# H. R. 1634

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, to reauthorize programs under part A of title XI of such Act, and for other purposes.

### IN THE HOUSE OF REPRESENTATIVES

March 21, 2007

Ms. ROYBAL-ALLARD (for herself and Mr. SIMPSON) 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, to reauthorize programs under part A of title XI of such Act, 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 2007".

#### 1 SEC. 2. FINDINGS.

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- 2 Congress finds the following:
- 3 (1) Each year, approximately 4,000,000 babies 4 are born in the United States, and all are offered 5 some type of newborn screening by State and private 6 laboratories to detect certain conditions that may 7 threaten their long-term health.
  - (2) However, there is a lack of uniformity in the number of conditions for which newborns are screened through State-based programs. Although a newborn may be screened and treated for a debilitating condition in one State, in another State the condition may go undetected and result in permanent disability or even death.
  - (3) In 2004, the American College of Medical Genetics (ACMG) completed a report commissioned by the Department of Health and Human Services which recommended that every baby born in the United States be screened for 29 specific disorders, which, if diagnosed early, can be successfully managed or treated to prevent severe and often lifelong health consequences.
  - (4) Currently only 11 States and the District of Columbia require infants to be screened for all 29 of these recommended disorders.

- 1 (5) The March of Dimes estimates that 1,000 2 of the 5,000 babies born every year in the United 3 States with one of the 29 core conditions do not re-4 ceive comprehensive newborn screening that includes 5 their particular disorder. This results in catastrophic 6 consequences for the child and the family and enor-7 mous costs for society.
- 8 (6) Continuity plays a critical role in the 9 screening, diagnosis, referral, and treatment of these 10 disorders. Currently there is no national contingency 11 plan for maintaining continuity of newborn screen-12 ing systems during a public health emergency, such 13 as a catastrophic natural disaster or a widespread 14 terrorist event, that results in State or regional dis-15 ruption of newborn screening services.

## 16 SEC. 3. AMENDMENT TO TITLE III OF THE PUBLIC HEALTH

- 17 SERVICE ACT.
- Part Q of title III of the Public Health Service Act
- 19 (42 U.S.C. 280h et seq.) is amended by adding at the end
- 20 the following:
- 21 "SEC. 399Z-1. NEWBORN SCREENING.
- 22 "(a) Authorization of Grant Programs.—
- 23 "(1) Grants to assist health care profes-
- 24 SIONALS.—From funds appropriated under sub-
- 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 newborn
10	screening 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.—
18	"(A) In general.—From funds appro-
19	priated under subsection (h), the Secretary, act-
20	ing through the Associate Administrator and in
21	consultation with the Advisory Committee, shall
22	award grants to eligible entities to enable such
23	entities to develop and deliver educational pro-
24	grams about newborn screening to parents,
25	families, and patient advocacy and support

groups. The educational materials accompanying such educational programs shall be provided at appropriate literacy levels.

"(B) AWARENESS OF THE AVAILABILITY OF PROGRAMS.—To the extent practicable, the Secretary shall make relevant health care providers aware of the availability of the educational programs supported pursuant to subparagraph (A).

"(3) Grants for quality newborn screenIng followup.—From funds appropriated under subsection (h), the Secretary, acting through the Associate Administrator and in consultation with the Advisory Committee, shall award grants to eligible entities to enable such entities to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.

"(b) APPLICATION.—An eligible entity that desires to receive a grant under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.

24 "(c) Selection of Grant Recipients.—

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1	"(1) In general.—Not later than 120 days
2	after receiving an application under subsection (b),
3	the Secretary, after considering the approval factors
4	under paragraph (2), shall determine whether to
5	award the eligible entity a grant under this section.
6	"(2) Approval factors.—
7	"(A) REQUIREMENTS FOR APPROVAL.—An
8	application submitted under subsection (b) may
9	not be approved by the Secretary unless the ap-
10	plication contains assurances that the eligible
11	entity—
12	"(i) will use grant funds only for the
13	purposes specified in the approved applica-
14	tion and in accordance with the require-
15	ments of this section; and
16	"(ii) will establish such fiscal control
17	and fund accounting procedures as may be
18	necessary to assure proper disbursement
19	and accounting of Federal funds paid to
20	the eligible entity under the grant.
21	"(B) Existing programs.—Prior to
22	awarding a grant under this section, the Sec-
23	retary shall—
24	"(i) conduct an assessment of existing
25	educational resources and training pro-

