

By Senator Simmons

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1                   A bill to be entitled  
2       An act relating to cancer clinical trials; creating s.  
3       385.2021, F.S.; providing legislative findings and  
4       intent; providing definitions; requiring cancer  
5       clinical trial programs to inform potential  
6       participants of the specified reimbursements for  
7       ancillary costs and travel expenses which may be  
8       available to them if they participate in a cancer  
9       clinical trial; authorizing corporations, individuals,  
10      public and private foundations, health care providers,  
11      and other stakeholders to offer financial assistance  
12      to support approved reimbursements of ancillary costs  
13      and travel expenses for participants in a cancer  
14      clinical trial; requiring the Department of Health to  
15      use specified criteria in reviewing and approving  
16      ancillary costs and travel expense reimbursements;  
17      authorizing the department to adopt rules; providing  
18      an effective date.

19  
20 Be It Enacted by the Legislature of the State of Florida:

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

24       385.2021 Legislative intent.—

25       (1) FINDINGS AND PURPOSE.—The Legislature finds and  
26 declares the following:

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

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30 rate or a homogenous participant group prevents segments of the  
31 population from benefiting from advances achieved through  
32 clinical research and creates uncertainties over the  
33 applicability of research findings. Diverse patient  
34 participation in cancer clinical trials depends on the ability  
35 of potential participants to afford ancillary costs during their  
36 course of participation, which prevents the benefits of clinical  
37 research from being equitably accessible among eligible  
38 potential participants.

39 (b) Cancer clinical trials do not cover all of the costs of  
40 participants, and there are often significant uncovered expenses  
41 associated with enrollment in a clinical trial. These expenses  
42 may include travel expenses to and from clinical sites, such as  
43 parking fees, car rental, gas, tolls, or lodging; fees for child  
44 care; and the expenses of the patient's family, friends, or  
45 chaperones who attend cancer clinical trial treatments to  
46 provide emotional, physical, and mental support to the  
47 participant.

48 (c) Some corporations, individuals, public and private  
49 foundations, health care providers, and other stakeholders are  
50 hesitant to contribute to or accept funds from programs that are  
51 organized to alleviate the financial burdens of patients who  
52 wish to participate in clinical trials and their caregivers.  
53 Federal regulations prohibiting inducements have unintentionally  
54 hindered the involvement and expansion of cancer clinical  
55 trials.

56 (d) It is the intent of the Legislature to enact  
57 legislation to distinguish between what may be considered an  
58 inducement for a patient to participate and the reimbursement of

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59 actual expenses associated with participation in a cancer  
60 clinical trial.

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

62 (a) "Cancer clinical trials" means research studies that  
63 test new cancer treatments on persons. Testing may include  
64 medications, chemotherapies, stem cell therapies, and similar  
65 treatments.

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

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

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

71 (a) Cancer clinical trial programs shall inform potential  
72 participants before their involvement in a cancer clinical trial  
73 that:

74 1. Reimbursement for travel and ancillary costs is  
75 available to all enrollees based on financial need;

76 2. Coverage of the travel and ancillary costs is offered to  
77 eliminate the financial barriers of enrollment in order to  
78 retain participants in clinical trials; and

79 3. Family, friends, or chaperones that attend the cancer  
80 clinical trial treatments to support the patient subject are  
81 eligible for reimbursement for their travel and ancillary  
82 expenses.

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

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88       (4) REIMBURSEMENT PROGRAMS.-

89       (a) Subject to applicable federal laws and this section,  
90 corporations, individuals, public and private foundations,  
91 health care providers, and other stakeholders may offer  
92 financial support to cover ancillary costs through their support  
93 of reimbursement programs offered by third-party nonprofit  
94 corporations and public charities to increase enrollment,  
95 retention, and minority participation in cancer clinical trials.

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

104       (c) The Department of Health shall review reimbursement  
105 programs offered by such nonprofit corporations and public  
106 charities to cover ancillary costs and travel expenses. If the  
107 department determines that patient subjects are fairly recruited  
108 and adequately informed and that ancillary costs and travel  
109 expenses are appropriate, it shall approve such programs.

110       (6) The department shall adopt rules to administer this  
111 section.

112       Section 2. This act shall take effect July 1, 2017.