[DISCUSSION DRAFT]

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 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.

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 ''Advancing Access to Precision Medicine Act''.

SEC. 2. NATIONAL ACADEMY OF MEDICINE STUDY.

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

and Human Services shall enter into an arrangement with the National Academy of Medicine under which the Academy agrees to study—

(1) how genetic and genomic testing may improve preventative care and precision medicine;

(2) how genetic and genomic testing may reduce health disparities;

(3) how the Federal Government may help to reduce barriers to genetic and genomic testing, including—

(A) encouraging the expansion of health insurance coverage of genetic and genomic testing, including diagnostic, predictive, and presymptomatic testing, and whole genome sequencing;

(B) supporting the collection of evidence for the clinical utility and appropriate use of genetic and genomic tests; and

(C) improving access to genetic counselors, pathologists, and other relevant professions, including strengthening related workforce education and training efforts;

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

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

(B) how the Centers for Medicare & Medicaid Services may make coverage determinations that better suit a precision medicine approach to treatment; and

(5) how genetic and genomic testing may improve health outcomes for all populations in the United States, including—

(A) individuals with a rare disease, including—

(i) a metabolic disease;

(ii) a hereditary cancer syndrome; and

(iii) a neurologic disease with known treatments; and

(B) special populations, including—

(i) infants and children;

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

(iii) transplant patients;

(iv) individuals with cardiac disease; and

(v) individuals with, or who have a family history of, a birth defect or developmental disability.

(b) REPORT.—

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

(A) the Secretary of Health and Human Services;

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

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

(2) CONSULTATION.—The arrangement under subsection (a) shall provide for the National Academy of Medicine, in developing the report required by paragraph (1), to consult with physicians, other health professionals, health educators, health professional organizations, relevant companies, patient organizations, the Health Resources and Services Administration, the National Cancer Institute, the Na-

tional Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services.

SEC. 3. 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, 2019, 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 Secretary)

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 purposes of section 1903(a), except that, during the first 8 fiscal year quarters that the State plan amendment is in effect, the Federal medical assistance percentage applicable to such payments shall be equal to 90 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, 2019, 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 deter-

mined 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 hospital 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 three 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. When appropriate and feasible, a health care provider shall use health information technology in providing the State with such information.

''(f) DEFINITIONS.—In this section:

''(1) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who—

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

''(B) 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;

''(C) has undergone treatment in an intensive care setting for an unresolved disease; and

''(D) has been seen by a medical specialist for such unresolved disease and is suspected to have a pediatric-onset genetic disease.

''(2) WHOLE GENOME SEQUENCING CLINICAL SERVICES.—The term 'whole genome sequencing clinical services' means services used to analyze and determine the sequence of deoxyribonucleic acid (DNA) in the genome of an eligible individual **[**or a biological relative of such individual - *This may include covering the cost of sequencing for individuals who are not eligible for Medicaid. Is that the intent? Keep language?***]** for the purpose of determining whether one or more potentially disease-causing genetic variants are present in such genome.''.