House of Representatives

General Assembly

File No. 282

February Session, 2024

Substitute House Bill No. 5367

House of Representatives, April 4, 2024

The Committee on Human Services reported through REP. GILCHREST of the 18th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

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

Statement of Legislative Commissioners:
In Subsecs. (c) and (d), references to "rules" were deleted for statutory consistency in accordance with the provisions of chapter 54 of the general statutes.

HS *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 25 $	FY 26 $
Social Services, Dept.	GF - Potential Cost	See Below	See Below

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill could result in a cost to the Department of Social Services (DSS) associated with requiring Medicaid coverage of rapid whole genome sequencing for certain critically ill infants. While this is currently covered via payments to hospitals, a cost may be incurred if DSS is required to establish a specific rate for this service outside of the current rate methodology. The bill also requires DSS to establish evidence-based medical necessity criteria for such rapid whole genome sequencing coverage. DSS would experience additional impact to the extent this varies from current coverage.

The Out Years

The annualized ongoing fiscal impact identified above would continue subject to the Medicaid rates established and associated utilization.

OLR Bill Analysis

sHB 5367

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

SUMMARY

This bill requires the Department of Social Services (DSS) commissioner to provide medically necessary Medicaid coverage for rapid whole genome sequencing for certain critically ill infants. These are tests for diagnosing genetic disorders in time to inform or change acute medical or surgical management of critically ill infants. The coverage requirement applies to infants ages 0 to 12 months who are enrolled in Medicaid and being treated in neonatal intensive care or pediatric intensive care units.

The bill sets requirements for how providers may use test data. It also requires DSS to set specific evidence-based medical necessity criteria for rapid whole genome sequencing.

The bill requires the DSS commissioner to take actions needed to implement the bill's provisions, including (1) adopting regulations on provider payments and (2) submitting any waiver applications and amendments or state plan amendments to the Centers for Medicare and Medicaid Services to ensure federal matching funds for this coverage.

EFFECTIVE DATE: July 1, 2024

TEST DATA REQUIREMENTS

Under the bill, the DSS commissioner must require that providers receiving payments for rapid whole genome sequencing certify in writing that any genetic data resulting from a test is:

1. used only to help diagnose and treat the infant;

2. protected under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA); and

3. not used in scientific research unless the infant's parent or legal guardian expressly consents.

MEDICAL NECESSITY CRITERIA

The bill requires the DSS commissioner, when developing regulations for provider payments, to set evidence-based medical necessity criteria. These criteria must include at least the following:

1. the infant has symptoms suggesting a broad differential diagnosis that would require an evaluation by multiple genetic tests if rapid whole genome sequencing is not used,

2. the infant's treating health care provider provided a written determination that rapid whole genome sequencing is needed to guide clinical decision making, and

3. the infant has complex or acute illness of unknown cause.

These complex or acute illnesses may include (1) congenital anomalies involving at least two organ systems or complex or multiple congenital anomalies in one organ system, (2) specific organ malformations highly suggesting a genetic cause, or (3) abnormal lab tests or abnormal chemistry profiles that suggest a genetic disease.

Existing law, unchanged by the bill, sets separate standards for medically necessary services in DSS's medical assistance programs, including Medicaid (see BACKGROUND).

BACKGROUND

Related Bill

sSB 307, favorably reported by the Human Services Committee, requires DSS to provide Medicaid coverage for biomarker testing, which, under the bill, includes whole genome sequencing.

Medically Necessary Services

By law, for DSS's medical assistance programs (e.g., Medicaid), "medically necessary" means health services required to prevent, identify, diagnose, treat, rehabilitate, or ameliorate a person's medical condition, or its effects, to attain or maintain achievable health and independent functioning. Medically necessary services must be:

1. consistent with generally accepted medical practice standards;
2. clinically appropriate in terms of type, frequency, timing, site, extent, and duration and considered effective for the person's illness, injury, or disease;
3. not primarily for the person's or health care provider's convenience;
4. not more costly than an alternative service that is at least as likely to produce equivalent therapeutic or diagnostic results for the illness, injury, or disease; and
5. based on an assessment of the person and his or her medical condition (CGS § 17b-259b).

COMMITTEE ACTION

Human Services Committee

Joint Favorable Substitute
Yea 21 Nay 0 (03/19/2024)