S T A T E O F N E W Y O R K

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2013-2014 Regular Sessions

I N A S S E M B L Y

January 17, 2013

Introduced by M. of A. GOTTFRIED, PAULIN, JACOBS, GUNTHER, ROSENTHAL, CAHILL, GALEF, ENGLEBRIGHT, MILLMAN, JAFFEE, ZEBROWSKI, MAISEL, HOOPER, 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:

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

S 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.

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:

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 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. THE COMMISSIONER SHALL ESTABLISH AN APPLICATION PROCESS BY WHICH ELIGIBLE APPLICANTS MAY APPLY FOR A GRANT UNDER THIS 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;

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

D. APPLICANT'S ABILITY TO PROVIDE PATIENT OUTREACH OR CLINICAL TRIAL EDUCATION AND NAVIGATION SERVICES, OR COORDINATE OR PROVIDE TRANSPORTATION AND LODGING FOR PATIENTS; AND

E. ANY OTHER INFORMATION THAT THE COMMISSIONER DEEMS RELEVANT AND 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, EDUCATION AND HEALTH CARE NAVIGATION SERVICES.

4. 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.

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

S 2. This act shall take effect immediately.