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117TH CONGRESS
1ST SESSION

H. R. 5989

To require the Secretary of Health and Human Services to conduct a demonstration program to genetic and genomic testing for certain children, to provide for a study by the National Academy of Medicine on the use of such testing to improve health care, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 16, 2021

Mr. SWALWELL (for himself, Mr. PETERS, and Mr. EMMER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To require the Secretary of Health and Human Services to conduct a demonstration program to genetic and genomic testing for certain children, to provide for a study by the National Academy of Medicine on the use of such 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 ‘‘Precision Medicine Answers for Kids Today Act’’.

SEC. 2. CENTERS FOR MEDICARE & MEDICAID SERVICES GUIDANCE ON THE EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT BENEFIT.

Not later than 6 months after the date of enactment of this Act, the Centers for Medicare & Medicaid Services shall issue guidance to States on authority and requirements under the Medicaid program under title XIX of the Social Security Act to provide medically necessary health care that falls within the scope of services specified under section 1905(r) of the Social Security Act (42 U.S.C. 1396d(r)) to a child, regardless of whether the service is available for adults under the State plan (or waiver of such plan) under such title. The guidance shall—

(1) include technical and educational assistance on how to increase the frequency of coverage under the State plan (or waiver) pursuant to paragraphs (4) and (16) of section 1905(a) of such Act (42 U.S.C. 1396d(a)) for genetic and genomic testing diagnostic services, including whole exome sequencing, whole genome sequencing, and gene panels when recommended by a qualified treating provider as a first-

or second-tier test for pediatric patients, including those who—

(A) have a positive result from a newborn screening program;

(B) have one or more neurodevelopmental or congenital anomalies;

(C) are experiencing developmental delay or intellectual disability;

(D) are having seizures;

(E) have been referred or admitted to a pediatric or neonatal intensive care unit for a chronic or undiagnosed disease;

(F) have been seen by at least one medical specialist for such chronic or undiagnosed disease; or

(G) are suspected by at least one healthcare provider to have a neonatal- or pediatric-onset genetic disease;

(2) provide education and support to providers to minimize denials of claims for medical assistance under the State plan under title XIX of the Social Security Act resulting from deficient or inadequate paperwork; and

(3) ensure that providers and Medicaid-eligible children and the families are aware of the Early and

Periodic Screening, Diagnostic and Treatment Benefit under title XIX of the Social Security Act and have access to required screenings and necessary treatment services.

SEC. 3. DEMONSTRATION PROGRAM TO PROVIDE GENETIC AND GENOMIC TESTING FOR CERTAIN CHILDREN.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into agreements with up to 15 States submitting applications under subsection (c) for the purpose of conducting, in accordance with this section, 3-year demonstration projects under section 1115 of the Social Security Act (42 U.S.C. 1315) in such States during the 3-year period beginning on the first date of the first fiscal quarter than begins on or after the date of the enactment of this section to test and evaluate the provision of medical assistance under the State plans under title XIX of such Act (or waivers of such plans) to eligible individuals for purposes of providing such individuals with genetic and genomic testing.

(b) DEMONSTRATION PROJECT PAYMENT REQUIREMENTS.—Under each demonstration project under this section conducted by a State, the following shall apply:

(1) The State shall provide a health care provider (as defined by the State) with payments for

the provision of genetic and genomic testing 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) of the Social Security Act (42 U.S.C. 1396b(a)), except that the Federal medical assistance percentage applicable to such payments shall be equal to 100 percent.

(2) The State shall specify the methodology the State will use for determining payment for the provision of genetic and genomic testing. Such methodology for determining payment shall be established consistent with section 1902(a)(30)(A) of such Act (42 U.S.C. 1396a(a)(30)(A)).

(c) APPLICATIONS.—

(1) IN GENERAL.—A State desiring to enter into an agreement under subsection (a) with the Secretary for conducting a demonstration project shall submit to the Secretary an application, in accordance with such form and manner, and application priorities, as specified by the Secretary and that at a minimum includes the following:

(A) An explanation of how and the extent to which genetic and genomic testing under the demonstration project of the State will provide information and data on how such services improve the diagnosis of eligible individuals.

(B) An explanation of how and the extent to which coverage under the State plan (or waiver) pursuant to the demonstration project will increase the use of genetic and genomic testing that may increase the use of genetic and genomic testing that may improve clinical outcomes for eligible individuals.

(C) 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 genetic and genomic testing.