1	grams and coordinated systems of followup
2	care with respect to newborn screening;
3	and
4	"(ii) take all necessary steps to mini-
5	mize the duplication of the resources and
6	programs described in clause (i).
7	"(d) COORDINATION.—The Secretary shall take all
8	necessary steps to coordinate programs funded with
9	grants received under this section.
10	"(e) USE OF GRANT FUNDS.—
11	"(1) Grants to assist health care profes-
12	SIONALS.—An eligible entity that receives a grant
13	under subsection (a)(1) may use the grant funds to
14	work with appropriate medical schools, nursing
15	schools, schools of public health, schools of genetic
16	counseling, internal education programs in State
17	agencies, nongovernmental organizations, and pro-
18	fessional organizations and societies to develop and
19	deliver education and training programs that in-
20	clude—
21	"(A) continuing medical education pro-
22	grams for health care professionals and new-
23	born screening laboratory personnel in newborn
24	screening;

1	"(B) education, technical assistance, and
2	training on new discoveries in newborn screen-
3	ing and the use of any related technology;
4	"(C) models to evaluate the prevalence of,
5	and assess and communicate the risks of, con-
6	genital conditions, including the prevalence and
7	risk of some of these conditions based on family
8	history;
9	"(D) models to communicate effectively
10	with parents and families about—
11	"(i) the process and benefits of new-
12	born screening;
13	"(ii) how to use information gathered
14	from newborn screening;
15	"(iii) the meaning of screening re-
16	sults, including the possibility of false posi-
17	tive findings;
18	"(iv) the right of refusal of newborn
19	screening, if applicable; and
20	"(v) the potential need for followup
21	care after newborns are screened;
22	"(E) information and resources on coordi-
23	nated systems of followup care after newborns
24	are screened;

1	"(F) information on the disorders for
2	which States require and offer newborn screen-
3	ing and options for newborn screening relating
4	to conditions in addition to such disorders;
5	"(G) information on additional newborn
6	screening that may not be required by the
7	State, but that may be available from other
8	sources; and
9	"(H) other items to carry out the purpose
10	described in subsection (a)(1) as determined ap-
11	propriate by the Secretary.
12	"(2) Grants to assist families.—An eligible
13	entity that receives a grant under subsection (a)(2)
14	may use the grant funds to develop and deliver to
15	parents, families, and patient advocacy and support
16	groups, educational programs about newborn screen-
17	ing that include information on—
18	"(A) what newborn screening is;
19	"(B) how newborn screening is performed;
20	"(C) who performs newborn screening;
21	"(D) where newborn screening is per-
22	formed;
23	"(E) the disorders for which the State re-
24	quires newborns to be screened:

1	"(F) different options for newborn screen-
2	ing for disorders other than those included by
3	the State in the mandated newborn screening
4	program;
5	"(G) the meaning of various screening re-
6	sults, including the possibility of false positive
7	and false negative findings;
8	"(H) the prevalence and risk of newborn
9	disorders, including the increased risk of dis-
10	orders that may stem from family history;
11	"(I) coordinated systems of followup care
12	after newborns are screened; and
13	"(J) other items to carry out the purpose
14	described in subsection (a)(2) as determined ap-
15	propriate by the Secretary.
16	"(3) Grants for quality newborn screen-
17	ING FOLLOWUP.—An eligible entity that receives a
18	grant under subsection (a)(3) shall use the grant
19	funds to—
20	"(A) expand on existing procedures and
21	systems, where appropriate and available, for
22	the timely reporting of newborn screening re-
23	sults to individuals, families, primary care phy-
24	sicians, and subspecialists in congenital, ge-
25	netic, and metabolic disorders;

1	"(B) coordinate ongoing followup treat-
2	ment with individuals, families, primary care
3	physicians, and subspecialists in congenital, ge-
4	netic, and metabolic disorders after a newborn
5	receives an indication of the presence or in-
6	creased risk of a disorder on a screening test
7	"(C) ensure the seamless integration of
8	confirmatory testing, tertiary care medical serv-
9	ices, comprehensive genetic services including
10	genetic counseling, and information about ac-
11	cess to developing therapies by participation in
12	approved clinical trials involving the primary
13	health care of the infant;
14	"(D) analyze data, if appropriate and
15	available, collected from newborn screenings to
16	identify populations at risk for disorders affect-
17	ing newborns, examine and respond to health
18	concerns, recognize and address relevant envi-
19	ronmental, behavioral, socioeconomic, demo-
20	graphic, and other relevant risk factors; and
21	"(E) carry out such other activities as the
22	Secretary may determine necessary.
23	"(f) Reports to Congress.—

