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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R.

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

Mr. SWALWELL of California introduced the following bill; which was referred to the Committee on _____

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.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Advancing Access to
3 Precision Medicine Act”.

4 **SEC. 2. STATE OPTION TO PROVIDE DNA SEQUENCING**
5 **CLINICAL SERVICES FOR CERTAIN CHIL-**
6 **DREN.**

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

10 **“SEC. 1947. STATE OPTION TO PROVIDE DNA SEQUENCING**
11 **CLINICAL SERVICES FOR CERTAIN CHIL-**
12 **DREN.**

13 “(a) IN GENERAL.—Notwithstanding section
14 1902(a)(1) (relating to statewideness), section
15 1902(a)(10)(B) (relating to comparability), and any other
16 provision of this title for which the Secretary determines
17 it is necessary to waive in order to implement this section,
18 beginning on the first day of the first fiscal quarter that
19 begins on or after the date of the enactment of this sec-
20 tion, a State, at its option as a State plan amendment,
21 may provide for medical assistance under this title to an
22 eligible individual for purposes of providing the individual
23 with DNA sequencing clinical services.

24 “(b) PAYMENTS.—

25 “(1) IN GENERAL.—A State shall provide a
26 health care provider (as defined by the State) with

1 payments for the provision of DNA sequencing clinical
2 ical services to any eligible individual. Payments
3 made to a health care provider for such services
4 shall be treated as medical assistance for purposes
5 of section 1903(a), except that, during the first 8
6 fiscal year quarters that the State plan amendment
7 is in effect, the Federal medical assistance percent-
8 age applicable to such payments shall be equal to 75
9 percent.

10 “(2) METHODOLOGY.—The State shall specify
11 in the State plan amendment the methodology the
12 State will use for determining payment for the provi-
13 sion of DNA sequencing clinical services. Such meth-
14 odology for determining payment shall be established
15 consistent with section 1902(a)(30)(A).

16 “(3) PLANNING GRANTS.—

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

24 “(B) STATE CONTRIBUTION.—A State
25 awarded a planning grant shall contribute an

1 amount equal to the State percentage deter-
2 mined under section 1905(b) for each fiscal
3 year for which the grant is awarded.

4 “(c) HOSPITAL REFERRALS.—A State shall include
5 in the State plan amendment a requirement for any hos-
6 pital that is a participating provider under the State plan
7 (or a waiver of such plan) to establish procedures for re-
8 ferring any eligible individual who seeks or needs treat-
9 ment in a hospital emergency department to a health care
10 provider who is qualified (as determined by the State) to
11 provide DNA sequencing clinical services.

12 “(d) REPORTS BY STATES.—Not later than three
13 years after the date on which the State plan amendment
14 under this section is approved, a State shall submit a re-
15 port to the Administrator of the Centers for Medicare &
16 Medicaid Services and the Administrator of the Health
17 Resources and Services Administration on—

18 “(1) the extent to which DNA sequencing clin-
19 ical services reduce health disparities; and

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

1 “(e) REPORTS BY HEALTH CARE PROVIDERS.—As a
2 condition for receiving payment for DNA sequencing clin-
3 ical services provided to an eligible individual, a health
4 care provider shall report to the State, in accordance with
5 such requirements as the Secretary shall specify, on all
6 applicable measures for determining the quality of such
7 services.

8 “(f) DEFINITIONS.—In this section:

9 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
10 individual’ means an individual who—

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

13 “(B) is under the age of 21 (or, at the op-
14 tion of the State, under the age of 20, 19, or
15 18 as the State may choose), or in the case of
16 an individual described in section
17 1902(a)(10)(A)(i)(IX), under the age of 26;

18 “(C) has been referred or admitted to a
19 pediatric intensive care unit for a chronic or
20 undiagnosed disease;

21 “(D) has been seen by at least one medical
22 specialist for such chronic or undiagnosed dis-
23 ease; and

1 “(E) is suspected by at least one medical
2 specialist to have a pediatric-onset genetic dis-
3 ease.

