

[First Reprint]

SENATE, No. 3098

STATE OF NEW JERSEY

221st LEGISLATURE

INTRODUCED APRIL 11, 2024

Sponsored by:

Senator VIN GOPAL

District 11 (Monmouth)

Senator TROY SINGLETON

District 7 (Burlington)

Co-Sponsored by:

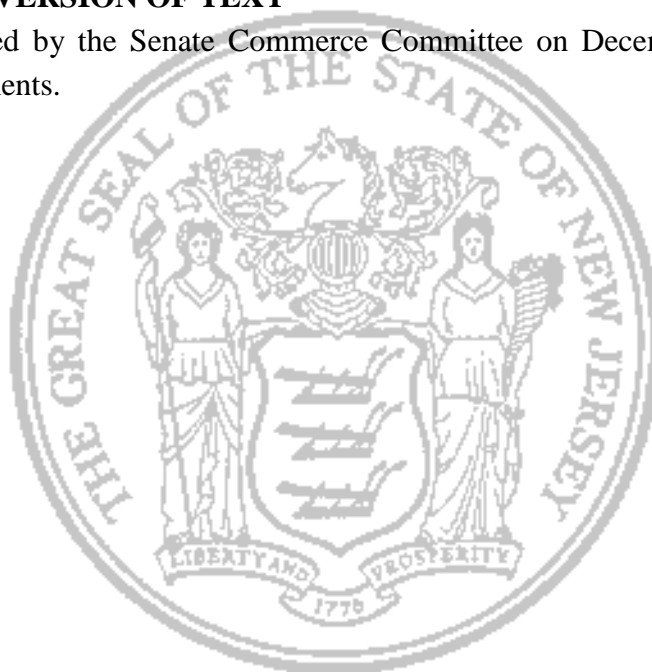
Senators A.M.Bucco, Johnson, Greenstein, Pennacchio, Diegnan, McKnight, Beach, Cruz-Perez, Zwicker, Bramnick, Burgess, Singer and Wimberly

SYNOPSIS

Requires health insurers to provide coverage for biomarker testing.

CURRENT VERSION OF TEXT

As reported by the Senate Commerce Committee on December 12, 2024, with amendments.



(Sponsorship Updated As Of: 3/17/2025)

1 AN ACT concerning health insurance coverage for biomarker testing
2 ¹**[and amending]**¹ and supplementing various parts of the
3 statutory law.

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
8 1. a. Each hospital service corporation contract that provides
9 hospital or medical expense benefits and is delivered, issued, executed,
10 or renewed in this State pursuant to P.L.1938, c.366 (C.17:48-1 et
11 seq.) or is approved for issuance or renewal in this State by the
12 Commissioner of Banking and Insurance, on or after the effective date
13 of P.L. , c. (C.) (pending before the Legislature as this bill),
14 shall provide coverage for biomarker testing, as defined by subsection
15 g. of this section.

16 b. Biomarker testing shall be covered for the purposes of
17 diagnosis, treatment, appropriate management, or ongoing monitoring
18 of a disease or condition of a subscriber when the test is supported by
19 medical and scientific evidence, including, but not limited to:

- 20 (1) labeled indications for an FDA-approved or FDA-cleared test;
21 (2) indicated tests for an FDA-approved drug;
22 (3) warnings and precautions on FDA-approved drug labels;
23 (4) Centers for Medicare and Medicaid Services National
24 Coverage Determinations or Medicare Administrative Contractor
25 Local Coverage Determinations; or
26 (5) nationally-recognized clinical practice guidelines and
27 consensus statements.

28 c. Coverage, pursuant to subsection b. of this section, shall be
29 provided in a manner that limits disruption, including multiple biopsies
30 or biospecimen samples, in the care of a subscriber.

31 d. (1) ¹**[Notwithstanding any other law, rule, or regulation to**
32 **the contrary, if]** ¹**If** utilization review is required, ¹**a hospital service**
33 **corporation shall provide**¹ a decision ¹**[shall be rendered on a prior**
34 **authorization request, and notice shall be sent to the subscriber and the**
35 **appropriate health care provider, and if the request is made through a**
36 **health care entity, to the health care entity, within 72 hours for a non-**
37 **urgent request or 24 hours for an urgent request]** pursuant to the
38 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1
39 et al.)¹.

40 (2) The subscriber and the treating health care provider or treating
41 health care entity prescribing biomarker testing for the subscriber shall
42 have access to clear, readily accessible, and conspicuous information
43 on the process to submit an appeal to an adverse determination.

EXPLANATION – Matter enclosed in bold-faced brackets **[thus]** in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Senate SCM committee amendments adopted December 12, 2024.

1 e. The benefits shall be provided to the same extent as for any
2 other medical condition under the contract.

3 f. The provisions of this section shall apply to all hospital service
4 corporation contracts in which the hospital service corporation has
5 reserved the right to change the premium.

6 g. As used in this section:

7 “Biomarker” means a characteristic that is objectively measured
8 and evaluated as an indicator of normal biological processes,
9 pathogenic processes, or pharmacologic responses to a specific
10 therapeutic intervention, including known gene-drug interactions for
11 medications being considered for use or already being administered.
12 Biomarkers shall also include, but not be limited to, gene mutations,
13 characteristics of genes, or protein expression.

