Rep. Monica Bristow

Adopted in House Comm. on Oct 28, 2019

AMENDMENT TO SENATE BILL 1711

AMENDMENT NO. _____. Amend Senate Bill 1711 by replacing everything after the enacting clause with the following:

"Section 1. Short title. This Act may be cited as the Cancer Clinical Trial Participation Program Act.

Section 5. Findings. The General Assembly finds that:

(1) The ability to translate medical findings from research to practice relies largely on robust subject participation and a diverse subject participation pool in clinical trials.

(2) Diverse subject participation in cancer clinical trials depends significantly on whether an individual is able to afford ancillary costs, including transportation and lodging, during the course of participation in a cancer clinical trial.

(3) A national study conducted in 2015 found that

individuals from households with an annual income of less than $50,000 were 30% less likely to participate in cancer clinical trials.

(4) Direct and indirect costs, including transportation, lodging, and child-care expenses, prevent eligible individuals from participating in cancer clinical trials according to the National Cancer Institute.

(5) The disparities in subject participation in cancer clinical trials threaten the basic ethical underpinning of clinical research, which requires the benefits of the research to be made available equitably among all eligible individuals.

(6) While the United States Food and Drug Administration recently confirmed to Congress and provided guidance on its website that reimbursement of direct subject-incurred expenses is not an undue inducement, many organizations, research sponsors, philanthropic individuals, charitable organizations, governmental entities, and other persons still operate under the misconception that such reimbursement is an undue inducement.

(7) It is the intent of the General Assembly to enact legislation to further define and establish a clear difference between items considered to be an undue inducement for a subject to participate in a cancer clinical trial and the reimbursement of expenses for

participating in a cancer clinical trial.

(8) Further clarification of the United States Food and Drug Administration's confirmation and guidance is appropriate and important to improve subject participation in cancer clinical trials, which is the primary intent of this legislation.

Section 10. Definitions. In this Act:

"Cancer clinical trial" means a research study that subjects an individual to a new cancer treatment, including a medication, chemotherapy, adult stem cell therapy, or other treatment.

"Cancer clinical trial sponsor" means a person, physician, professor, or researcher who initiates a cancer clinical trial; a government entity or agency that initiates a cancer clinical trial; or an industry, including, but not limited to, a pharmaceutical, biotechnology, or medical device company, that initiates a cancer clinical trial.

"Independent third-party organization" means an entity or organization, whether public or private, that is not a sponsor or host of a cancer clinical trial, or in any way directly affiliated with a sponsor or host of a cancer clinical trial, and has experience in patient advocacy and direct patient reimbursement of cancer clinical trial participation costs.

"Inducement" means providing a person something of value, including money, as part of participation in a clinical trial.

"Program" means the cancer clinical trial participation program established under this Act.

"Subject" means an individual who participates in the program.

"Undue inducement" means the value of something received by a potential clinical trial research subject, which value is so large that it causes the research subject to take risks that are not in his or her best interests.

Section 15. Establishment. An independent third-party organization may develop and implement the cancer clinical trial participation program to provide reimbursement to subjects for ancillary costs associated with participation in a cancer clinical trial, including costs for:

(1) travel;

(2) lodging;

(3) parking and tolls; and

(4) other costs considered appropriate by the organization.

Section 20. Requirements; notice.

(a) The program:

(1) must collaborate with physicians, health care providers, and cancer clinical trial sponsors to notify a prospective subject about the program when:

(A) the prospective subject consents to a cancer

clinical trial; or

(B) funding is available to provide the program for the cancer clinical trial in which the prospective subject participates;

(2) must reimburse subjects based on financial need, which may include reimbursement to subjects whose income is at or below 700% of the federal poverty level;

(3) must provide reimbursement for ancillary costs, including costs described under Section 15, to eliminate the financial barriers to enrollment in a cancer clinical trial;

(4) may provide reimbursement for reasonable ancillary costs, including costs described under Section 15, to one family member, friend, or other person who attends a cancer clinical trial to support a subject; and

(5) must comply with applicable federal and State laws.

(b) The independent third-party organization administering the program shall provide written notice to prospective subjects of the requirements described under subsection (a).

Section 25. Reimbursement requirements; notice.

(a) A reimbursement under the program at a trial site that conducts cancer clinical trials must:

(1) be reviewed and approved by the institutional review board associated with the cancer clinical trial for which the reimbursement is provided; and

(2) comply with applicable federal and State laws.

(b) The independent third-party organization operating the program is not required to obtain approval from an institutional review board on the financial eligibility of a subject who is medically eligible for a cancer clinical trial.

(c) The independent third-party organization operating the program shall provide written notice to a subject on:

(1) the nature and availability of the ancillary financial support under the program; and

(2) the program's general guidelines on financial eligibility.

Section 30. Reimbursement status as undue inducement. Reimbursement to a subject of ancillary costs under the program:

(1) does not constitute an undue inducement to participate in a cancer clinical trial;

(2) is not considered coercion or the exertion of undue influence to participate in a cancer clinical trial; and

(3) is meant to accomplish parity in access to cancer clinical trials and remove barriers to participation in cancer clinical trials for financially burdened subjects.

Section 35. Funding. The independent third-party organization that administers the program may accept gifts, grants, and donations from any public or private source to

implement this Act.

Section 99. Effective date. This Act takes effect upon becoming law.".