

109TH CONGRESS  
2D SESSION

# S. 3743

To amend the Public Health Service Act to improve newborn screening activities, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JULY 26, 2006

Mrs. CLINTON (for herself and Mr. ALLEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health Service Act to improve newborn screening activities, 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       (a) SHORT TITLE.—This Act may be cited as the  
5       “Screening for Health of Infants and Newborns Act” or  
6       the “SHINE Act”.

7       **SEC. 2. PURPOSES.**

8       The purposes of this Act are the following:

9              (1) To ensure the health and quality of life of  
10          all newborns in the United States by enhancing the

1 capacity to screen for heritable diseases. This enhanced capacity will assist the States in making  
2 progress toward the following goals:

3 (A) All babies born in hospitals in the  
4 United States and the territories of the United  
5 States should have access to, and be screened  
6 for, certain core conditions.

7 (B) Appropriate newborn screening evaluations  
8 should be conducted for all newborns to  
9 allow appropriate referrals and provisions for  
10 early medical intervention.

11 (C) Newborn screening data collection  
12 should be standardized, and conditions detected  
13 by newborn screening should be tracked and  
14 monitored.

15 (D) Information on newborn screening and  
16 conditions for which a patient can be screened  
17 should be readily accessible, current, and under-  
18 standable to both health care providers and par-  
19 ents. Information should include the following:

20 (i) A component for rehabilitation,  
21 medical, and early intervention options  
22 that ensure linkage to any new and exist-  
23 ing national or State system of interven-  
24 tion.

(ii) Rehabilitative services for newborns with the conditions.

7                   (2) To expand newborn screening, and improve  
8 systems to make newborn screening more efficient  
9 and effective, by authorizing—

(A) statewide newborn screening and medical evaluation systems and intervention programs;

13 (B) technical assistance;

14 (C) national demonstration grant pro-  
15 grams; and

16 (D) interagency collaborations between the  
17 appropriate Federal agencies, including the  
18 Agency for Healthcare Research and Quality,  
19 Centers for Disease Control and Prevention,  
20 Food and Drug Administration, Health Re-  
21 sources and Services Administration, and Na-  
22 tional Institutes of Health.

1   **SEC. 3. NEWBORN SCREENING GUIDELINES AND GRANT**

2                   **PROGRAMS.**

3       Part A of title XI of the Public Health Service Act  
4   (42 U.S.C. 300b–1 et seq.) is amended by adding at the  
5   end the following:

6   **“SEC. 1112. RECOMMENDED GUIDELINES FOR NEWBORN**  
7                   **SCREENING AND DATA COLLECTION; MONI-**  
8                   **TORING AND EVALUATION.**

9       “(a) RECOMMENDED GUIDELINES FOR NEWBORN  
10   SCREENING AND DATA COLLECTION.—

11       “(1) IN GENERAL.—The Director of the Cen-  
12   ters for Disease Control and Prevention (referred to  
13   in this section as the ‘Director’), in collaboration  
14   with the Associate Administrator of the Maternal  
15   and Child Health Bureau of the Health Resources  
16   and Services Administration and the Advisory Com-  
17   mittee on Heritable Disorders and Genetic Diseases  
18   in Newborns and Children (referred to in this sec-  
19   tion as the ‘Advisory Committee’), shall develop spe-  
20   cific guidelines that the States may follow in report-  
21   ing newborn screening data, as requested by the Ad-  
22   visory Committee, from newborn screening tests, in-  
23   cluding the screening tests for the core conditions  
24   designated by the Newborn Screening Expert Group  
25   convened by the American College of Medical Genet-

1       ics, as commissioned by the Health Resources and  
2       Services Administration.

3           “(2) GUIDELINES.—The guidelines developed  
4       under paragraph (1) shall include—

5               “(A) standardizing the case definitions and  
6       names of the disorders for which newborn  
7       screening tests are performed and the defini-  
8       tions of performance measures used to evaluate  
9       such tests so that performance criteria and out-  
10      comes among all States may be evaluated;

11              “(B) establishing procedures for standard-  
12      ized newborn screening data collection and re-  
13      porting; and

14              “(C) ensuring that tests and technologies  
15      used by each State meet established standards  
16      for detecting and reporting positive screening  
17      results.