14 “Biomarker testing” means the analysis of tissue, blood, or other
15 biospecimen for the presence of a biomarker. Biomarker testing
16 includes but is not limited to, single-analyte tests, multiplex panel
17 tests, protein expression, and whole exome, whole genome, and whole
18 transcriptome sequencing.

19 ¹“Consensus statement” means a statement developed by an
20 independent, multidisciplinary panel of experts utilizing a transparent
21 methodology and reporting structure and with a conflict of interest
22 policy. The statement shall be aimed at specific clinical circumstances
23 and be based on the best available evidence for the purpose of
24 optimizing the outcomes of clinical care.¹

25 “Nationally-recognized clinical practice guidelines” means
26 evidence-based clinical practice guidelines developed by independent
27 organizations or medical professional societies utilizing a transparent
28 methodology and reporting structure and with a conflict of interest
29 policy. The guidelines establish standards of care informed by a
30 systematic review of evidence and an assessment of the benefits and
31 risks of alternative care options and include recommendations intended
32 to optimize patient care.

33

34 2. a. Each medical service corporation contract that provides
35 hospital or medical expense benefits and is delivered, issued, executed,
36 or renewed in this State pursuant to P.L.1940, c.74 (C.17:48A-1 et
37 seq.) or is approved for issuance or renewal in this State by the
38 Commissioner of Banking and Insurance, on or after the effective date
39 of P.L. , c. (C.) (pending before the Legislature as this bill),
40 shall provide coverage for biomarker testing, as defined by subsection
41 g. of this section.

42 b. Biomarker testing shall be covered for the purposes of
43 diagnosis, treatment, appropriate management, or ongoing monitoring
44 of a disease or condition of a subscriber when the test is supported by
45 medical and scientific evidence, including, but not limited to:

46 (1) labeled indications for an FDA-approved or -cleared test;

47 (2) indicated tests for an FDA-approved drug;

48 (3) warnings and precautions on FDA-approved drug labels;

1 (4) Centers for Medicare and Medicaid Services National
2 Coverage Determinations or Medicare Administrative Contractor
3 Local Coverage Determinations; or

4 (5) nationally-recognized clinical practice guidelines and
5 consensus statements.

6 c. Coverage, pursuant to subsection b. of this section, shall be
7 provided in a manner that limits disruption, including multiple biopsies
8 or biospecimen samples, in the care of a subscriber.

9 d. (1) ¹【Notwithstanding any other law, rule, or regulation to
10 the contrary, if】 If¹ utilization review is required, ¹a medical service
11 corporation shall provide¹ a decision ¹【shall be rendered on a prior
12 authorization request, and notice shall be sent to the subscriber and the
13 appropriate health care provider, and if the request is made through a
14 health care entity, to the health care entity, within 72 hours for a non-
15 urgent request or 24 hours for an urgent request】 pursuant to the
16 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1
17 et. al)¹.

18 (2) The subscriber and the treating health care provider or treating
19 health care entity prescribing biomarker testing for the subscriber shall
20 have access to clear, readily accessible, and conspicuous information
21 on the process to submit an appeal to an adverse determination.

22 e. The benefits shall be provided to the same extent as for any
23 other medical condition under the contract.

24 f. The provisions of this section shall apply to all medical service
25 corporation contracts in which the medical service corporation has
26 reserved the right to change the premium.

27 g. As used in this section:

28 “Biomarker” means a characteristic that is objectively measured
29 and evaluated as an indicator of normal biological processes,
30 pathogenic processes, or pharmacologic responses to a specific
31 therapeutic intervention, including known gene-drug interactions for
32 medications being considered for use or already being administered.
33 Biomarkers shall also include, but not be limited to, gene mutations,
34 characteristics of genes, or protein expression.

35 “Biomarker testing” means the analysis of tissue, blood, or other
36 biospecimen for the presence of a biomarker. Biomarker testing
37 includes but is not limited to, single-analyte tests, multiplex panel
38 tests, protein expression, and whole exome, whole genome, and whole
39 transcriptome sequencing.

40 ¹【“Consensus statement” means a statement developed by an
41 independent, multidisciplinary panel of experts utilizing a transparent
42 methodology and reporting structure and with a conflict of interest
43 policy. The statement shall be aimed at specific clinical circumstances
44 and be based on the best available evidence for the purpose of
45 optimizing the outcomes of clinical care.】¹

46 “Nationally-recognized clinical practice guidelines” means
47 evidence-based clinical practice guidelines developed by independent

1 organizations or medical professional societies utilizing a transparent
2 methodology and reporting structure and with a conflict of interest
3 policy. The guidelines establish standards of care informed by a
4 systematic review of evidence and an assessment of the benefits and
5 risks of alternative care options and include recommendations intended
6 to optimize patient care.

7
8 3. a. Each health service corporation contract that provides
9 hospital or medical expense benefits and is delivered, issued, executed,
10 or renewed in this State pursuant to P.L.1985, c.236 (C.17:48E-1 et
11 seq.) or is approved for issuance or renewal in this State by the
12 Commissioner of Banking and Insurance, on or after the effective date
13 of P.L. , c. (C.) (pending before the Legislature as this bill),
14 shall provide coverage for biomarker testing, as defined by subsection
15 g. of this section.

