

115TH CONGRESS
2D SESSION

H. R. 5062

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

FEBRUARY 15, 2018

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 Energy and Commerce

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
9 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 whole genome se-
14 quencing;

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

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

22 (4)(A) the extent to which coverage provisions
23 in the Medicare and Medicaid programs under titles
24 XVIII and XIX of the Social Security Act (42
25 U.S.C. 1395 et seq., 1396 et seq.) may restrain the

1 use of genetic and genomic testing that may improve
2 clinical outcomes for beneficiaries; and

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

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

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

12 (i) a metabolic disease;

13 (ii) a hereditary cancer syndrome; and

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

16 (B) special populations, including—

17 (i) infants and children;

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

20 (iii) transplant patients;

21 (iv) individuals with cardiac disease;

22 and

23 (v) individuals with, or who have a
24 family history of, a birth defect or develop-
25 mental disability.

1 (b) REPORT.—

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

7 (A) the Secretary of Health and Human
8 Services;

9 (B) the Committee on Ways and Means
10 and the Committee on Energy and Commerce
11 of the House of Representatives; and

12 (C) the Committee on Finance and the
13 Committee on Health, Education, Labor, and
14 Pensions of the Senate.

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

1 **SEC. 3. 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 1943 the
6 following new section:

7 **“SEC. 1944. 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 for which the Secretary determines
14 it is necessary to waive in order to implement this section,
15 beginning January 1, 2019, a State, at its option as a
16 State 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 8 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 2019, 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 three
8 years after the date on which the State plan amendment
9 under this section is approved, a State shall submit a re-
10 port to the Administrator of the Centers for Medicare &
11 Medicaid Services and the Administrator of the Health
12 Resources and Services Administration on—

13 “(1) the extent to which whole genomic se-
14 quencing clinical services reduce health disparities;
15 and

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

21 “(e) REPORTS BY HEALTH CARE PROVIDERS.—As a
22 condition for receiving payment for whole genome sequenc-
23 ing clinical services provided to an eligible individual, a
24 health care provider shall report to the State, in accord-
25 ance with such requirements as the Secretary shall specify,

1 on all applicable measures for determining the quality of
2 such services.

3 “(f) DEFINITIONS.—In this section:

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

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

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

13 “(C) has been referred or admitted to a
14 pediatric intensive care unit for a chronic or
15 undiagnosed disease;

16 “(D) has been seen by at least one medical
17 specialist for such chronic or undiagnosed dis-
18 ease; and

19 “(E) is suspected by at least one medical
20 specialist to have a pediatric-onset genetic dis-
21 ease.

22 “(2) WHOLE GENOME SEQUENCING CLINICAL
23 SERVICES.—The term ‘whole genome sequencing
24 clinical services’, with respect to an eligible indi-
25 vidual—

1 “(A) means the unbiased sequencing of all
2 deoxyribonucleic acid bases in the genome of
3 such individual and, if for the sole benefit of
4 the individual, a biological parent of such indi-
5 vidual for the purpose of determining whether
6 one or more potentially disease-causing genetic
7 variants are present in the genome of such indi-
8 vidual or such biological parent; and
9 “(B) includes any analysis, interpretation,
10 and data report derived from such sequenc-
11 ing.”.

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