

[Second Reprint]

**ASSEMBLY, No. 4163**

**STATE OF NEW JERSEY**

**221st LEGISLATURE**

INTRODUCED APRIL 8, 2024

**Sponsored by:**

**Assemblywoman SHAVONDA E. SUMTER**

**District 35 (Bergen and Passaic)**

**Assemblyman GARY S. SCHAER**

**District 36 (Bergen and Passaic)**

**Assemblywoman SHAMA A. HAIDER**

**District 37 (Bergen)**

**Senator VIN GOPAL**

**District 11 (Monmouth)**

**Senator TROY SINGLETON**

**District 7 (Burlington)**

**Co-Sponsored by:**

**Assemblywomen Bagolie, Hall, Donlon, Matsikoudis, Lopez, Pintor Marin, Assemblymen Clifton, Sampson, Karabinchak, Assemblywoman Flynn, Assemblymen DePhillips, Calabrese, Barlas, Assemblywoman Speight, Assemblymen Spearman, DiMaio, Assemblywoman Peterpaul, Assemblymen McClellan, Simonsen, Hutchison, Verrelli, Assemblywoman Park, Assemblyman Stanley, Assemblywoman Reynolds-Jackson, Assemblymen Azzariti Jr., Inganamort, Auth, Assemblywoman N.Munoz, Assemblyman Schnall, Assemblywomen Drulis, Dunn, Morales, Ramirez, Assemblyman Rodriguez, Assemblywoman Swain, Assemblyman Tully, Senators A.M.Bucco, Johnson, Greenstein, Pennacchio, Diegnan, McKnight, Beach, Cruz-Perez, Zwicker, Bramnick, Burgess, Singer, Wimberly and O'Scanlon**

**SYNOPSIS**

Requires health insurers to provide coverage for biomarker precision medical testing.

**CURRENT VERSION OF TEXT**

As amended by the Senate on March 24, 2025.

(Sponsorship Updated As Of: 3/24/2025)

1 AN ACT concerning health insurance coverage for biomarker  
2 <sup>2</sup>precision medical<sup>2</sup> testing <sup>1</sup>**[and amending]**<sup>1</sup> and supplementing  
3 various parts of the 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,  
10 executed, or renewed in this State pursuant to P.L.1938, c.366  
11 (C.17:48-1 et seq.) or is approved for issuance or renewal in this  
12 State by the Commissioner of Banking and Insurance, on or after  
13 the effective date of <sup>2</sup>**[P.L. , c. (C. ) (pending before the**  
14 **Legislature as this bill)]** this act<sup>2</sup>, shall provide coverage for  
15 biomarker <sup>2</sup>precision medical<sup>2</sup> testing, as defined by subsection g. of  
16 this section.

17 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
18 the purposes of diagnosis, treatment, appropriate management, or  
19 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
20 asymptomatic screening, to guide treatment decisions<sup>2</sup> of a subscriber  
21 when the <sup>2</sup>**[test is supported by medical and scientific evidence,**  
22 **including, but not limited to]** efficacy and appropriateness of  
23 biomarker precision medical testing for the diagnosis, treatment,  
24 appropriate management, or guiding treatment decisions for a  
25 subscriber's disease or condition is recognized by<sup>2</sup>:

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

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

29 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
30 approved drug labels;

31 (4) Centers for Medicare and Medicaid Services National  
32 Coverage Determinations or Medicare Administrative Contractor  
33 Local Coverage Determinations; or

34 (5) nationally-recognized clinical practice guidelines <sup>2</sup>**[and**  
35 **consensus statements]**<sup>2</sup>.

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

39 d. (1) <sup>1</sup>**[Notwithstanding any other law, rule, or regulation**  
40 **to the contrary, if]** If<sup>1</sup> utilization review is required, <sup>1</sup>a hospital  
41 service corporation shall provide<sup>1</sup> a decision <sup>1</sup>**[shall be rendered on**  
42 **a prior authorization request, and notice shall be sent to the**  
43 **subscriber and the appropriate health care provider, and if the**

**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:

<sup>1</sup>Assembly AFI committee amendments adopted October 24, 2024.

<sup>2</sup>Senate floor amendments adopted March 24, 2025.

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

5 (2) The subscriber and the treating health care provider or  
6 treating health care entity prescribing biomarker <sup>2</sup>precision medical<sup>2</sup>  
7 testing for the subscriber shall have access to clear, readily  
8 accessible, and conspicuous information on the process to submit an  
9 appeal to an adverse determination.

