

[DISCUSSION DRAFT]

117TH CONGRESS
1ST SESSION

H. R. _____

To require the Secretary of Health and Human Services to conduct a demonstration program to genetic and genomic testing for certain children, to provide for a study by the National Academy of Medicine on the use of such testing to improve health care, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To require the Secretary of Health and Human Services to conduct a demonstration program to genetic and genomic testing for certain children, to provide for a study by the National Academy of Medicine on the use of such 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 “Precision Medicine An-
5 swers for Kids Today Act”.

1 **SEC. 2. CENTERS FOR MEDICARE & MEDICAID SERVICES**
2 **GUIDANCE ON THE EARLY AND PERIODIC**
3 **SCREENING, DIAGNOSTIC, AND TREATMENT**
4 **BENEFIT.**

5 Not later than 6 months after the date of enactment
6 of this Act, the Centers for Medicare & Medicaid Services
7 shall issue guidance to States on authority and require-
8 ments under the Medicaid program under title XIX of the
9 Social Security Act to provide medically necessary health
10 care that falls within the scope of services specified under
11 section 1905(r) of the Social Security Act (42 U.S.C.
12 1396d(r)) to a child, regardless of whether the service is
13 available for adults under the State plan (or waiver of
14 such plan) under such title. The guidance shall—

15 (1) include technical and educational assistance
16 on how to increase the frequency of coverage under
17 the State plan (or waiver) pursuant to paragraphs
18 (4) and (16) of section 1905(a) of such Act (42
19 U.S.C. 1396d(a)) for genetic and genomic testing di-
20 agnostic services, including whole exome sequencing,
21 whole genome sequencing, and gene panels when rec-
22 ommended by a qualified treating provider as a first-
23 or second-tier test for pediatric patients, including
24 those who—

25 (A) have a positive result from a newborn
26 screening program;

1 (B) have one or more neurodevelopmental
2 or congenital anomalies;

3 (C) are experiencing developmental delay
4 or intellectual disability;

5 (D) are having seizures;

6 (E) have been referred or admitted to a
7 pediatric or neonatal intensive care unit for a
8 chronic or undiagnosed disease;

9 (F) have been seen by at least one medical
10 specialist for such chronic or undiagnosed dis-
11 ease; or

12 (G) are suspected by at least one
13 healthcare provider to have a neonatal- or pedi-
14 atric-onset genetic disease;

15 (2) provide education and support to providers
16 to minimize denials of claims for medical assistance
17 under the State plan under title XIX of the Social
18 Security Act resulting from deficient or inadequate
19 paperwork; and

20 (3) ensure that providers and Medicaid-eligible
21 children and the families are aware of the Early and
22 Periodic Screening, Diagnostic and Treatment Ben-
23 efit under title XIX of the Social Security Act and
24 have access to required screenings and necessary
25 treatment services.

1 **SEC. 3. DEMONSTRATION PROGRAM TO PROVIDE GENETIC**
2 **AND GENOMIC TESTING FOR CERTAIN CHIL-**
3 **DREN.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services shall enter into agreements with up to
6 15 States submitting applications under subsection (c) for
7 the purpose of conducting, in accordance with this section,
8 demonstration projects under section 1115 of the Social
9 Security Act (42 U.S.C. 1315) in such States during the
10 3-year period beginning on the first date of the first fiscal
11 quarter than begins on or after the date of the enactment
12 of this section to test and evaluate the provision of medical
13 assistance under the State plans under title XIX of such
14 Act (or waivers of such plans) to eligible individuals for
15 purposes of providing such individuals with genetic and
16 genomic testing.

17 (b) DEMONSTRATION PROJECT PAYMENT REQUIRE-
18 MENTS.—Under each demonstration project under this
19 section conducted by a State, the following shall apply:

20 (1) The State shall provide a health care pro-
21 vider (as defined by the State) with payments for
22 the provision of genetic and genomic testing to any
23 eligible individual. Payments made to a health care
24 provider for such services shall be treated as medical
25 assistance for purposes of section 1903(a) of the So-
26 cial Security Act (42 U.S.C. 1396b(a)), except that

1 the Federal medical assistance percentage applicable
2 to such payments shall be equal to 100 percent.

