

108TH CONGRESS
1ST SESSION

S. 1909

To amend the Public Health Service Act to improve stroke prevention, diagnosis, treatment, and rehabilitation.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 20, 2003

Mr. COCHRAN (for himself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to improve stroke prevention, diagnosis, treatment, and rehabilitation.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stroke Treatment and
5 Ongoing Prevention Act of 2003”.

6 **SEC. 2. FINDINGS AND GOAL.**

7 (a) FINDINGS.—The Congress finds as follows:

8 (1) Stroke is the third leading cause of death
9 in the United States. Each year over 750,000 Amer-

1 icans suffer a new or recurrent stroke and 160,000
2 Americans die from stroke.

3 (2) Stroke costs the United States
4 \$31,000,000,000 in direct costs and
5 \$20,200,000,000 in indirect costs each year.

6 (3) Stroke is one of the leading causes of adult
7 disability in the United States. Between 15 percent
8 and 30 percent of stroke survivors are permanently
9 disabled. Presently, there are 4,700,000 stroke sur-
10 vivors living in the United States.

11 (4) Members of the general public have dif-
12 ficulty recognizing the symptoms of stroke and are
13 unaware that stroke is a medical emergency. Fre-
14 quently, stroke patients wait as many as 22 hours
15 or more before presenting at the emergency room.
16 Forty-two percent of individuals over the age of 50
17 do not recognize numbness or paralysis in the face,
18 arm, or leg as a sign of stroke and 17 percent of
19 them cannot name a single stroke symptom.

20 (5) Recent advances in stroke treatment can
21 significantly improve the outcome for stroke pa-
22 tients, but these therapies must be administered
23 properly and promptly. Only 3 percent of stroke pa-
24 tients who are candidates for acute stroke intra-

1 venous thrombolytic drug therapy receive the appro-
2 priate medication.

3 (6) New technologies, therapies, and diagnostic
4 approaches are currently being developed that will
5 extend the therapeutic timeframe and result in
6 greater treatment efficacy for stroke patients.

7 (7) Few States and communities have developed
8 and implemented stroke awareness programs, pre-
9 vention programs, or comprehensive stroke care sys-
10 tems.

11 (8) The degree of disability resulting from
12 stroke can be reduced substantially by educating the
13 general public about stroke and by improving the
14 systems for the provision of stroke care in the
15 United States.

16 (b) GOAL.—It is the goal of this Act to improve the
17 provision of stroke care in every State and territory and
18 in the District of Columbia, and to increase public aware-
19 ness about the prevention, detection, and treatment of
20 stroke.

21 **SEC. 3. AMENDMENT REGARDING STROKE PREVENTION,**
22 **TREATMENT, AND REHABILITATION.**

23 Title III of the Public Health Service Act (42 U.S.C.
24 241 et seq.) is amended by adding at the end the fol-
25 lowing:

1 **“PART R—STROKE PREVENTION, TREATMENT,**
2 **AND REHABILITATION PROGRAMS**

3 **“Subpart I—Authorities and Duties of the Secretary**

4 **“SEC. 399AA. RESPONSIBILITIES OF THE SECRETARY.**

5 “(a) IN GENERAL.—The Secretary shall, with respect
6 to stroke care—

7 “(1) establish and evaluate a grant program
8 under section 399DD to enable States to develop
9 statewide stroke care systems;

10 “(2) foster the development of appropriate,
11 modern systems of stroke care through the sharing
12 of information among agencies and individuals in-
13 volved in the study and provision of such care;

14 “(3) provide to State and local agencies tech-
15 nical assistance;

16 “(4) develop a model curriculum for training
17 emergency medical services personnel, including dis-
18 patchers, first responders, emergency medical techni-
19 cians, and paramedics, in the identification, assess-
20 ment, stabilization, and prehospital treatment of
21 stroke patients;

22 “(5) issue recommendations or guidelines on
23 best practices for the establishment and operation of
24 statewide stroke systems, including recommendations
25 or guidelines on best practices for the establishment
26 and operation of stroke care centers; and

1 “(6) provide, to the extent practicable, informa-
2 tion to the public on the recognition of the signs and
3 symptoms of stroke and the appropriate actions to
4 take to assist an individual in obtaining appropriate
5 and timely care following a stroke.

