

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5703

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.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 28, 2002

Ms. ROYBAL-ALLARD (for herself, Mr. SERRANO, Mr. FROST, Ms. MILLENDER-MCDONALD, Mr. SANDERS, Ms. SOLIS, Ms. NORTON, Mr. WAXMAN, Ms. MCCOLLUM, Mr. PAYNE, Mr. OWENS, Ms. LEE, Mr. CROWLEY, Mr. McDERMOTT, Ms. DELAURO, Mr. WEXLER, Mr. MENENDEZ, and Mrs. NAPOLITANO) introduced the following bill; which was referred to the Committee on the Energy and Commerce

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## 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 2002”.

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 2003; and

19 “(2) such sums as may be necessary for each  
20 of fiscal years 2004 through 2007.”.

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