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

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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 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 Diagnosed Condition Awareness Act of 2007''.

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 diagnosed conditions, as well as to provide up-to-date, science-based information about life-expectancy, development potential, and quality of life

for a child born with Down syndrome or other prenatally diagnosed condition;

(2) provide 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 testing into existing State-based surveillance programs for birth defects and prenatally 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 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) PRENATALLY DIAGNOSED CONDITION.—The term ‘prenatally diagnosed condition’ means any fetal health condition identified by prenatal genetic testing or prenatal screening procedures.

“(4) 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.—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—

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

“(2) 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 diagnosed conditions, including—

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

“(B) the establishment of a clearinghouse of scientific information, clinical course, life expectancy, development potential, and quality of life relating to Down syndrome or other prenatally diagnosed conditions;

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

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

“(E) the establishment of awareness and education programs for health care providers who provide the results of prenatal tests for Down syndrome or other prenatally diagnosed conditions, to patients, consistent with the purpose described in section 2(b)(1) of the Prenatally Diagnosed Condition Awareness Act of 2007.

“(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 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 testing.

“(d) PROVISION OF INFORMATION BY PROVIDERS.—The Secretary shall ensure that in the case of a health care provider that performs prenatal tests for Down syndrome or other prenatally diagnosed conditions, such provider is eligible to participate in an activity carried out under subsection (b) or (c) only if such provider (or a designee of such provider) provides assurances satisfactory to the Secretary that upon receipt of a positive test result from such a test performed on a patient, the provider (or designee) will 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 diagnosed conditions.

"(2) Referral to supportive services providers, including information hotlines specific to Down syndrome or other prenatally 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 the enactment of this section, and every 2 years thereafter, the Secretary shall submit to Congress a report concerning the implementation of the guidelines described in subsection (e)(2).

''(2) GAO REPORT.—Not later than 1 year after the date of the enactment of this section, the Government Accountability Office shall submit to Congress a report concerning the effectiveness of current health care 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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