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(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R.

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

A BILL

To 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Advancing Access to
5 Precision Medicine Act”.

6 **SEC. 2. NATIONAL ACADEMY OF MEDICINE STUDY.**

7 (a) IN GENERAL.—Not later than 60 days after the
8 date of the enactment of this Act, the Secretary of Health

1 and Human Services shall enter into an arrangement with
2 the National Academy of Medicine under which the Acad-
3 emy agrees to study—

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

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

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

11 (A) encouraging the expansion of health
12 insurance coverage of genetic and genomic test-
13 ing, including diagnostic, predictive, and pre-
14 symptomatic testing, and whole genome se-
15 quencing;

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; and

4 (B) how the Centers for Medicare & Medicaid
5 Services may make coverage determinations that
6 better suit a precision medicine approach to treat-
7 ment; and

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

11 (A) individuals with a rare disease, includ-
12 ing—

13 (i) a metabolic disease;

14 (ii) a hereditary cancer syndrome; and

15 (iii) a neurologic disease with known
16 treatments; and

17 (B) special populations, including—

18 (i) infants and children;

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

21 (iii) transplant patients;

22 (iv) individuals with cardiac disease;

23 and

1 (v) individuals with, or who have a
2 family history of, a birth defect or develop-
3 mental disability.

4 (b) REPORT.—

5 (1) IN GENERAL.—The arrangement under sub-
6 section (a) shall provide for the National Academy
7 of Medicine to submit, not later than 3 years after
8 the date of enactment of this Act, a report on the
9 results of the study under subsection (a) to—

10 (A) the Secretary of Health and Human
11 Services;

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

15 (C) the Committee on Finance and the
16 Committee on Help, Education, Labor, and
17 Pensions of the Senate.

18 (2) CONSULTATION.—The arrangement under
19 subsection (a) shall provide for the National Acad-
20 emy of Medicine, in developing the report required
21 by paragraph (1), to consult with physicians, other
22 health professionals, health educators, health profes-
23 sional organizations, relevant companies, patients,
24 patient organizations, the Health Resources and
25 Services Administration, the National Cancer Insti-

1 tute, the National Institutes of Health, the Agency
2 for Healthcare Research and Quality, and the Cen-
3 ters for Medicare & Medicaid Services.

4 **SEC. 3. STATE OPTION TO PROVIDE WHOLE GENOME SE-**
5 **QUENCING CLINICAL SERVICES FOR CER-**
6 **TAIN CHILDREN.**

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

10 **“SEC. 1944. STATE OPTION TO PROVIDE WHOLE GENOME**
11 **SEQUENCING CLINICAL SERVICES FOR CER-**
12 **TAIN CHILDREN.**

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 January 1, 2019, a State, at its option as a
19 State plan amendment, may provide for medical assistance
20 under this title to an eligible individual for purposes of
21 providing the individual with whole genome sequencing
22 clinical services.

23 “(b) PAYMENTS.—

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

1 payments for the provision of whole genome sequenc-
2 ing clinical services to any eligible individual. Pay-
3 ments made to a health care provider for such serv-
4 ices shall be treated as medical assistance for pur-
5 poses of section 1903(a), except that, during the
6 first 8 fiscal year quarters that the State plan
7 amendment is in effect, the Federal medical assist-
8 ance percentage applicable to such payments shall be
9 equal to 75 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 whole genome sequencing clinical services.
14 Such methodology for determining payment shall be
15 established consistent with section 1902(a)(30)(A).

16 “(3) PLANNING GRANTS.—

17 “(A) IN GENERAL.—Beginning January 1,
18 2019, the Secretary may award planning grants
19 to States for purposes of developing a State
20 plan amendment under this section. A planning
21 grant awarded to a State under this paragraph
22 shall remain available until expended.

23 “(B) STATE CONTRIBUTION.—A State
24 awarded a planning grant shall contribute an
25 amount equal to the State percentage deter-

1 mined under section 1905(b) for each fiscal
2 year for which the grant is awarded.

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

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

17 “(1) the extent to which whole genomic se-
18 quencing clinical services reduce health disparities;
19 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 whole genome sequenc-
3 ing clinical services provided to an eligible individual, a
4 health care provider shall report to the State, in accord-
5 ance with such requirements as the Secretary shall specify,
6 on all applicable measures for determining the quality of
7 such 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) WHOLE GENOME SEQUENCING CLINICAL
5 SERVICES.—The term ‘whole genome sequencing
6 clinical services’, with respect to an eligible indi-
7 vidual—

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

16 “(B) includes any analysis, interpretation,
17 and data report derived from such sequenc-
18 ing.”.