



**ARIZONA STATE SENATE**  
*Fifty-Fifth Legislature, Second Regular Session*

**AMENDED**  
FACT SHEET FOR H.B. 2144

health insurance coverage; biomarker testing

Purpose

Requires, for contracts, evidences of coverage and policies issued on or after January 1, 2023, a hospital or medical service corporation, health care services organization, disability insurer and group or blanket disability insurer (health insurer) to provide biomarker testing. Requires the Arizona Health Care Cost Containment System (AHCCCS) and its contractors to provide biomarker testing and outlines processes and requirements for biomarker testing coverage.

Background

Biomarker testing aids in the diagnosing and monitoring of cancer during and after treatment. Each person's cancer presents a unique pattern of biomarkers and some cancer treatments may only work for individuals whose cancers have certain biomarkers ([NCI](#)).

The Department of Insurance and Financial Institutions regulates policies, certificates, evidences of coverage and contracts of insurance that are issued or delivered by health care insurers. *Health care insurers* include disability insurers, group disability insurers, blanket disability insurers, health care services organizations, hospital service corporations and medical service corporations ([A.R.S. § 20-1379](#)).

AHCCCS contracts with health professionals to provide medically necessary health and medical services to eligible members, including inpatient and outpatient health services and early and periodic health screening and diagnostic services ([A.R.S. § 36-2907](#)).

The Joint Legislative Budget Committee (JLBC) fiscal note estimates that AHCCCS's contracted health plans and the state employee health plan would be affected by H.B. 2144, as introduced. Based on input from AHCCCS, JLBC estimates that H.B. 2144, as introduced, would not have a significant impact to AHCCCS-offered health plans. The Arizona Department of Administration has not provided a response regarding the fiscal impact on the state employee health plan ([JLBC fiscal note](#)).

Provisions

***Health Insurer Biomarker Testing Coverage***

1. Requires a health insurer that issues, amends, delivers or renews a subscription contract, evidence of coverage or policy on or after January 1, 2023, to provide coverage for biomarker testing.

2. Requires subscription contracts, evidences of coverage and policies to cover biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a subscriber's, enrollee's or insured's disease or condition to guide treatment decisions when the test provides clinical utility as demonstrated by medical and scientific evidence, including:
  - a) labeled indications for tests that are approved or cleared by the Food and Drug Administration (FDA) or indicated tests for an FDA-approved drug;
  - b) U.S. Centers for Medicare and Medicaid Services (CMS) national coverage determinations or Medicare Administrative Contractor (MAC) local coverage determinations; or
  - c) nationally recognized clinical practice guidelines and consensus statements.
3. Requires health insurers to ensure that coverage is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.
4. Requires a subscriber, enrollee or insured and the prescribing practitioner to have access to a clear, readily accessible and convenient process to request an exception to a health insurer's coverage policy.
5. Requires the exception process to be readily accessible on the health insurer's website.
6. Specifies that the coverage exception process requirements are not required if the health insurer's existing process complies with the outlined coverage exception process requirements.

#### ***AHCCCS Biomarker Testing Coverage***

7. Requires AHCCCS and its contractors to provide biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an AHCCCS member's disease or condition to guide treatment decisions when the test provides clinical utility as demonstrated by medical and scientific evidence, including:
  - a) labeled indications for tests that are approved or cleared by the FDA or indicated tests for an FDA-approved drug;
  - b) CMS national coverage determinations or MAC local coverage determinations; or
  - c) nationally recognized clinical practice guidelines and consensus statements.
8. Requires AHCCCS and its contractors to provide biomarker testing with the same scope, duration and frequency as AHCCCS otherwise provides to AHCCCS members.
9. Requires an AHCCCS member and the prescribing practitioner to have access to a clear, readily accessible and convenient online process to request an exception to an AHCCCS coverage policy.
10. Requires any request for a coverage exception to be submitted by the prescribing practitioner.
11. Specifies that the coverage exception process requirements are not required if AHCCCS's and its contractor's existing process complies with the outlined coverage exception process requirements.

*Miscellaneous*

12. Defines *biomarker* as a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention, including gene mutations or protein expression.
13. Defines *biomarker testing* as the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker, including single-analyte tests, multiplex panel tests and whole genome sequencing.
14. Defines *clinical utility* as the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.
15. Specifies that the most appropriate biomarker test may include both information that is actionable and some information that cannot be immediately used in the formulation of a clinical decision.
16. Defines *consensus statements* and *nationally recognized clinical practice guidelines*.
17. Becomes effective on the general effective date.

Amendments Adopted by Committee

1. Requires a covered biomarker test to provide clinical utility as demonstrated by medical and scientific evidence, rather than to be supported by medical and scientific evidence.
2. Defines *clinical utility* and specifies that the most appropriate biomarker test may include outlined information.
3. Makes technical and conforming changes.

House Action

HHS            2/14/22    DPA    9-0-0-0  
3<sup>rd</sup> Read       2/24/22                    59-0-1

Senate Action

FIN            3/16/22    DPA    8-1-1

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