6 “(b) GRANTS, COOPERATIVE AGREEMENTS, AND
7 CONTRACTS.—The Secretary may make grants, and enter
8 into cooperative agreements and contracts, for the purpose
9 of carrying out subsection (a).

10 “(c) RULES OF CONSTRUCTION.—

11 “(1) EXISTING GUIDELINES.—Nothing in sub-
12 section (a)(5) shall be construed to require the Sec-
13 retary to issue new recommendations or guidelines
14 where existing recommendations or guidelines issued
15 or adopted by the Secretary are applicable to the es-
16 tablishment of statewide stroke systems. Where an
17 existing recommendation or guideline is applicable to
18 the establishment of statewide stroke systems, the
19 Secretary may deem such recommendation or guide-
20 line to have been issued under subsection (a)(5).

21 “(2) ADVISORY NATURE OF GUIDELINES.—Rec-
22 ommendations or guidelines issued under subsection
23 (a)(5) shall be considered advisory in nature and
24 shall not be construed to constitute a standard of
25 care for the treatment of stroke.

1 **“SEC. 399BB. PAUL COVERDELL NATIONAL ACUTE STROKE**
2 **REGISTRY.**

3 “The Secretary shall maintain the Paul Coverdell Na-
4 tional Acute Stroke Registry by—

5 “(1) continuing to develop and collect specific
6 data points as well as appropriate benchmarks for
7 analyzing care of acute stroke patients;

8 “(2) continuing to develop a national registry
9 model that measures the delivery of care to patients
10 with acute stroke in order to provide real-time data
11 and analysis to reduce death and disability from
12 stroke and improve the quality of life for acute
13 stroke survivors;

14 “(3) fostering the development of effective,
15 modern stroke care systems (including the develop-
16 ment of policies related to emergency services sys-
17 tems) through the sharing of information among
18 agencies and individuals involved in planning, fur-
19 nishing, and studying such systems;

20 “(4) collecting, compiling, and disseminating in-
21 formation on the achievements of, and problems ex-
22 perience by, State and local agencies and private
23 entities in developing and implementing stroke care
24 systems and, in carrying out this paragraph, giving
25 special consideration to the unique needs of rural fa-
26 cilities and those facilities with inadequate resources

1 for providing high-quality prevention, acute treat-
2 ment, post-acute treatment, and rehabilitation serv-
3 ices for stroke patients; and

4 “(5) carrying out any other activities the Sec-
5 retary determines to be useful to fulfill the purposes
6 of the Paul Coverdell National Acute Stroke Reg-
7 istry.

8 **“Subpart II—State Stroke Care Systems**

9 **“SEC. 399DD. GRANTS TO STATES FOR STROKE CARE SYS-**
10 **TEMS.**

11 “(a) GRANTS.—The Secretary shall award grants to
12 States for the development and implementation of stroke
13 care systems that provide high-quality prevention, diag-
14 nosis, treatment, and rehabilitation.

15 “(b) REQUIRED USES.—

16 “(1) IN GENERAL.—In carrying out activities
17 described in subsection (a), each State that is
18 awarded a grant under this section shall—

19 “(A) establish, enhance, or expand a state-
20 wide stroke care system for the purpose of en-
21 suring access to high-quality stroke prevention,
22 diagnosis, treatment, and rehabilitation, except
23 that activities conducted under this subpara-
24 graph shall be consistent with guidelines or rec-
25 ommendations issued by the Secretary under

1 section 399AA(a)(5) to the extent that such
2 guidelines or recommendations have been
3 issued;

4 “(B) establish, enhance, or expand, as ap-
5 propriate, stroke care centers, except that ac-
6 tivities conducted under this subparagraph shall
7 be consistent with guidelines or recommenda-
8 tions issued by the Secretary under section
9 399AA(a)(5), to the extent that such guidelines
10 or recommendations have been issued;

