

Calendar No. 701

110TH CONGRESS
2D SESSION

S. 1810

To amend the Public Health Service Act to increase the provision of scientifically sound information and support services to patients receiving a positive test diagnosis for Down syndrome or other prenatally and postnatally diagnosed conditions.

IN THE SENATE OF THE UNITED STATES

JULY 18 (legislative day, JULY 17), 2007

Mr. BROWNBACK (for himself, Mr. KENNEDY, and Mr. DORGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 21, 2008

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Public Health Service Act to increase the provision of scientifically sound information and support services to patients receiving a positive test diagnosis for Down syndrome or other prenatally and postnatally diagnosed conditions.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Prenatally and
3 Postnatally Diagnosed Conditions Awareness Act”.

4 **SEC. 2. FINDINGS AND PURPOSES.**

5 (a) **FINDINGS.**—Congress makes the following find-
6 ings:

7 (1) Pregnant women who choose to undergo
8 prenatal genetic testing should have access to timely,
9 scientific, and nondirective counseling about the con-
10 ditions being tested for and the accuracy of such
11 tests, from health care professionals qualified to pro-
12 vide and interpret these tests. Informed consent is a
13 critical component of all genetic testing.

14 (2) A recent, peer-reviewed study and two re-
15 ports from the Centers for Disease Control and Pre-
16 vention on prenatal testing found a deficiency in the
17 data needed to understand the epidemiology of pre-
18 natally diagnosed conditions, to monitor trends accu-
19 rately, and to increase the effectiveness of health
20 intervention.

21 (b) **PURPOSES.**—It is the purpose of this Act, after
22 the diagnosis of a fetus with Down syndrome or other pre-
23 natally diagnosed conditions, to—

24 (1) increase patient referrals to providers of key
25 support services for women who have received a
26 positive test diagnosis for Down syndrome, or other

1 prenatally or postnatally diagnosed conditions; as
 2 well as to provide up-to-date, comprehensive infor-
 3 mation about life expectancy, development potential,
 4 and quality of life for a child born with Down syn-
 5 drome or other prenatally or postnatally diagnosed
 6 condition;

7 (2) strengthen existing networks of support
 8 through a Centers for Disease Control and Preven-
 9 tion patient and provider outreach program;

10 (3) improve available data by incorporating in-
 11 formation directly revealed by prenatal or postnatal
 12 testing into existing State-based surveillance pro-
 13 grams for birth defects and prenatally or postnatally
 14 diagnosed conditions; and

15 (4) ensure that patients receive up-to-date, sci-
 16 entific information about the accuracy of the test.

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

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

1 **~~“SEC. 399R. SUPPORT FOR PATIENTS RECEIVING A POSI-~~**
 2 **~~TIVE TEST DIAGNOSIS OF DOWN SYNDROME~~**
 3 **~~OR OTHER PRENATALLY OR POSTNATALLY~~**
 4 **~~DIAGNOSED CONDITIONS.~~**

5 ~~“(a) DEFINITIONS.—In this section:~~

6 ~~“(1) DOWN SYNDROME.—The term ‘Down syn-~~
 7 ~~drome’ refers to a chromosomal disorder caused by~~
 8 ~~an error in cell division that results in the presenece~~
 9 ~~of an extra whole or partial copy of chromosome 21.~~

10 ~~“(2) HEALTH CARE PROVIDER.—The term~~
 11 ~~‘health care provider’ means any person or entity re-~~
 12 ~~quired by State or Federal law or regulation to be~~
 13 ~~licensed, registered, or certified to provide health~~
 14 ~~care services, and who is so licensed, registered, or~~
 15 ~~certified.~~

16 ~~“(3) POSTNATALLY DIAGNOSED CONDITION.—~~
 17 ~~The term ‘postnatally diagnosed condition’ means~~
 18 ~~any health condition identified by postnatal genetic~~
 19 ~~testing or postnatal screening procedures during the~~
 20 ~~12-month period beginning at birth.~~

