SPONSOR: Sen. Mantzavinos & Rep. Bush
Sens. Cruce, Hansen, Hoffner, Seigfried, Walsh, Wilson;
Reps. Berry, Carson, Gorman, Lambert, Morrison,
Ross Levin, Snyder-Hall, Wilson-Anton

DELAWARE STATE SENATE
153rd GENERAL ASSEMBLY

SENATE SUBSTITUTE NO. 1
FOR
SENATE BILL NO. 120

AN ACT TO AMEND TITLES 18, 29, AND 31 OF THE DELAWARE CODE RELATING TO HEALTH INSURANCE.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 33, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows and by redesignating accordingly:

§3370N. Biomarker testing.

(a) For purposes of this section:

(1) "Biomarker" means 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 known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include gene mutations, characteristics of genes, and protein expression. A biomarker is not an assessment of how a covered person or enrollee feels, functions or survives.

(2) "Biomarker testing" means the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. A clinical practice guideline establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

(4) “Medically Necessary” means as defined in §3371.

(5) “Screening” means a medical procedure or test for a covered person who has yet to display symptoms of a particular disease or condition for the purpose of determining the person’s likelihood of having the disease or condition.

(6) “Investigatory and experimental biomarker tests” means biomarker tests that are subject to the United States food and drug administration’s investigational device exemption (21 CFR 812).

(b) All individual health insurance policies, contracts, or certificates that are delivered, issued for delivery, renewed, extended, or modified in this State shall provide coverage for biomarker testing to guide or inform treatment decisions for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is medically necessary as demonstrated by medical and scientific evidence, including any of the following:

(1) Labeled indications for an FDA-approved or FDA-cleared test.

(2) Indicated tests for an FDA-approved drug.

(3) Warnings and precautions on FDA-approved drug labels.

(4) Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations.

(5) Nationally recognized clinical practice guidelines.

(c) A biomarker test that meets one of the medical and scientific evidence outlined in (b)(1)-(b)(5) shall not be considered an investigational or experimental health-care service.

(d) Insurers, health-benefit plans, and health-service corporations must ensure that coverage for biomarker testing, as required by subsection (b) of this section, is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(e) Nothing in this section prevents the operation of a policy provision required by this section as a deductible, coinsurance, allowable charge limitation, coordination of benefits, or a provision restricting coverage to services by a licensed, certified, or carrier-approved provider or facility.

(f) Nothing in this section restricts the use of utilization management.

(g) Nothing in this section shall be construed to require coverage of biomarker testing for screening purposes or coverage of investigatory and experimental biomarker tests.

(h) This section does not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, disability income, or other limited benefit health insurance policies.

Section 2. Amend Chapter 35, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows and by redesignating accordingly:

§ 3571FF. Biomarker testing.

(a) For purposes of this section:

(1) "Biomarker" means 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 known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include gene mutations, characteristics of genes, and protein expression. A biomarker is not an assessment of how a covered person or enrollee feels, functions or survives.

(2) "Biomarker testing" means the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. A clinical practice guideline establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

(4) “Medically Necessary” means as defined in §3581 of Title 18.

(5) “Screening” means a medical procedure or test for a covered person who has yet to display symptoms of a particular disease or condition for the purpose of determining the person’s likelihood of having the disease or condition.

(6) “Investigatory and experimental biomarker tests” means biomarker tests that are subject to the United States food and drug administration’s investigational device exemption (21 CFR 812).

(b) All group and blanket health insurance policies, contracts, or certificates that are delivered, issued for delivery, renewed, extended, or modified in this State shall provide coverage for biomarker testing to guide or inform treatment decisions for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is medically necessary as demonstrated by medical and scientific evidence, including any of the following:

(1) Labeled indications for an FDA-approved or FDA-cleared test.

(2) Indicated tests for an FDA-approved drug.

(3) Warnings and precautions on FDA-approved drug labels.

(4) Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations.

(5) Nationally recognized clinical practice guidelines.

(c) A biomarker test that meets one of the medical and scientific evidence outlined in (b)(1)-(b)(5) shall not be considered an investigational or experimental health-care service.

(d) Insurers, health-benefit plans, and health-service corporations must ensure that coverage for biomarker testing, as required by subsection (b) of this section, is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(e) Nothing in this section prevents the operation of a policy provision required by this section as a deductible, coinsurance, allowable charge limitation, coordination of benefits, or a provision restricting coverage to services by a licensed, certified, or carrier-approved provider or facility.

(f) Nothing in this section restricts the use of utilization management.

(g) Nothing in this section shall be construed to require coverage of biomarker testing for screening or coverage of investigatory and experimental biomarker tests.

(h) This section does not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, disability income, or other limited benefit health insurance policies.

Section 3. Amend Chapter 52, Title 29 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows and by redesignating accordingly:

§5224. Biomarker testing.