11 “(C) conduct evaluation activities to mon-
12 itor clinical outcomes and procedures and to
13 verify resources, infrastructure, and operations
14 devoted to stroke care;

15 “(D) enhance, develop, and implement
16 model curricula for training emergency medical
17 services personnel in the identification, assess-
18 ment, stabilization, and prehospital treatment
19 of stroke patients which may, at the discretion
20 of the State, consist of or be based on the
21 model curriculum developed by the Secretary
22 under section 399AA(a)(4);

23 “(E) enhance coordination of emergency
24 medical services with respect to stroke care;

1 “(F) establish, enhance, or improve a cen-
2 tral data reporting and analysis system de-
3 scribed in subsection (c);

4 “(G) establish, enhance, or improve a sup-
5 port network described in subsection (d) to pro-
6 vide assistance to facilities with smaller popu-
7 lations of stroke patients or less advanced on-
8 site stroke treatment resources;

9 “(H) consult with organizations and indi-
10 viduals with expertise in stroke prevention, di-
11 agnosis, treatment, and rehabilitation; and

12 “(I) with respect to carrying out subpara-
13 graph (C) through (H), use the best available
14 evidence and consensus recommendations of
15 professional associations.

16 “(2) PERMISSIBLE USES.—In developing and
17 implementing a stroke care system described in
18 paragraph (1), each State that is awarded a grant
19 under this section may—

20 “(A) improve existing State stroke preven-
21 tion programs;

22 “(B) conduct a stroke education and infor-
23 mation campaign, including by—

24 “(i) making public service announce-
25 ments about the warning signs of stroke

1 and the importance of treating stroke as
2 a medical emergency; and

3 “(ii) providing education regarding
4 ways to prevent stroke and the effective-
5 ness of stroke treatment; and

6 “(C) make grants to public and non-profit
7 private entities for medical professional develop-
8 ment in accordance with subsection (e).

9 “(c) CENTRAL DATA REPORTING AND ANALYSIS
10 SYSTEM.—A central data reporting and analysis system
11 described in this subsection is a system that collects data
12 from facilities that provide direct care to stroke patients
13 and uses the data—

14 “(1) to identify the number of stroke patients
15 treated in the State;

16 “(2) to monitor patient care in the State for
17 stroke patients at all phases of stroke for the pur-
18 pose of evaluating the diagnosis, treatment, and
19 treatment outcome of such stroke patients;

20 “(3) to identify the total amount of uncompen-
21 sated and under-compensated stroke care expendi-
22 tures for each fiscal year by each stroke care facility
23 in the State;

24 “(4) to identify the number of acute stroke pa-
25 tients who receive advanced drug therapy;

1 “(5) to identify patients transferred within the
2 statewide stroke care system, including reasons for
3 such transfer; and

4 “(6) to communicate to the greatest extent
5 practicable with the Paul Coverdell National Acute
6 Stroke Registry.

7 “(d) SUPPORT NETWORK.—A support network de-
8 scribed in this subsection may include the following:

9 “(1) The use of telehealth technology to connect
10 facilities described in subsection (b)(1)(G) to more
11 advanced stroke care facilities.

12 “(2) The provision of neuroimaging, laboratory,
13 and any other equipment necessary to facilitate the
14 establishment of a telehealth network.

15 “(3) The use of phone consultation, where use-
16 ful.

17 “(4) The use of referral links when a patient
18 needs more advanced care than is available at the
19 facility providing initial care.

20 “(5) Any other assistance determined appro-
21 priate by the State.

22 “(e) MEDICAL PROFESSIONAL DEVELOPMENT IN AD-
23 VANCED STROKE TREATMENT AND PREVENTION.—

24 “(1) IN GENERAL.—A State may use funds re-
25 ceived under a grant under this section to make sub-

1 grants to public and non-profit private entities for
2 the development and implementation of education
3 programs for appropriate medical personnel and
4 health professionals in the use of newly developed di-
5 agnostic approaches, technologies, and therapies for
6 the prevention and treatment of stroke.