10 e. The benefits shall be provided to the same extent as for any  
11 other medical condition under the contract<sup>2</sup>, including  
12 determinations of clinical review criteria used for utilization review of  
13 health care services along with copayment, deductible, and  
14 coinsurance provisions<sup>2</sup>.

15 f. The provisions of this section shall apply to all hospital  
16 service corporation contracts in which the hospital service  
17 corporation has reserved the right to change the premium.

18 g. As used in this section:

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

26 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
27 tissue, blood, or other biospecimen for the presence of a biomarker.  
28 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
29 to, single-analyte tests, multiplex panel tests, protein expression,  
30 and whole exome, whole genome, and whole transcriptome  
31 sequencing.

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

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

1        2. a. Each medical service corporation contract that provides  
2 hospital or medical expense benefits and is delivered, issued,  
3 executed, or renewed in this State pursuant to P.L.1940, c.74  
4 (C.17:48A-1 et seq.) or is approved for issuance or renewal in this  
5 State by the Commissioner of Banking and Insurance, on or after  
6 the effective date of <sup>2</sup>[P.L. , c. (C. ) (pending before the  
7 Legislature as this bill)] this act<sup>2</sup>, shall provide coverage for  
8 biomarker <sup>2</sup>precision medical<sup>2</sup> testing, as defined by subsection g. of  
9 this section.

10        b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
11 the purposes of diagnosis, treatment, appropriate management, or  
12 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
13 asymptomatic screening, to guide treatment decisions<sup>2</sup> of a subscriber  
14 when the <sup>2</sup>[test is supported by medical and scientific evidence,  
15 including, but not limited to] efficacy and appropriateness of  
16 biomarker precision medical testing for the diagnosis, treatment,  
17 appropriate management, or guiding treatment decisions for a  
18 subscriber's disease or condition is recognized by<sup>2</sup>:

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

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

21            (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
22 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 <sup>2</sup>[and  
27 consensus statements]<sup>2</sup>.

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

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

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

45        e. The benefits shall be provided to the same extent as for any  
46 other medical condition under the contract<sup>2</sup>, including

1 determinations of clinical review criteria used for utilization review of  
2 health care services along with copayment, deductible, and  
3 coinsurance provisions<sup>2</sup>.

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

7 g. As used in this section:

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

15 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
16 tissue, blood, or other biospecimen for the presence of a biomarker.  
17 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
18 to, single-analyte tests, multiplex panel tests, protein expression,  
19 and whole exome, whole genome, and whole transcriptome  
20 sequencing.

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

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

35  
36 3. a. Each health service corporation contract that provides  
37 hospital or medical expense benefits and is delivered, issued,  
38 executed, or renewed in this State pursuant to P.L.1985, c.236  
39 (C.17:48E-1 et seq.) or is approved for issuance or renewal in this  
40 State by the Commissioner of Banking and Insurance, on or after  
41 the effective date of <sup>2</sup>[P.L. , c. (C. ) (pending before the  
42 Legislature as this bill)] this act<sup>2</sup>, shall provide coverage for  
43 biomarker <sup>2</sup>precision medical<sup>2</sup> testing, as defined by subsection g. of  
44 this section.

45 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
46 the purposes of diagnosis, treatment, appropriate management, or  
47 ongoing monitoring of a disease or condition<sup>2</sup>, excluding

1 asymptomatic screening, to guide treatment decisions<sup>2</sup> of a subscriber  
2 when the <sup>2</sup>**[test is supported by medical and scientific evidence,**  
3 **including, but not limited to]** efficacy and appropriateness of  
4 biomarker precision medical testing for the diagnosis, treatment,  
5 appropriate management, or guiding treatment decisions for a  
6 subscriber’s disease or condition is recognized by<sup>2</sup>:

- 7 (1) labeled indications for an FDA-approved or -cleared test;  
8 (2) indicated tests for an FDA-approved drug;  
9 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
10 approved drug labels;  
11 (4) Centers for Medicare and Medicaid Services National  
12 Coverage Determinations or Medicare Administrative Contractor  
13 Local Coverage Determinations; or  
14 (5) nationally-recognized clinical practice guidelines <sup>2</sup>**[and**  
15 **consensus statements]**<sup>2</sup>.

