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116TH CONGRESS
1ST SESSION

H. R. 4144

To enable States to better provide access to whole genome sequencing clinical services for certain undiagnosed children under the Medicaid program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2019

Mr. PETERS (for himself, Mr. SHIMKUS, and Mr. VARGAS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To enable States to better provide access to whole genome sequencing clinical services for certain undiagnosed children under the Medicaid program, 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 ''Ending the Diagnostic Odyssey Act of 2019''.

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

Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1943 the following new section:

"SEC. 1944. STATE OPTION TO PROVIDE WHOLE GENOME 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 January 1, 2020, 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 whole genome 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 whole genome sequencing clinical services to any eligible individual. Payments made to a health care provider for such services shall be treated as medical assistance for pur-

poses of section 1903(a), except that, during the first 12 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 whole genome 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 January 1, 2020, 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 hos-

pital 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 whole genome sequencing clinical services.

''(d) REPORTS BY STATES.—Not later than 3 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 whole genomic 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 whole genome 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—

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

''(B) who 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; and

''(C) who—

''(i) 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

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

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

"(A) means the unbiased sequencing of all 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 any analysis, interpretation, and data report derived from such sequencing.".

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