The LIVINGSTON floor amendment:

**Children’s Health Insurance Program (CHIP)**

1. Specifies that the increased income threshold for CHIP eligibility is subject to approval by the Centers for Medicare and Medicaid Services (CMS).

**Dementia Awareness**

2. Extends the DHS dementia awareness campaign report deadline from June 30, 2024 to June 30, 2025.

**AHCCCS Rapid Whole Genome Sequencing Pilot Coverage**

3. Requires AHCCCS for FY 2024-2026, subject to any required CMS approval, to provide pilot coverage of rapid whole genome sequencing as a separately payable service for members who are under one years old, have a complex or acute illness of unknown etiology and is receiving inpatient hospital services in an intensive care unit or a high acuity pediatric care unit.

4. Specifies that rapid whole genome sequencing may be subject to applicable evidence-based medical necessity criteria.

5. Requires genetic data generated as a result of performing covered rapid whole genome sequencing to:
   a) Have a primary use of assisting the ordering health care professional and treating care team to diagnose and treat the patient; and
   b) Be protected health information subject to the applicable requirements as set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act and their attendant regulations, including HIPAA Privacy Standards.

6. Directs the AHCCCS Director to:
   a) Submit any new waiver application, amendment to an existing waiver or Medicaid state plan amendment necessary for CMS approval of rapid whole genome sequencing coverage; and
b) Adopt any rules or take any administrative actions to implement rapid whole genome sequencing coverage.

7. Repeals the AHCCCS rapid whole genome sequencing requirements on January 1, 2027.

8. Defines terms.
Page 2, line 34, after the comma insert "SUBJECT TO THE APPROVAL OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES."

Page 11, line 28, strike "2024" insert "2025"

Between lines 32 and 33, insert:

"Sec. 9.  AHCCCS; rapid whole genome sequencing; pilot coverage requirements; rules; administrative action; delayed repeal; definitions

A. Subject to any required approval of the centers for medicare and medicaid services, for fiscal years 2023-2024, 2024-2025 and 2025-2026, the Arizona health care cost containment system administration and its contractors shall provide pilot coverage of rapid whole genome sequencing as a separately payable service for members if the member meets all of the following criteria:

1. Is under one year of age.

2. Has a complex or acute illness of unknown etiology that is not confirmed to be caused by an environmental exposure, toxic ingestion, infection with normal response to therapy or trauma.

3. Is receiving inpatient hospital services in an intensive care unit or a high acuity pediatric care unit.

B. The pilot coverage provided pursuant to this section may be subject to applicable evidence-based medical necessity criteria that are based on any of the following:
1. The patient 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 patient's treating health care provider determines that timely identification of a molecular diagnosis is necessary to guide clinical decision-making and that testing results may guide the treatment or management of the patient's condition.

3. The patient has a complex or acute illness of unknown etiology, including at least one of the following conditions:

   (a) Congenital anomalies involving at least two organ systems or complex or multiple congenital anomalies in one organ system.
   (b) Specific organ malformations suggestive of a genetic etiology.
   (c) Abnormal laboratory tests or abnormal chemistry profiles suggesting the presence of a genetic disease, complex metabolic disorder or inborn error of metabolism.
   (d) Refractory or severe hypoglycemia or hyperglycemia.
   (e) An abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems.
   (f) Severe muscle weakness, rigidity or spasticity.
   (g) Refractory seizures.
   (h) A high-risk stratification on evaluation for a brief resolved unexplained event with any of the following:
      (i) A recurrent event without respiratory infection.
      (ii) A recurrent seizure-like event.
      (iii) A recurrent cardiopulmonary resuscitation.
      (i) Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis or structural heart disease.
(j) Abnormal diagnostic imaging studies or physiologic function studies suggestive of an underlying genetic condition or etiology.

(k) Family genetic history related to the patient's condition.

C. Genetic data generated as a result of performing rapid whole genome sequencing that is covered pursuant to this section:
   1. Shall have a primary use of assisting the ordering health care professional and treating care team to diagnose and treat the patient.
   2. Is protected health information that is subject to the requirements applicable to protected health information as set forth in the health insurance portability and accountability act of 1996 and the health information technology for economic and clinical health act, and their attendant regulations, including the health insurance portability and accountability act privacy standards (45 Code of Federal Regulations part 160 and part 164, subparts A and E).

D. The director of the Arizona health cost care containment system administration shall submit any new waiver application, amendment to an existing waiver or medicaid state plan amendment necessary for approval from the centers for medicare and medicaid services for pilot coverage of rapid whole genome sequencing as prescribed in this section. The director may adopt any rules or take any other administrative action necessary to implement this section.

E. This section is repealed from and after December 31, 2026.

F. For the purposes of this section:
   1. "Member" has the same meaning prescribed in section 36-2901, Arizona Revised Statutes.
   2. "Rapid whole genome sequencing":
      (a) Means as an investigation of the entire human genome, including coding and noncoding regions and mitochondrial deoxyribonucleic acid, that identifies disease-causing genetic changes and that returns the preliminary positive results within five days and final results within fourteen days.
House Amendments to H.B. 2816

1 (b) Includes patient-only whole genome sequencing and duo and trio whole genome sequencing of the patient and the patient's biological parent or parents."
2
3 Renumber to conform
4 Amend title to conform

DAVID LIVINGSTON

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