

Senate Bill 223

By: Senators Watson of the 1st, Tillery of the 19th, Brass of the 28th, Hufstetler of the 52nd, Robertson of the 29th and others

AS PASSED

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 1 of Title 31 of the Official Code of Georgia Annotated, relating to
2 general provisions regarding health, so as to authorize reimbursement of patient incurred
3 expenses related to participation in a cancer clinical trial; to provide for definitions; to require
4 certain information to be provided to potential participants during the informed consent
5 process; to provide that reimbursement shall not be considered undue inducement; to provide
6 for review of information provided to potential participants to be reviewed by the relevant
7 federally designated institutional review board; to require disclosure of ancillary support; to
8 provide for related matters; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 **SECTION 1.**

11 Chapter 1 of Title 31 of the Official Code of Georgia Annotated, relating to general
12 provisions regarding health, is amended by adding a new Code section to read as follows:

13 "31-1-25.

14 (a) As used in this Code section, the term:

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

17 (2) 'Inducement' means paying a person money, including a lump sum or salary payment,
18 to participate in a cancer clinical trial.

19 (3) 'Patient-subject' means a person participating in a cancer clinical trial.

20 (b) All sponsors of cancer clinical trials shall provide potential patient-subjects at the time
21 of the informed consent process the following information:

22 (1) Whether reimbursement for travel and ancillary costs may be available to
23 patient-subjects;

24 (2) That coverage of the travel and ancillary costs is provided to eliminate financial
25 barriers to enrollment in order to retain patient-subjects in the cancer clinical trial; and

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

29 (c)(1) Reimbursement of travel, ancillary costs, and other direct patient incurred
30 expenses related to cancer clinical trial participation shall not be considered an undue
31 inducement for participation in a cancer clinical trial.

32 (2) Reimbursement for travel and ancillary costs shall not be considered coercive or as
33 exerting undue influence for participation in a cancer clinical trial, but rather, shall be
34 considered a means to create parity in cancer clinical trial access and remove a barrier to
35 participation for financially burdened patient-subjects.

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

41 (d)(1) Language informing patient-subjects that reimbursement entities or programs that
42 cover travel, ancillary costs, and other direct patient incurred expenses may be available
43 shall be submitted for review to the relevant federally designated institutional review

44 board in conjunction with the review of a proposed cancer clinical trial and included in
45 the informed consent form approved by the institutional review board.

46 (2) A reimbursement entity or program shall disclose the nature of the ancillary support
47 and general guidelines on financial eligibility to interested patient-subjects and shall
48 employ a reimbursement process that conforms to federal law and guidance."

49 **SECTION 2.**

50 All laws and parts of laws in conflict with this Act are repealed.