21 ~~“(4) PRENATALLY DIAGNOSED CONDITION.—~~
 22 ~~The term ‘prenatally diagnosed condition’ means any~~
 23 ~~fetal health condition identified by prenatal genetic~~
 24 ~~testing or prenatal screening procedures.~~

25 ~~“(5) POSTNATAL TEST.—The term ‘postnatal~~
 26 ~~test’ means diagnostic or screening tests offered with~~

1 respect to an individual from birth to 1 year of age
 2 that is administered on a required or recommended
 3 basis by a health care provider based on medical his-
 4 tory, family background, ethnic background, pre-
 5 vious test results, symptoms the child is presenting,
 6 or other risk factors.

7 “(6) **PRENATAL TEST.**—The term ‘prenatal
 8 test’ means diagnostic or screening tests offered to
 9 pregnant women seeking routine prenatal care that
 10 are administered on a required or recommended
 11 basis by a health care provider based on medical his-
 12 tory, family background, ethnic background, pre-
 13 vious test results, or other risk factors.

14 “(b) **INFORMATION AND SUPPORT SERVICES.**—

15 “(1) **IN GENERAL.**—The Secretary, acting
 16 through the Director of the National Institutes of
 17 Health, the Director of the Centers for Disease Con-
 18 trol and Prevention, or the Administrator of the
 19 Health Resources and Services Administration, may
 20 authorize and oversee certain activities, including the
 21 awarding of grants, contracts or cooperative agree-
 22 ments, to—

23 “(A) collect, synthesize, and disseminate
 24 current scientific information relating to Down

1 syndrome or other prenatally or postnatally di-
2 agnosed conditions; and

3 “(B) coordinate the provision of, and ac-
4 cess to, new or existing supportive services for
5 patients receiving a positive test diagnosis for
6 Down syndrome or other prenatally or
7 postnatally diagnosed conditions; including—

8 “(i) the establishment of a resource
9 telephone hotline and Internet website ac-
10 cessible to patients receiving a positive test
11 result;

12 “(ii) the expansion and further devel-
13 opment of the National Dissemination
14 Center for Children with Disabilities; so
15 that such Center can more effectively con-
16 duct outreach to new and expecting par-
17 ents and provide them with up-to-date in-
18 formation on the clinical course, life ex-
19 pectancy, development potential, quality of
20 life, and available resources and services
21 for children with Down syndrome or other
22 prenatally and postnatally diagnosed condi-
23 tions;

24 “(iii) the expansion and further devel-
25 opment of national and local peer-support

1 programs, so that such programs can more
2 effectively serve parents of newly diagnosed
3 children;

4 “(iv) the establishment of a national
5 registry, or network of local registries, of
6 families willing to adopt newborns with
7 Down syndrome or other prenatally or
8 postnatally diagnosed conditions, and links
9 to adoption agencies willing to place babies
10 with Down syndrome or other prenatally or
11 postnatally diagnosed conditions, with fam-
12 ilies willing to adopt; and

13 “(v) the establishment of awareness
14 and education programs for health care
15 providers who provide the results of pre-
16 natal or postnatal tests for Down syn-
17 drome or other prenatally or postnatally
18 diagnosed conditions, to patients, con-
19 sistent with the purpose described in sec-
20 tion 2(b)(1) of the Prenatally and
21 Postnatally Diagnosed Conditions Aware-
22 ness Act.

23 “(2) DISTRIBUTION.—In distributing funds
24 under this subsection, the Secretary shall place an

1 emphasis on funding partnerships between health
2 care groups and disability advocacy organizations.

