By Senator Simmons

9-00940-20 2020840__

A bill to be entitled

An act relating to cancer clinical trials; creating s. 385.2021, F.S.; providing legislative findings and intent; defining terms; requiring cancer clinical trial programs to inform prospective patient subjects of specified reimbursements for ancillary and travel expenses which may be available to them and their caregivers if they participate in a cancer clinical trial; specifying that reimbursement offers may not be coercive or exert an undue influence and are not considered inducements for participation; authorizing corporations, individuals, public and private foundations, health care providers, and other stakeholders to offer financial assistance to support approved reimbursements of ancillary and travel expenses for patient subjects in a cancer clinical trial and their caregivers; requiring certain entities that offer reimbursement programs to secure the informed consent of patient subjects; requiring that a patient subject be informed of financial eligibility guidelines and the reimbursement process; providing that participation in a cancer clinical trial may not begin without such informed consent; requiring the Department of Health to review certain reimbursement programs; requiring the department to approve programs that meet certain criteria; requiring the department to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 385.2021, Florida Statutes, is created to read:

385.2021 Cancer clinical trials; communication with prospective patients; offers to reimburse.—

(1) LEGISLATIVE FINDINGS AND INTENT.—

(a) The Legislature finds that:

1. The ability to translate medical findings from research to practice relies on having robust and diverse patient participation in cancer clinical trials. Low participation rates or homogenous participant groups prevent segments of the population from benefiting from advances achieved through clinical research and create uncertainties regarding the applicability of research findings. Diverse patient participation in cancer clinical trials depends on the ability of prospective participants to afford ancillary expenses during the course of participation, a financial challenge that prevents the benefits of clinical research from being equitably accessible by eligible prospective participants.

2. Cancer clinical trials do not cover all of participants' expenses, and there are often significant uncovered expenses associated with enrollment in a clinical trial. These expenses may include travel expenses to and from clinical sites, such as parking fees, car rentals, fuel, tolls, or lodging, and the expenses incurred by the patient subject's family, friends, or individuals who attend cancer clinical trial treatments as caregivers to provide emotional, physical, and mental support to the patient subject.

3. The United States Food and Drug Administration has

confirmed that reimbursement of direct patient-incurred expenses is a means to create equal access among potential clinical trial subjects and is not considered an inducement. Despite the United States Food and Drug Administration's guidance issued to clarify what constitutes an inducement, a fear of unknowingly violating federal prohibitions against inducements has unintentionally hindered the participation in and expansion of cancer clinical trials. Corporations, individuals, public and private foundations, health care providers, and other stakeholders remain hesitant to contribute to or accept funds from programs that are established to alleviate the financial burdens of patients who wish to participate in clinical trials and their caregivers.

(b) It is the intent of the Legislature to:

1. Enact legislation to distinguish between what may be considered an inducement for a patient to participate and the reimbursement of actual expenses associated with participation in a cancer clinical trial.

2. Increase enrollment and retention of minority patient subjects in cancer clinical trials.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Cancer clinical trial" means a research study that tests new cancer treatments on individuals. Treatments tested may include medications, chemotherapies, stem cell therapies, and similar treatments.

(b) "Inducement" means paying money to an individual in exchange for his or her participation in a cancer clinical trial.

(c) "Patient subject" means an individual participating in

a cancer clinical trial.

(3) COMMUNICATION WITH PROSPECTIVE PATIENTS; OFFERS TO REIMBURSE.—

(a) Cancer clinical trial programs shall inform prospective patient subjects before their participation in a cancer clinical trial that:

1. Reimbursement for travel and ancillary expenses is available to all patient subjects based on financial need;

2. Reimbursement for travel and ancillary expenses is offered to eliminate the financial barriers to participation and to help retain patient subjects in clinical trials; and

3. Family, friends, or individuals who attend cancer clinical trial treatments as caregivers to support the patient subject are eligible for reimbursement for travel and ancillary expenses.

(b) The offer to reimburse travel and ancillary expenses may not be coercive or exert an undue influence on a patient subject or a potential patient subject and, in the absence of such coercion or exertion of undue influence, is not considered an inducement for participation in a cancer clinical trial.

(4) REIMBURSEMENT PROGRAMS.—

(a) Subject to applicable federal laws and this section, corporations, individuals, public and private foundations, health care providers, and other stakeholders may offer financial support to cover ancillary expenses through their support of reimbursement programs offered by third-party nonprofit corporations and public charities to increase the enrollment and retention of minority patient subjects in cancer clinical trials.

(b) A third-party nonprofit corporation or public charity that offers a reimbursement program under this subsection shall implement a process for securing the informed consent of patient subjects. A patient subject must be informed of financial eligibility guidelines and the reimbursement process. A patient subject may not begin his or her participation in a cancer clinical trial in the absence of a declaration of such informed consent.

(c) The Department of Health shall review reimbursement programs offered by third-party nonprofit corporations and public charities to cover ancillary and travel expenses of patient subjects and their caregivers. If the department determines that patient subjects are fairly recruited and adequately informed in a manner that is consistent with federal regulations and guidance and that ancillary and travel expenses are appropriate, it must approve such programs.

(5) RULEMAKING.—The department shall adopt rules to administer this section.

Section 2. This act shall take effect July 1, 2020.