2688

2013-2014 Regular Sessions

IN ASSEMBLY

January 17, 2013

Introduced by M. of A. GOTTFRIED, PAULIN, JACOBS, GUNTHER, ROSENTHAL, CAHILL, GALEF, ENGLEBRIGHT, MILLMAN, JAFFEE, ZEBROWSKI, MAISEL, HOOP-ER, LUPARDO, SCHIMEL, TITONE, CASTRO, KELLNER, BROOK-KRASNY, ABINANTI -- read once and referred 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 "ELIGIBLE APPLICANT" MEANS (I) A MEDICAL SCHOOL THAT SPONSORS A Α. 7 CLINICAL TRIAL, (II) A NOT-FOR-PROFIT ORGANIZATION WITH EXPERIENCE AND 8 EXPERTISE WORKING WITH PATIENTS WITH LIFE-THREATENING OR DISABLING CONDITIONS OR DISEASES, (III) A HEALTH CARE PROVIDER ORGANIZATION, ASSO-9 10 CIATION OR SOCIETY, (IV) A GENERAL HOSPITAL DEFINED IN ARTICLE TWENTY-EIGHT OF THIS CHAPTER, (V) A COUNTY OR CITY HEALTH DEPARTMENT, OR 11 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 DEPARTMENT A CLINICAL TRIAL ACCESS AND EDUCATION FUND. SUBJECT TO APPRO-16 17 PRIATIONS, THE DEPARTMENT SHALL PROVIDE GRANTS TO ELIGIBLE APPLICANTS ON COMPETITIVE REQUEST FOR PROPOSAL BASIS TO PROVIDE ONE OR MORE OF THE 18 А FOLLOWING SERVICES TO PATIENTS WITH LIFE-THREATENING OR DISABLING CONDI-19 TIONS OR DISEASES, AS SUCH TERMS ARE DEFINED IN SECTION FORTY-NINE 20 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:

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

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A. TRANSPORTATION SERVICES AND LODGING TO PROVIDE PATIENTS WITH ACCESS TO CLINICAL TRIALS OR OTHER RELATED TREATMENTS WHILE ENROLLED IN A CLIN-ICAL TRIAL OR TO ACCESS TESTING AND OTHER SERVICES TO DETERMINE PATIENT ELIGIBILITY FOR A CLINICAL TRIAL;

5 B. PATIENT OUTREACH AND EDUCATION SERVICES TO EDUCATE PATIENTS, THEIR 6 FAMILIES AND HEALTH CARE PROVIDERS ABOUT THE EXISTENCE OF AND HOW 7 PATIENTS MAY ENROLL IN CLINICAL TRIALS, UNDER SECTION TWO HUNDRED SEVEN 8 OF THIS CHAPTER; AND

9 C. PATIENT NAVIGATION SERVICES TO HELP PATIENTS TO DETERMINE IF THEY 10 ARE ELIGIBLE FOR CLINICAL TRIALS, TO HELP PATIENTS TO ENROLL IN CLINICAL 11 TRIALS AND TO ASSIST PATIENTS IN DEALING WITH INSURANCE OR OTHER ISSUES 12 WHICH SERVE AS BARRIERS TO PATIENT ENROLLMENT IN CLINICAL TRIALS.

13 3. APPLICATIONS. THE COMMISSIONER SHALL ESTABLISH AN APPLICATION PROC-14 ESS BY WHICH ELIGIBLE APPLICANTS MAY APPLY FOR A GRANT UNDER THIS 15 SECTION. THE APPLICATION SHALL INCLUDE:

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

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

18 C. APPLICANT'S EXPERIENCE WORKING WITH PATIENTS WITH LIFE-THREATENING 19 OR DISABLING CONDITIONS OR DISEASES;

20 D. APPLICANT'S ABILITY TO PROVIDE PATIENT OUTREACH OR CLINICAL TRIAL 21 EDUCATION AND NAVIGATION SERVICES, OR COORDINATE OR PROVIDE TRANSPORTA-22 TION AND LODGING FOR PATIENTS; AND

23 E. ANY OTHER INFORMATION THAT THE COMMISSIONER DEEMS RELEVANT AND 24 APPROPRIATE.

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

4. REPORTS. GRANTEES SHALL FILE AN ANNUAL REPORT WITH THE COMMISSION80 ER, IN SUCH FORM AND WITH SUCH INFORMATION AND DATA AS THE COMMISSIONER
81 PRESCRIBES DETAILING THE EXPENDITURE OF GRANT FUNDS AND SUMMARIZING THE
82 EFFORTS UNDERTAKEN TO INCREASE PATIENT ACCESS TO CLINICAL TRIALS.

33 5. THE COMMISSIONER SHALL MAKE REGULATIONS REASONABLY NECESSARY TO 34 IMPLEMENT THE PROVISIONS OF THIS SECTION.

35 S 2. This act shall take effect immediately.