Genomic Answers for Children's Health Act

Reps. Scott Peters (CA-50) & Gus Bilirakis (FL-12)

Section-by-Section

Section 1. Short Title.

- Names the legislation the Genomic Answers for Children's Health Act.

Section 2(a) + 2(b). Clarifying Access to Genomic Testing for Children with Undiagnosed/Rare Diseases.

- This section amends the definition of "early and period screening, diagnostic, and treatment services" under Section 1905(r) of the Social Security Act to clarify that whole genome sequencing and whole exome sequencing are included under "Such other necessary health care, diagnostic services, treatment, and other measures" pursuant to paragraph (5).
- The provision ensures such coverage includes whole genome sequencing and whole exome sequencing services when recommended by a physician or other licensed clinician within the scope of their practice under state law as a first-tier test for individuals up to age 21 suspected to have a genetic disorder, rare disease, or a health condition of unknown origin, including but not limited to one or more congenital anomalies, global developmental delay, or intellectual disability.
- The legislation clarifies that such coverage includes sequencing of such individual and a first degree biological relative or relatives of such individual for purposes of determining whether one or more potentially disease-causing genetic variants are present in such individual or biological first-degree relative.
- It requires that such coverage includes sequencing of the whole genome or the whole exome and any analysis, interpretation, and data report derived from such sequencing.
- It requires that state Medicaid programs must provide a payment separate from the bundled inpatient rate for genomic sequencing performed in the inpatient setting.

Section 2(c). Ensuring Awareness of Access to Genomic Testing.

- This section directs the Administrator for the Centers for Medicare & Medicaid Services (CMS) to take steps to improve awareness of Medicaid coverage of whole genome and whole exome sequencing, including by:
    - Convening stakeholders (including children's hospitals, provider organizations, laboratory test developers, geneticists, and others) to identify challenges and opportunities in policy implementation, including potential best practices to minimize denials of claims for medical assistance under Medicaid state plans from prior authorization or administrative requirements.
    - Issuing a report after 24 months on state reimbursement fees for whole genome and whole exome sequencing services and aggregated information on the number and health outcomes of children receiving such services under Medicaid.

Section 2(d). GAO Report.

- This section directs GAO to publish a report 24 months after enactment of the Genomic Answers for Children's Health Act that includes:
    - Feedback on whole genome sequencing and whole exome sequencing coverage changes and CMS implementation activities under the Act, including patient access to such services, remaining challenges to access, and provider awareness of coverage;
    - Assessment of prior authorization, reimbursement, and workforce-related issues for impacts on access; and
    - Recommendations to CMS regarding additional guidance or improvements to ensure patient access to clinical sequencing services.