7 “(2) USE OF FUNDS.—A public or non-profit
8 private entity shall use amounts received under a
9 subgrant under this subsection for the continuing
10 education of appropriate medical personnel in the
11 use of newly developed diagnostic approaches, tech-
12 nologies, and therapies for the prevention and treat-
13 ment of stroke.

14 “(3) DISTRIBUTION OF SUBGRANTS.—In
15 awarding subgrants under this subsection, the Sec-
16 retary shall ensure that such subgrants are equitably
17 distributed among the geographical regions of the
18 State and between urban and rural populations.

19 “(4) APPLICATION.—A public or non-profit pri-
20 vate entity desiring a subgrant under this subsection
21 shall prepare and submit to the State involved an
22 application at such time, in such manner, and con-
23 taining such information as the State may require,
24 including a plan for the rigorous evaluation of activi-

1 ties carried out with amounts received under such a
2 subgrant.

3 “(f) RESTRICTIONS ON USE OF PAYMENTS.—The
4 Secretary may not, except as provided in paragraph (2),
5 make payments to a State under this section for a fiscal
6 year unless the State agrees that the payments will not
7 be expended—

8 “(1) to make cash payments to intended recipi-
9 ents of services provided pursuant to this section;

10 “(2) to satisfy any requirement for the expendi-
11 ture of non-Federal funds as a condition for the re-
12 ceipt of Federal funds;

13 “(3) to provide financial assistance to any enti-
14 ty other than a public or nonprofit private entity; or

15 “(4) for construction, alteration, or improve-
16 ment of any building or facility.

17 “(g) FAILURE TO COMPLY WITH AGREEMENTS.—

18 “(1) REPAYMENT OF PAYMENTS.—

19 “(A) REQUIREMENT.—The Secretary may,
20 in accordance with paragraph (2), require a
21 State to repay any payments received by the
22 State under this section that the Secretary de-
23 termines were not expended by the State in ac-
24 cordance with the agreements required to be

1 made by the State as a condition of the receipt
2 of payments.

3 “(B) OFFSET OF AMOUNTS.—If a State
4 fails to make a repayment required in subpara-
5 graph (A), the Secretary may offset the amount
6 of the repayment against any amount due to be
7 paid to the State under this section.

8 “(2) OPPORTUNITY FOR A HEARING.—Before
9 requiring repayment of payments under paragraph
10 (1), the Secretary shall provide to the State an op-
11 portunity for a hearing.

12 “(h) APPLICATION REQUIREMENTS.—The Secretary
13 may not award a grant to a State under this section un-
14 less—

15 “(1) the State submits an application con-
16 taining agreements in accordance with this section;

17 “(2) the agreements are made through certifi-
18 cation from the chief executive officer of the State;

19 “(3) with respect to such agreements, the appli-
20 cation provides assurances of compliance satisfactory
21 to the Secretary;

22 “(4) the application contains the plan provi-
23 sions and the information required to be submitted
24 to the Secretary; and

1 “(5) the application otherwise is in such form,
2 is made in such manner, and contains such agree-
3 ments, assurances, and information as the Secretary
4 determines to be necessary to carry out this section.

5 “(i) TECHNICAL ASSISTANCE.—The Secretary shall,
6 without charge to a State receiving payments under this
7 section, provide to the State (or to any public or nonprofit
8 entity designated by the State) technical assistance with
9 respect to the planning, development, and operation of any
10 program carried out pursuant to this section. The Sec-
11 retary may provide such technical assistance directly,
12 through contract, or through grants.

13 “(j) SUPPLIES AND SERVICES IN LIEU OF GRANT
14 FUNDS.—

15 “(1) IN GENERAL.—Upon the request of a
16 State receiving payments under this section, the Sec-
17 retary may, subject to paragraph (2), provide sup-
18 plies, equipment, and services to the State and may
19 detail to the State any officer or employee of the De-
20 partment of Health and Human Services, for the
21 purpose of assisting the State to achieve the purpose
22 of the payments.

