State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-4372/1
CMH:cdc

2019 SENATE BILL 489

AN ACT ***to create*** 146.348 of the statutes; **relating to:** allowing reimbursement of certain expenses for patients participating in cancer clinical trials.

Analysis by the Legislative Reference Bureau

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 146.348 of the statutes is created to read:

146.348 Reimbursement in cancer clinical trial programs. (1) In this section:

(a) "Cancer clinical trial" means a research study that tests a new cancer treatment regimen on patients, including chemotherapy and other new treatments.

(b) "Inducement" means paying a person money, including a lump sum or salary payment, to participate in a cancer clinical trial.

(c) "Patient-subject" means a person participating in a cancer clinical trial.

(2) All sponsors of cancer clinical trials shall provide potential patient–subjects at the time of the informed consent process the following information:

(a) Whether reimbursement for travel and ancillary costs may be available to patient–subjects.

(b) That coverage of the travel and ancillary costs is done to eliminate financial barriers to enrollment in order to retain patient–subjects in the cancer clinical trial.

(c) Whether family members, friends, or chaperones who attend the cancer clinical trial treatments to support the patient–subject may be eligible for reimbursement of their travel and ancillary costs.

(3) (a) Reimbursement of travel, ancillary costs, and other direct patient–incurred expenses related to cancer clinical trial participation will not be considered an undue inducement to participate in a cancer clinical trial.

(b) Reimbursement for travel and ancillary costs may not be considered coercive or as exerting undue influence to participate in a cancer clinical trial, but rather shall be considered a means to create parity in cancer clinical trial access and remove a barrier to participation for financially burdened patient–subjects.

(c) Government, industry, public charities, private foundations and other nonprofit organizations, associations, corporations and other business entities, individuals, and any other legal or commercial entities may offer financial support to patient–subjects, or the family, friends, or chaperones of patient–subjects, to cover ancillary costs through their support of a reimbursement entity or program.

(4) (a) Language informing patient–subjects that reimbursement entities or programs that cover travel, ancillary costs, and other direct patient–incurred expenses may be available must be submitted for review to the relevant federally designated institutional review board in conjunction with the review of a proposed

cancer clinical trial and included in the informed consent form approved by the institutional review board.

(b) A reimbursement entity or program must disclose the nature of the ancillary support and general guidelines on financial eligibility to interested patient–subjects and employ a reimbursement process that conforms to federal law and guidance.

SECTION 2. Nonstatutory provisions.

(1) LEGISLATIVE INTENT STATEMENT. It is the intent of the legislature to define and establish a clear difference between what is considered undue inducement for a patient to participate in a cancer clinical trial and direct reimbursement of patient–incurred expenses for participating in a cancer clinical trial.

(2) LEGISLATIVE FINDINGS. The legislature finds all of the following:

(a) The ability to translate medical findings from research to practice relies largely on having robust and diverse patient participation in cancer clinical trials.

(b) A low participation rate or a homogenous participant group prevents segments of the population from benefiting from advances achieved through clinical research and creates uncertainties over the applicability of research findings.

(c) Diverse patient participation in cancer clinical trials depends, in part, on whether a participant can afford ancillary medical and other costs, including transportation for clinical visits required by cancer clinical trial participation, which are not covered by standard of care, or lodging during the course of his or her participation.

(d) Another barrier to cancer clinical trial participation is the costs of travel, lodging, and other expenses for a patient–subject's travel companion, including a family member, friend, health care provider, or chaperone who attends cancer

clinical trial treatments to provide emotional, physical, and mental support to the patient–subject. Some patient–subjects are too old, too young, or too ill to simply travel on their own.

(e) Cancer clinical trials often cover only the actual costs of the drug being tested and very rarely the direct costs of participation by a patient–subject. There are often significant expenses associated with enrollment in a cancer clinical trial that are not covered by the cancer clinical trial site or sponsor. These include travel expenses to and from the clinical sites whether by air, car, bus, train, taxi, or other public transportation, along with the travel costs of parking, car rental, gas, tolls, and lodging.

(f) According to the National Cancer Institute, Cancer Clinical Trials Resource Guide, some of the barriers preventing individuals, with cancer or at high risk of developing cancer, from participating in cancer clinical trials are direct and indirect financial and personal costs, including travel.

(g) Some corporations, individuals, public and private foundations, health care providers, and other stakeholders are hesitant to contribute to or accept funds from programs that are organized to alleviate financial burdens faced by patients who wish to participate in cancer clinical trials and their caregivers due to concerns that the federal food and drug administration or other federal regulators would view the payments made from those funds as prohibited inducements for patients to receive the health care services provided during cancer clinical trials.

(h) While the federal food and drug administration recently confirmed to Congress and provided guidance that, in fact, reimbursement of direct patient–incurred expenses is not undue inducement, many organizations, pharmaceutical companies, philanthropic individuals, charitable organizations, and

government entities still operate with the understanding that such reimbursement could be, in fact, considered undue inducement.

(END)