

**Senate Study Bill 3001 - Introduced**

SENATE FILE \_\_\_\_\_  
BY (PROPOSED COMMITTEE  
ON COMMERCE BILL BY  
CHAIRPERSON BROWN)

**A BILL FOR**

1 An Act relating to insurance coverage for biomarker testing.  
2 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514C.36 Biomarker testing —  
2 coverage.

3 1. As used in this section, unless the context otherwise  
4 requires:

5 a. "*Biomarker*" means a characteristic that is objectively  
6 measured and evaluated as an indicator of normal biological  
7 processes, pathogenic processes, or pharmacologic responses to  
8 a specific therapeutic intervention, including but not limited  
9 to genetic mutations or protein expression.

10 b. "*Biomarker testing*" means the analysis of an individual's  
11 tissue, blood, or other biospecimen for the presence of a  
12 biomarker, including but not limited to single-analyte tests,  
13 multiplex panel tests, or whole genome sequencing.

14 c. "*Consensus statement*" means a statement developed by  
15 an independent, multidisciplinary panel of experts, none of  
16 whom have a conflict of interest, who utilize a transparent  
17 methodology and reporting structure. A consensus statement  
18 concerns specific clinical circumstances and is based on the  
19 best available evidence for the purpose of optimizing the  
20 outcomes of clinical care.

21 d. "*Covered person*" means a policyholder, subscriber, or  
22 other person participating in a policy, contract, or plan that  
23 provides for third-party payment or prepayment of health or  
24 medical expenses.

25 e. "*Health care professional*" means the same as defined in  
26 section 514J.102.

27 f. "*Local coverage determinations*" means the same as defined  
28 in section 1869(f)(2)(B) of the federal Social Security Act.

29 g. "*National coverage determinations*" means the same as  
30 defined in section 1869(f)(1)(B) of the federal Social Security  
31 Act.

32 h. "*Nationally recognized clinical practice guidelines*"  
33 means evidence-based clinical practice guidelines developed by  
34 independent organizations or medical professional societies,  
35 none of which have a conflict of interest, that utilize a

1 transparent methodology and reporting structure. Clinical  
2 practice guidelines establish standards of care informed  
3 by a systematic review of evidence and assessment of the  
4 costs and benefits of alternative care options and include  
5 recommendations intended to optimize patient care.

6 2. Notwithstanding the uniformity of treatment requirements  
7 of section 514C.6, a policy, contract, or plan providing for  
8 third-party payment or prepayment of medical expenses shall  
9 provide coverage for biomarker testing for the purposes of  
10 diagnosis, treatment, appropriate management, or ongoing  
11 monitoring of a covered person's disease or condition when the  
12 test is supported by medical and scientific evidence, including  
13 but not limited to any of the following:

14 a. Labeled indications for a test approved or cleared by  
15 the United States food and drug administration or indicated  
16 tests for a drug approved by the United States food and drug  
17 administration.

18 b. Centers for Medicare and Medicaid services of the  
19 United States department of health and human services national  
20 coverage determinations or Medicare administrative contractor  
21 local coverage determinations.

22 c. Nationally recognized clinical practice guidelines and  
23 consensus statements.

24 3. Coverage required under this section shall limit  
25 disruptions in care, including mitigating the need for a  
26 covered person to undergo multiple biopsies or to provide  
27 multiple biospecimen samples.

28 4. A covered person and the covered person's health care  
29 professional shall have access to a clear and convenient  
30 process available on the health carrier's internet site to  
31 request an exception to coverage provided under this section.

32 5. a. This section applies to the following classes of  
33 third-party payment provider policies, contracts, or plans  
34 delivered, issued for delivery, continued, or renewed in this  
35 state on or after January 1, 2025:

1 (1) Individual or group accident and sickness insurance  
2 providing coverage on an expense-incurred basis.

3 (2) An individual or group hospital or medical service  
4 contract issued pursuant to chapter 509, 514, or 514A.

5 (3) An individual or group health maintenance organization  
6 contract regulated under chapter 514B.

7 (4) A plan established pursuant to chapter 509A for public  
8 employees.

9 b. This section shall apply to all of the following:

10 (1) The medical assistance program under chapter 249A.

11 (2) The healthy and well kids in Iowa (Hawki) program under  
12 chapter 514I.

13 (3) A managed care organization acting pursuant to a  
14 contract with the department of health and human services under  
15 chapter 249A, or with the healthy and well kids in Iowa (Hawki)  
16 program under chapter 514I.

17 c. This section shall not apply to accident-only,  
18 specified disease, short-term hospital or medical, hospital  
19 confinement indemnity, credit, dental, vision, Medicare  
20 supplement, long-term care, basic hospital and medical-surgical  
21 expense coverage as defined by the commissioner, disability  
22 income insurance coverage, coverage issued as a supplement  
23 to liability insurance, workers' compensation or similar  
24 insurance, or automobile medical payment insurance.

25 6. The commissioner of insurance shall adopt rules pursuant  
26 to chapter 17A to administer this section.

27 EXPLANATION

28 The inclusion of this explanation does not constitute agreement with  
29 the explanation's substance by the members of the general assembly.

30 This bill relates to health insurance coverage for biomarker  
31 testing.

32 The bill defines "biomarker testing" as an analysis of  
33 an individual's tissue, blood, or other biospecimen for the  
34 presence of a biomarker. "Biomarker" is also defined in the  
35 bill.

1 The bill requires a health carrier that offers individual,  
2 group, or small group contracts, policies, or plans in this  
3 state that provide for third-party payment or prepayment of  
4 health or medical expenses to offer coverage for biomarker  
5 testing for a covered person when the test is supported by  
6 medical and scientific evidence as detailed in the bill.  
7 Coverage shall be provided in a manner which limits disruptions  
8 in a person's care. The bill requires a health carrier to  
9 provide a process on its internet site for a person and the  
10 person's health care professional to seek an exception to  
11 coverage required under the bill.

12 The bill applies to third-party payment provider contracts,  
13 policies, or plans delivered, issued for delivery, continued,  
14 or renewed in this state on or after January 1, 2025, by the  
15 third-party payment providers enumerated in the bill. The bill  
16 specifies the types of specialized health-related insurance  
17 which are not subject to the bill's coverage requirements.

18 The bill applies to the medical assistance program  
19 under Code chapter 249A, the healthy and well kids in Iowa  
20 (Hawki) program under Code chapter 514I, and a managed care  
21 organization acting pursuant to a contract with the department  
22 of health and human services to administer either the medical  
23 assistance program or the Hawki program.

24 The commissioner of insurance is required to adopt rules to  
25 administer the bill.