STATE OF NEW YORK

180--A

2021-2022 Regular Sessions

IN ASSEMBLY

(Prefiled)

January 6, 2021

Introduced by M. of A. GOTTFRIED, PAULIN, GUNTHER, L. ROSENTHAL, CAHILL, GALEF, ENGLEBRIGHT, ZEBROWSKI, LUPARDO, ABINANTI, WEPRIN, SAYEGH, SALKA, SEAWRIGHT -- Multi-Sponsored by -- M. of A. CARROLL -- read once and referred to the Committee on Health -- reported and referred to the Committee on Ways and Means -- recommitted to the Committee on Ways and Means in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to establishing the clinical trial access and education fund

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The public health law is amended by adding a new section 2424 to read as follows:

§ 2424. Clinical trial access and education fund. 1. Definitions. For the purposes of this section, the following terms shall have the following meanings:

a. "Eligible applicant" means (i) a medical school that sponsors a clinical trial, (ii) a not-for-profit organization with experience and expertise working with patients with life-threatening or disabling conditions or diseases, (iii) a health care provider organization, association or society, (iv) a general hospital defined in article twenty-eight of this chapter, (v) a county or city health department, or (vi) a municipality.

b. "Clinical trial" shall have the same meaning as in subdivision two-b of section forty-nine hundred of this chapter.

c. "Ancillary costs" means costs associated with participation in a clinical trial, including but not limited to costs for:

(i) travel;

(ii) lodging;

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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(iii) parking and tolls;

(iv) a travel companion to assist patients who are elderly, very young, or too ill to travel alone; and

(v) other costs considered appropriate jointly by the department, the service providing organization and the trial site.

2. Establishment of fund. There is hereby established within the department a clinical trial access and education fund. Subject to appropriations, the department shall provide grants to eligible applicants on a competitive request for proposal basis to provide one or more of the following services to patients with life-threatening or disabling conditions or diseases, as such terms are defined in section forty-nine hundred of this chapter, to facilitate access to or education on clinical trials of treatments for the patient's condition or disease:

a. transportation services and lodging to provide patients with access to clinical trials or other related treatments while enrolled in a clinical trial or to access testing and other services to determine patient eligibility for a clinical trial;

b. patient outreach and education services to educate patients, their families and health care providers about the existence of and how patients may enroll in clinical trials, under section two hundred seven of this chapter; and

c. patient navigation services to help patients to determine if they are eligible for clinical trials, to help patients to enroll in clinical trials and to assist patients in dealing with insurance or other issues which serve as barriers to patient enrollment in clinical trials.

3. Applications. a. The commissioner shall establish an application process by which eligible applicants may apply for a grant under this section. The application shall include:

(i) the geographic area in which the services shall be provided;

(ii) a detailed description of the services to be provided;

(iii) applicant's experience working with patients with life-threatening or disabling conditions or diseases;

(iv) applicant's ability to provide patient outreach or clinical trial education and navigation services, or coordinate or provide transportation and lodging for patients; and

(v) any other information that the commissioner deems relevant and appropriate.

b. Eligible applicants shall:

(i) have experience and expertise working with patients with life-threatening or disabling conditions or diseases;

(ii) provide patient outreach, education and health care navigation services;

(iii) collaborate with physicians, health care providers, and clinical trial sponsors to notify a prospective subject about the program when:

(1) the prospective subject consents to a clinical trial; and

(2) funding is available to provide the program for the clinical trial in which the prospective subject participates; and

(iv) reimburse subjects based on financial need to subjects whose income is at or below seven hundred percent of the federal poverty level, which shall include reimbursement for reasonable ancillary costs.

4. Institutional review board requirements. A reimbursement program under this section shall:

a. be approved by the institutional review board associated with the clinical trial; and

b. comply with applicable federal and state laws.

5. Reimbursement. Reimbursement to a subject of ancillary costs under the program:

a. does not constitute an undue inducement to participate in a clinical trial;

b. is not considered coercion or the exertion of undue influence to participate in a clinical trial; and

c. is meant to accomplish parity in access to clinical trials and remove barriers to participation in clinical trials for financially burdened subjects.

6. Reports. Grantees shall file an annual report with the commissioner, in such form and with such information and data as the commissioner prescribes detailing the expenditure of grant funds and summarizing the efforts undertaken to increase patient access to clinical trials.

7. Regulations. The commissioner shall make regulations reasonably necessary to implement the provisions of this section.

§ 2. This act shall take effect immediately.