18           “(3) IMPLEMENTATION.—The Director shall  
19      submit the guidelines described in this subsection to  
20      the Secretary. Not later than 90 days after receiving  
21      the guidelines, the Secretary, in consultation with  
22      the Director, the Administrator of the Health Re-  
23      sources and Services Administration (referred to in  
24      this section as the ‘Administrator’), and the Assist-

1           ant Administrator of the Maternal and Child Health  
2           Bureau, shall implement such guidelines.

3           “(4) ANNUAL REPORT.—Not later than 2 years  
4           after the date of enactment of the Screening for  
5           Health of Infants and Newborns Act, and each year  
6           thereafter, the Advisory Committee shall—

7                 “(A) publish an annual report on newborn  
8                 screening guidelines in the United States;

9                 “(B) submit such report to the appropriate  
10               committees of Congress, the Secretary, and the  
11               State departments of health; and

12                 “(C) disseminate such report on as wide a  
13               basis as practicable.

14           “(b) RECOMMENDED GUIDELINES FOR MONITORING,  
15           EVALUATION, AND SURVEILLANCE OF NEWBORN  
16           SCREENING.—

17                 “(1) IN GENERAL.—

18                 “(A) DEVELOPMENT.—The Secretary, act-  
19               ing through the Administrator and in consulta-  
20               tion with the Director and the Advisory Com-  
21               mittee, shall develop guidelines to—

22                 “(i) monitor and evaluate newborn  
23               screening activities, including diagnosis,  
24               screening, follow-up, and treatment activi-  
25               ties, in the United States; and

1                         “(ii) coordinate the results of surveil-  
2                         lance activities in order to enhance moni-  
3                         toring of newborn diseases.

4                         “(B) DUTIES.—In carrying out this para-  
5                         graph, the Administrator, in consultation with  
6                         the Advisory Committee and the Director, shall  
7                         collaborate with non-Governmental organiza-  
8                         tions, such as the Joint Commission on Accredita-  
9                         tion of Hospital Organizations, laboratories  
10                         certified by the Clinical Laboratory Improve-  
11                         ment Amendment (referred to in the part as  
12                         ‘CLIA’), and the Association of Public Health  
13                         Laboratories to ensure effective monitoring and  
14                         evaluation of newborn screening activities.

15                         “(2) IMPLEMENTATION.—Not later than 90  
16                         days after the development of the guidelines under  
17                         paragraph (1), the Secretary, in consultation with  
18                         the Director, the Administrator, and the Assistant  
19                         Administrator of the Maternal and Child Health Bu-  
20                         reau, shall implement such guidelines.

21                         “(c) SURVEILLANCE AND IDENTIFICATION RE-  
22                         SEARCH.—The Secretary, acting through the Director and  
23                         the National Center on Birth Defects and Developmental  
24                         Disabilities, and in consultation with the Administrator  
25                         and Advisory Committee, shall develop a surveillance sys-

1 item for newborn screening. The system shall use the  
2 standardized procedures and guidelines developed under  
3 subsection (b) for data management and tracking program  
4 effectiveness and costs, in order to—

5           “(1) ensure quality monitoring of newborn  
6 screening and medical evaluation systems and inter-  
7 vention programs;

8           “(2) provide technical assistance on data collec-  
9 tion and management;

10          “(3) study the cost and effectiveness of new-  
11 born screening and medical evaluation systems and  
12 intervention programs conducted by State-based pro-  
13 grams in order to answer issues of importance to na-  
14 tional and State policymakers; and

15          “(4) identify the causes of, and risk factors for,  
16 heritable disorders.