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

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

28 (2) The subscriber and the treating health care provider or  
29 treating health care entity prescribing biomarker <sup>2</sup>precision medical<sup>2</sup>  
30 testing for the subscriber shall have access to clear, readily  
31 accessible, and conspicuous information on the process to submit an  
32 appeal to an adverse determination.

33 e. The benefits shall be provided to the same extent as for any  
34 other medical condition under the contract<sup>2</sup>, including  
35 determinations of clinical review criteria used for utilization review of  
36 health care services along with copayment, deductible, and  
37 coinsurance provisions<sup>2</sup>.

38 f. The provisions of this section shall apply to all health  
39 service corporation contracts in which the health service  
40 corporation has reserved the right to change the premium.

41 g. As used in this section:

42 “Biomarker” means a characteristic that is objectively measured  
43 and evaluated as an indicator of normal biological processes,  
44 pathogenic processes, or pharmacologic responses to a specific  
45 therapeutic intervention, including known gene-drug interactions  
46 for medications being considered for use or already being

1 administered. Biomarkers shall also include, but not be limited to,  
2 gene mutations, characteristics of genes, or protein expression.

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

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

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

23

24 4. a. Each individual health insurance policy that provides  
25 hospital or medical expense benefits and is delivered, issued,  
26 executed, or renewed in this State pursuant to chapter 26 of Title  
27 17B of the New Jersey Statutes or is approved for issuance or  
28 renewal in this State by the Commissioner of Banking and  
29 Insurance, on or after the effective date of <sup>2</sup>[P.L. , c. (C. )  
30 (pending before the Legislature as this bill)] this act<sup>2</sup>, shall provide  
31 coverage for biomarker <sup>2</sup>precision medical<sup>2</sup> testing, as defined by  
32 subsection g. of this section.

33 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
34 the purposes of diagnosis, treatment, appropriate management, or  
35 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
36 asymptomatic screening, to guide treatment decisions<sup>2</sup> of an insured  
37 when the <sup>2</sup>[test is supported by medical and scientific evidence,  
38 including, but not limited to] efficacy and appropriateness of  
39 biomarker precision medical testing for the diagnosis, treatment,  
40 appropriate management, or guiding treatment decisions for an  
41 insured’s disease or condition is recognized by<sup>2</sup>:

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

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

44 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
45 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 <sup>2</sup>and  
5 consensus statements<sup>2</sup>.

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

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

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

23 e. The benefits shall be provided to the same extent as for any  
24 other medical condition under the contract<sup>2</sup>, including  
25 determinations of clinical review criteria used for utilization review of  
26 health care services along with copayment, deductible, and  
27 coinsurance provisions<sup>2</sup>.

28 f. The provisions of this section shall apply to all health  
29 benefits plans in which the carrier has reserved the right to change  
30 the premium.

31 g. As used in this section:

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

39 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
40 tissue, blood, or other biospecimen for the presence of a biomarker.  
41 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
42 to, single-analyte tests, multiplex panel tests, protein expression,  
43 and whole exome, whole genome, and whole transcriptome  
44 sequencing.

45 <sup>1</sup>“Consensus statement” means a statement developed by an  
46 independent, multidisciplinary panel of experts utilizing a  
47 transparent methodology and reporting structure and with a conflict

1 of interest policy. The statement shall be aimed at specific clinical  
2 circumstances and be based on the best available evidence for the  
3 purpose of optimizing the outcomes of clinical care.】<sup>1</sup>

4 “Nationally-recognized clinical practice guidelines” means  
5 evidence-based clinical practice guidelines developed by  
6 independent organizations or medical professional societies  
7 utilizing a transparent methodology and reporting structure and with  
8 a conflict of interest policy. The guidelines establish standards of  
9 care informed by a systematic review of evidence and an  
10 assessment of the benefits and risks of alternative care options and  
11 include recommendations intended to optimize patient care.  
12

13 5. a. Each group health insurance policy that provides hospital  
14 or medical expense benefits and is delivered, issued, executed, or  
15 renewed in this State pursuant to chapter 27 of Title 17B of the New  
16 Jersey Statutes or is approved for issuance or renewal in this State  
17 by the Commissioner of Banking and Insurance, on or after the  
18 effective date of <sup>2</sup>【P.L. , c. (C. ) (pending before the  
19 Legislature as this bill)】 this act<sup>2</sup>, shall provide benefits for  
20 biomarker <sup>2</sup>precision medical<sup>2</sup> testing, as defined by subsection g. of  
21 this section.

