

4492

2009-2010 Regular Sessions

I N S E N A T E

April 24, 2009

Introduced by Sens. DUANE, HASSELL-THOMPSON -- 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 ASSEMBLY, 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 S 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
11 TWENTY-EIGHT OF THIS CHAPTER, (V) A COUNTY OR CITY HEALTH DEPARTMENT, OR
12 (VI) A 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 2. ESTABLISHMENT OF FUND. THERE IS HEREBY ESTABLISHED WITHIN THE
16 DEPARTMENT A CLINICAL TRIAL ACCESS AND EDUCATION FUND. SUBJECT TO APPRO-
17 PRIATIONS, THE DEPARTMENT SHALL PROVIDE GRANTS TO ELIGIBLE APPLICANTS ON
18 A COMPETITIVE REQUEST FOR PROPOSAL BASIS TO PROVIDE ONE OR MORE OF THE
19 FOLLOWING SERVICES TO PATIENTS WITH LIFE-THREATENING OR DISABLING CONDI-
20 TIONS OR DISEASES, AS SUCH TERMS ARE DEFINED IN SECTION FORTY-NINE
21 HUNDRED OF THIS CHAPTER, TO FACILITATE ACCESS TO OR EDUCATION ON CLIN-
22 ICAL TRIALS OF TREATMENTS FOR THE PATIENT'S CONDITION OR DISEASE:

23 A. TRANSPORTATION SERVICES AND LODGING TO PROVIDE PATIENTS WITH ACCESS
24 TO CLINICAL TRIALS OR OTHER RELATED TREATMENTS WHILE ENROLLED IN A CLIN-

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

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1 ICAL TRIAL OR TO ACCESS TESTING AND OTHER SERVICES TO DETERMINE PATIENT
2 ELIGIBILITY FOR A CLINICAL TRIAL;

3 B. PATIENT OUTREACH AND EDUCATION SERVICES TO EDUCATE PATIENTS, THEIR
4 FAMILIES AND HEALTH CARE PROVIDERS ABOUT THE EXISTENCE OF AND HOW
5 PATIENTS MAY ENROLL IN CLINICAL TRIALS, UNDER SECTION TWO HUNDRED SEVEN
6 OF THIS CHAPTER; AND

7 C. PATIENT NAVIGATION SERVICES TO HELP PATIENTS TO DETERMINE IF THEY
8 ARE ELIGIBLE FOR CLINICAL TRIALS, TO HELP PATIENTS TO ENROLL IN CLINICAL
9 TRIALS AND TO ASSIST PATIENTS IN DEALING WITH INSURANCE OR OTHER ISSUES
10 WHICH SERVE AS BARRIERS TO PATIENT ENROLLMENT IN CLINICAL TRIALS.

11 3. APPLICATIONS. THE COMMISSIONER SHALL ESTABLISH AN APPLICATION PROC-
12 ESS BY WHICH ELIGIBLE APPLICANTS MAY APPLY FOR A GRANT UNDER THIS
13 SECTION. THE APPLICATION SHALL INCLUDE:

14 A. THE GEOGRAPHIC AREA IN WHICH THE SERVICES SHALL BE PROVIDED;

15 B. A DETAILED DESCRIPTION OF THE SERVICES TO BE PROVIDED;

16 C. APPLICANT'S EXPERIENCE WORKING WITH PATIENTS WITH LIFE-THREATENING
17 OR DISABLING CONDITIONS OR DISEASES;

18 D. APPLICANT'S ABILITY TO PROVIDE PATIENT OUTREACH OR CLINICAL TRIAL
19 EDUCATION AND NAVIGATION SERVICES, OR COORDINATE OR PROVIDE TRANSPORTA-
20 TION AND LODGING FOR PATIENTS; AND

21 E. ANY OTHER INFORMATION THAT THE COMMISSIONER DEEMS RELEVANT AND
22 APPROPRIATE.

23 THE COMMISSIONER SHALL GIVE PREFERENCE TO ELIGIBLE APPLICANTS WHO HAVE
24 EXPERIENCE AND EXPERTISE WORKING WITH PATIENTS WITH LIFE-THREATENING OR
25 DISABLING CONDITIONS OR DISEASES AND PROVIDING PATIENT OUTREACH, EDUCA-
26 TION AND HEALTH CARE NAVIGATION SERVICES.

27 4. REPORTS. GRANTEEES SHALL FILE AN ANNUAL REPORT WITH THE COMMISSION-
28 ER, IN SUCH FORM AND WITH SUCH INFORMATION AND DATA AS THE COMMISSIONER
29 PRESCRIBES DETAILING THE EXPENDITURE OF GRANT FUNDS AND SUMMARIZING THE
30 EFFORTS UNDERTAKEN TO INCREASE PATIENT ACCESS TO CLINICAL TRIALS.

31 5. THE COMMISSIONER SHALL MAKE REGULATIONS REASONABLY NECESSARY TO
32 IMPLEMENT THE PROVISIONS OF THIS SECTION.

33 S 2. This act shall take effect immediately.