1	"(1) In General.—Subject to paragraph (2),
2	the Secretary shall submit to the appropriate com-
3	mittees of Congress reports—
4	"(A) evaluating the effectiveness and the
5	impact of the grants awarded under this sec-
6	tion—
7	"(i) in promoting newborn screen-
8	ing—
9	"(I) education and resources for
10	families; and
11	"(II) education, resources, and
12	training for health care professionals;
13	"(ii) on the successful diagnosis and
14	treatment of congenital, genetic, and meta-
15	bolic disorders; and
16	"(iii) on the continued development of
17	coordinated systems of followup care after
18	newborns are screened;
19	"(B) describing and evaluating the effec-
20	tiveness of the activities carried out with grant
21	funds received under this section; and
22	"(C) that include recommendations for
23	Federal actions to support—
24	"(i) education and training in new-
25	born screening; and

1	"(ii) followup care after newborns are
2	screened.
3	"(2) Timing of Reports.—The Secretary shall
4	submit—
5	"(A) an interim report that includes the
6	information described in paragraph (1), not
7	later than 30 months after the date on which
8	the first grant funds are awarded under this
9	section; and
10	"(B) a subsequent report that includes the
11	information described in paragraph (1), not
12	later than 60 months after the date on which
13	the first grant funds are awarded under this
14	section.
15	"(g) Definition of Eligible Entity.—In this sec-
16	tion, the term 'eligible entity' means—
17	"(1) a State or a political subdivision of a
18	State;
19	"(2) a consortium of 2 or more States or polit-
20	ical subdivisions of States;
21	"(3) a territory;
22	"(4) an Indian tribe or a hospital or outpatient
23	health care facility of the Indian Health Service; or

1	"(5) a nongovernmental organization with ap-
2	propriate expertise in newborn screening, as deter-
3	mined by the Secretary.
4	"(h) National Contingency Plan for Newborn
5	Screening.—
6	"(1) In general.—Not later than 180 days
7	after the date of enactment of this section, the Sec-
8	retary, acting through the Director of the Centers
9	for Disease Control and Prevention and in consulta-
10	tion with the Associate Administrator, shall develop
11	a national contingency plan for newborn screening
12	for use in the event of a public health emergency
13	that results in State or regional disruption of new-
14	born screening services.
15	"(2) Requirements.—The contingency plan
16	developed under paragraph (1) shall include a plan
17	for—
18	"(A) the collection and transport of speci-
19	mens;
20	"(B) the shipment of specimens to State
21	newborn screening laboratories;
22	"(C) the processing of specimens;
23	"(D) the reporting of screening results to
24	physicians and families;

1	"(E) the diagnostic confirmation of posi-
2	tive screening results;
3	"(F) ensuring the availability of treatment
4	and management resources;
5	"(G) educating families about newborn
6	screening; and
7	"(H) carrying out other activities deter-
8	mined appropriate by the Secretary.
9	"(i) Authorization of Appropriations.—There
10	are authorized to be appropriated to carry out this sec-
11	tion—
12	" $(1)$ \$15,000,000 for fiscal year 2008; and
13	"(2) such sums as may be necessary for each
14	of fiscal years 2009 through 2012.".
15	SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR
16	HERITABLE DISORDERS.
17	Section 1109 of the Public Health Service Act (42
18	U.S.C. 300b–8) is amended—
19	(1) in subsection $(c)(2)$ —
20	(A) in subparagraph (E), by striking
21	"and" after the semicolon;
22	(B) by redesignating subparagraph (F) as
23	subparagraph (G); and
24	(C) by inserting after subparagraph (E)
25	the following:

1 "(F) an assurance that the entity has 2 adopted and implemented, is in the process of 3 adopting and implementing, or will use grant 4 amounts received under this section to adopt 5 and implement the guidelines and recommendations of the Advisory Committee on Heritable 6 7 Disorders in Newborns and Children established 8 under section 1111 (referred to in this section 9 as the 'Advisory Committee') that are adopted 10 by the Secretary and in effect at the time the 11 grant is awarded or renewed under this section, 12 which shall include the screening of each new-13 born for the heritable disorders recommended 14 by the Advisory Committee and adopted by the 15 Secretary and the reporting of results; and"; 16 and 17

(2) in subsection (i), by striking "such sums" and all that follows through the period at the end and inserting "\$25,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012.".