3 ~~“(c) DATA COLLECTION.—~~

4 ~~“(1) PROVISION OF ASSISTANCE.—The Sec-~~
5 ~~retary, acting through the Director of Centers for~~
6 ~~Disease Control and Prevention, shall provide assist-~~
7 ~~ance to State and local health departments to inte-~~
8 ~~grate the results of prenatal or postnatal testing into~~
9 ~~State-based vital statistics and birth defects surveil-~~
10 ~~lance programs.~~

11 ~~“(2) ACTIVITIES.—The Secretary shall ensure~~
12 ~~that activities carried out under paragraph (1) are~~
13 ~~sufficient to extract population-level data relating to~~
14 ~~national rates and results of prenatal or postnatal~~
15 ~~testing.~~

16 ~~“(3) INFORMED CONSENT.—Prior to the report-~~
17 ~~ing of the results of a prenatal or postnatal test to~~
18 ~~a State or local public health department under this~~
19 ~~subsection, the patient involved shall be provided~~
20 ~~with a disclosure statement that describes the man-~~
21 ~~ner in which the results of such tests will be used.~~
22 ~~Such results may not be reported unless the patient~~
23 ~~consents to such reporting after receipt of such dis-~~
24 ~~closure statement.~~

1 “(d) ~~PROVISION OF INFORMATION BY PROVIDERS.—~~

2 Upon receipt of a positive test result from a prenatal or
 3 postnatal test for Down syndrome or other prenatally or
 4 postnatally diagnosed conditions performed on a patient;
 5 the health care provider involved (or his or her designee)
 6 shall provide the patient with the following:

7 “(1) Up-to-date, scientific, written information
 8 concerning the life expectancy, clinical course, and
 9 intellectual and functional development and treat-
 10 ment options for a fetus diagnosed with or child
 11 born with Down syndrome or other prenatally or
 12 postnatally diagnosed conditions.

13 “(2) Referral to supportive services providers,
 14 including information hotlines specific to Down syn-
 15 drome or other prenatally or postnatally diagnosed
 16 conditions; resource centers or clearinghouses; and
 17 other education and support programs as described
 18 in subsection (b)(2).

19 “(e) ~~PRIVACY.—~~

20 “(1) ~~IN GENERAL.—~~Notwithstanding sub-
 21 sections (c) and (d), nothing in this section shall be
 22 construed to permit or require the collection, mainte-
 23 nance, or transmission, without the health care pro-
 24 vider obtaining the prior, written consent of the pa-
 25 tient, of—

1 “(A) health information or data that iden-
2 tify a patient, or with respect to which there is
3 a reasonable basis to believe the information
4 could be used to identify the patient (including
5 a patient’s name, address, healthcare provider,
6 or hospital); and

7 “(B) data that are not related to the epi-
8 demiology of the condition being tested for.

9 “(2) GUIDANCE.—Not later than 180 days
10 after the date of enactment of this section, the Sec-
11 retary shall establish guidelines concerning the im-
12 plementation of paragraph (1) and subsection (d).

13 “(f) REPORTS.—

14 “(1) IMPLEMENTATION REPORT.—Not later
15 than 2 years after the date of enactment of this sec-
16 tion, and every 2 years thereafter, the Secretary
17 shall submit a report to Congress concerning the im-
18 plementation of the guidelines described in sub-
19 section (e)(2).

20 “(2) GAO REPORT.—Not later than 1 year
21 after the date of enactment of this section, the Gov-
22 ernment Accountability Office shall submit a report
23 to Congress concerning the effectiveness of current
24 healthcare and family support programs serving as

1 resources for the families of children with disabil-
 2 ities.

3 ~~“(g) AUTHORIZATION OF APPROPRIATIONS.—~~There
 4 is authorized to be appropriated to carry out this section;
 5 \$5,000,000 for each of fiscal years 2008 through 2012.”.

