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2011-2012 Regular Sessions

I N A S S E M B L Y

(PREFILED)

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Introduced by M. of A. GOTTFRIED, PAULIN, JACOBS, GUNTHER, ROSENTHAL, CAHILL, GALEF, N. RIVERA, ENGLEBRIGHT, MILLMAN, SPANO, JAFFEE, ZEBROWSKI, MAISEL, HOOPER, LUPARDO, SCHIMEL, TITONE, CASTRO, KELLNER, BROOK-KRASNY, SCHROEDER -- 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 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

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

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1 HUNDRED OF THIS CHAPTER, TO FACILITATE ACCESS TO OR EDUCATION ON CLIN-
2 ICAL TRIALS OF TREATMENTS FOR THE PATIENT'S CONDITION OR DISEASE:

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

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

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

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

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

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

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

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

25 E. ANY OTHER INFORMATION THAT THE COMMISSIONER DEEMS RELEVANT AND
26 APPROPRIATE.

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

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

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

37 S 2. This act shall take effect immediately.