

STATE OF NEW YORK

4793

2023-2024 Regular Sessions

IN SENATE

February 14, 2023

Introduced by Sens. RIVERA, SEPULVEDA -- read twice and ordered printed,
and when printed to be committed to the Committee on Health

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 Assem-
bly, do enact as follows:

1 Section 1. The public health law is amended by adding a new section
2 2424 to read as follows:

3 § 2424. Clinical trial access and education fund. 1. Definitions. For
4 the purposes of this section, the following terms shall have the follow-
5 ing meanings:

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

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

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

17 (i) travel;

18 (ii) lodging;

19 (iii) parking and tolls;

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

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

24 2. Establishment of fund. There is hereby established within the
25 department a clinical trial access and education fund. Subject to appro-

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

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1 priations, the department shall provide grants to eligible applicants on
2 a competitive request for proposal basis to provide one or more of the
3 following services to patients with life-threatening or disabling condi-
4 tions or diseases, as such terms are defined in section forty-nine
5 hundred of this chapter, to facilitate access to or education on clin-
6 ical trials of treatments for the patient's condition or disease:

7 a. transportation services and lodging to provide patients with access
8 to clinical trials or other related treatments while enrolled in a clin-
9 ical trial or to access testing and other services to determine patient
10 eligibility for a clinical trial;

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

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

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

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

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

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

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

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

31 b. Eligible applicants shall:

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

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

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

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

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

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

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

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

48 b. comply with applicable federal and state laws.

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

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

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

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

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

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

10 § 2. This act shall take effect immediately.