

110TH CONGRESS
1ST SESSION

H. R. 3112

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 diagnosed conditions.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 2007

Mr. SENSENBRENNER (for himself, Mrs. McMORRIS RODGERS, and Mr. SESSIONS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 diagnosed conditions.

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 “Prenatally Diagnosed
5 Condition Awareness Act of 2007”.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

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

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

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

21 (1) increase patient referrals to providers of key
22 support services for women who have received a
23 positive test diagnosis for Down syndrome, or other
24 prenatally diagnosed conditions, as well as to provide
25 up-to-date, science-based information about life-ex-
26 pectancy, development potential, and quality of life

1 for a child born with Down syndrome or other pre-
2 nately diagnosed condition;

3 (2) provide networks of support through a Cen-
4 ters for Disease Control and Prevention patient and
5 provider outreach program;

6 (3) improve available data by incorporating in-
7 formation directly revealed by prenatal testing into
8 existing State-based surveillance programs for birth
9 defects and prenatally diagnosed conditions; and

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

12 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
13 **ACT.**

14 Part P of title III of the Public Health Service Act
15 (42 U.S.C. 280g et seq.) is amended by adding at the end
16 the following:

17 **“SEC. 399R. SUPPORT FOR PATIENTS RECEIVING A POSI-**
18 **TIVE TEST DIAGNOSIS OF DOWN SYNDROME**
19 **OR OTHER PRENATALLY DIAGNOSED CONDI-**
20 **TIONS.**

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

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

1 “(2) HEALTH CARE PROVIDER.—The term
2 ‘health care provider’ means any person or entity re-
3 quired by State or Federal law or regulation to be
4 licensed, registered, or certified to provide health
5 care services, and who is so licensed, registered, or
6 certified.

7 “(3) PRENATALLY DIAGNOSED CONDITION.—
8 The term ‘prenatally diagnosed condition’ means any
9 fetal health condition identified by prenatal genetic
10 testing or prenatal screening procedures.

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

18 “(b) INFORMATION AND SUPPORT SERVICES.—The
19 Secretary, acting through the Director of the National In-
20 stitutes of Health, the Director of the Centers for Disease
21 Control and Prevention, or the Administrator of the
22 Health Resources and Services Administration, may au-
23 thorize and oversee certain activities, including the award-
24 ing of grants, contracts, or cooperative agreements, to—

1 “(1) collect, synthesize, and disseminate current
2 scientific information relating to Down syndrome or
3 other prenatally diagnosed conditions; and

4 “(2) coordinate the provision of, and access to,
5 new or existing supportive services for patients re-
6 ceiving a positive test diagnosis for Down syndrome
7 or other prenatally diagnosed conditions, including—

8 “(A) the establishment of a resource tele-
9 phone hotline and Internet website accessible to
10 patients receiving a positive test result;

11 “(B) the establishment of a clearinghouse
12 of scientific information, clinical course, life ex-
13 pectancy, development potential, and quality of
14 life relating to Down syndrome or other pre-
15 natally diagnosed conditions;

16 “(C) the establishment of national and
17 local peer-support programs;

18 “(D) the establishment of a national reg-
19 istry, or network of local registries, of families
20 willing to adopt newborns with Down syndrome
21 or other prenatally diagnosed conditions, and
22 links to adoption agencies willing to place ba-
23 bies with Down syndrome or other prenatally
24 diagnosed conditions, with families willing to
25 adopt; and

1 “(E) the establishment of awareness and
2 education programs for health care providers
3 who provide the results of prenatal tests for
4 Down syndrome or other prenatally diagnosed
5 conditions, to patients, consistent with the pur-
6 pose described in section 2(b)(1) of the Pre-
7 natally Diagnosed Condition Awareness Act of
8 2007.

9 “(c) DATA COLLECTION.—

10 “(1) PROVISION OF ASSISTANCE.—The Sec-
11 retary, acting through the Director of Centers for
12 Disease Control and Prevention, shall provide assist-
13 ance to State and local health departments to inte-
14 grate the results of prenatal testing into State-based
15 vital statistics and birth defects surveillance pro-
16 grams.

17 “(2) ACTIVITIES.—The Secretary shall ensure
18 that activities carried out under paragraph (1) are
19 sufficient to extract population-level data relating to
20 national rates and results of prenatal testing.

21 “(d) PROVISION OF INFORMATION BY PROVIDERS.—
22 The Secretary shall ensure that in the case of a health
23 care provider that performs prenatal tests for Down syn-
24 drome or other prenatally diagnosed conditions, such pro-
25 vider is eligible to participate in an activity carried out

1 under subsection (b) or (c) only if such provider (or a des-
2 ignee of such provider) provides assurances satisfactory to
3 the Secretary that upon receipt of a positive test result
4 from such a test performed on a patient, the provider (or
5 designee) will provide the patient with the following:

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

12 “(2) Referral to supportive services providers,
13 including information hotlines specific to Down syn-
14 drome or other prenatally diagnosed conditions, re-
15 source centers or clearinghouses, and other edu-
16 cation and support programs as described in sub-
17 section (b)(2).

18 “(e) PRIVACY.—

19 “(1) IN GENERAL.—Notwithstanding sub-
20 sections (c) and (d), nothing in this section shall be
21 construed to permit or require the collection, mainte-
22 nance, or transmission, without the health care pro-
23 vider obtaining the prior, written consent of the pa-
24 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 the enactment of this
16 section, and every 2 years thereafter, the Secretary
17 shall submit to Congress a report 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 the enactment of this section, the
22 Government Accountability Office shall submit to
23 Congress a report concerning the effectiveness of
24 current health care and family support programs

1 serving as resources for the families of children with
2 disabilities.

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.”.

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