114TH CONGRESS
1ST SESSION

H. R. 3441

To amend the Public Health Service Act to establish education programs for patients and health care providers regarding cell-free DNA prenatal screening, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 4, 2015

Ms. HERRERA BEUTLER (for herself and Ms. ROYBAL-ALLARD) 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 education programs for patients and health care providers regarding cell-free DNA prenatal screening, and for other purposes.

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 "Accurate Education for Prenatal Screenings Act".

SEC. 2. CELL-FREE DNA PRENATAL SCREENING EDUCATION PROGRAMS.

Part B of title III of the Public Health Service Act is amended by inserting, after section 317T (42 U.S.C. 247b–22), the following:

"SEC. 317U. CELL-FREE DNA PRENATAL SCREENING EDUCATION PROGRAMS.

''(a) EDUCATION PROGRAMS.—With respect to cell-free DNA prenatal screening, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop, implement, and maintain two programs, one for patients and one for health care providers, to educate patients and health care providers regarding matters including—

''(1) the purposes and definitions of such screenings;

''(2) the reasons for patients and health care providers to consider such screenings;

''(3) the conditions such screenings may detect, including accurate and up-to-date information about such conditions' clinical features, prognoses, and treatments according to relevant national disability organizations and medical professional societies;

''(4) the risks and benefits of, and alternatives to, the various methods of administering such screenings and prenatal diagnostic testings, including the option to forego such screenings and testings, as per guidelines established by medical professional societies;

"(5) the possible results of such screenings;

"(6) the accuracy of the results of such screenings, including positive predictive value, negative predictive value, specificity, sensitivity, the inability of such screenings to reliably diagnose chromosomal abnormalities, and the fact that such screenings may yield false-positive and false-negative results;

"(7) the need for diagnostic testing, and counseling by a genetics professional, for patients whose screenings yield positive, abnormal, or indeterminate results; and

"(8) the need for communication of screening results to patients and appropriate follow up per guidelines established by medical professional societies.

"(b) MATERIALS.—Each program developed under this section shall include the provision of materials that—

"(1) contain information that is peer-reviewed, balanced, accurate, and up-to-date;

"(2) enable the respective target audience to understand the available options with regards to cell-free DNA prenatal screenings, other prenatal screenings, and diagnostic tests;

"(3) promote the informed consent, and enhance the decision-making processes of, the respective target audience before and after such screenings;

"(4) contain information that appropriately addresses the diversity of the patient population, including patients proficient in languages other than English; and

"(5) contain contact information for relevant services and support organizations for patients.

"(c) ASSESSMENT.—In developing, implementing, and maintaining programs and materials under this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(1) consult with relevant medical professional, disability support, patient advocacy, parents, and genetics professionals organizations;

"(2) consult with companies and laboratories that perform cell-free DNA prenatal screenings or develop the technologies for such screenings;

"(3) assess and evaluate existing education activities and materials for health care providers and patients related to such screenings; and

"(4) take the results of such consultations, assessment, and evaluation into account in developing educational programs and materials under this section.

"(d) ANNUAL REPORT.—Not later than 16 months after the date of enactment of this section and annually thereafter, the Secretary shall submit a progress report to the Congress with respect to—

"(1) the development and implementation of the education programs established under this section;

"(2) the accessibility of each program to its respective target audience;

"(3) the adoption of each program by its respective target audience; and

"(4) the Secretary's efforts to ensure health care providers and patients receive the materials created pursuant to this section.

"(e) DEADLINE.—The Secretary shall develop and implement the education programs required by section 317U of the Public Health Service Act (as added by subsection (a)) not later than 1 year after the date of enactment of this Act".

○