22 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
23 the purposes of diagnosis, treatment, appropriate management, or  
24 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
25 asymptomatic screening, to guide treatment decisions<sup>2</sup> of an insured  
26 when the <sup>2</sup>【test is supported by medical and scientific evidence,  
27 including, but not limited to】 efficacy and appropriateness of  
28 biomarker precision medical testing for the diagnosis, treatment,  
29 appropriate management, or guiding treatment decisions for an  
30 insured’s disease or condition is recognized by<sup>2</sup>:

- 31 (1) labeled indications for an FDA-approved or -cleared test;  
32 (2) indicated tests for an FDA-approved drug;  
33 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
34 approved drug labels;  
35 (4) Centers for Medicare and Medicaid Services National  
36 Coverage Determinations or Medicare Administrative Contractor  
37 Local Coverage Determinations; or  
38 (5) nationally-recognized clinical practice guidelines <sup>2</sup>【and  
39 consensus statements】<sup>2</sup>.

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

43 d. (1) <sup>1</sup>【Notwithstanding any other law, rule, or regulation  
44 to the contrary, if】 If<sup>1</sup> utilization review is required, <sup>1</sup>an insurer  
45 shall provide<sup>1</sup> a decision <sup>1</sup>【shall be rendered on a prior  
46 authorization request, and notice shall be sent to the insured and the

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

6 (2) The insured and the treating health care provider or treating  
7 health care entity prescribing biomarker <sup>2</sup>precision medical<sup>2</sup> testing  
8 for the insured 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 contract<sup>2</sup>, including  
13 determinations of clinical review criteria used for utilization review of  
14 health care services along with copayment, deductible, and  
15 coinsurance provisions<sup>2</sup>.

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

18 g. As used in this section:

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

26 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
27 tissue, blood, or other biospecimen for the presence of a biomarker.  
28 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
29 to, single-analyte tests, multiplex panel tests, protein expression,  
30 and whole exome, whole genome, and whole transcriptome  
31 sequencing.

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

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

1       6. a. Each individual health benefits plan that provides hospital  
2 or medical expense benefits and is delivered, issued, executed, or  
3 renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et  
4 seq.) or is approved for issuance or renewal in this State by the  
5 Commissioner of Banking and Insurance, on or after the effective  
6 date of <sup>2</sup>[P.L. , c. (C. ) (pending before the Legislature as  
7 this bill)] this act<sup>2</sup>, shall provide benefits for biomarker <sup>2</sup>precision  
8 medical<sup>2</sup> testing, as defined by subsection g. of this section.

9       b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
10 the purposes of diagnosis, treatment, appropriate management, or  
11 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
12 asymptomatic screening, to guide treatment decisions<sup>2</sup> of a covered  
13 person when the <sup>2</sup>[test is supported by medical and scientific  
14 evidence, including, but not limited to] efficacy and appropriateness  
15 of biomarker precision medical testing for the diagnosis, treatment,  
16 appropriate management, or guiding treatment decisions for a covered  
17 person's disease or condition is recognized by<sup>2</sup>:

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

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

20       (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
21 approved drug labels;

22       (4) Centers for Medicare and Medicaid Services National  
23 Coverage Determinations or Medicare Administrative Contractor  
24 Local Coverage Determinations; or

25       (5) nationally-recognized clinical practice guidelines <sup>2</sup>[and  
26 consensus statements]<sup>2</sup>.

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

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

39       (2) The covered person and the treating health care provider or  
40 treating health care entity prescribing biomarker <sup>2</sup>precision medical<sup>2</sup>  
41 testing for the covered person shall have access to clear, readily  
42 accessible, and conspicuous information on the process to submit an  
43 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 health benefits plan<sup>2</sup>, including  
46 determinations of clinical review criteria used for utilization review of

1 health care services along with copayment, deductible, and  
2 coinsurance provisions<sup>2</sup>.

3 f. The provisions of this section shall apply to all health  
4 benefits plans in which the carrier has reserved the right to change  
5 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  
11 for medications being considered for use or already being  
12 administered. Biomarkers shall also include, but not be limited to,  
13 gene mutations, characteristics of genes, or protein expression.

14 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
15 tissue, blood, or other biospecimen for the presence of a biomarker.  
16 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
17 to, single-analyte tests, multiplex panel tests, protein expression,  
18 and whole exome, whole genome, and whole transcriptome  
19 sequencing.