16 b. Biomarker testing shall be covered for the purposes of
17 diagnosis, treatment, appropriate management, or ongoing monitoring
18 of a disease or condition of a subscriber when the test is supported by
19 medical and scientific evidence, including, but not limited to:

- 20 (1) labeled indications for an FDA-approved or -cleared test;
21 (2) indicated tests for an FDA-approved drug;
22 (3) warnings and precautions on FDA-approved drug labels;
23 (4) Centers for Medicare and Medicaid Services National
24 Coverage Determinations or Medicare Administrative Contractor
25 Local Coverage Determinations; or
26 (5) nationally-recognized clinical practice guidelines and
27 consensus statements.

28 c. Coverage, pursuant to subsection b. of this section, shall be
29 provided in a manner that limits disruption, including multiple biopsies
30 or biospecimen samples, in the care of a subscriber.

31 d. (1) ¹【Notwithstanding any other law, rule, or regulation to
32 the contrary, if】 If¹ utilization review is required, ¹a health service
33 corporation shall provide¹ a decision ¹【shall be rendered on a prior
34 authorization request, and notice shall be sent to the subscriber and the
35 appropriate health care provider, and if the request is made through a
36 health care entity, to the health care entity, within 72 hours for a non-
37 urgent request or 24 hours for an urgent request】 pursuant to the
38 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1
39 et al.)¹.

40 (2) The subscriber and the treating health care provider or treating
41 health care entity prescribing biomarker testing for the subscriber shall
42 have access to clear, readily accessible, and conspicuous information
43 on the process to submit an appeal to an adverse determination.

44 e. The benefits shall be provided to the same extent as for any
45 other medical condition under the contract.

46 f. The provisions of this section shall apply to all health service
47 corporation contracts in which the health service corporation has
48 reserved the right to change the premium.

1 g. As used in this section:

2 “Biomarker” means a characteristic that is objectively measured
3 and evaluated as an indicator of normal biological processes,
4 pathogenic processes, or pharmacologic responses to a specific
5 therapeutic intervention, including known gene-drug interactions for
6 medications being considered for use or already being administered.
7 Biomarkers shall also include, but not be limited to, gene mutations,
8 characteristics of genes, or protein expression.

9 “Biomarker testing” means the analysis of tissue, blood, or other
10 biospecimen for the presence of a biomarker. Biomarker testing
11 includes but is not limited to, single-analyte tests, multiplex panel
12 tests, protein expression, and whole exome, whole genome, and whole
13 transcriptome sequencing.

14 ¹“Consensus statement” means a statement developed by an
15 independent, multidisciplinary panel of experts utilizing a transparent
16 methodology and reporting structure and with a conflict of interest
17 policy. The statement shall be aimed at specific clinical circumstances
18 and be based on the best available evidence for the purpose of
19 optimizing the outcomes of clinical care.¹

20 “Nationally-recognized clinical practice guidelines” means
21 evidence-based clinical practice guidelines developed by independent
22 organizations or medical professional societies utilizing a transparent
23 methodology and reporting structure and with a conflict of interest
24 policy. The guidelines establish standards of care informed by a
25 systematic review of evidence and an assessment of the benefits and
26 risks of alternative care options and include recommendations intended
27 to optimize patient care.

28

29 4. a. Each individual health insurance policy that provides
30 hospital or medical expense benefits and is delivered, issued, executed,
31 or renewed in this State pursuant to chapter 26 of Title 17B of the New
32 Jersey Statutes or is approved for issuance or renewal in this State by
33 the Commissioner of Banking and Insurance, on or after the effective
34 date of P.L. , c. (C.) (pending before the Legislature as this
35 bill), shall provide coverage for biomarker testing, as defined by
36 subsection g. of this section.

37 b. Biomarker testing shall be covered for the purposes of
38 diagnosis, treatment, appropriate management, or ongoing monitoring
39 of a disease or condition of an insured when the test is supported by
40 medical and scientific evidence, including, but not limited to:

41 (1) labeled indications for an FDA-approved or -cleared test;

42 (2) indicated tests for an FDA-approved drug;

43 (3) warnings and precautions on FDA-approved drug labels;

44 (4) Centers for Medicare and Medicaid Services National
45 Coverage Determinations or Medicare Administrative Contractor
46 Local Coverage Determinations; or

47 (5) nationally-recognized clinical practice guidelines and
48 consensus statements.

1 c. Coverage, pursuant to subsection b. of this section, shall be
2 provided in a manner that limits disruption, including multiple biopsies
3 or biospecimen samples, in the care of an insured.

4 d. (1) ¹~~Notwithstanding any other law, rule, or regulation to~~
5 ~~the contrary, if~~ If¹ utilization review is required, ¹a carrier shall
6 provide¹ a decision ¹~~shall be rendered on a prior authorization~~
7 ~~request, and notice shall be sent to the insured and the appropriate~~
8 ~~health care provider, and if the request is made through a health care~~
9 ~~entity, to the health care entity, within 72 hours for a non-urgent~~
10 ~~request or 24 hours for an urgent request~~ pursuant to the guidelines
11 and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

12 (2) The insured and the treating health care provider or treating
13 health care entity prescribing biomarker testing for the insured shall
14 have access to clear, readily accessible, and conspicuous information
15 on the process to submit an appeal to an adverse determination.

