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116TH CONGRESS
1ST SESSION

H. R. 4393

To amend title XIX of the Social Security Act to provide for a State option under the State Medicaid plan to provide DNA sequencing clinical services for certain children, provide for a study by the National Academy of Medicine on the use of genetic and genomic testing to improve health care, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2019

Mr. SWALWELL of California (for himself, Mr. FITZPATRICK, Mr. GALLEGO, Mr. ROUDA, and Ms. NORTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XIX of the Social Security Act to provide for a State option under the State Medicaid plan to provide DNA sequencing clinical services for certain children, provide for a study by the National Academy of Medicine on the use of genetic and genomic testing to improve health care, 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 ''Advancing Access to Precision Medicine Act''.

SEC. 2. STATE OPTION TO PROVIDE DNA SEQUENCING CLINICAL SERVICES FOR CERTAIN CHILDREN.

Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by adding at the end the following new section:

"SEC. 1947. STATE OPTION TO PROVIDE DNA SEQUENCING CLINICAL SERVICES FOR CERTAIN CHILDREN.

''(a) IN GENERAL.—Notwithstanding section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(B) (relating to comparability), and any other provision of this title for which the Secretary determines it is necessary to waive in order to implement this section, beginning on the first day of the first fiscal quarter that begins on or after the date of the enactment of this section, a State, at its option as a State plan amendment, may provide for medical assistance under this title to an eligible individual for purposes of providing the individual with DNA sequencing clinical services.

''(b) PAYMENTS.—

''(1) IN GENERAL.—A State shall provide a health care provider (as defined by the State) with payments for the provision of DNA sequencing clinical services to any eligible individual. Payments made to a health care provider for such services

shall be treated as medical assistance for purposes of section 1903(a), except that, during the first 8 fiscal year quarters that the State plan amendment is in effect, the Federal medical assistance percentage applicable to such payments shall be equal to 75 percent.

''(2) METHODOLOGY.—The State shall specify in the State plan amendment the methodology the State will use for determining payment for the provision of DNA sequencing clinical services. Such methodology for determining payment shall be established consistent with section 1902(a)(30)(A).

''(3) PLANNING GRANTS.—

''(A) IN GENERAL.—Beginning on the date described in subsection (a), the Secretary may award planning grants to States for purposes of developing a State plan amendment under this section. A planning grant awarded to a State under this paragraph shall remain available until expended.

''(B) STATE CONTRIBUTION.—A State awarded a planning grant shall contribute an amount equal to the State percentage determined under section 1905(b) for each fiscal year for which the grant is awarded.

''(c) HOSPITAL REFERRALS.—A State shall include in the State plan amendment a requirement for any hospital that is a participating provider under the State plan (or a waiver of such plan) to establish procedures for referring any eligible individual who seeks or needs treatment in a hospital emergency department to a health care provider who is qualified (as determined by the State) to provide DNA sequencing clinical services.

''(d) REPORTS BY STATES.—Not later than three years after the date on which the State plan amendment under this section is approved, a State shall submit a report to the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Health Resources and Services Administration on—

''(1) the extent to which DNA sequencing clinical services reduce health disparities; and

''(2) the extent to which coverage under the State plan (or a waiver of such plan) impedes the use of genetic and genomic testing that may improve clinical outcomes for eligible individuals enrolled in the State plan (or under a waiver of such plan).

''(e) REPORTS BY HEALTH CARE PROVIDERS.—As a condition for receiving payment for DNA sequencing clinical services provided to an eligible individual, a health care provider shall report to the State, in accordance with

such requirements as the Secretary shall specify, on all applicable measures for determining the quality of such services.

''(f) DEFINITIONS.—In this section:

''(1) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who—

''(A) is eligible for medical assistance under the State plan (or a waiver of such plan);

''(B) is under the age of 21 (or, at the option of the State, under the age of 20, 19, or 18 as the State may choose), or in the case of an individual described in section 1902(a)(10)(A)(i)(IX), under the age of 26;

''(C) has been referred or admitted to a pediatric intensive care unit for a chronic or undiagnosed disease;

''(D) has been seen by at least one medical specialist for such chronic or undiagnosed disease; and

''(E) is suspected by at least one medical specialist to have a pediatric-onset genetic disease.

''(2) DNA SEQUENCING CLINICAL SERVICES.—The term 'DNA sequencing clinical services', with respect to an eligible individual—

"(A) means a determination of an exact sequence of deoxyribonucleic acid bases in the genome of such individual, and, if for the sole benefit of the individual, a biological parent of such individual for the purpose of determining whether one or more potentially disease-causing genetic variants are present in the genome of such individual or such biological parent; and

"(B) includes—

"(i) sequencing of the entire genome, of the exome, of a panel of genes, or other regions of the genome; and

"(ii) any analysis, interpretation, and data report derived from such sequencing.".

SEC. 3. NATIONAL ACADEMY OF MEDICINE STUDY.

(a) IN GENERAL.—Not later than 4 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall enter into an arrangement with the National Academy of Medicine under which the Academy agrees to study—

(1) how genetic and genomic testing may improve preventative care and precision medicine;

(2) how genetic and genomic testing may reduce health disparities;

(3) how the Federal Government may help to reduce barriers to genetic and genomic testing, including—

(A) encouraging the expansion of health insurance coverage of genetic and genomic testing, including diagnostic, predictive, and presymptomatic testing, and DNA sequencing clinical services (as defined in section 1947 of the Social Security Act (as added by section 2));

(B) supporting the collection of evidence for the clinical utility and appropriate use of genetic and genomic tests; and

(C) improving access to genetic counselors, pathologists, and other relevant professions, including strengthening related workforce education and training efforts;

(4)(A) the extent to which coverage provisions in the Medicare and Medicaid programs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq., 1396 et seq.) may restrain the use of genetic and genomic testing that may improve clinical outcomes for beneficiaries;

(B) the extent to which coverage provided pursuant to section 1947 of the Social Security Act (as added by section 2) increased the use of genetic and

genomic testing and improved clinical outcomes for beneficiaries; and

(C) how the Centers for Medicare & Medicaid Services may make coverage determinations that better suit a precision medicine approach to treatment; and

(5) how genetic and genomic testing may improve health outcomes for all populations in the United States, including—

(A) individuals with a rare disease, including—

(i) a metabolic disease;

(ii) a hereditary cancer syndrome; and

(iii) a neurologic disease with known treatments; and

(B) special populations, including—

(i) infants and children;

(ii) critically ill (non-infectious and non-trauma) patients;

(iii) transplant patients;

(iv) individuals with cardiac disease; and

(v) individuals with, or who have a family history of, a birth defect or developmental disability.

(b) REPORT.—

(1) IN GENERAL.—The arrangement under subsection (a) shall provide for the National Academy of Medicine to submit, not later than 6 years after the date of enactment of this Act, a report on the results of the study under subsection (a) to—

(A) the Secretary of Health and Human Services;

(B) the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives; and

(C) the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate.

(2) CONSULTATION.—The arrangement under subsection (a) shall provide for the National Academy of Medicine, in developing the report required by paragraph (1), to consult with physicians, other health professionals, health educators, health professional organizations, relevant companies, patients, patient organizations, the Health Resources and Services Administration, the National Cancer Institute, the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services.

(3) USE OF INFORMATION.—The National Academy of Medicine shall, to the extent possible, in conducting the study under subsection (a), utilize information included in the reports submitted pursuant to subsections (d) and (e) of section 1947 of the Social Security Act (as added by section 2).

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