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

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

34

35 7. a. Each small employer health benefits plan that provides  
36 hospital or medical expense benefits and is delivered, issued,  
37 executed, or renewed in this State pursuant to P.L.1992, c.162  
38 (C.17B:27A-17 et seq.) or is approved for issuance or renewal in  
39 this State by the Commissioner of Banking and Insurance, on or  
40 after the effective date of <sup>2</sup>【P.L. , c. (C. ) (pending before  
41 the Legislature as this bill)】 this act<sup>2</sup>, shall provide benefits for  
42 biomarker <sup>2</sup>precision medical<sup>2</sup> testing, as defined by subsection g. of  
43 this section.

44 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
45 the purposes of diagnosis, treatment, appropriate management, or  
46 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
47 asymptomatic screening, to guide treatment decisions<sup>2</sup> of a covered

1 person when the <sup>2</sup>[test is supported by medical and scientific  
2 evidence, including, but not limited to] efficacy and appropriateness  
3 of biomarker precision medical testing for the diagnosis, treatment,  
4 appropriate management, or guiding treatment decisions for a covered  
5 person's disease or condition is recognized by<sup>2</sup>:

- 6 (1) labeled indications for an FDA-approved or -cleared test;
- 7 (2) indicated tests for an FDA-approved drug;
- 8 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
9 approved drug labels;
- 10 (4) Centers for Medicare and Medicaid Services National  
11 Coverage Determinations or Medicare Administrative Contractor  
12 Local Coverage Determinations; or
- 13 (5) nationally-recognized clinical practice guidelines <sup>2</sup>[and  
14 consensus statements]<sup>2</sup>.

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

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

27 (2) The covered person and the treating health care provider or  
28 treating health care entity prescribing biomarker <sup>2</sup>precision medical<sup>2</sup>  
29 testing for the covered person shall have access to clear, readily  
30 accessible, and conspicuous information on the process to submit an  
31 appeal to an adverse determination.

32 e. The benefits shall be provided to the same extent as for any  
33 other medical condition under the health benefits plan<sup>2</sup>, including  
34 determinations of clinical review criteria used for utilization review of  
35 health care services along with copayment, deductible, and  
36 coinsurance provisions<sup>2</sup>.

37 f. The provisions of this section shall apply to all health  
38 benefits plans in which the carrier has reserved the right to change  
39 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  
45 for medications being considered for use or already being  
46 administered. Biomarkers shall also include, but not be limited to,  
47 gene mutations, characteristics of genes, or protein expression.

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

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

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

21

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

31 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
32 the purposes of diagnosis, treatment, appropriate management, or  
33 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
34 asymptomatic screening, to guide treatment decisions<sup>2</sup> of an enrollee  
35 when the <sup>2</sup>【test is supported by medical and scientific evidence,  
36 including, but not limited to】 efficacy and appropriateness of  
37 biomarker precision medical testing for the diagnosis, treatment,  
38 appropriate management, or guiding treatment decisions for an  
39 enrollee’s disease or condition is recognized by<sup>2</sup>:

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

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

42 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
43 approved drug labels;

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

1 (5) nationally-recognized clinical practice guidelines <sup>2</sup>and  
2 consensus statements<sup>2</sup>.

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

6 d. (1) <sup>1</sup>Notwithstanding any other law, rule, or regulation  
7 to the contrary, if <sup>1</sup>If utilization review is required, <sup>1</sup>a health  
8 maintenance organization shall provide<sup>1</sup> a decision <sup>1</sup>shall be  
9 rendered on a prior authorization request, and notice shall be sent to  
10 the enrollee and the appropriate health care provider, and if the  
11 request is made through a health care entity, to the health care  
12 entity, within 72 hours for a non-urgent request or 24 hours for an  
13 urgent request <sup>1</sup>pursuant to the guidelines and timeframes set forth  
14 in P.L.2023, c.296 (C.17B:30-55.1 et al.)<sup>1</sup>.

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

20 e. The health care services shall be provided to the same extent  
21 as for any other medical condition under the contract<sup>2</sup>, including  
22 determinations of clinical review criteria used for utilization review of  
23 health care services along with copayment, deductible, and  
24 coinsurance provisions<sup>2</sup>.

25 f. The provisions of this section shall apply to those contracts  
26 for health care services by health maintenance organizations under  
27 which the right to change the schedule of charges for enrollee  
28 coverage is reserved.