6 **SECTION 1. SHORT TITLE.**

7 *This Act may be cited as the “Prenatally and*
 8 *Postnatally Diagnosed Conditions Awareness Act”.*

9 **SEC. 2. PURPOSES.**

10 *It is the purpose of this Act to—*

11 *(1) increase patient referrals to providers of key*
 12 *support services for women who have received a posi-*
 13 *tive diagnosis for Down syndrome, or other pre-*
 14 *natally or postnatally diagnosed conditions, as well*
 15 *as to provide up-to-date information on the range of*
 16 *outcomes for individuals living with the diagnosed*
 17 *condition, including physical, developmental, edu-*
 18 *cational, and psychosocial outcomes;*

19 *(2) strengthen existing networks of support*
 20 *through the Centers for Disease Control and Preven-*
 21 *tion, the Health Resources and Services Administra-*
 22 *tion, and other patient and provider outreach pro-*
 23 *grams; and*

1 (3) *ensure that patients receive up-to-date, evi-*
 2 *dence-based information about the accuracy of the*
 3 *test.*

4 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.**

5 *Part P of title III of the Public Health Service Act*
 6 *(42 U.S.C. 280g et seq.) is amended by adding at the end*
 7 *the following:*

8 **“SEC. 399R. SUPPORT FOR PATIENTS RECEIVING A POSI-**
 9 **TIVE DIAGNOSIS OF DOWN SYNDROME OR**
 10 **OTHER PRENATALLY OR POSTNATALLY DIAG-**
 11 **NOSED CONDITIONS.**

12 “(a) *DEFINITIONS.—In this section:*

13 “(1) *DOWN SYNDROME.—The term ‘Down syn-*
 14 *drome’ refers to a chromosomal disorder caused by an*
 15 *error in cell division that results in the presence of*
 16 *an extra whole or partial copy of chromosome 21.*

17 “(2) *HEALTH CARE PROVIDER.—The term*
 18 *‘health care provider’ means any person or entity re-*
 19 *quired by State or Federal law or regulation to be li-*
 20 *censed, registered, or certified to provide health care*
 21 *services, and who is so licensed, registered, or cer-*
 22 *tified.*

23 “(3) *POSTNATALLY DIAGNOSED CONDITION.—The*
 24 *term ‘postnatally diagnosed condition’ means any*

1 *health condition identified during the 12-month pe-*
 2 *riod beginning at birth.*

3 “(4) *PRENATALLY DIAGNOSED CONDITION.*—*The*
 4 *term ‘prenatally diagnosed condition’ means any fetal*
 5 *health condition identified by prenatal genetic testing*
 6 *or prenatal screening procedures.*

7 “(5) *PRENATAL TEST.*—*The term ‘prenatal test’*
 8 *means diagnostic or screening tests offered to preg-*
 9 *nant women seeking routine prenatal care that are*
 10 *administered on a required or recommended basis by*
 11 *a health care provider based on medical history, fam-*
 12 *ily background, ethnic background, previous test re-*
 13 *sults, or other risk factors.*

14 “(b) *INFORMATION AND SUPPORT SERVICES.*—

15 “(1) *IN GENERAL.*—*The Secretary, acting*
 16 *through the Director of the National Institutes of*
 17 *Health, the Director of the Centers for Disease Control*
 18 *and Prevention, or the Administrator of the Health*
 19 *Resources and Services Administration, may author-*
 20 *ize and oversee certain activities, including the*
 21 *awarding of grants, contracts or cooperative agree-*
 22 *ments to eligible entities, to—*

23 “(A) *collect, synthesize, and disseminate*
 24 *current evidence-based information relating to*

1 *Down syndrome or other prenatally or*
2 *postnatally diagnosed conditions; and*

3 “(B) coordinate the provision of, and access
4 to, new or existing supportive services for pa-
5 tients receiving a positive diagnosis for Down
6 syndrome or other prenatally or postnatally di-
7 agnosed conditions, including—

8 “(i) the establishment of a resource
9 telephone hotline accessible to patients re-
10 ceiving a positive test result or to the par-
11 ents of newly diagnosed infants with Down
12 syndrome and other diagnosed conditions;

13 “(ii) the expansion and further devel-
14 opment of the National Dissemination Cen-
15 ter for Children with Disabilities, so that
16 such Center can more effectively conduct
17 outreach to new and expecting parents and
18 provide them with up-to-date information
19 on the range of outcomes for individuals liv-
20 ing with the diagnosed condition, including
21 physical, developmental, educational, and
22 psychosocial outcomes;