3 (2) The State shall specify the methodology the
4 State will use for determining payment for the provi-
5 sion of genetic and genomic testing. Such method-
6 ology for determining payment shall be established
7 consistent with section 1902(a)(30)(A) of such Act
8 (42 U.S.C. 1396a(a)(30)(A)).

9 (c) APPLICATIONS.—

10 (1) IN GENERAL.—A State desiring to enter
11 into an agreement under subsection (a) with the
12 Secretary for conducting a demonstration project
13 shall submit to the Secretary an application, in ac-
14 cordance with such form and manner, and applica-
15 tion priorities, as specified by the Secretary and that
16 at a minimum includes the following:

17 (A) An explanation of how and the extent
18 to which genetic and genomic testing under the
19 demonstration project of the State will provide
20 information and data on how such services im-
21 prove the diagnosis of eligible individuals.

22 (B) An explanation of how and the extent
23 to which coverage under the State plan (or
24 waiver) pursuant to the demonstration project
25 will increase the use of genetic and genomic

1 testing that may increase the use of genetic and
2 genomic testing that may improve clinical out-
3 comes for eligible individuals.

4 (C) Procedures for referring any eligible
5 individual who seeks or needs treatment in a
6 hospital emergency department to a health care
7 provider who is qualified (as determined by the
8 State) to provide genetic and genomic testing.

9 (D) An explanation of how genetic and
10 genomic testing may improve health outcomes
11 for all populations in the State, including—

12 (i) individuals with a rare genetic dis-
13 ease, including a metabolic disease,
14 neurologic disorders, or hereditary cancer
15 teting in the presence of a suspected or
16 confirmed cancer diagnosis; and

17 (ii) special populations, including in-
18 fants and children who are critically ill
19 (non-infectious and non-trauma) patients,
20 transplant patients, individuals with car-
21 diac disease, and individuals with, or who
22 have a family history of, a birth defect or
23 developmental disability.

24 (2) PREFERENCES IN CONSIDERING APPLICA-
25 TIONS.—In considering applications submitted under

1 paragraph (1), the Secretary of Health and Human
2 Services shall give preference to States that can
3 demonstrate underutilization of genetic and genomic
4 sequencing clinical services (with priority given to
5 states that do not cover whole-genome sequencing or
6 do not cover the majority of genetic and genomic
7 clinical services) in pediatric populations under the
8 State plan under title XIX of the Social Security Act
9 (or waiver of such plan).

10 (d) TECHNICAL ASSISTANCE.—The Secretary of
11 Health and Human Services shall provide technical assist-
12 ance to assist States in planning and designing the dem-
13 onstration project for purposes of applying for conducting
14 such project under this section.

15 (e) REPORTS BY STATES.—Not later than one year
16 after the date on which a State enters into an agreement
17 under subsection (a) with the Secretary for conducting a
18 demonstration project, the State shall submit a report to
19 the Administrator of the Centers for Medicare & Medicaid
20 Services and the Administrator of the Health Resources
21 and Services Administration on the extent to which genetic
22 and genomic testing improved outcomes and reduced
23 health disparities. Such report shall include information
24 on the number of patients receiving genetic and genomic

1 testing, the types of services provided, and such other in-
2 formation as the Secretary shall prescribe.

3 (f) REPORTS BY HEALTH CARE PROVIDERS.—As a
4 condition for receiving payment for genetic and genomic
5 testing provided to an eligible individual under a dem-
6 onstration project conducted by a State under this section,
7 a health care provider shall report to the State, in accord-
8 ance with such requirements as the Secretary shall specify,
9 on all applicable measures for determining the quality and
10 efficacy of such services.

11 (g) DEFINITIONS.—In this section:

12 (1) ELIGIBLE INDIVIDUAL.—The term “eligible
13 individual” means, with respect to a State, an indi-
14 vidual who—

15 (A) is eligible for medical assistance under
16 the State plan under title XIX of the Social Se-
17 curity Act (or a waiver of such plan);

18 (B) is under the age of 21 (or, at the op-
19 tion of the State, under the age of 20, 19, or
20 18 as the State may choose), or in the case of
21 an individual described in section
22 1902(a)(10)(A)(i)(IX) of such Act (42 U.S.C.
23 1396a(a)(10)(A)(i)(IX)), under the age of 26;

24 (C) has been referred or admitted to an in-
25 tensive care unit, or has been seen by at least

1 one medical specialist, for a suspected genetic
2 or undiagnosed disease; or

3 (D) is suspected by at least one medical
4 specialist to have a neonatal-onset or pediatric-
5 onset genetic disease.