16 e. The benefits shall be provided to the same extent as for any
17 other medical condition under the contract.

18 f. The provisions of this section shall apply to all health benefits
19 plans in which the carrier has reserved the right to change the
20 premium.

21 g. As used in this section:

22 “Biomarker” means a characteristic that is objectively measured
23 and evaluated as an indicator of normal biological processes,
24 pathogenic processes, or pharmacologic responses to a specific
25 therapeutic intervention, including known gene-drug interactions for
26 medications being considered for use or already being administered.
27 Biomarkers shall also include, but not be limited to, gene mutations,
28 characteristics of genes, or protein expression.

29 “Biomarker testing” means the analysis of tissue, blood, or other
30 biospecimen for the presence of a biomarker. Biomarker testing
31 includes but is not limited to, single-analyte tests, multiplex panel
32 tests, protein expression, and whole exome, whole genome, and whole
33 transcriptome sequencing.

34 ¹~~“Consensus statement” means a statement developed by an~~
35 ~~independent, multidisciplinary panel of experts utilizing a transparent~~
36 ~~methodology and reporting structure and with a conflict of interest~~
37 ~~policy. The statement shall be aimed at specific clinical circumstances~~
38 ~~and be based on the best available evidence for the purpose of~~
39 ~~optimizing the outcomes of clinical care.~~¹

40 “Nationally-recognized clinical practice guidelines” means
41 evidence-based clinical practice guidelines developed by independent
42 organizations or medical professional societies utilizing a transparent
43 methodology and reporting structure and with a conflict of interest
44 policy. The guidelines establish standards of care informed by a
45 systematic review of evidence and an assessment of the benefits and
46 risks of alternative care options and include recommendations intended
47 to optimize patient care.

1 5. a. Each group health insurance policy that provides hospital or
2 medical expense benefits and is delivered, issued, executed, or
3 renewed in this State pursuant to chapter 27 of Title 17B of the New
4 Jersey Statutes or is approved for issuance or renewal in this State by
5 the Commissioner of Banking and Insurance, on or after the effective
6 date of P.L. , c. (C.) (pending before the Legislature as this
7 bill), shall provide benefits for biomarker testing, as defined by
8 subsection g. of this section.

9 b. Biomarker testing shall be covered for the purposes of
10 diagnosis, treatment, appropriate management, or ongoing monitoring
11 of a disease or condition of an insured when the test is supported by
12 medical and scientific evidence, including, but not limited to:

13 (1) labeled indications for an FDA-approved or -cleared test;

14 (2) indicated tests for an FDA-approved drug;

15 (3) warnings and precautions on FDA-approved drug labels;

16 (4) Centers for Medicare and Medicaid Services National
17 Coverage Determinations or Medicare Administrative Contractor
18 Local Coverage Determinations; or

19 (5) nationally-recognized clinical practice guidelines and
20 consensus statements.

21 c. Coverage, pursuant to subsection b. of this section, shall be
22 provided in a manner that limits disruption, including multiple biopsies
23 or biospecimen samples, in the care of an insured.

24 d. (1) ¹~~Notwithstanding any other law, rule, or regulation to~~
25 ~~the contrary, if~~ ¹If utilization review is required, ¹an insurer shall
26 provide¹ a decision ¹~~shall be rendered on a prior authorization~~
27 request, and notice shall be sent to the insured and the appropriate
28 health care provider, and if the request is made through a health care
29 entity, to the health care entity, within 72 hours for a non-urgent
30 request or 24 hours for an urgent request ¹~~pursuant to the guidelines~~
31 and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

32 (2) The insured and the treating health care provider or treating
33 health care entity prescribing biomarker testing for the insured shall
34 have access to clear, readily accessible, and conspicuous information
35 on the process to submit an appeal to an adverse determination.

36 e. The benefits shall be provided to the same extent as for any
37 other medical condition under the contract.

38 f. The provisions of this section shall apply to all policies in
39 which the insurer has reserved the right to change the premium.

40 g. As used in this section:

41 “Biomarker” means a characteristic that is objectively measured
42 and evaluated as an indicator of normal biological processes,
43 pathogenic processes, or pharmacologic responses to a specific
44 therapeutic intervention, including known gene-drug interactions for
45 medications being considered for use or already being administered.
46 Biomarkers shall also include, but not be limited to, gene mutations,
47 characteristics of genes, or protein expression.

1 “Biomarker testing” means the analysis of tissue, blood, or other
2 biospecimen for the presence of a biomarker. Biomarker testing
3 includes but is not limited to, single-analyte tests, multiplex panel
4 tests, protein expression, and whole exome, whole genome, and whole
5 transcriptome sequencing.

6 ¹“Consensus statement” means a statement developed by an
7 independent, multidisciplinary panel of experts utilizing a transparent
8 methodology and reporting structure and with a conflict of interest
9 policy. The statement shall be aimed at specific clinical circumstances
10 and be based on the best available evidence for the purpose of
11 optimizing the outcomes of clinical care.¹

12 “Nationally-recognized clinical practice guidelines” means
13 evidence-based clinical practice guidelines developed by independent
14 organizations or medical professional societies utilizing a transparent
15 methodology and reporting structure and with a conflict of interest
16 policy. The guidelines establish standards of care informed by a
17 systematic review of evidence and an assessment of the benefits and
18 risks of alternative care options and include recommendations intended
19 to optimize patient care.