17          “(d) ADVISORY COMMITTEE MEETINGS.—The Advi-  
18 sory Committee shall meet not less than annually to—

19          “(1) assess the implementation of the guidelines  
20 and surveillance activities developed under this sec-  
21 tion;

22          “(2) advise the Secretary with respect to—

23            “(A) such guidelines; and

24            “(B) monitoring and evaluating newborn  
25 screening and surveillance activities;

1           “(3) consider ways to ensure that States attain  
2       the capacity to screen for the core conditions de-  
3       scribed in subsection (a)(1), and include in such con-  
4       sideration the results of the demonstration projects  
5       funded under section 1115; and

6           “(4) consider any addition to the list of the core  
7       conditions described in subsection (a)(1), and in-  
8       clude in such consideration the results of the dem-  
9       onstration projects funded under section 1116.

10          “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
11       are authorized to be appropriated to carry out this sec-  
12       tion—

13           “(1) \$10,000,000 for fiscal year 2007; and

14           “(2) such sums as necessary for fiscal year  
15       2008 through 2011.

16 **“SEC. 1113. CLEARINGHOUSE OF NEWBORN SCREENING IN-**  
17           **FORMATION.**

18          “(a) CLEARINGHOUSE.—The Secretary shall direct  
19       the Maternal and Child Health Bureau of the Health Re-  
20       sources and Services Administration, working through the  
21       Regional Genetic and Newborn Screening Collaborative  
22       Groups of such Bureau, the National Coordinating Center,  
23       and the National Newborn Screening and Genetic Re-  
24       source Center, to collaborate with the Director of the Cen-  
25       ters for Disease Control and Prevention and the National

1 Library of Medicine of the National Institutes of Health  
2 to establish and maintain a central clearinghouse of cur-  
3 rent educational and family support and services informa-  
4 tion, materials, resources, research, and data on newborn  
5 screening to—

6           “(1) enable parents and family members of  
7 newborns, health professionals, industry representa-  
8 tives, and other members of the public to increase  
9 their awareness, knowledge, and understanding of  
10 newborn screening;

11           “(2) increase awareness, knowledge, and under-  
12 standing of newborn diseases and screening services  
13 for individuals wishing to have children and expect-  
14 ant families; and

15           “(3) develop and maintain current data on  
16 quality indicators to measure performance of new-  
17 born screening entities, such as false-positive rates  
18 and other quality indicators as determined by the  
19 Advisory Committee described under section 1112.

20        “(b) INTERNET AVAILABILITY.—The Health Re-  
21 sources and Services Administration shall ensure that the  
22 clearinghouse described under subsection (a)—

23           “(1) is available on the Internet;

24           “(2) includes an interactive forum;

1               “(3) is updated on a regular basis, but not less  
2               than quarterly; and

3               “(4) provides—

4               “(A) links to Government-sponsored, non-  
5               profit, and other websites of laboratories that  
6               have demonstrated expertise in newborn screen-  
7               ing that supply research-based information on  
8               newborn screening tests currently available  
9               throughout the United States;

10             “(B) information about newborn conditions  
11              and screening services available in each State,  
12              including the ability of infants to obtain addi-  
13              tional comprehensive screening services that  
14              may not be required in the State where the in-  
15              fant is born, from CLIA-certified laboratories  
16              for disorders;

17             “(C) current research on both treatable  
18              and not-yet treatable conditions for which new-  
19              born screening tests are available;

20             “(D) information about newborn diseases  
21              and screening services available in each State;  
22              and

23             “(E) other relevant information as deter-  
24              mined appropriate by the Secretary.

1       “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
2 are authorized to be appropriated to carry out this sec-  
3 tion—

4           “(1) \$5,000,000 for fiscal year 2007; and

5           “(2) such sums as necessary for fiscal years  
6 2008 through 2011.

7 **“SEC. 1114. INTERAGENCY GRANT REVIEW PANEL.**

8       “(a) DEFINITION OF SHINE GRANT PROGRAM.—In  
9 this section, the term ‘Screening for Health of Infants and  
10 Newborns grant program’ or ‘SHINE grant program’  
11 means any grant program under section 1115 or 1116.

12       “(b) REVIEW PANEL.—The Secretary shall appoint  
13 an Interagency Grant Review Panel to review grant appli-  
14 cations and provide oversight of the SHINE grant pro-  
15 gram.

