HB 2144: health insurance coverage; biomarker testing
Sponsor: Representative Cobb, LD 5
Senate Engrossed

Overview
Requires health care insurers, the Arizona Health Care Cost Containment System (AHCCCS) and its contractors to provide coverage for biomarker testing. Prescribes processes and requirements for the usage and coverage of biomarker testing.

History
Statute’s definition of a health care insurer includes a disability insurer, group disability insurer, blanket disability insurer, health care services organization, hospital service corporation and a medical service corporation.

Hospital service corporations and medical service corporations are corporations organized under state law for the purposes of establishing, maintaining and operating nonprofit hospital service or medical service plans or a combination of plans. Hospital and medical services may be provided by hospitals or by specified physicians. A health care service organization means any person that undertakes to conduct one or more health care plans. Health care services organizations include a provider-sponsored health care service organization unless the context requires otherwise.

Blanket disability insurance is a form of disability insurance that covers special groups of individuals under policies or contracts specified in statute. Group disability insurance is a form of disability insurance coverings groups of persons under a policy issued by certain entities without one or more members of their families or one or more of their dependents, or covering one or more members of the families or one or more dependents of persons in the eligible groups (A.R.S. §§ 20-822, 20-1051, 20-1401, 20-1404, 20-2501).

AHCCCS is Arizona’s Medicaid program that oversees contracted health plans for the delivery of health care to individuals and families who qualify for Medicaid and other medical assistance programs. Through contracted health plans across the state, AHCCCS delivers health care to qualifying individuals including low-income adults, their children or people with certain disabilities. Current statute outlines covered health and medical services offered to AHCCCS members (A.R.S. § 36-2907).

Provisions
1. Requires a hospital service corporation, medical service corporation, health care service organization, disability insurer or group or blanket disability insurer that issues, amends, delivers or renews a policy or contract by January 1, 2023, to provide coverage for biomarker testing. (Sec. 1, 2, 3, 4)

2. Stipulates a subscription contract, evidence of coverage or a policy providing coverage of biomarker testing must use the testing for the purposes of the diagnosis, treatment, appropriate management or ongoing monitoring of a subscriber, enrollee or insured's disease
or condition to guide treatment decisions when the test is supported by medical and scientific evidence. (Sec. 1, 2, 3, 4, 5)

3. Specifies that medical and scientific evidence supporting the use of biomarker testing may include the following:
   a) Labeled indications for tests approved or cleared by the Food and Drug Administration (FDA) or indicated tests for a drug approved by FDA;
   b) Determinations made by Centers for Medicare and Medicaid services national coverage or Medicare administrative contractor local coverage; and
   c) Nationally recognized clinical practice guidelines and consensus statements. (Sec. 1, 2, 3, 4, 5)

4. Specifies an entity providing coverage of biomarker testing must ensure coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples. (Sec. 1, 2, 3, 4)

5. Asserts that the prescribing practitioner, subscriber, enrollee or insured must have access to a clear, accessible and convenient process to request an exception to a coverage policy of an entity providing coverage of biomarker testing and that the process must be readily available on the entities website. (Sec. 1, 2, 3, 4)

6. Clarifies that the requirement for health care insurers to have a clear, accessible and convenient process to request an exception to a coverage policy does not require a separate process if their existing process already complies with this requirement. (Sec. 1, 2, 3, 4)

7. Requires AHCCCS and its contractors to provide biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a member’s disease or condition to guide treatment decisions when the test is supported by medical and scientific evidence. (Sec. 5)

8. Directs that AHCCCS must provide biomarker testing with the same scope, duration and frequency as AHCCCS provides to its members with regards to other provided treatments. (Sec. 5)

9. Requires AHCCCS members and prescribing practitioners to have access to a clear, readily accessible and convenient online process to request an exception to a coverage policy of the system and specifies that this does not require a separate process if AHCCCS’s existing process already complies with this requirement. (Sec. 5)

10. States that any request to AHCCCS for a coverage exception must be submitted electronically by the prescribing practitioner. (Sec. 5)

11. Defines the following terms:
    a) Biomarker;
    b) Biomarker testing;
    c) Consensus statements; and
    d) Nationally recognized clinical practice guidelines. (Sec. 1, 2, 3, 4, 5)

**Senate Amendments**

1. Specifies that a covered biomarker test must provide clinical utility as demonstrated by medical and scientific evidence, rather than being supported by medical and scientific evidence.

2. Defines clinical utility.

3. Makes technical and conforming changes.