20
21 6. a. Each individual health benefits plan that provides hospital
22 or medical expense benefits and is delivered, issued, executed, or
23 renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et
24 seq.) or is approved for issuance or renewal in this State by the
25 Commissioner of Banking and Insurance, on or after the effective date
26 of P.L. , c. (C.) (pending before the Legislature as this bill),
27 shall provide benefits for biomarker testing, as defined by subsection
28 g. of this section.

29 b. Biomarker testing shall be covered for the purposes of
30 diagnosis, treatment, appropriate management, or ongoing monitoring
31 of a disease or condition of a covered person when the test is
32 supported by medical and scientific evidence, including, but not
33 limited to:

- 34 (1) labeled indications for an FDA-approved or -cleared test;
35 (2) indicated tests for an FDA-approved drug;
36 (3) warnings and precautions on FDA-approved drug labels;
37 (4) Centers for Medicare and Medicaid Services National
38 Coverage Determinations or Medicare Administrative Contractor
39 Local Coverage Determinations; or
40 (5) nationally-recognized clinical practice guidelines and
41 consensus statements.

42 c. Coverage, pursuant to subsection b. of this section, shall be
43 provided in a manner that limits disruption, including multiple biopsies
44 or biospecimen samples, in the care of a covered person.

45 d. (1) ¹“Notwithstanding any other law, rule, or regulation to
46 the contrary, if” If¹ utilization review is required, ¹a carrier shall
47 provide¹ a decision ¹“shall be rendered on a prior authorization
48 request, and notice shall be sent to the covered person and the

1 appropriate health care provider, and if the request is made through a
2 health care entity, to the health care entity, within 72 hours for a non-
3 urgent request or 24 hours for an urgent request] pursuant to the
4 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1
5 et al.)¹.

6 (2) The covered person and the treating health care provider or
7 treating health care entity prescribing biomarker testing for the
8 covered person shall have access to clear, readily accessible, and
9 conspicuous information on the process to submit an appeal to an
10 adverse determination.

11 e. The benefits shall be provided to the same extent as for any
12 other medical condition under the health benefits plan.

13 f. The provisions of this section shall apply to all health benefits
14 plans in which the carrier has reserved the right to change the
15 premium.

16 g. As used in this section:

17 “Biomarker” means a characteristic that is objectively measured
18 and evaluated as an indicator of normal biological processes,
19 pathogenic processes, or pharmacologic responses to a specific
20 therapeutic intervention, including known gene-drug interactions for
21 medications being considered for use or already being administered.
22 Biomarkers shall also include, but not be limited to, gene mutations,
23 characteristics of genes, or protein expression.

24 “Biomarker testing” means the analysis of tissue, blood, or other
25 biospecimen for the presence of a biomarker. Biomarker testing
26 includes but is not limited to, single-analyte tests, multiplex panel
27 tests, protein expression, and whole exome, whole genome, and whole
28 transcriptome sequencing.

29 ¹“Consensus statement” means a statement developed by an
30 independent, multidisciplinary panel of experts utilizing a transparent
31 methodology and reporting structure and with a conflict of interest
32 policy. The statement shall be aimed at specific clinical circumstances
33 and be based on the best available evidence for the purpose of
34 optimizing the outcomes of clinical care.]¹

35 “Nationally-recognized clinical practice guidelines” means
36 evidence-based clinical practice guidelines developed by independent
37 organizations or medical professional societies utilizing a transparent
38 methodology and reporting structure and with a conflict of interest
39 policy. The guidelines establish standards of care informed by a
40 systematic review of evidence and an assessment of the benefits and
41 risks of alternative care options and include recommendations intended
42 to optimize patient care.

43

44 7. a. Each small employer health benefits plan that provides
45 hospital or medical expense benefits and is delivered, issued, executed,
46 or renewed in this State pursuant to P.L.1992, c.162 (C.17B:27A-17 et
47 seq.) or is approved for issuance or renewal in this State by the
48 Commissioner of Banking and Insurance, on or after the effective date

1 of P.L. , c. (C.) (pending before the Legislature as this bill),
2 shall provide benefits for biomarker testing, as defined by subsection
3 g. of this section.

4 b. Biomarker testing shall be covered for the purposes of
5 diagnosis, treatment, appropriate management, or ongoing monitoring
6 of a disease or condition of a covered person when the test is
7 supported by medical and scientific evidence, including, but not
8 limited to:

- 9 (1) labeled indications for an FDA-approved or -cleared test;
10 (2) indicated tests for an FDA-approved drug;
11 (3) warnings and precautions on FDA-approved drug labels;
12 (4) Centers for Medicare and Medicaid Services National
13 Coverage Determinations or Medicare Administrative Contractor
14 Local Coverage Determinations; or
15 (5) nationally-recognized clinical practice guidelines and
16 consensus statements.

17 c. Coverage, pursuant to subsection b. of this section, shall be
18 provided in a manner that limits disruption, including multiple biopsies
19 or biospecimen samples, in the care of a covered person.