16       “(c) MEMBERSHIP.—The Secretary shall ensure that  
17 the Interagency Grant Review Panel includes representa-  
18 tion from all appropriate Federal agencies, including the  
19 Agency for Healthcare Research and Quality, the Centers  
20 for Disease Control and Prevention, the Food and Drug  
21 Administration, the Health Resources and Services Ad-  
22 ministration, and the National Institutes of Health.

23       “(d) DUTIES.—

24           “(1) DUTIES OF THE SECRETARY.—After the  
25 last day of the application period for a SHINE

1       grant program, the Secretary shall forward the  
2       grant applications received for the program to the  
3       Interagency Grant Review Panel.

4                 “(2) DUTIES OF THE INTERAGENCY GRANT RE-  
5       VIEW PANEL.—

6                 “(A) SELECTION OF GRANT RECIPIENTS.—  
7       Upon receipt of the grant applications for a  
8       SHINE grant program from the Secretary, the  
9       Interagency Grant Review Panel shall review  
10      the applications for grants under the program  
11      and shall select, on a competitive basis, all of  
12      the grant recipients for the program and the  
13      amount of each grant award.

14                 “(B) SUBMISSION OF GRANT RECIPI-  
15       ENTS.—The Interagency Grant Review Panel  
16      shall submit the list of award recipients for  
17      grants under a SHINE grant program to the  
18      Secretary at a time determined by the Sec-  
19      retary, but not later than 90 days after the last  
20      day of the application period for a grant under  
21      such program.

22                 “(C) OVERSIGHT OF GRANTS.—The Inter-  
23       agency Grant Review Panel shall provide over-  
24       sight of the programs and activities funded by  
25       grants under a SHINE grant program, and

1 shall report to the Secretary on the program  
2 and activities as the Secretary or the Panel de-  
3 termines necessary.

4 **“SEC. 1115. CAPACITY GRANT PROGRAM.**

5 “(a) IN GENERAL.—The Secretary shall award  
6 grants, in conjunction with the Interagency Grant Review  
7 Panel established under section 1114, to eligible entities  
8 for demonstration projects that increase the capacity of  
9 a State to screen for all of the core conditions designated  
10 by the Advisory Committee described under section 1112.  
11 Such grants shall be made on a competitive basis.

12 “(b) ELIGIBILITY.—To be eligible to receive a grant  
13 under this section, an entity shall—

14 “(1) submit to the Secretary an application at  
15 such time, in such manner, and containing such in-  
16 formation as the Secretary may require;

17 “(2) be a public or private organization, includ-  
18 ing an academic research center, medical center,  
19 physician group, newborn screening program, or  
20 CLIA-certified laboratory with expertise in newborn  
21 metabolic screening;

22 “(3) provide assurance that such organization  
23 will work in consultation with the appropriate State  
24 department of health;

1           “(4) have the capacity to perform the core new-  
2       born screening tests described in subsection (a) and  
3       to collect and report data on the costs, benefits, and  
4       effectiveness of such tests, in consultation with the  
5       appropriate State department of health and in ac-  
6       cordance with the guidelines implemented under sec-  
7       tion 1112;

8           “(5) demonstrate sustainability of such activi-  
9       ties based on the outcomes of the demonstration  
10      project; and

11          “(6) if applicable, submit to the Secretary a  
12       plan for follow-up, diagnosis, and treatment of those  
13       infants who test positive on newborn screening tests  
14       developed under this section.

15          “(c) REPORT TO SECRETARY AND INTERAGENCY  
16  PANEL.—An organization that receives a grant under this  
17  section shall, on an annual basis, submit to the Secretary  
18  and the Interagency Grant Review Panel established  
19  under section 1114 a report that describes the activities  
20  conducted pursuant to such grant and the outcomes of  
21  such activities.

22          “(d) EVALUATION AND RESULTS.—The Secretary  
23  shall—

24           “(1) evaluate the demonstration projects funded  
25  under this section; and

1               “(2) on an annual basis—

2                     “(A) publish and disseminate the results of  
3                     such evaluation on as wide a basis as is prac-  
4                     ticable; and

5                     “(B) submit to the appropriate committees  
6                     of Congress the results of such evaluation.

