HOUSE . . . . . No. 4211

The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES, November 19, 2019.

The committee on Public Health to whom was referred the petition (accompanied by bill, House, No. 1933) of Hannah Kane and others for legislation to improve patient access to cancer clinical trial programs, reports recommending that the accompanying bill (House, No. 4211) ought to pass.

For the committee,

JOHN J. MAHONEY.

FILED ON: 11/15/2019

HOUSE . . . . . No. 4211

The Commonwealth of Massachusetts

In the One Hundred and Ninety-First General Court
(2019-2020)

An Act to improve patient access to cancer clinical trial programs.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 111 of the General Laws, as appearing in the 2018 Official Edition, is hereby amended by adding the following section:-

Section 238. (a) As used in this section, the following words shall have the following meanings:

"Cancer clinical trials", research studies that test new cancer treatments on people, including but not limited to, medications, chemotherapies, stem cell therapies, and other treatments.

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

"Subject", a person who participates in a cancer clinical trial.

"Travel and ancillary costs", any reasonable costs incurred by a person in connection with their participation in a cancer clinical trial, including but not limited to travel and lodging expenses.

(b) (i) Reimbursement of a subject's travel and ancillary costs shall not be deemed an inducement or as exerting undue influence to participate in a cancer clinical trial.

(ii) A sponsor of a cancer clinical trial shall inform potential subjects at the time informed consent is provided if:

(A) Reimbursement for travel and ancillary costs is available to subjects based on financial need;

(B) Reimbursement of travel and ancillary costs is provided to eliminate financial barriers to enrollment in order to retain subjects in the clinical trial; and

(C) Family, friends, or chaperones that attend the cancer clinical trial treatments to support the subject are eligible for reimbursement of their reasonable travel and ancillary expenses.

(c) Governmental entities, study sponsors, public and private foundations, corporations, and individuals may offer financial support to cover travel and ancillary costs through their support of third party nonprofit corporations and public charities that seek to increase enrollment, retention, and minority participation in cancer clinical trials.

(d) Reimbursement programs to cover travel and ancillary costs must be reviewed and approved by the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) of a health care facility in conjunction with the review of the proposed cancer clinical trial. The

nature of the support for travel and ancillary costs and general guidelines on financial eligibility must be disclosed to subjects. The reimbursement process must conform to state and federal laws and guidance.