23 “(iii) the expansion and further devel-
24 opment of national and local peer-support
25 programs, so that such programs can more

1 *effectively serve women who receive a posi-*
 2 *tive diagnosis for Down syndrome or other*
 3 *prenatal conditions or parents of infants*
 4 *with a postnatally diagnosed condition;*

5 “(iv) *the establishment of a national*
 6 *registry, or network of local registries, of*
 7 *families willing to adopt newborns with*
 8 *Down syndrome or other prenatally or*
 9 *postnatally diagnosed conditions, and links*
 10 *to adoption agencies willing to place babies*
 11 *with Down syndrome or other prenatally or*
 12 *postnatally diagnosed conditions, with fam-*
 13 *ilies willing to adopt; and*

14 “(v) *the establishment of awareness*
 15 *and education programs for health care pro-*
 16 *viders who provide, interpret, or inform*
 17 *parents of the results of prenatal tests for*
 18 *Down syndrome or other prenatally or*
 19 *postnatally diagnosed conditions, to pa-*
 20 *tients, consistent with the purpose described*
 21 *in section 2(b)(1) of the Prenatally and*
 22 *Postnatally Diagnosed Conditions Aware-*
 23 *ness Act.*

24 “(2) *ELIGIBLE ENTITY.*—*In this subsection, the*
 25 *term ‘eligible entity’ means—*

1 “(A) a State or a political subdivision of a
2 State;

3 “(B) a consortium of 2 or more States or
4 political subdivisions of States;

5 “(C) a territory;

6 “(D) a health facility or program operated
7 by or pursuant to a contract with or grant from
8 the Indian Health Service; or

9 “(E) any other entity with appropriate ex-
10 pertise in prenatally and postnatally diagnosed
11 conditions (including nationally recognized dis-
12 ability groups), as determined by the Secretary.

13 “(3) *DISTRIBUTION.*—In distributing funds
14 under this subsection, the Secretary shall place an
15 emphasis on funding partnerships between health care
16 professional groups and disability advocacy organiza-
17 tions.

18 “(c) *PROVISION OF INFORMATION TO PROVIDERS.*—

19 “(1) *IN GENERAL.*—A grantee under this section
20 shall make available to health care providers of par-
21 ents who receive a prenatal or postnatal diagnosis the
22 following:

23 “(A) Up-to-date, evidence-based, written in-
24 formation concerning the range of outcomes for
25 individuals living with the diagnosed condition,

1 *including physical, developmental, educational,*
 2 *and psychosocial outcomes.*

3 “(B) *Contact information regarding sup-*
 4 *port services, including information hotlines spe-*
 5 *cific to Down syndrome or other prenatally or*
 6 *postnatally diagnosed conditions, resource cen-*
 7 *ters or clearinghouses, national and local peer*
 8 *support groups, and other education and support*
 9 *programs as described in subsection (b)(2).*

10 “(2) *INFORMATIONAL REQUIREMENTS.—Informa-*
 11 *tion provided under this subsection shall be—*

12 “(A) *culturally and linguistically appro-*
 13 *priate as needed by women receiving a positive*
 14 *prenatal diagnosis or the family of infants re-*
 15 *ceiving a postnatal diagnosis; and*

16 “(B) *approved by the Secretary.*

17 “(d) *REPORT.—Not later than 2 years after the date*
 18 *of enactment of this section, the Government Accountability*
 19 *Office shall submit a report to Congress concerning the effec-*
 20 *tiveness of current healthcare and family support programs*
 21 *serving as resources for the families of children with disabil-*
 22 *ities.*

23 “(e) *AUTHORIZATION OF APPROPRIATIONS.—There is*
 24 *authorized to be appropriated to carry out this section,*
 25 *\$5,000,000 for each of fiscal years 2008 through 2012.”.*

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