20 d. (1) ¹【Notwithstanding any other law, rule, or regulation to
21 the contrary, if】 If¹ utilization review is required, ¹a carrier shall
22 provide¹ a decision ¹【shall be rendered on a prior authorization
23 request, and notice shall be sent to the covered person and the
24 appropriate health care provider, and if the request is made through a
25 health care entity, to the health care entity, within 72 hours for a non-
26 urgent request or 24 hours for an urgent request】 pursuant to the
27 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1
28 et al.)¹.

29 (2) The covered person and the treating health care provider or
30 treating health care entity prescribing biomarker testing for the
31 covered person shall have access to clear, readily accessible, and
32 conspicuous information on the process to submit an appeal to an
33 adverse determination.

34 e. The benefits shall be provided to the same extent as for any
35 other medical condition under the health benefits plan.

36 f. The provisions of this section shall apply to all health benefits
37 plans in which the carrier has reserved the right to change the
38 premium.

39 g. As used in this section:

40 “Biomarker” means a characteristic that is objectively measured
41 and evaluated as an indicator of normal biological processes,
42 pathogenic processes, or pharmacologic responses to a specific
43 therapeutic intervention, including known gene-drug interactions for
44 medications being considered for use or already being administered.
45 Biomarkers shall also include, but not be limited to, gene mutations,
46 characteristics of genes, or protein expression.

47 “Biomarker testing” means the analysis of tissue, blood, or other
48 biospecimen for the presence of a biomarker. Biomarker testing

1 includes but is not limited to, single-analyte tests, multiplex panel
2 tests, protein expression, and whole exome, whole genome, and whole
3 transcriptome sequencing.

4 ¹["Consensus statement" means a statement developed by an
5 independent, multidisciplinary panel of experts utilizing a transparent
6 methodology and reporting structure and with a conflict of interest
7 policy. The statement shall be aimed at specific clinical circumstances
8 and be based on the best available evidence for the purpose of
9 optimizing the outcomes of clinical care.]¹

10 "Nationally-recognized clinical practice guidelines" means
11 evidence-based clinical practice guidelines developed by independent
12 organizations or medical professional societies utilizing a transparent
13 methodology and reporting structure and with a conflict of interest
14 policy. The guidelines establish standards of care informed by a
15 systematic review of evidence and an assessment of the benefits and
16 risks of alternative care options and include recommendations intended
17 to optimize patient care.

18

19 8. a. Each health maintenance organization contract for health
20 care services that is delivered, issued, executed, or renewed in this
21 State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or is approved for
22 issuance or renewal in this State by the Commissioner of Banking and
23 Insurance, on or after the effective date of P.L. , c. (C.)
24 (pending before the Legislature as this bill), shall provide health care
25 services for biomarker testing, as defined by subsection g. of this
26 section.

27 b. Biomarker testing shall be covered for the purposes of
28 diagnosis, treatment, appropriate management, or ongoing monitoring
29 of a disease or condition of an enrollee when the test is supported by
30 medical and scientific evidence, including, but not limited to:

31 (1) labeled indications for an FDA-approved or -cleared test;

32 (2) indicated tests for an FDA-approved drug;

33 (3) warnings and precautions on FDA-approved drug labels;

34 (4) Centers for Medicare and Medicaid Services National
35 Coverage Determinations or Medicare Administrative Contractor
36 Local Coverage Determinations; or

37 (5) nationally-recognized clinical practice guidelines and
38 consensus statements.

39 c. Coverage, pursuant to subsection b. of this section, shall be
40 provided in a manner that limits disruption, including multiple biopsies
41 or biospecimen samples, in the care of an enrollee.

42 d. (1) ¹["Notwithstanding any other law, rule, or regulation to
43 the contrary, if] If¹ utilization review is required, ¹a health
44 maintenance organization shall provide¹ a decision ¹["shall be rendered
45 on a prior authorization request, and notice shall be sent to the enrollee
46 and the appropriate health care provider, and if the request is made
47 through a health care entity, to the health care entity, within 72 hours

1 for a non-urgent request or 24 hours for an urgent request] pursuant to
2 the guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-
3 55.1 et al.)¹.

4 (2) The enrollee and the treating health care provider or treating
5 health care entity prescribing biomarker testing for the enrollee shall
6 have access to clear, readily accessible, and conspicuous information
7 on the process to submit an appeal to an adverse determination.

8 e. The health care services shall be provided to the same extent as
9 for any other medical condition under the contract.

10 f. The provisions of this section shall apply to those contracts for
11 health care services by health maintenance organizations under which
12 the right to change the schedule of charges for enrollee coverage is
13 reserved.

14 g. As used in this section:

15 “Biomarker” means a characteristic that is objectively measured
16 and evaluated as an indicator of normal biological processes,
17 pathogenic processes, or pharmacologic responses to a specific
18 therapeutic intervention, including known gene-drug interactions for
19 medications being considered for use or already being administered.
20 Biomarkers shall also include, but not be limited to, gene mutations,
21 characteristics of genes, or protein expression.

22 “Biomarker testing” means the analysis of tissue, blood, or other
23 biospecimen for the presence of a biomarker. Biomarker testing
24 includes but is not limited to, single-analyte tests, multiplex panel
25 tests, protein expression, and whole exome, whole genome, and whole
26 transcriptome sequencing.