6 (2) GENETIC AND GENOMIC TESTING.—The
7 term “genetic and genomic testing”, with respect to
8 an eligible individual—

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

17 (B) includes—

18 (i) the sequencing of the whole ge-
19 nome, the whole exome, or a panel of
20 genes; and

21 (ii) any analysis, interpretation, and
22 data report derived from such sequencing.

23 **SEC. 4. NATIONAL ACADEMY OF MEDICINE STUDY.**

24 (a) IN GENERAL.—Not later than one year after the
25 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) disparities in access to precision diagnostics
7 and associated therapeutics;

8 (3) how genetic and genomic testing may be
9 used to reduce health disparities in marginalized
10 communities;

11 (4) how the Federal Government may help to
12 reduce barriers to genetic and genomic testing, in-
13 cluding—

14 (A) encouraging the expansion of health
15 insurance coverage of genetic and genomic test-
16 ing, including diagnostic, predictive, and pre-
17 symptomatic testing, and genetic and genomic
18 testing (as defined in section 2(h)(2));

19 (B) supporting the collection of evidence
20 for the clinical utility and appropriate use of ge-
21 netic and genomic tests; and

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

1 (5)(A) the extent to which coverage provisions
2 in the Medicare and Medicaid programs under titles
3 XVIII and XIX of the Social Security Act (42
4 U.S.C. 1395 et seq., 1396 et seq.) may restrain the
5 use of genetic and genomic testing that may improve
6 clinical outcomes for beneficiaries;

7 (B) the extent to which coverage provided pur-
8 suant to section 2 increased the use of genetic and
9 genomic testing and improved clinical outcomes for
10 beneficiaries; and

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

15 (6) how genetic and genomic testing may im-
16 prove health outcomes for all pediatric populations
17 in the United States, including—

18 (A) children with a rare disease, including
19 a metabolic disease, neurologic disorder, or he-
20 reditary cancer testing in the presence of a sus-
21 pected or confirmed cancer diagnosis; and

22 (B) special populations, including—

23 (i) critically ill (non-infectious and
24 non-trauma) patients;

25 (ii) transplant patients;

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

6 (b) REPORT.—

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

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

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

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

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

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

6 (3) USE OF INFORMATION.—The National
7 Academy of Medicine shall, to the extent possible, in
8 conducting the study under subsection (a), utilize in-
9 formation included in the reports submitted pursu-
10 ant to subsections (f) and (g) of section 2.

11 **SEC. 5. CENTERS FOR MEDICARE & MEDICAID SERVICES**
12 **REPORT ON MEDICAID COVERAGE FOR GE-**
13 **NETIC AND GENOMIC TESTING.**

14 Not later than one year after the date of the enact-
15 ment of this Act, and annually thereafter for the subse-
16 quent 3 years, the Centers for Medicare & Medicaid Serv-
17 ices shall submit to the Secretary of Health and Human
18 Services, the Committees on Ways and Means and on En-
19 ergy and Commerce of the House of Representatives, and
20 the Committees on Finance and Health, Education,
21 Labor, and Pensions of the Senate a report on the extent
22 to which each of the 50 States provide coverage under the
23 State plan under title XIX of the Social Security Act (or
24 waiver of such plan) of genetic and genomic testing (as
25 defined in section 2(f)(2)) (including whole exome, whole

1 genome, gene panels, single gene tests, Chromosomal
2 microarray analysis, Fluorescence in situ hybridization,
3 and other genetic and genomic tests), including informa-
4 tion on—

5 (1) how often genetic and genomic diagnostic
6 testing services are covered and reimbursed;

7 (2) the frequency of denials for coverage and
8 the rationale for denying coverage;

9 (3) an analysis of which genetic and genomic
10 diagnostic tests are being approved or denied;

11 (4) how often test genetic counseling is covered
12 pre- and post- genetic and genomic diagnostic test-
13 ing;

14 (5) the turn-around time for prior authorization
15 requests; and

16 (6) any barriers to coverage of genetic and
17 genomic testing services identified.