23 “(2) REDUCTION IN PAYMENTS.—With respect
24 to a request described in paragraph (1), the Sec-
25 retary shall reduce the amount of payments to the

1 State under this section by an amount equal to the
2 costs of detailing personnel and the fair market
3 value of any supplies, equipment, or services pro-
4 vided by the Secretary. The Secretary shall, for the
5 payment of expenses incurred in complying with
6 such request, expend the amounts withheld.

7 “(k) REPORT.—Not later than 3 years after the date
8 of the enactment of the Stroke Treatment and Ongoing
9 Prevention Act of 2003, the Secretary shall report to the
10 appropriate committees of the Congress on the activities
11 of the States carried out pursuant to this section and sec-
12 tion 399EE. Such report shall include an assessment of
13 the extent to which Federal and State efforts to identify
14 stroke centers, develop support networks, and enhance
15 emergency medical services coordination and the training
16 of emergency medical personnel, have increased the num-
17 ber of stroke patients who have received acute stroke con-
18 sultation or therapy within the appropriate timeframe and
19 reduced the level of disability due to stroke.

20 “(l) LIMITATION ON ADMINISTRATIVE EXPENSES.—
21 The Secretary may not award a grant to a State under
22 this section unless the State agrees to use not more than
23 10 percent of amounts received under the grant for admin-
24 istrative expenses.

1 **“SEC. 399EE. PLANNING GRANTS.**

2 “(a) GRANTS.—The Secretary may award a grant to
3 a State to assist such State in formulating a plan to de-
4 velop a stroke care system in accordance with section
5 399DD or in otherwise meeting the requirements of such
6 section.

7 “(b) SUBMISSION TO SECRETARY.—The chief execu-
8 tive officer of a State that receives a grant under this sec-
9 tion shall submit to the Secretary a copy of the plan devel-
10 oped using the amounts provided under such grant. Such
11 plan shall be submitted to the Secretary as soon as prac-
12 ticable after the plan has been developed.

13 “(c) SINGLE GRANT LIMITATION.—A State is not eli-
14 gible to receive a grant under this section if the State pre-
15 viously received a grant under this section.

16 **“SEC. 399FF. SPECIAL CONSIDERATION.**

17 “In awarding grants under this subpart, the Sec-
18 retary shall give special consideration to any State that
19 has submitted an application for carrying out programs
20 under such a grant—

21 “(1) in geographic areas in which there is—

22 “(A) an elevated incidence or prevalence of
23 disability resulting from stroke; or

24 “(B) an elevated incidence or prevalence of
25 stroke; or

1 “(2) that demonstrates a significant need for
2 assistance in establishing a comprehensive stroke
3 care system.

4 **“Subpart III—General Provisions**

5 **SEC. 399GG. GENERAL PROVISIONS..**

6 “(a) CONSULTATIONS.—In carrying out this part, the
7 Secretary shall consult with organizations and individuals
8 with expertise in stroke prevention, diagnosis, treatment,
9 and rehabilitation.

10 “(b) DEFINITIONS.—In this part:

11 “(1) STATE.—The term ‘State’ means each of
12 the several States, the District of Columbia, the
13 Commonwealth of Puerto Rico, the Indian tribes,
14 the Virgin Islands, Guam, American Samoa, and the
15 Commonwealth of the Northern Mariana Islands.

16 “(2) STROKE CARE SYSTEM.—The term ‘stroke
17 care system’ means a statewide system to provide
18 for the diagnosis, prehospital care, hospital definitive
19 care, and rehabilitation of stroke patients.

20 “(3) STROKE.—The term ‘stroke’ means a
21 ‘brain attack’ in which blood flow to the brain is in-
22 terrupted or in which a blood vessel or aneurysm in
23 the brain breaks or ruptures.

24 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
25 are authorized to be appropriated to carry out this part

1 such sums as may be necessary for fiscal years 2004
2 through 2008.”.

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