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Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. White and West

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SUMMARY

- Requires health benefit plans and the Medicaid program to cover biomarker testing for specified purposes when need for the test is supported by medical and scientific evidence.
- Requires health benefit plans 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, and include gene mutations or protein expressions.[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; or

[1] R.C. 3902.62(A) and 5164.13(A)(1).

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

The bill requires health benefit plans and the Medicaid program to cover biomarker testing by analysis of tissue, blood, or another biospecimen for the presence of a biomarker for these purposes when the test is supported by medical and scientific evidence, including any of the following:

- Labeled indications for a U.S. Food and Drug Administration (FDA) approved or cleared test, or indicated tests for a drug approved by the FDA;
- 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, which the bill defines as evidence-based guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict of interest policy;
- Consensus statements, which the bill defines as statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict of interest policy.[3]

Under the bill, health plan issuers must ensure biomarker testing coverage in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.[4] The Medicaid program is not subject to this requirement.

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.[5] The appeal process must be made accessible to all parties both in writing and online.[6]

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

[2] R.C. 3902.62(B) and 5164.13(B).

[3] R.C. 3902.62(A) and (C) and 5164.13(A) and (C).

[4] R.C. 3902.62(D).

[5] R.C. 3902.62(E) and 5164.13(D); R.C. 1751.82, Chapter 3922, and 5160.31, not in the bill.

[6] R.C. 3902.62(E) and 5164.13(D).

and equally in all respects to employee benefit plans subject to regulation by the federal "Employee Retirement Income Security Act of 1974" (ERISA),[7] 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.[8] The bill contains provisions that exempt its requirements from this restriction.[9]

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.[10]

"**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.[11]

HISTORY

Action	Date
Introduced	03-29-22

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[7] 29 United States Code (U.S.C.) 1001, as amended.

[8] 29 U.S.C. 1144.

[9] R.C. 3902.62(B).

[10] R.C. 3902.50 and 3922.01, not in the bill.

[11] R.C. 3902.50 and 3922.01, not in the bill.