SUBJECT: Authorizing a cancer clinical trial participation program

COMMITTEE: Public Health — committee substitute recommended

VOTE: 10 ayes — S. Thompson, Wray, Allison, Coleman, Frank, Guerra, Ortega, Price, Sheffield, Zedler

0 nays

1 absent — Lucio

WITNESSES: For — (*Registered, but did not testify*: Marina Hench, American Cancer Society Cancer Action Network; Bill Kelberlau; Gregory Young)

Against — None

BACKGROUND: Interested parties have noted that individuals from households with low annual incomes are less likely to participate in cancer clinical trials and that disparities in subject participation undermines equitable access to research benefits among those eligible to participate.

DIGEST: CSHB 3147 would allow independent, third-party organizations to develop and implement a cancer clinical trial participation program. The program would provide reimbursement to subjects for costs associated with participation in a cancer clinical trial, including costs for travel, lodging, parking and tolls, and other costs considered appropriate by the organization.

Program requirements. The program would have to collaborate with physicians and health care providers to notify a prospective subject about the program when:

- the prospective subject provided informed consent for a cancer clinical trial; or
- funding was available to provide the program for the cancer clinical trial in which the prospective subject participated.

The program also would have to reimburse subjects based on financial need, which could include reimbursement to subjects whose incomes were at or below 700 percent of the federal poverty level. The program would have to provide reimbursement for ancillary costs in order to eliminate the financial barriers to enrollment in a clinical trial.

The program could provide reimbursement for reasonable ancillary costs to one family member, friend, or other person who attended a cancer clinical trial to support a subject. The program would have to comply with applicable federal and state laws.

An independent, third-party organization that administered the program would have to provide written notice to prospective subjects of the requirements of the cancer clinical trial participation program.

Reimbursement requirements. A reimbursement under the program would have to be reviewed and approved by the institutional review board (IRB) associated with the cancer clinical trial for which the reimbursement was provided and would have to comply with applicable federal and state laws.

An independent, third-party organization operating the program would not have to obtain approval from an IRB on the financial eligibility of a subject who was medically eligible for the program. The organization would be required to provide notice to a subject on the nature and availability of the ancillary financial support under the program and the program's general financial eligibility guidelines.

Inducement. Reimbursement of ancillary costs under the bill would not constitute an inducement to participate in a cancer clinical trial and would not be considered coercion or the exertion of undue influence to participate in a cancer clinical trial. Reimbursement would be meant to accomplish parity in access to cancer clinical trials and to remove barriers to participation in cancer clinical trials for financially burdened subjects.

Funding. An organization that administered the program could accept gifts, grants, and donations from any public or private source to implement this bill's provisions.

Collaboration. An organization that administered the program could collaborate with the Cancer Prevention and Research Institute of Texas to provide reimbursement under the program.

The bill would allow a person awarded money from the cancer prevention and research fund or from 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 would take effect September 1, 2019.