OHIO LEGISLATIVE SERVICE COMMISSION

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H.B. 24
135th General Assembly

Bill Analysis

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Version: As Reported by House Insurance

Primary Sponsor: Rep. White

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SUMMARY

- Requires health benefit plans and the Medicaid program to cover medically necessary biomarker testing for specified purposes when need for the test is supported by medical or scientific evidence.
- Requires health benefit plans and the Medicaid program to ensure biomarker testing coverage in a manner that limits disruptions in care.
- Requires that any appeal of a biomarker testing coverage determination be handled in accordance with the health plan issuer's appeal policy and any relevant provision of the laws governing insurance and Medicaid appeals.

DETAILED ANALYSIS

Biomarker testing coverage

Under the bill, biomarkers are objectively measured and evaluated characteristics used as indicators of normal biological processes, pathogenic processes, or pharmacologic responses to specific therapeutic intervention, including known gene-drug interactions for drugs being considered for use or already available for use. Biomarkers include gene mutations, characteristics of genes, or protein expressions. A biomarker test analyzes tissue, blood, or another biospecimen for the presence of a biomarker.[1] The bill requires health benefit plans and the Medicaid program to cover biomarker testing for any of the following purposes:

- Diagnosis;
- Treatment and appropriate management of a disease or condition;

[1] R.C. 3902.64(A) and 5164.13(A)(1) and (A)(2).

- Ongoing monitoring of a disease or condition.[2]

However, the bill specifically does not require any coverage of biomarker testing when that testing is done purely for screening purposes.[3]

The bill requires health benefit plans and the Medicaid program to cover biomarker testing for these purposes when the test is ordered and deemed medically necessary by a qualified healthcare provider treating the patient. The bill specifies that coverage is required only if the healthcare provider is working within their scope of practice for the diagnosis, treatment, management, or monitoring of a disease or condition. Additionally, the test must be supported by medical or scientific evidence, including at least one of the following:

- Labeled indications for a U.S. Food and Drug Administration (FDA) approved or cleared test;
- Indicated tests for a drug approved by the FDA;
- Warnings and precautions for FDA approved drug labels;
- National coverage determinations made by the U.S. Centers for Medicare and Medicaid Services;
- Medicare Administrative Contractor local coverage determinations;
- Nationally recognized clinical practice guidelines;
- Nationally recognized and peer reviewed studies indicating that the test materially improves health outcomes.[4]

Under the bill, health plan issuers and the Medicaid program must ensure biomarker testing coverage in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.[5]

The bill also requires that any appeal of a biomarker testing coverage determination by a health insurer or the Medicaid program be handled in accordance with the health plan issuer's appeal policy and any relevant provision of law, including those provisions governing internal and external review and Medicaid appeals.[6] The appeal process must be made accessible to all parties both in writing and online.[7]

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[2] R.C. 3902.64(B) and 5164.13(B).

[3] R.C. 3902.64(F).

[4] R.C. 3902.64(A) and (C) and 5164.13(A) and (C).

[5] R.C. 3902.64(D) and 5164.13(D).

[6] R.C. 3902.64(E) and 5164.13(E); R.C. 1751.82, Chapter 3922, and 5160.31, not in the bill.

[7] R.C. 3902.64(E) and 5164.13(E).

Legislative intent

The bill states the legislature's intent to ensure coverage of biomarker testing supported by medical or scientific evidence to improve health outcomes and reduce healthcare costs. It does not intend to create a situation that allows manufacturers and administrators of biomarker tests to raise prices of those tests, thereby taking advantage of the bill's mandated coverage to inflate revenue.[8]

Exemption from review by the Superintendent of Insurance

The bill's provisions requiring health benefit plans to cover biomarker testing might be considered a mandated health benefit. Under R.C. 3901.71, if the General Assembly enacts a provision for mandated health benefits, that provision cannot be applied to any health benefit plan until the Superintendent of Insurance determines that the provision can be applied fully and equally in all respects to employee benefit plans subject to regulation by the federal "Employee Retirement Income Security Act of 1974" (ERISA),[9] and to employee benefit plans established or modified by the state or any of its political subdivisions. ERISA appears to preempt any state regulation of such plans.[10] The bill contains provisions that exempt its requirements from this restriction.[11]

Definitions

"**Health benefit plan**" means an agreement offered by a health plan issuer to provide or reimburse the costs of health care services. "Health benefit plan" also means a limited benefit plan, except for a policy that covers only accident, dental, disability income, long-term care, hospital indemnity, supplemental coverage, specified disease, vision care, and other specified types of coverage. "Health benefit plan" does not include a Medicare, Medicaid, or federal employee plan.[12]

"**Health plan issuer**" means an entity subject to Ohio insurance laws that provides or reimburses the costs of health care services under a health benefit plan. The term includes a sickness and accident insurance company, a health insuring corporation, a fraternal benefit society, a self-funded multiple employer welfare arrangement, a nonfederal government health plan, or a third-party administrator.[13]

[8] Section 2.

[9] 29 United States Code (U.S.C.) 1001, as amended.

[10] 29 U.S.C. 1144.

[11] R.C. 3902.64(B).

[12] R.C. 3902.50; R.C. 3922.01, not in the bill.

[13] R.C. 3902.50; R.C. 3922.01, not in the bill.

"**Medical or scientific evidence**" means evidence found in any of the following sources:

- Peer-reviewed scientific studies published in, or accepted for publication by, medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
- Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus and Elsevier Science Ltd. for indexing in Excerpta Medica;
- Medical journals recognized by the Secretary of Health and Human Services under the federal Social Security Act;
- The following standard reference compendia:
  - The American Hospital Formulary Service Drug Information;
  - Drug Facts and Comparisons;
  - The American Dental Association Accepted Dental Therapeutics;
  - The United States Pharmacopeia drug information.
- Findings, studies or research conducted by or under the auspices of a federal government agency or nationally recognized federal research institute, including any of the following:
  - The federal Agency for Healthcare Research and Quality;
  - The National Institutes of Health;
  - The National Cancer Institute;
  - The National Academy of Sciences;
  - The Centers for Medicare and Medicaid Services;
  - The federal Food and Drug Administration;
  - Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services.
- Any other medical or scientific evidence that is comparable.[14]

Under the bill, "**nationally recognized clinical practice guidelines**" means evidence-based clinical practice guidelines establishing standards of care informed by a systematic review and assessment of benefits and risks of alternative care options and include

[14] R.C. 3902.64(C) and 5164.13(C); R.C. 3922.01(S), not in the bill.

recommendations intended to optimize patient care, developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy.[15]

HISTORY

Action	Date
Introduced	02-15-23
Reported, H. Insurance	06-17-24

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[15] R.C. 5164.13(A)(4).