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1	SEC. 5. EVALUATING THE EFFECTIVENESS OF NEWBORN-
2	AND CHILD-SCREENING PROGRAMS.
3	Section 1110 of the Public Health Service Act (42
4	U.S.C. 300b-9) is amended by adding at the end the fol-
5	lowing:
6	"(d) Authorization of Appropriations.—There
7	are authorized to be appropriated to carry out this section
8	\$5,000,000 for fiscal year 2008 and such sums as may
9	be necessary for each of the fiscal years 2009 through
10	2012.".
11	SEC. 6. ADVISORY COMMITTEE ON HERITABLE DISORDERS
12	IN NEWBORNS AND CHILDREN.
13	Section 1111 of the Public Health Service Act (42
14	U.S.C. 300b–10) is amended—
15	(1) in subsection (b)—
16	(A) by redesignating paragraph (3) as
17	paragraph (5);
18	(B) in paragraph (2), by striking "and"
19	after the semicolon;
20	(C) by inserting after paragraph (2) the
21	following:
22	"(3) recommend a uniform screening panel for
23	newborn screening programs that includes the heri-
24	table disorders for which all newborns should be
25	screened including secondary conditions that may be

1	identified as a result of the laboratory methods used
2	for screening;
3	"(4) develop a model decision-matrix for new-
4	born screening program expansion, and periodically
5	update the recommended uniform screening panel
6	described in paragraph (3) based on such decision-
7	matrix; and"; and
8	(D) in paragraph (5) (as redesignated by
9	subparagraph (A)), by striking the period at the
10	end and inserting ", including recommenda-
11	tions, advice, or information dealing with—
12	"(A) followup activities, including those
13	necessary to achieve rapid diagnosis in the
14	short term, and those that ascertain long-term
15	case management outcomes and appropriate ac-
16	cess to related services;
17	"(B) diagnostic and other technology used
18	in screening;
19	"(C) the availability and reporting of test-
20	ing for conditions for which there is no existing
21	treatment;
22	"(D) minimum standards and related poli-
23	cies and procedures for State newborn screen-
24	ing programs;

1	"(E) quality assurance, oversight, and
2	evaluation of State newborn screening pro-
3	grams;
4	"(F) data collection for assessment of new-
5	born screening programs;
6	"(G) public and provider awareness and
7	education;
8	"(H) language and terminology used by
9	State newborn screening programs;
10	"(I) confirmatory testing and verification
11	of positive results; and
12	"(J) harmonization of laboratory defini-
13	tions for results that are within the expected
14	range and results that are outside of the ex-
15	pected range."; and
16	(2) by adding at the end the following:
17	"(d) Decision on Recommendations.—
18	"(1) In general.—Not later than 180 days
19	after the Advisory Committee issues a recommenda-
20	tion pursuant to this section, the Secretary shall
21	adopt or reject such recommendation.
22	"(2) Pending recommendations.—The Sec-
23	retary shall adopt or reject any recommendation
24	issued by the Advisory Committee that is pending on
25	the date of enactment of the Newborn Screening

- 1 Saves Lives Act of 2007 by not later than 180 days
- 2 after the date of enactment of such Act.
- 3 "(3) Determinations to be made public.—
- 4 The Secretary shall publicize any determination on
- 5 adopting or rejecting a recommendation of the Advi-
- 6 sory Committee pursuant to this subsection, includ-
- 7 ing the justification for the determination.
- 8 "(e) Continuation of Operation of Com-
- 9 MITTEE.—Notwithstanding section 14 of the Federal Ad-
- 10 visory Committee Act (5 U.S.C. App.), the Advisory Com-
- 11 mittee shall continue to operate during the 5-year period
- 12 beginning on the date of enactment of the Newborn
- 13 Screening Saves Lives Act of 2007.".
- 14 SEC. 7. LABORATORY QUALITY AND SURVEILLANCE.
- 15 Part A of title XI of the Public Health Service Act
- 16 (42 U.S.C. 300b–1 et seq.) is amended by adding at the
- 17 end the following:
- 18 "SEC. 1112. LABORATORY QUALITY.
- 19 "(a) In General.—The Secretary, acting through
- 20 the Director of the Centers for Disease Control and Pre-
- 21 vention and in consultation with the Advisory Committee
- 22 on Heritable Disorders in Newborns and Children estab-
- 23 lished under section 1111, shall provide for—
- 24 "(1) quality assurance for laboratories involved
- in screening newborns and children for heritable dis-