4 “(2) DNA SEQUENCING CLINICAL SERVICES.—
5 The term ‘DNA sequencing clinical services’, with
6 respect to an eligible individual—

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

15 “(B) includes—

16 “(i) sequencing of the entire genome,
17 of the exome, of a panel of genes, or other
18 regions of the genome; and

19 “(ii) any analysis, interpretation, and
20 data report derived from such sequenc-
21 ing.”.

22 **SEC. 3. NATIONAL ACADEMY OF MEDICINE STUDY.**

23 (a) IN GENERAL.—Not later than 4 years after the
24 date of the enactment of this Act, the Secretary of Health
25 and Human Services shall enter into an arrangement with

1 the National Academy of Medicine under which the Acad-
2 emy agrees to study—

3 (1) how genetic and genomic testing may im-
4 prove preventative care and precision medicine;

5 (2) how genetic and genomic testing may re-
6 duce health disparities;

7 (3) how the Federal Government may help to
8 reduce barriers to genetic and genomic testing, in-
9 cluding—

10 (A) encouraging the expansion of health
11 insurance coverage of genetic and genomic test-
12 ing, including diagnostic, predictive, and pre-
13 symptomatic testing, and DNA sequencing clin-
14 ical services (as defined in section 1947 of the
15 Social Security Act (as added by section 2));

16 (B) supporting the collection of evidence
17 for the clinical utility and appropriate use of ge-
18 netic and genomic tests; and

19 (C) improving access to genetic counselors,
20 pathologists, and other relevant professions, in-
21 cluding strengthening related workforce edu-
22 cation and training efforts;

23 (4)(A) the extent to which coverage provisions
24 in the Medicare and Medicaid programs under titles
25 XVIII and XIX of the Social Security Act (42

1 U.S.C. 1395 et seq., 1396 et seq.) may restrain the
2 use of genetic and genomic testing that may improve
3 clinical outcomes for beneficiaries;

4 (B) the extent to which coverage provided pur-
5 suant to section 1947 of the Social Security Act (as
6 added by section 2) increased the use of genetic and
7 genomic testing and improved clinical outcomes for
8 beneficiaries; and

9 (C) how the Centers for Medicare & Medicaid
10 Services may make coverage determinations that
11 better suit a precision medicine approach to treat-
12 ment; and

13 (5) how genetic and genomic testing may im-
14 prove health outcomes for all populations in the
15 United States, including—

16 (A) individuals with a rare disease, includ-
17 ing—

18 (i) a metabolic disease;

19 (ii) a hereditary cancer syndrome; and

20 (iii) a neurologic disease with known
21 treatments; and

22 (B) special populations, including—

23 (i) infants and children;

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

- 1 (iii) transplant patients;
2 (iv) individuals with cardiac disease;
3 and
4 (v) individuals with, or who have a
5 family history of, a birth defect or develop-
6 mental disability.

7 (b) REPORT.—

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

13 (A) the Secretary of Health and Human
14 Services;

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

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

21 (2) CONSULTATION.—The arrangement under
22 subsection (a) shall provide for the National Acad-
23 emy of Medicine, in developing the report required
24 by paragraph (1), to consult with physicians, other
25 health professionals, health educators, health profes-

1 sional organizations, relevant companies, patients,
2 patient organizations, the Health Resources and
3 Services Administration, the National Cancer Insti-
4 tute, the National Institutes of Health, the Agency
5 for Healthcare Research and Quality, and the Cen-
6 ters for Medicare & Medicaid Services.

7 (3) USE OF INFORMATION.—The National
8 Academy of Medicine shall, to the extent possible, in
9 conducting the study under subsection (a), utilize in-
10 formation included in the reports submitted pursu-
11 ant to subsections (d) and (e) of section 1947 of the
12 Social Security Act (as added by section 2).