27 ¹“Consensus statement” means a statement developed by an
28 independent, multidisciplinary panel of experts utilizing a transparent
29 methodology and reporting structure and with a conflict of interest
30 policy. The statement shall be aimed at specific clinical circumstances
31 and be based on the best available evidence for the purpose of
32 optimizing the outcomes of clinical care.]¹

33 “Nationally-recognized clinical practice guidelines” means
34 evidence-based clinical practice guidelines developed by independent
35 organizations or medical professional societies utilizing a transparent
36 methodology and reporting structure and with a conflict of interest
37 policy. The guidelines establish standards of care informed by a
38 systematic review of evidence and an assessment of the benefits and
39 risks of alternative care options and include recommendations intended
40 to optimize patient care.

41
42 9. a. The State Health Benefits Commission shall ensure that
43 every contract providing hospital or medical expense benefits, which is
44 purchased by the commission on or after the effective date of
45 P.L. , c. (C.) (pending before the Legislature as this bill),
46 provides coverage for biomarker testing, as defined by subsection e. of
47 this section.

1 b. Biomarker testing shall be covered for the purposes of
2 diagnosis, treatment, appropriate management, or ongoing monitoring
3 of a disease or condition of a covered person when the test is
4 supported by medical and scientific evidence, including, but not
5 limited to:

6 (1) labeled indications for an FDA-approved or -cleared test;

7 (2) indicated tests for an FDA-approved drug;

8 (3) warnings and precautions on FDA-approved drug labels;

9 (4) Centers for Medicare and Medicaid Services National
10 Coverage Determinations or Medicare Administrative Contractor
11 Local Coverage Determinations; or

12 (5) nationally-recognized clinical practice guidelines and
13 consensus statements.

14 c. Coverage, pursuant to subsection b. of this section, shall be
15 provided in a manner that limits disruption, including multiple biopsies
16 or biospecimen samples, in the care of a covered person.

17 d. (1) ¹~~Notwithstanding any other law, rule, or regulation to~~
18 ~~the contrary, if~~ ¹~~If~~ utilization review is required, a decision shall be
19 rendered ¹~~on a prior authorization request, and notice shall be sent to~~
20 ~~the covered person and the appropriate health care provider, and if the~~
21 ~~request is made through a health care entity, to the health care entity,~~
22 ~~within 72 hours for a non-urgent request or 24 hours for an urgent~~
23 ~~request]~~ pursuant to the guidelines and timeframes set forth in
24 P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

25 (2) The covered person and the treating health care provider or
26 treating health care entity prescribing biomarker testing to the covered
27 person shall have access to clear, readily accessible, and conspicuous
28 information on the process to submit an appeal to an adverse
29 determination.

30 e. As used in this section:

31 “Biomarker” means a characteristic that is objectively measured
32 and evaluated as an indicator of normal biological processes,
33 pathogenic processes, or pharmacologic responses to a specific
34 therapeutic intervention, including known gene-drug interactions for
35 medications being considered for use or already being administered.
36 Biomarkers shall also include, but not be limited to, gene mutations,
37 characteristics of genes, or protein expression.

38 “Biomarker testing” means the analysis of tissue, blood, or other
39 biospecimen for the presence of a biomarker. Biomarker testing
40 includes but is not limited to, single-analyte tests, multiplex panel
41 tests, protein expression, and whole exome, whole genome, and whole
42 transcriptome sequencing.

43 ¹~~“Consensus statement” means a statement developed by an~~
44 ~~independent, multidisciplinary panel of experts utilizing a transparent~~
45 ~~methodology and reporting structure and with a conflict of interest~~
46 ~~policy. The statement shall be aimed at specific clinical circumstances~~

1 and be based on the best available evidence for the purpose of
2 optimizing the outcomes of clinical care.]¹

3 “Nationally-recognized clinical practice guidelines” means
4 evidence-based clinical practice guidelines developed by independent
5 organizations or medical professional societies utilizing a transparent
6 methodology and reporting structure and with a conflict of interest
7 policy. The guidelines establish standards of care informed by a
8 systematic review of evidence and an assessment of the benefits and
9 risks of alternative care options and include recommendations intended
10 to optimize patient care.

11

12 10. a. The School Employees’ Health Benefits Commission shall
13 ensure that every contract providing hospital or medical expense
14 benefits, which is purchased by the commission on or after the
15 effective date of P.L. , c. (C.) (pending before the Legislature
16 as this bill), provides coverage for biomarker testing, as defined by
17 subsection e. of this section.

18 b. Biomarker testing shall be covered for the purposes of
19 diagnosis, treatment, appropriate management, or ongoing monitoring
20 of a disease or condition of a covered person when the test is
21 supported by medical and scientific evidence, including, but not
22 limited to:

23 (1) labeled indications for an FDA-approved or -cleared test;

24 (2) indicated tests for an FDA-approved drug;

25 (3) warnings and precautions on FDA-approved drug labels;

26 (4) Centers for Medicare and Medicaid Services National
27 Coverage Determinations or Medicare Administrative Contractor
28 Local Coverage Determinations; or

29 (5) nationally-recognized clinical practice guidelines and
30 consensus statements.

31 c. Coverage, pursuant to subsection b. of this section, shall be
32 provided in a manner that limits disruption, including multiple biopsies
33 or biospecimen samples, in the care of a covered person.

