

STATE OF NEW YORK

1169--A

2021-2022 Regular Sessions

IN SENATE

January 7, 2021

Introduced by Sens. RIVERA, SEPULVEDA -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- reported favorably from said committee and committed to the Committee on Finance -- 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;

(iii) parking and tolls;

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

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

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

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

11 a. transportation services and lodging to provide patients with access
12 to clinical trials or other related treatments while enrolled in a clin-
13 ical trial or to access testing and other services to determine patient
14 eligibility for a clinical trial;

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

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

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

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

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

28 (iii) applicant's experience working with patients with life-threaten-
29 ing or disabling conditions or diseases;

30 (iv) applicant's ability to provide patient outreach or clinical trial
31 education and navigation services, or coordinate or provide transporta-
32 tion and lodging for patients; and

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

35 b. Eligible applicants shall:

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

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

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

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

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

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

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

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

52 b. comply with applicable federal and state laws.

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

55 a. does not constitute an undue inducement to participate in a clin-
56 ical trial;

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

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

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

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

12 § 2. This act shall take effect immediately.