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)