II

110TH CONGRESS
1ST 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 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 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Prenatally and Postnatally Diagnosed Conditions Awareness Act".

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) Pregnant women who choose to undergo prenatal genetic testing should have access to timely, scientific, and nondirective counseling about the conditions being tested for and the accuracy of such tests, from health care professionals qualified to provide and interpret these tests. Informed consent is a critical component of all genetic testing.

(2) A recent, peer-reviewed study and two reports from the Centers for Disease Control and Prevention on prenatal testing found a deficiency in the data needed to understand the epidemiology of prenatally diagnosed conditions, to monitor trends accurately, and to increase the effectiveness of health intervention.

(b) PURPOSES.—It is the purpose of this Act, after the diagnosis of a fetus with Down syndrome or other prenatally diagnosed conditions, to—

(1) increase patient referrals to providers of key support services for women who have received a positive test diagnosis for Down syndrome, or other prenatally or postnatally diagnosed conditions, as well as to provide up-to-date, comprehensive information about life expectancy, development potential,

and quality of life for a child born with Down syndrome or other prenatally or postnatally diagnosed condition;

(2) strengthen existing networks of support through a Centers for Disease Control and Prevention patient and provider outreach program;

(3) improve available data by incorporating information directly revealed by prenatal or postnatal testing into existing State-based surveillance programs for birth defects and prenatally or postnatally diagnosed conditions; and

(4) ensure that patients receive up-to-date, scientific information about the accuracy of the test.

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

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

"SEC. 399R. SUPPORT FOR PATIENTS RECEIVING A POSITIVE TEST DIAGNOSIS OF DOWN SYNDROME OR OTHER PRENATALLY OR POSTNATALLY DIAGNOSED CONDITIONS.

"(a) DEFINITIONS.—In this section:

"(1) DOWN SYNDROME.—The term 'Down syndrome' refers to a chromosomal disorder caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21.

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

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

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

“(5) POSTNATAL TEST.—The term ‘postnatal test’ means diagnostic or screening tests offered with respect to an individual from birth to 1 year of age that is administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, symptoms the child is presenting, or other risk factors.

''(6) PRENATAL TEST.—The term 'prenatal test' means diagnostic or screening tests offered to pregnant women seeking routine prenatal care that are administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, or other risk factors.

''(b) INFORMATION AND SUPPORT SERVICES.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, or the Administrator of the Health Resources and Services Administration, may authorize and oversee certain activities, including the awarding of grants, contracts or cooperative agreements, to—

''(A) collect, synthesize, and disseminate current scientific information relating to Down syndrome or other prenatally or postnatally diagnosed conditions; and

''(B) coordinate the provision of, and access to, new or existing supportive services for patients receiving a positive test diagnosis for Down syndrome or other prenatally or postnatally diagnosed conditions, including—

“(i) the establishment of a resource telephone hotline and Internet website accessible to patients receiving a positive test result;

“(ii) the expansion and further development of the National Dissemination Center for Children with Disabilities, so that such Center can more effectively conduct outreach to new and expecting parents and provide them with up-to-date information on the clinical course, life expectancy, development potential, quality of life, and available resources and services for children with Down syndrome or other prenatally and postnatally diagnosed conditions;

“(iii) the expansion and further development of national and local peer-support programs, so that such programs can more effectively serve parents of newly diagnosed children;

“(iv) the establishment of a national registry, or network of local registries, of families willing to adopt newborns with Down syndrome or other prenatally or postnatally diagnosed conditions, and links to adoption agencies willing to place babies with Down syndrome or other prenatally or postnatally diagnosed conditions, with families willing to adopt; and

''(v) the establishment of awareness and education programs for health care providers who provide the results of prenatal or postnatal tests for Down syndrome or other prenatally or postnatally diagnosed conditions, to patients, consistent with the purpose described in section 2(b)(1) of the Prenatally and Postnatally Diagnosed Conditions Awareness Act.

''(2) DISTRIBUTION.—In distributing funds under this subsection, the Secretary shall place an emphasis on funding partnerships between health care groups and disability advocacy organizations.

''(c) DATA COLLECTION.—

''(1) PROVISION OF ASSISTANCE.—The Secretary, acting through the Director of Centers for Disease Control and Prevention, shall provide assistance to State and local health departments to integrate the results of prenatal or postnatal testing into

State-based vital statistics and birth defects surveillance programs.

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

"(3) INFORMED CONSENT.—Prior to the reporting of the results of a prenatal or postnatal test to a State or local public health department under this subsection, the patient involved shall be provided with a disclosure statement that describes the manner in which the results of such tests will be used. Such results may not be reported unless the patient consents to such reporting after receipt of such disclosure statement.

"(d) PROVISION OF INFORMATION BY PROVIDERS.—Upon receipt of a positive test result from a prenatal or postnatal test for Down syndrome or other prenatally or postnatally diagnosed conditions performed on a patient, the health care provider involved (or his or her designee) shall provide the patient with the following:

"(1) Up-to-date, scientific, written information concerning the life expectancy, clinical course, and intellectual and functional development and treatment options for a fetus diagnosed with or child born with Down syndrome or other prenatally or postnatally diagnosed conditions.

''(2) Referral to supportive services providers, including information hotlines specific to Down syndrome or other prenatally or postnatally diagnosed conditions, resource centers or clearinghouses, and other education and support programs as described in subsection (b)(2).

''(e) PRIVACY.—

''(1) IN GENERAL.—Notwithstanding subsections (c) and (d), nothing in this section shall be construed to permit or require the collection, maintenance, or transmission, without the health care provider obtaining the prior, written consent of the patient, of—

''(A) health information or data that identify a patient, or with respect to which there is a reasonable basis to believe the information could be used to identify the patient (including a patient's name, address, healthcare provider, or hospital); and

''(B) data that are not related to the epidemiology of the condition being tested for.

“(2) GUIDANCE.—Not later than 180 days after the date of enactment of this section, the Secretary shall establish guidelines concerning the implementation of paragraph (1) and subsection (d).

“(f) REPORTS.—

“(1) IMPLEMENTATION REPORT.—Not later than 2 years after the date of enactment of this section, and every 2 years thereafter, the Secretary shall submit a report to Congress concerning the implementation of the guidelines described in subsection (e)(2).

“(2) GAO REPORT.—Not later than 1 year after the date of enactment of this section, the Government Accountability Office shall submit a report to Congress concerning the effectiveness of current healthcare and family support programs serving as resources for the families of children with disabilities.

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

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