(D) An explanation of how genetic and genomic testing may improve health outcomes for all populations in the State, including—

(i) individuals with a rare genetic disease, including a metabolic disease, neurologic disorders, or hereditary cancer testing in the presence of a suspected or confirmed cancer diagnosis; and

(ii) special populations, including infants and children who are critically ill (non-infectious and non-trauma) patients, transplant patients, individuals with cardiac disease, and individuals with, or who have a family history of, a birth defect or developmental disability.

(2) PREFERENCES IN CONSIDERING APPLICATIONS.—In considering applications submitted under paragraph (1), the Secretary of Health and Human Services shall give preference to States that can demonstrate underutilization of genetic and genomic sequencing clinical services (with priority given to States that do not cover whole-genome sequencing or do not cover the majority of genetic and genomic clinical services) in pediatric populations under the State plan under title XIX of the Social Security Act (or waiver of such plan).

(d) TECHNICAL ASSISTANCE.—The Secretary of Health and Human Services shall provide technical assistance to assist States in planning and designing the demonstration project for purposes of applying for conducting such project under this section.

(e) REPORTS BY STATES.—Not later than one year after the date on which a State enters into an agreement under subsection (a) with the Secretary for conducting a demonstration project, the 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 the extent to which genetic and genomic testing improved outcomes and reduced health disparities. Such report shall include information on the number of patients receiving genetic and genomic testing, the types of services provided, and such other information as the Secretary shall prescribe.

(f) REPORTS BY HEALTH CARE PROVIDERS.—As a condition for receiving payment for genetic and genomic testing provided to an eligible individual under a demonstration project conducted by a State under this section, 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 and efficacy of such services.

(g) DEFINITIONS.—In this section:

(1) ELIGIBLE INDIVIDUAL.—The term ''eligible individual'' means, with respect to a State, an individual who—

(A) is eligible for medical assistance under the State plan under title XIX of the Social Security Act (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) of such Act (42 U.S.C. 1396a(a)(10)(A)(i)(IX)), under the age of 26;

(C) has been referred or admitted to an intensive care unit, or has been seen by at least one medical specialist, for a suspected genetic or undiagnosed disease; or

(D) is suspected by at least one medical specialist to have a neonatal-onset or pediatric-onset genetic disease.

(2) GENETIC AND GENOMIC TESTING.—The term "genetic and genomic testing", with respect to an eligible individual—

(A) means the determination of a 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) the sequencing of the whole genome, the whole exome, or a panel of genes; and

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

SEC. 4. NATIONAL ACADEMY OF MEDICINE STUDY.

(a) IN GENERAL.—Not later than one year 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) disparities in access to precision diagnostics and associated therapeutics;

(3) how genetic and genomic testing may be used to reduce health disparities in marginalized communities;

(4) 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 genetic and genomic testing (as defined in section 2(h)(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;

(5)(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 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

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

(A) children with a rare disease, including a metabolic disease, neurologic disorder, or hereditary cancer testing in the presence of a suspected or confirmed cancer diagnosis; and

(B) special populations, including—

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

(ii) transplant patients;

(iii) individuals with cardiac disease; and

(iv) 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 2 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 (f) and (g) of section 2.

SEC. 5. CENTERS FOR MEDICARE & MEDICAID SERVICES REPORT ON MEDICAID COVERAGE FOR GENETIC AND GENOMIC TESTING.

Not later than one year after the date of the enactment of this Act, and annually thereafter for the subsequent 3 years, the Centers for Medicare & Medicaid Services shall submit to the Secretary of Health and Human Services, the Committees on Ways and Means and on Energy and Commerce of the House of Representatives, and the Committees on Finance and Health, Education, Labor, and Pensions of the Senate a report on the extent to which each of the 50 States provide coverage under the State plan under title XIX of the Social Security Act (or waiver of such plan) of genetic and genomic testing (as defined in section 2(f)(2)) (including whole exome, whole genome, gene panels, single gene tests, Chromosomal microarray analysis, Fluorescence in situ hybridization, and other genetic and genomic tests), including information on—

(1) how often genetic and genomic diagnostic testing services are covered and reimbursed;

(2) the frequency of denials for coverage and the rationale for denying coverage;

(3) an analysis of which genetic and genomic diagnostic tests are being approved or denied;

(4) how often test genetic counseling is covered pre- and post-genetic and genomic diagnostic testing;

(5) the turn-around time for prior authorization requests; and

(6) any barriers to coverage of genetic and genomic testing services identified.

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