(a) For purposes of this section:

(1) "Biomarker" means 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 known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include gene mutations, characteristics of genes, and protein expression. A biomarker is not an assessment of how a covered person or enrollee feels, functions or survives.

(2) "Biomarker testing" means the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. A clinical practice guideline establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

(4) “Medically Necessary” means as defined in §3581 of Title 18.

(5) “Screening” means a medical procedure or test for a covered person who has yet to display symptoms of a particular disease or condition for the purpose of determining the person’s likelihood of having the disease or condition.

(6) “Investigatory and experimental biomarker tests” means biomarker tests that are subject to the United States food and drug administration’s investigational device exemption (21 CFR 812).

(b) This plan shall provide coverage for biomarker testing to guide or inform treatment decisions for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is medically necessary as demonstrated by medical and scientific evidence, including any of the following:

(1) Labeled indications for an FDA-approved or FDA-cleared test.

(2) Indicated tests for an FDA-approved drug.

(3) Warnings and precautions on FDA-approved drug labels.

(4) Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations.

(5) Nationally recognized clinical practice guidelines.

(c) A biomarker test that meets one of the medical and scientific evidence outlined in (b)(1)-(b)(5) shall not be considered an investigational or experimental health-care service.

(d) Carriers must ensure that coverage for biomarker testing, as required by subsection (b) of this section, is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(e) Nothing in this section prevents the operation of a policy provision required by this section as a deductible, coinsurance, allowable charge limitation, coordination of benefits, or a provision restricting coverage to services by a licensed, certified, or carrier-approved provider or facility.

(f) Nothing in this section restricts the use of utilization management.

(g) Nothing in this section shall be construed to require coverage of biomarker testing for screening purposes or coverage of investigatory and experimental biomarker tests.

Section 4. Amend Chapter 5, Title 31 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows and by redesignating accordingly:

§ 539. Biomarker testing.

(a) For purposes of this section:

(1) "Biomarker" means 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 known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include gene mutations, characteristics of genes, and protein expression. A biomarker is not an assessment of how a covered person or enrollee feels, functions or survives.

(2) "Biomarker testing" means the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes single-analyte tests, multi-plex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing.

(3) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by independent organizations or medical professional societies using a transparent methodology and reporting structure and with a conflict-of-interest policy. A clinical practice guideline establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

(4) “Medically Necessary” means as defined in §3581 of Title 18.

(5) "Screening" means a medical procedure or test for a covered person who has yet to display symptoms of a particular disease or condition for the purpose of determining the person's likelihood of having the disease or condition.

(6) "Investigatory and experimental biomarker tests" means biomarker tests that are subject to the United States Food and Drug Administration's investigational device exemption (21 CFR 812).

(b) Carriers shall provide, in all health benefit plans delivered or issued for delivery under § 503(3) of this title, coverage for biomarker testing to guide or inform treatment decisions for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is medically necessary as demonstrated by medical and scientific evidence, including any of the following:

(1) Labeled indications for an FDA-approved or FDA-cleared test.

(2) Indicated tests for an FDA-approved drug.

(3) Warnings and precautions on FDA-approved drug labels.

(4) Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations.

(5) Nationally recognized clinical practice guidelines.

(c) A biomarker test that meets one of the medical and scientific evidence outlined in (b)(1)-(b)(5) shall not be considered an investigational or experimental health-care service.

(d) Carriers must ensure that coverage for biomarker testing, as required by subsection (b) of this section, is provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(e) Nothing in this section prevents the operation of a policy provision required by this section as a deductible, coinsurance, allowable charge limitation, coordination of benefits, or a provision restricting coverage to services by a licensed, certified, or carrier-approved provider or facility.

(f) Nothing in this section restricts the use of utilization management.

(g) Nothing in this section shall be construed to require coverage of biomarker testing for screening purposes or coverage of investigatory and experimental biomarker tests.

Section 5. Effective Date. This Act applies to all policies, contracts, or certificates issued, renewed, modified, altered, amended, or reissued after December 31, 2027.

SYNOPSIS

This Act requires that individual, group, State employee, and public assistance insurance plans provide coverage for biomarker testing, when the test is supported by medical and scientific evidence. The Act applies to all such policies, contracts, or certificates issued, renewed, modified, altered, amended, or reissued after December 31, 2027.

This Act is a substitute for and differs from Senate Bill No. 120 in that this Act clarifies that it does not prevent a provision restricting coverage to services by a licensed, certified, or carrier-approved provider or facility, restrict the use of utilization management, or require coverage of biomarker testing for screening purposes or coverage of investigatory and experimental biomarker tests. In addition, the Act differs from Senate Bill No. 120 in that it applies to policies, contracts, or certificates issued, renewed, modified, altered, amended, or reissued after December 31, 2027, rather than December 31, 2026.

Author: Senator Mantzavinos