

116TH CONGRESS
1ST SESSION

S. 3116

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 SENATE OF THE UNITED STATES

DECEMBER 19, 2019

Ms. COLLINS (for herself, Mr. JONES, Ms. MCSALLY, and Mr. MENENDEZ) introduced the following bill; which was read twice and referred to the Committee on Finance

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Ending the Diagnostic
5 Odyssey Act of 2019”.

1 **SEC. 2. STATE OPTION TO PROVIDE WHOLE GENOME SE-**
 2 **QUENCING CLINICAL SERVICES FOR CER-**
 3 **TAIN CHILDREN.**

4 Title XIX of the Social Security Act (42 U.S.C. 1396
 5 et seq.) is amended by inserting after section 1946 the
 6 following new section:

7 **“SEC. 1947. STATE OPTION TO PROVIDE WHOLE GENOME**
 8 **SEQUENCING CLINICAL SERVICES FOR CER-**
 9 **TAIN CHILDREN.**

10 “(a) IN GENERAL.—Notwithstanding section
 11 1902(a)(1) (relating to statewideness), section
 12 1902(a)(10)(B) (relating to comparability), and any other
 13 provision of this title which the Secretary determines is
 14 necessary to waive in order to implement this section, be-
 15 ginning January 1, 2020, a State, at its option as a State
 16 plan amendment, may provide for medical assistance
 17 under this title to an eligible individual for purposes of
 18 providing the individual with whole genome sequencing
 19 clinical services.

20 “(b) PAYMENTS.—

21 “(1) IN GENERAL.—A State shall provide a
 22 health care provider (as defined by the State) with
 23 payments for the provision of whole genome sequenc-
 24 ing clinical services to any eligible individual. Pay-
 25 ments made to a health care provider for such serv-
 26 ices shall be treated as medical assistance for pur-

1 poses of section 1903(a), except that, during the
2 first 12 fiscal year quarters that the State plan
3 amendment is in effect, the Federal medical assist-
4 ance percentage applicable to such payments shall be
5 equal to 75 percent.

6 “(2) METHODOLOGY.—The State shall specify
7 in the State plan amendment the methodology the
8 State will use for determining payment for the provi-
9 sion of whole genome sequencing clinical services.
10 Such methodology for determining payment shall be
11 established consistent with section 1902(a)(30)(A).

12 “(3) PLANNING GRANTS.—

13 “(A) IN GENERAL.—Beginning January 1,
14 2020, the Secretary may award planning grants
15 to States for purposes of developing a State
16 plan amendment under this section. A planning
17 grant awarded to a State under this paragraph
18 shall remain available until expended.

19 “(B) STATE CONTRIBUTION.—A State
20 awarded a planning grant shall contribute an
21 amount equal to the State percentage deter-
22 mined under section 1905(b) for each fiscal
23 year for which the grant is awarded.

24 “(c) HOSPITAL REFERRALS.—A State shall include
25 in the State plan amendment a requirement for any hos-

1 pital that is a participating provider under the State plan
 2 (or a waiver of such plan) to establish procedures for re-
 3 ferring any eligible individual who seeks or needs treat-
 4 ment in a hospital emergency department to a health care
 5 provider who is qualified (as determined by the State) to
 6 provide whole genome sequencing clinical services.

7 “(d) REPORTS BY STATES.—Not later than 3 years
 8 after the date on which a State plan amendment under
 9 this section is approved, the State shall submit a report
 10 to the Administrator of the Centers for Medicare & Med-
 11 icaid Services and the Administrator of the Health Re-
 12 sources and Services Administration on—

13 “(1) the extent to which whole genome sequenc-
 14 ing clinical services reduce health disparities; and

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

20 “(e) REPORTS BY HEALTH CARE PROVIDERS.—Each
 21 State that provides medical assistance for whole genome
 22 sequencing clinical services under this section shall require
 23 that, as a condition for receiving payment for whole ge-
 24 nome sequencing clinical services provided to an eligible
 25 individual, a health care provider shall report to the State,

1 in accordance with such requirements as the Secretary
2 shall specify, on all applicable measures for determining
3 the quality of such services.

4 “(f) DEFINITIONS.—In this section:

5 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
6 individual’ means an individual—

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

9 “(B) who is under the age of 21 (or, at the
10 option of the State, under the age of 20, 19, or
11 18 as the State may choose), or in the case of
12 an individual described in section
13 1902(a)(10)(A)(i)(IX), under the age of 26;
14 and

15 “(C) who—

16 “(i) has been referred or admitted to
17 an intensive care unit, or has been seen by
18 at least 1 medical specialist, for a sus-
19 pected genetic or undiagnosed disease; or

20 “(ii) is suspected by at least 1 medical
21 specialist to have a neonatal- or pediatric-
22 onset genetic disease.

23 “(2) WHOLE GENOME SEQUENCING CLINICAL
24 SERVICES.—The term ‘whole genome sequencing

1 clinical services', with respect to an eligible indi-
2 vidual—

3 “(A) means the unbiased sequencing of all
4 deoxyribonucleic acid bases in the genome of
5 such individual and, if for the sole benefit of
6 the individual, a biological parent of such indi-
7 vidual for the purpose of determining whether
8 one or more potentially disease-causing genetic
9 variants are present in the genome of such indi-
10 vidual or such biological parent; and

11 “(B) includes any analysis, interpretation,
12 and data report derived from such sequenc-
13 ing.”.

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