34 d. (1) ¹[Notwithstanding any other law, rule, or regulation to
35 the contrary, if] It¹ utilization review is required, a decision shall be
36 rendered ¹[on a prior authorization request, and notice shall be sent to
37 the covered person and the appropriate health care provider, and if the
38 request is made through a health care entity, to the health care entity,
39 within 72 hours for a non-urgent request or 24 hours for an urgent
40 request] pursuant to the guidelines and timeframes set forth in
41 P.L.2023, c.296 (C.17B:30-55.1 et al.)¹.

42 (2) The covered person and the treating health care provider or
43 treating health care entity prescribing biomarker testing for the
44 covered person shall have access to clear, readily accessible, and
45 conspicuous information on the process to submit an appeal to an
46 adverse determination.

47 e. As used in this section:

1 “Biomarker” means a characteristic that is objectively measured
2 and evaluated as an indicator of normal biological processes,
3 pathogenic processes, or pharmacologic responses to a specific
4 therapeutic intervention, including known gene-drug interactions for
5 medications being considered for use or already being administered.
6 Biomarkers shall also include, but not be limited to, gene mutations,
7 characteristics of genes, or protein expression.

8 “Biomarker testing” means the analysis of tissue, blood, or other
9 biospecimen for the presence of a biomarker. Biomarker testing
10 includes but is not limited to, single-analyte tests, multiplex panel
11 tests, protein expression, and whole exome, whole genome, and whole
12 transcriptome sequencing.

13 ¹“Consensus statement” means a statement developed by an
14 independent, multidisciplinary panel of experts utilizing a transparent
15 methodology and reporting structure and with a conflict of interest
16 policy. The statement shall be aimed at specific clinical circumstances
17 and be based on the best available evidence for the purpose of
18 optimizing the outcomes of clinical care.¹

19 “Nationally-recognized clinical practice guidelines” means
20 evidence-based clinical practice guidelines developed by independent
21 organizations or medical professional societies utilizing a transparent
22 methodology and reporting structure and with a conflict of interest
23 policy. The guidelines establish standards of care informed by a
24 systematic review of evidence and an assessment of the benefits and
25 risks of alternative care options and include recommendations intended
26 to optimize patient care.

27

28 11. a. Notwithstanding any State law or regulation to the contrary,
29 the Department of Human Services shall ensure that expenses incurred
30 for biomarker testing shall be provided with no cost-sharing to persons
31 served under the Medicaid program, established pursuant to P.L.1968,
32 c.413 (C.30:4D-1 et seq.).

33 b. Biomarker testing shall be covered for the purposes of
34 diagnosis, treatment, appropriate management, or ongoing monitoring
35 of a disease or condition of an individual when the test is supported by
36 medical and scientific evidence, including, but not limited to:

37 (1) labeled indications for an FDA-approved or -cleared test;

38 (2) indicated tests for an FDA-approved drug;

39 (3) warnings and precautions on FDA-approved drug labels;

40 (4) Centers for Medicare and Medicaid Services National
41 Coverage Determinations or Medicare Administrative Contractor
42 Local Coverage Determinations; or

43 (5) nationally-recognized clinical practice guidelines and
44 consensus statements.

45 c. Coverage, pursuant to subsection b. of this section, shall be
46 provided in a manner that limits disruption, including multiple biopsies
47 or biospecimen samples, in the care of an individual.

1 d. If the Division of Medical Assistance and Health Services in
2 the Department of Human Services contracts with a third-party entity
3 to deliver biomarker testing services pursuant to this section to
4 beneficiaries under the Medicaid program, the third-party entity shall
5 provide biomarker testing at the same scope, duration and frequency as
6 the Medicaid program otherwise provides to individuals.

7 e. (1) ¹【Notwithstanding any other law, rule, or regulation to
8 the contrary, if】 If¹ utilization review is required, a decision ¹【shall be
9 rendered on a prior authorization request, and notice be sent to an
10 individual, the appropriate health care provider, and, if necessary, the
11 requisite health care entity if the request for prior authorization was
12 submitted through the entity, within 72 hours for a non-urgent request
13 or 24 hours for an urgent request】 shall be provided pursuant to the
14 guidelines and timeframes set forth in P.L.2023, c.296 (C.17B:30-55.1
15 et al.)¹.

16 (2) The individual and the treating health care provider or treating
17 health care entity prescribing biomarker testing for the individual shall
18 have access to clear, readily accessible, and conspicuous information
19 on the process to submit an appeal to an adverse determination.

20 f. As used in this section:

21 “Biomarker” means a characteristic that is objectively measured
22 and evaluated as an indicator of normal biological processes,
23 pathogenic processes, or pharmacologic responses to a specific
24 therapeutic intervention, including known gene-drug interactions for
25 medications being considered for use or already being administered.
26 Biomarkers shall also include, but not be limited to, gene mutations,
27 characteristics of genes, or protein expression.

28 “Biomarker testing” means the analysis of tissue, blood, or other
29 biospecimen for the presence of a biomarker. Biomarker testing
30 includes but is not limited to, single-analyte tests, multiplex panel
31 tests, protein expression, and whole exome, whole genome, and whole
32 transcriptome sequencing.

33
34 12. This act shall take effect on the 90th day next following
35 enactment and shall apply to policies and contracts issued or
36 renewed on or after the effective date.