7               “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
8               are authorized to be appropriated to carry out this sec-  
9               tion—

10               “(1) \$10,000,000 for fiscal year 2007; and

11               “(2) such sums as necessary for fiscal years  
12               2008 through 2011.

13 **“SEC. 1116. HUNTER KELLY GRANT PROGRAM.**

14               “(a) ADDITIONAL NEWBORN SCREENING TESTS  
15               GRANTS.—

16               “(1) IN GENERAL.—The Secretary shall award  
17               grants (to be known as Hunter Kelly Newborn  
18               Screening grants), in conjunction with the Inter-  
19               agency Grant Review Panel established under sec-  
20               tion 1114, to eligible entities to carry out dem-  
21               onstration projects that develop screening tests for  
22               additional newborn conditions, such as tests for  
23               Krabbe disease and Insulin Dependent Diabetes  
24               Mellitus, or develop multiple markers to increase the

1 specificity of newborn screening tests. Such grants  
2 shall be made on a competitive basis.

3       “(2) ADDITIONAL NEWBORN CONDITION.—For  
4 purposes of this subsection, the term ‘additional  
5 newborn condition’ means any condition that is not  
6 one of the core conditions designated by the Advi-  
7 sory Committee described under section 1112.

8       “(b) ELIGIBILITY.—To be eligible to receive a grant  
9 under this section, an entity shall—

10       “(1) submit to the Secretary an application at  
11 such time, in such manner, and containing such in-  
12 formation as the Secretary may require;

13       “(2) be a public or private organization includ-  
14 ing, an academic research center, medical center,  
15 physician group, newborn screening program, or  
16 CLIA-certified laboratory with expertise in newborn  
17 metabolic screening;

18       “(3) provide assurance that such entity will  
19 work in consultation with the appropriate State de-  
20 partment of health;

21       “(4) submit to the Secretary a strategic plan  
22 for performing additional newborn screening tests  
23 and for collecting and reporting data on the costs,  
24 benefits, and effectiveness of such tests, in consulta-

1       tion with the appropriate State department of  
2       health;

3           “(5) demonstrate sustainability of such activi-  
4       ties based on the outcomes of the demonstration  
5       project;

6           “(6) provide assurance that the entity will de-  
7       velop newborn screening tests that are not currently  
8       performed in the State in which the entity is located;  
9       and

10          “(7) if applicable, submit to the Secretary a  
11       plan for short- and long-term follow-up, diagnosis,  
12       and treatment of those infants who test positive on  
13       newborn screening tests developed under this sec-  
14       tion.

15          “(c) REPORT TO SECRETARY AND INTERAGENCY  
16  PANEL.—An organization that receives a grant under this  
17  section shall, on an annual basis, submit to the Secretary  
18  and the Interagency Grant Review Panel established  
19  under section 1114 a report that describes the activities  
20  conducted pursuant to such grant and the outcomes of  
21  such activities.

22          “(d) EVALUATION AND RESULTS.—The Secretary  
23  shall—

24           “(1) evaluate the demonstration projects funded  
25  under this section; and

1               “(2) on an annual basis—

2                     “(A) publish and disseminate the results of  
3                     such evaluation on as wide a basis as is prac-  
4                     ticable; and

5                     “(B) submit to the appropriate committees  
6                     of Congress the results of such evaluation.

7               “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
8                     are authorized to be appropriated to carry out this sec-  
9                     tion—

10               “(1) \$30,000,000 for fiscal year 2007; and

11               “(2) such sums as necessary for fiscal years  
12                     2008 through 2011.

13 **“SEC. 1117. PRIVACY PROTECTIONS.**

14               “Except to the extent inconsistent with this part, the  
15                     provision of information pursuant to sections 1112  
16                     through 1116, and any subsequent transfer of such infor-  
17                     mation in accordance with those sections, are subject to  
18                     any requirement that would otherwise apply under the reg-  
19                     ulations promulgated pursuant to section 264(c) of the  
20                     Health Insurance Portability and Accountability Act of  
21                     1996.”.

○