facility in compliance with Section 503B of the Federal Food, Drug, and Cosmetic Act to do the following:

- manufacture and provide compounded drugs;
- provide chimeric antigen receptor T-cell treatment and other gene therapies, including precision medicine; and
- provide advanced laboratories for quality control, preparation, and compounding of drugs in support of innovative therapeutics and drug research.

The bill requires the facility to be operated by a 501(c)(3) tax-exempt organization established by the board and authorizes the facility to charge fees to persons to whom the facility provides drugs, treatment, supplies or other services to support the operational costs of the facility, including overhead and margin.

C.S.H.B. 4990 requires the board to contract with a person to provide advanced health care claims analytics software to support the programs and entities created by the bill and to support population health research. The bill requires the board to develop criteria for the evaluation of applications or proposals submitted by a person seeking to contract with the board to provide such software.

C.S.H.B. 4990 authorizes the board to enter into an agreement with a person to establish a facility that manufactures generic biological products and generic drugs in compliance with any FDA requirements. The bill requires the board to prioritize savings and access to affordable medications in entering into the agreement. The bill requires the board to develop criteria for the evaluation of applications or proposals submitted by a person seeking to contract with the board relating to the manufacturing facility. The bill defines "generic biological product" as a biological product approved pursuant to an application under the federal Public Health Service Act and "generic drug" as a prescription drug approved pursuant to an application under the Federal Food, Drug, and Cosmetic Act.

C.S.H.B. 4990 makes confidential and exempt from disclosure under state public information law any information received by the board, a program or entity created by the bill, a state entity participating in the initiative, or a contractor or agent of the board that, if directly or indirectly disclosed, is likely to compromise the financial, competitive, or proprietary nature of the information.

C.S.H.B. 4990 creates the Texas Pharmaceutical Initiative Fund as a trust fund held by the comptroller of public accounts outside the state treasury, consisting of money from gifts, grants, or donations to the fund; any additional legislative appropriations of money for the purposes of the fund; and interest, dividends, and other income of the fund. The bill restricts the board's use of money in the fund to carrying out the bill's purposes and requires the board to develop procedures for administration and approval of fund expenditures. The bill authorizes the board to accept gifts, grants, and donations from any public or private source for the purpose of carrying out the bill's provisions.

C.S.H.B. 4990 requires the board, not later than December 31 of each year, to submit to the legislature a written report on the initiative's activities and objectives, any cost savings for state entities that that participate in the initiative, and any recommendations for legislative or other action.

EFFECTIVE DATE

On passage, or, if the bill does not receive the necessary vote, September 1, 2023.

COMPARISON OF INTRODUCED AND SUBSTITUTE

While C.S.H.B. 4990 may differ from the introduced in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

The substitute changes the entity granted rulemaking authority from the initiative's governing board, as in the introduced, to the executive commissioner of HHSC, but the substitute includes a provision not in the introduced requiring the board to recommend rules necessary to implement the bill for adoption by the executive commissioner.

While both the introduced and the substitute establish the initiative for the purpose of providing cost-effective access to prescription drugs for certain individuals, the substitute additionally includes cost-effective access to other medical supplies for those individuals as a purpose of the initiative. In a bill provision specifying those qualifying individuals, the substitute omits other public, non-profit, and for-profit entities not specified in the bill, which were included in the introduced.

The substitute requires the board to establish procedures and policies for the administration of the initiative, whereas the introduced required the board to establish procedures and policies for the administration of the board. The substitute requires the board to execute contracts and other instruments and conduct all activities it determines necessary to carry out the bill's purposes, whereas the introduced required the board to execute all contracts and other documents, adopt all proceedings, and conduct all activities it determines necessary for those purposes. The substitute omits a provision from the introduced authorizing the board to delegate to a committee or other entity created by the board administrative duties and other powers as the board deems necessary.

Whereas the introduced conditioned the board's duty to implement a bill provision on the legislature appropriating money specifically for that purpose and, if the legislature did not do so, made that implementation discretionary, the substitute authorizes the board to refrain from establishing a program or entity under the bill's provisions if the board determines that establishment is not feasible with current resources or considering other state-funded programs.

Whereas the introduced required the board to establish and implement a statewide transparent PBM, the substitute requires the board to contract for a statewide PBM as provided under applicable provisions of the State Purchasing and General Services Act. The substitute omits a provision from the introduced authorizing the PBM to charge fees for startup, enrollment, and ongoing management to support operational costs, program development, and expansion.

The substitute clarifies the nature of the pharmaceutical advanced preparation facility that must be established by the board by doing the following:

- omitting a specification present in the introduced that the purpose of the requirement for the board to establish such a facility is to provide FDA-approved 503B compounding, manufacturing, CAR-T and other gene therapies, precision medicine, and advanced labs for quality control, preparation and compounding in support of innovative therapeutics and drug research; and

- specifying that the facility serves as an outsourcing facility in compliance with Section 503B of the Federal Food, Drug, and Cosmetic Act.

While the introduced authorized the facility to charge fees for drug preparation, manufacturing, CAR-T, gene therapy, and 503B compounding, the substitute authorizes the facility to charge fees to persons to whom the facility provides drugs, treatment, supplies, or other services.

While the introduced authorized the board to enter into an agreement to establish a facility that manufactures generic drugs, the substitute authorizes the board to enter into an agreement to establish a facility that manufactures such drugs or generic biological products in compliance with any FDA requirements. The substitute defines "generic biological product" and "generic drug," whereas the introduced did not.

In a bill provision authorizing the board to use money in the fund to carry out the bill's purposes, the substitute expressly restricts the board's authority to use the money for that purpose, and the introduced did not. Whereas the introduced established that the fund consists of money from gifts, grants, or donations to the executive committee, in addition to any other source appropriated or designated by the legislature, the substitute instead establishes that the fund consists of money from gifts grants, and donations to the fund, in addition to any additional legislative appropriations of money for the purposes of the fund.

Whereas the introduced required the annual report to include any legislative recommendations, the substitute instead requires the annual report to include any recommendations for legislative or other action.

The substitute includes provisions absent from the introduced that do the following:

- authorize a state entity that provides health benefit plan coverage to individuals specified by the bill to elect to provide access to prescription drugs and other medical supplies under the initiative;
- establish that board members serve staggered six-year terms;
- establish that board members serve without compensation but may be reimbursed for travel and other actual and reasonable expenses incurred in the performance of a member's duties on the board;
- require the board to ensure that a program or entity created under the bill's provisions meets any applicable licensing or accreditation requirements under state or federal law;
- require a contract or agreement executed under the bill's provisions to comply with the Professional Services Procurement Act, if applicable;
- require the board to develop criteria for the evaluation of applications or proposals submitted by a person seeking to contract with the board for advanced health care claims analytics software or for a generic biological product and generic drug manufacturing facility;
- establish that certain information received by the board is confidential and not subject to disclosure under state public information law; and

establish that the Texas Pharmaceutical Initiative Fund consists in part of interest, dividends, and other income of the fund.