General Assembly

Substitute Bill No. 5367

February Session, 2024

HB05367APP 041524

AN ACT CONCERNING MEDICAID COVERAGE OF RAPID WHOLE GENOME SEQUENCING FOR CRITICALLY ILL INFANTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2024*) (a) As used in this section, (1) "rapid whole genome sequencing" means a test designed to diagnose genetic disorders in time to inform or change acute medical or surgical management of a critically ill infant, and (2) "infant" means a child from birth to age twelve months. The Commissioner of Social Services shall provide medically necessary Medicaid coverage for rapid whole genome sequencing of a critically ill infant enrolled in the Medicaid program who is being treated in a neonatal intensive care or pediatric intensive care unit.

(b) The commissioner shall require that any health care provider receiving reimbursement for such test certify, in writing, that any genetic data resulting from such test is (1) used only to assist in diagnosing and treating the infant, (2) protected in accordance with the federal Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended from time to time, and (3) not used in scientific research unless a parent or legal guardian of the infant expressly consents to such use.

(c) The commissioner shall take actions necessary to implement the

provisions of this section, including, but not limited to, (1) promulgating regulations in accordance with chapter 54 of the general statutes to provide payment for such rapid whole genome sequencing, and (2) submitting to the Centers for Medicare and Medicaid Services any new waiver application, amendment to an existing waiver or Medicaid state plan amendment necessary to ensure federal financial participation for Medicaid coverage of such rapid whole genome sequencing.

(d) In developing regulations pursuant to subsection (c) of this section, the commissioner shall establish evidence-based medical necessity criteria for such rapid whole genome sequencing coverage that shall include, but need not be limited to: (1) The infant has symptoms that suggest a broad differential diagnosis that would require an evaluation by multiple genetic tests if rapid whole genome sequencing is not performed, (2) the infant's treating health care provider has provided a written determination that rapid whole genome sequencing is necessary to guide clinical decision making, and (3) the infant has complex or acute illness of unknown etiology, which may include (A) congenital anomalies involving at least two organ systems or complex or multiple congenital anomalies in one organ system, (B) specific organ malformations highly suggestive of a genetic etiology, or (C) abnormal laboratory tests or abnormal chemistry profiles suggesting the presence of a genetic disease.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2024*	New section

HS *Joint Favorable Subst.*

APP *Joint Favorable*