

108TH CONGRESS
2D SESSION

H. R. 4493

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 2, 2004

Ms. ROYBAL-ALLARD (for herself, Mr. SIMPSON, Mr. SERRANO, Mr. KILDEE, Mr. GORDON, Mr. ANDREWS, Mr. GREEN of Texas, Mr. WALSH, Mr. WEXLER, Mr. MEEHAN, Mr. CUNNINGHAM, and Mr. SCHIFF) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, and for other purposes.

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 “Newborn Screening
5 Saves Lives Act of 2004”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Currently, it is possible to test for at least
4 30 disorders through newborn screening.

5 (2) There is a lack of uniform newborn screen-
6 ing throughout the United States. While a newborn
7 with a debilitating condition may receive screening,
8 early detection, and treatment in one location, in an-
9 other location the condition may go undetected and
10 result in catastrophic consequences.

11 (3) Each year more than 4,000,000 babies are
12 screened to detect conditions that may threaten their
13 long-term health.

14 (4) There are more than 2,000 babies born
15 every year in the United States with detectable and
16 treatable disorders that go unscreened through new-
17 born screening.

18 **SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.**

19 Part Q of title III of the Public Health Service Act
20 (42 U.S.C. 280h et seq.) is amended by adding at the end
21 the following:

22 **“SEC. 399AA. NEWBORN SCREENING.**

23 **“(a) AUTHORIZATION OF GRANT PROGRAMS.—**

24 **“(1) GRANTS TO ASSIST HEALTH CARE PROFES-**
25 **SIONALS.—**From funds appropriated under sub-
26 section (h), the Secretary, acting through the Asso-

1 ciate Administrator of the Maternal and Child
2 Health Bureau of the Health Resources and Services
3 Administration (referred to in this section as the
4 ‘Associate Administrator’) and in consultation with
5 the Advisory Committee on Heritable Disorders in
6 Newborns and Children (referred to in this section
7 as the ‘Advisory Committee’), shall award grants to
8 eligible entities to enable such entities to assist in
9 providing health care professionals and State health
10 department laboratory personnel with—

11 “(A) education in newborn screening; and

12 “(B) training in—

13 “(i) relevant and new technologies in
14 newborn screening; and

15 “(ii) congenital, genetic, and meta-
16 bolic disorders.

17 “(2) GRANTS TO ASSIST FAMILIES.—From
18 funds appropriated under subsection (h), the Sec-
19 retary, acting through the Associate Administrator
20 and in consultation with the Advisory Committee,
21 shall award grants to eligible entities to enable such
22 entities to develop and deliver educational programs
23 about newborn screening to parents, families, and
24 patient advocacy and support groups.

1 “(3) GRANTS FOR NEWBORN SCREENING FOL-
2 LOWUP.—From funds appropriated under subsection
3 (h), the Secretary, acting through the Associate Ad-
4 ministrators and in consultation with the Advisory
5 Committee, shall award grants to eligible entities to
6 enable such entities to establish, maintain, and oper-
7 ate a system to assess and coordinate treatment re-
8 lating to congenital, genetic, and metabolic dis-
9 orders.

10 “(b) APPLICATION.—An eligible entity that desires to
11 receive a grant under this section shall submit an applica-
12 tion to the Secretary at such time, in such manner, and
13 accompanied by such information as the Secretary may
14 require.

15 “(c) SELECTION OF GRANT RECIPIENTS.—

16 “(1) IN GENERAL.—Not later than 120 days
17 after receiving an application under subsection (b),
18 the Secretary, after considering the approval factors
19 under paragraph (2), shall determine whether to
20 award the eligible entity a grant under this section.

21 “(2) APPROVAL FACTORS.—

22 “(A) REQUIREMENTS FOR APPROVAL.—An
23 application submitted under subsection (b) may
24 not be approved by the Secretary unless the ap-

1 plication contains assurances that the eligible
2 entity—

3 “(i) will use grant funds only for the
4 purposes specified in the approved applica-
5 tion and in accordance with the require-
6 ments of this section; and

7 “(ii) will establish such fiscal control
8 and fund accounting procedures as may be
9 necessary to assure proper disbursement
10 and accounting of Federal funds paid to
11 the eligible entity under the grant.

12 “(B) EXISTING PROGRAMS.—Prior to
13 awarding a grant under this section, the Sec-
14 retary shall—

15 “(i) conduct an assessment of existing
16 educational resources and training pro-
17 grams and coordinated systems of followup
18 care with respect to newborn screening;
19 and

20 “(ii) take all necessary steps to mini-
21 mize the duplication of the resources and
22 programs described in clause (i).

23 “(d) COORDINATION.—The Secretary shall take all
24 necessary steps to coordinate programs funded with
25 grants received under this section.

1 “(e) USE OF GRANT FUNDS.—

2 “(1) GRANTS TO ASSIST HEALTH CARE PROFES-
3 SIONALS.—An eligible entity that receives a grant
4 under subsection (a)(1) may use the grant funds to
5 work with appropriate medical schools, nursing
6 schools, schools of public health, internal education
7 programs in State agencies, nongovernmental orga-
8 nizations, and professional organizations and soci-
9 eties to develop and deliver education and training
10 programs that include—

11 “(A) continuing medical education pro-
12 grams for health care professionals and State
13 health department laboratory personnel in new-
14 born screening;

15 “(B) education, technical assistance, and
16 training on new discoveries in newborn screen-
17 ing and the use of any related technology;

18 “(C) models to evaluate what a newborn
19 should be screened for and when and where
20 that screening should take place;

