

Senate File 2159

S-5123

1 Amend Senate File 2159 as follows:

2 1. By striking everything after the enacting clause and
3 inserting:

4 <Section 1. NEW SECTION. 514C.36 Biomarker testing —
5 coverage.

6 1. As used in this section, unless the context otherwise
7 requires:

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

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

17 c. "*Clinical utility*" means sufficient medical and
18 scientific evidence indicating the use of a specific biomarker
19 test will provide meaningful information that will affect
20 treatment decisions and improve a covered person's outcome.

21 d. "*Consensus statement*" means a statement developed by
22 an independent, multidisciplinary panel of experts, none of
23 whom have a conflict of interest, who utilize a transparent
24 methodology and reporting structure. A consensus statement
25 concerns specific clinical circumstances and is based on the
26 best available evidence for the purpose of optimizing the
27 outcomes of clinical care.

28 e. "*Covered person*" means a policyholder, subscriber, or
29 other person participating in a policy, contract, or plan that
30 provides for third-party payment or prepayment of health or
31 medical expenses.

32 f. "*Health care professional*" means the same as defined in
33 section 514J.102.

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

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1 *h. "National coverage determinations"* means the same as
2 defined in section 1869(f)(1)(B) of the federal Social Security
3 Act.

4 *i. "Nationally recognized clinical practice guidelines"*
5 means evidence-based clinical practice guidelines developed by
6 independent organizations or medical professional societies,
7 none of which have a conflict of interest, that utilize a
8 transparent methodology and reporting structure. Clinical
9 practice guidelines establish standards of care informed
10 by a systematic review of evidence and assessment of the
11 costs and benefits of alternative care options and include
12 recommendations intended to optimize patient care.

13 2. Notwithstanding the uniformity of treatment requirements
14 of section 514C.6, a policy, contract, or plan providing for
15 third-party payment or prepayment of medical expenses shall
16 provide coverage for biomarker testing for the purposes of
17 diagnosing, treating, appropriately managing, or monitoring a
18 disease or condition in a covered person when the biomarker
19 testing has demonstrated clinical utility, including but not
20 limited to any of the following:

21 *a.* Labeled indications for a test approved or cleared by
22 the United States food and drug administration or indicated
23 tests for a drug approved by the United States food and drug
24 administration.

25 *b.* Centers for Medicare and Medicaid services of the
26 United States department of health and human services national
27 coverage determinations or Medicare administrative contractor
28 local coverage determinations.

29 *c.* Nationally recognized clinical practice guidelines and
30 consensus statements.

31 3. Coverage required under this section shall limit
32 disruptions in care, including mitigating the need for a
33 covered person to undergo multiple biopsies or to provide
34 multiple biospecimen samples.

35 4. A covered person and the covered person's health care

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1 professional shall have access to a clear and convenient
2 process available on the health carrier's internet site to
3 request an exception to coverage provided under this section.

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

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

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

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

14 (4) A plan established pursuant to chapter 509A for public
15 employees.

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

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

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

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

24 *c.* This section shall not apply to accident-only,
25 specified disease, short-term hospital or medical, hospital
26 confinement indemnity, credit, dental, vision, Medicare
27 supplement, long-term care, basic hospital and medical-surgical
28 expense coverage as defined by the commissioner, disability
29 income insurance coverage, coverage issued as a supplement
30 to liability insurance, workers' compensation or similar
31 insurance, or automobile medical payment insurance.

32 6. The commissioner of insurance may adopt rules pursuant to
33 chapter 17A to administer this section.

34 Sec. 2. DEPARTMENT OF HEALTH AND HUMAN SERVICES — REQUIRED
35 REPORT. Before November 1, 2025, the department of health

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1 and human services shall report the number of biomarker tests
2 provided during fiscal year 2025, and the resulting cost of
3 providing the biomarker tests during fiscal year 2025, to
4 individuals pursuant to this Act that are covered by the
5 medical assistance program under chapter 249A and the healthy
6 and well kids in Iowa (Hawki) program under chapter 514I.>

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