

110TH CONGRESS
1ST SESSION

H. R. 2889

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 27, 2007

Mr. REYNOLDS introduced the following bill; which was referred to the Committee on Energy and Commerce

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 en-
2 hanced capacity will assist the States in making
3 progress toward the following goals:

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

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

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

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

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

1 (ii) Rehabilitative services for
2 newborns with the conditions.

3 (E) Newborn screening should be expanded
4 to include more conditions, and additional new-
5 born screening tests should be developed to en-
6 hance the health of newborns.

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

10 (A) statewide newborn screening and med-
11 ical evaluation systems and intervention pro-
12 grams;

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 Accredi-
9 tation 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 tem 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 2008; and

14 “(2) such sums as necessary for fiscal year
15 2009 through 2012.

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 2008; and

5 “(2) such sums as necessary for fiscal years
6 2009 through 2012.

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 2008; and

11 “(2) such sums as necessary for fiscal years
12 2009 through 2012.

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 2008; and

11 “(2) such sums as necessary for fiscal years
12 2009 through 2012.

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.”.

○