BILL ANALYSIS

C.S.H.B. 3147
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Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

It has been suggested that patient participation in cancer clinical trials has suffered due to the economic barrier caused by the high ancillary costs of participating in the trial. This barrier mitigates against obtaining a cross-spectrum distribution of trial participants, which may threaten the advancement of cancer clinical research. In order to address these socioeconomic disparities and incentivize a more diverse participant pool, C.S.H.B. 3147 specifies that independent third-party organizations may provide financial assistance through a cancer clinical trial program.

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 this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

C.S.H.B. 3147 amends the Health and Safety Code to authorize an independent third-party organization to develop and implement a cancer clinical trial participation program to provide reimbursement to an individual who participates in the program for ancillary costs associated with participation in a cancer clinical trial. The bill sets out certain requirements for the program relating to collaboration with physicians and health care providers to provide notification about the program, reimbursement to the participating individuals, and compliance with applicable federal and state laws. The bill requires the organization to provide written notice to prospective participating individuals of those requirements and authorizes the program to provide reimbursement for reasonable ancillary costs to one person who attends a cancer clinical trial to support a participating individual.

C.S.H.B. 3147 requires a reimbursement under the program to comply with applicable federal and state laws and to be reviewed and approved by the institutional review board associated with the cancer clinical trial for which the reimbursement is provided. The organization is not required to obtain approval from an institutional review board on the financial eligibility of an individual who is medically eligible for the program.

C.S.H.B. 3147 requires the organization to provide written notice to a participating individual on the nature and availability of the ancillary financial support under the program and the program's general guidelines on financial eligibility. The bill establishes that reimbursement to a participating individual does not constitute an inducement to participate in a cancer clinical trial, is not considered coercion or the exertion of undue influence to participate in a cancer clinical trial, and is meant to accomplish parity in access to cancer clinical trials and remove barriers to

participation in cancer clinical trials for financially burdened subjects.

C.S.H.B. 3147 authorizes the organization to accept gifts, grants, and donations from any public or private source to implement the bill's provisions and to collaborate with the Cancer Prevention and Research Institute of Texas to provide reimbursement under the program. The bill authorizes money awarded from the cancer prevention and research fund or related bond proceeds to be used for reimbursement for costs of participation incurred by cancer clinical trial participants, including transportation, lodging, and any costs reimbursed under the program. The bill sets out certain legislative findings.

EFFECTIVE DATE

September 1, 2019.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 3147 may differ from the original 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 type of entity authorized to develop and implement the program from a nonprofit organization to an independent third-party organization.

The substitute includes the following provisions:

- a requirement for the program to collaborate with physicians and health care providers to notify a prospective participating individual about the program when that individual provides informed consent for a cancer clinical trial or when funding is available to provide the program for the cancer clinical trial in which the individual participates;
- an authorization for the organization administering the program to collaborate with the Cancer Prevention and Research Institute of Texas to provide reimbursement under the program;
- an authorization for money awarded from the cancer prevention and research fund or related bond proceeds to be used for reimbursement for costs of participation incurred by cancer clinical trial participants; and
- specifications that reimbursement under the program is not considered coercion or the exertion of undue influence to participate in a cancer clinical trial and that reimbursement is meant to accomplish parity in access to cancer clinical trials and remove barriers to participation in such trials for financially burdened subjects.

The substitute does not include child care costs among the ancillary costs to be reimbursed but does include costs for parking and tolls.

The substitute revises the legislative findings.