21 “(D) models to evaluate the prevalence of,
22 and assess and communicate the risks of, new-
23 born disorders, including the prevalence and
24 risk of certain newborn disorders based on fam-
25 ily history;

1 “(E) models to communicate effectively
2 with parents and families about—

3 “(i) the process and benefits of new-
4 born screening;

5 “(ii) how to use information gathered
6 from newborn screening;

7 “(iii) the meaning of screening re-
8 sults, including the rate of false positives;

9 “(iv) the right of refusal of newborn
10 screening; and

11 “(v) the potential need for followup
12 care after newborns are screened;

13 “(F) information and resources on coordi-
14 nated systems of followup care after newborns
15 are screened;

16 “(G) information on the disorders for
17 which States require and offer newborn screen-
18 ing and options for newborn screening relating
19 to conditions in addition to such disorders;

20 “(H) information on supplemental newborn
21 screening that the States do not require and
22 offer but that parents may want; and

23 “(I) other items to carry out the purpose
24 described in subsection (a)(1) as determined ap-
25 propriate by the Secretary.

1 “(2) GRANTS TO ASSIST FAMILIES.—An eligible
2 entity that receives a grant under subsection (a)(2)
3 may use the grant funds to develop and deliver to
4 parents, families, and patient advocacy and support
5 groups, educational programs about newborn screen-
6 ing that include information on—

7 “(A) what is newborn screening;

8 “(B) how newborn screening is performed;

9 “(C) who performs newborn screening;

10 “(D) where newborn screening is per-
11 formed;

12 “(E) the disorders for which the State re-
13 quires newborns to be screened;

14 “(F) different options for newborn screen-
15 ing for disorders other than those included by
16 the State in the mandated newborn screening
17 program;

18 “(G) the meaning of various screening re-
19 sults including the rate of false positives;

20 “(H) the prevalence and risk of newborn
21 disorders, including the increased risk of dis-
22 orders that may stem from family history;

23 “(I) coordinated systems of followup care
24 after newborns are screened; and

1 “(J) other items to carry out the purpose
2 described in subsection (a)(2) as determined ap-
3 propriate by the Secretary.

4 “(3) GRANTS FOR QUALITY NEWBORN SCREEN-
5 ING FOLLOWUP.—An eligible entity that receives a
6 grant under subsection (a)(3) shall use the grant
7 funds to—

8 “(A) expand on existing procedures and
9 systems, where appropriate and available, for
10 the timely reporting of newborn screening re-
11 sults to individuals, families, primary care phy-
12 sicians, and subspecialists in congenital, ge-
13 netic, and metabolic disorders;

14 “(B) coordinate ongoing followup treat-
15 ment with individuals, families, primary care
16 physicians, and subspecialists in congenital, ge-
17 netic, and metabolic disorders after a newborn
18 receives an indication of the presence of a dis-
19 order on a screening test;

20 “(C) ensure the seamless integration of
21 confirmatory testing, tertiary care medical serv-
22 ices, comprehensive genetic services including
23 genetic counseling, and information about ac-
24 cess to developing therapies by participation in

1 approved clinical trials involving the primary
2 health care of the infant;

3 “(D) analyze data, if appropriate and
4 available, collected from newborn screenings to
5 identify populations at risk for disorders affect-
6 ing newborns, examine and respond to health
7 concerns, recognize and address relevant envi-
8 ronmental, behavioral, socioeconomic, demo-
9 graphic, and other relevant risk factors; and

10 “(E) carry out such other activities as the
11 Secretary may determine necessary.

12 “(f) REPORTS TO CONGRESS.—

13 “(1) IN GENERAL.—Subject to paragraph (2),
14 the Secretary shall submit to the appropriate com-
15 mittees of Congress reports—

16 “(A) evaluating the effectiveness and the
17 impact of the grants awarded under this sec-
18 tion—

19 “(i) in promoting newborn screen-
20 ing—

21 “(I) education and resources for
22 families; and

23 “(II) education, resources, and
24 training for health care professionals;

1 “(ii) on the successful diagnosis and
2 treatment of congenital, genetic, and meta-
3 bolic disorders; and

4 “(iii) on the continued development of
5 coordinated systems of followup care after
6 newborns are screened;

7 “(B) describing and evaluating the effec-
8 tiveness of the activities carried out with grant
9 funds received under this section; and

10 “(C) that include recommendations for
11 Federal actions to support—

12 “(i) education and training in new-
13 born screening; and

14 “(ii) followup care after newborns are
15 screened.

16 “(2) TIMING OF REPORTS.—The Secretary shall
17 submit—

18 “(A) an interim report that includes the
19 information described in paragraph (1), not
20 later than 30 months after the date on which
21 the first grant funds are awarded under this
22 section; and

23 “(B) a subsequent report that includes the
24 information described in paragraph (1), not
25 later than 60 months after the date on which

1 the first grant funds are awarded under this
2 section.

3 “(g) DEFINITION OF ELIGIBLE ENTITY.—In this sec-
4 tion, the term ‘eligible entity’ means—

5 “(1) a State or a political subdivision of a
6 State;

7 “(2) a consortium of 2 or more States or polit-
8 ical subdivisions of States;

9 “(3) a territory;

10 “(4) an Indian tribe or a hospital or outpatient
11 health care facility of the Indian Health Service; or

12 “(5) a nongovernmental organization with ap-
13 propriate expertise in newborn screening, as deter-
14 mined by the Secretary.

15 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
16 are authorized to be appropriated to carry out this sec-
17 tion—

18 “(1) \$15,000,000 for fiscal year 2005; and

19 “(2) such sums as may be necessary for each
20 of fiscal years 2006 through 2009.”.

○