1	orders, including quality assurance for newborn-
2	screening tests, performance evaluation services, and
3	technical assistance and technology transfer to new-
4	born screening laboratories to ensure analytic valid-
5	ity and utility of screening tests; and
6	"(2) population-based pilot testing for new
7	screening tools for evaluating use on a mass scale.
8	"(b) Authorization of Appropriations.—For the
9	purpose of carrying out this section, there are authorized
10	to be appropriated \$5,000,000 for fiscal year 2008 and
11	such sums as may be necessary for each of the fiscal years
12	2009 through 2012.
13	"SEC. 1113. SURVEILLANCE PROGRAMS FOR HERITABLE
14	DISORDERS SCREENING.
15	"(a) In General.—The Secretary, acting through
16	the Director of the Centers for Disease Control and Pre-
17	vention, in consultation with the Associate Administrator
18	of the Maternal and Child Health Bureau of the Health

21 "(1) to collect, analyze, and make available data 22 on the heritable disorders recommended by the Advi-23 sory Committee on Heritable Disorders in Newborns

19 Resources and Services Administration, shall carry out

and Children established under section 1111, includ-

programs—

1	ing data on the causes of such disorders and on the
2	incidence and prevalence of such disorders;
3	"(2) to operate regional centers for the conduct
4	of applied epidemiological research on the prevention
5	of such disorders;
6	"(3) to provide information and education to
7	the public on the prevention of such disorders; and
8	"(4) to conduct research on and to promote the
9	prevention of such disorders, and secondary health
10	conditions among individuals with such disorders.
11	"(b) Grants and Contracts.—
12	"(1) In general.—In carrying out subsection
13	(a), the Secretary may make grants to and enter
14	into contracts with public and nonprofit private enti-
15	ties.
16	"(2) Supplies and services in lieu of
17	AWARD FUNDS.—
18	"(A) IN GENERAL.—Upon the request of a
19	recipient of an award of a grant or contract
20	under paragraph (1), the Secretary may, sub-
21	ject to subparagraph (B), provide supplies,
22	equipment, and services for the purpose of aid-
23	ing the recipient in carrying out the purposes
24	for which the award is made and, for such pur-

poses, may detail to the recipient any officer or

employee of the Department of Health and Human Services.

"(B) Reduction.—With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

"(3) APPLICATION FOR AWARD.—The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.

"(c) BIENNIAL REPORT.—Not later than February 1 of fiscal year 2008 and of every second such year thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pen-

- sions of the Senate, a report that, with respect to the pre-1 2 ceding 2 fiscal years— 3 "(1) contains information regarding the incidence and prevalence of heritable disorders and the 5 health status of individuals with such disorders and 6 the extent to which such disorders have contributed 7 to the incidence and prevalence of infant mortality 8 and affected quality of life; 9 "(2) contains information under paragraph (1) that is specific to various racial and ethnic groups 10 11 (including Hispanics, non-Hispanic whites, Blacks, 12 Native Americans, and Asian Americans); 13 "(3) contains an assessment of the extent to 14 which various approaches of preventing heritable dis-15 orders and secondary health conditions among indi-16 viduals with such disorders have been effective; 17 "(4) describes the activities carried out under 18 this section; 19 "(5) contains information on the incidence and 20 prevalence of individuals living with heritable dis-
  - "(5) contains information on the incidence and prevalence of individuals living with heritable disorders, information on the health status of individuals with such disorders, information on any health disparities experienced by such individuals, and recommendations for improving the health and wellness and quality of life of such individuals;

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1	"(6) contains a summary of recommendations
2	from all heritable disorders research conferences
3	sponsored by the Centers for Disease Control and
4	Prevention; and
5	"(7) contains any recommendations of the Sec-
6	retary regarding this section.
7	"(d) Applicability of Privacy Laws.—The provi-
8	sions of this section shall be subject to the requirements
9	of section 552a of title 5, United States Code. All Federa
10	laws relating to the privacy of information shall apply to
11	the data and information that is collected under this sec-
12	tion.
13	"(e) Coordination.—
14	"(1) In general.—In carrying out this sec-
15	tion, the Secretary shall coordinate, to the extent
16	practicable, programs under this section with pro-
17	grams on birth defects and developmental disabilities
18	authorized under section 317C.
19	"(2) Priority in grants and contracts.—
20	In making grants and contracts under this section
21	the Secretary shall give priority to entities that dem-
22	onstrate the ability to coordinate activities under a
23	grant or contract made under this section with exist

ing birth defects surveillance activities.

- 1 "(f) AUTHORIZATION OF APPROPRIATIONS.—For the
- 2 purpose of carrying out this section, there are authorized
- 3 to be appropriated \$15,000,000 for fiscal year 2008 and
- 4 such sums as may be necessary for each of the fiscal years

5 2009 through 2012.".

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