29 g. As used in this section:

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

37 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
38 tissue, blood, or other biospecimen for the presence of a biomarker.  
39 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
40 to, single-analyte tests, multiplex panel tests, protein expression,  
41 and whole exome, whole genome, and whole transcriptome  
42 sequencing.

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

1 circumstances and be based on the best available evidence for the  
2 purpose of optimizing the outcomes of clinical care.<sup>1</sup>

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

11

12 9. a. The State Health Benefits Commission shall ensure that  
13 every contract providing hospital or medical expense benefits,  
14 which is purchased by the commission on or after the effective date  
15 of <sup>2</sup>[P.L. , c. (C. ) (pending before the Legislature as this  
16 bill)] this act<sup>2</sup>, provides coverage for biomarker <sup>2</sup>precision medical<sup>2</sup>  
17 testing, as defined by subsection e. of this section.

18 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
19 the purposes of diagnosis, treatment, appropriate management, or  
20 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
21 asymptomatic screening, to guide treatment decisions<sup>2</sup> of a covered  
22 person when the <sup>2</sup>[test is supported by medical and scientific  
23 evidence, including, but not limited to] efficacy and appropriateness  
24 of biomarker precision medical testing for the diagnosis, treatment,  
25 appropriate management, or guiding treatment decisions for a covered  
26 person’s disease or condition is recognized by<sup>2</sup>:

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

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

29 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
30 approved drug labels;

31 (4) Centers for Medicare and Medicaid Services National  
32 Coverage Determinations or Medicare Administrative Contractor  
33 Local Coverage Determinations; or

34 (5) nationally-recognized clinical practice guidelines <sup>2</sup>[and  
35 consensus statements]<sup>2</sup>.

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

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

1 (2) The covered person and the treating health care provider or  
2 treating health care entity prescribing biomarker <sup>2</sup>precision medical<sup>2</sup>  
3 testing to the covered person shall have access to clear, readily  
4 accessible, and conspicuous information on the process to submit an  
5 appeal to an adverse determination.

6 e. 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  
11 for medications being considered for use or already being  
12 administered. Biomarkers shall also include, but not be limited to,  
13 gene mutations, characteristics of genes, or protein expression.

14 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
15 tissue, blood, or other biospecimen for the presence of a biomarker.  
16 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
17 to, single-analyte tests, multiplex panel tests, protein expression,  
18 and whole exome, whole genome, and whole transcriptome  
19 sequencing.

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

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

34  
35 10. a. The School Employees’ Health Benefits Commission  
36 shall ensure that every contract providing hospital or medical  
37 expense benefits, which is purchased by the commission on or after  
38 the effective date of <sup>2</sup>[P.L. , c. (C. ) (pending before the  
39 Legislature as this bill)] this act<sup>2</sup>, provides coverage for biomarker  
40 <sup>2</sup>precision medical<sup>2</sup> testing, as defined by subsection e. of this  
41 section.

42 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
43 the purposes of diagnosis, treatment, appropriate management, or  
44 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
45 asymptomatic screening, to guide treatment decisions<sup>2</sup> of a covered  
46 person when the <sup>2</sup>[test is supported by medical and scientific  
47 evidence, including, but not limited to] efficacy and appropriateness

1 of biomarker precision medical testing for the diagnosis, treatment,  
2 appropriate management, or guiding treatment decisions for a covered  
3 person's disease or condition is recognized by<sup>2</sup>:

- 4 (1) labeled indications for an FDA-approved or -cleared test;  
5 (2) indicated tests for an FDA-approved drug;  
6 (3) actions to address<sup>2</sup> warnings and precautions on FDA-  
7 approved drug labels;  
8 (4) Centers for Medicare and Medicaid Services National  
9 Coverage Determinations or Medicare Administrative Contractor  
10 Local Coverage Determinations; or  
11 (5) nationally-recognized clinical practice guidelines <sup>2</sup>[and  
12 consensus statements]<sup>2</sup>.

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

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

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

29 e. As used in this section:

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

37 “Biomarker precision medical<sup>2</sup> testing” means the analysis of  
38 tissue, blood, or other biospecimen for the presence of a biomarker.  
39 Biomarker precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
40 to, single-analyte tests, multiplex panel tests, protein expression,  
41 and whole exome, whole genome, and whole transcriptome  
42 sequencing.

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

1 circumstances and be based on the best available evidence for the  
2 purpose of optimizing the outcomes of clinical care.】<sup>1</sup>

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

11

12 11. a. Notwithstanding any State law or regulation to the  
13 contrary, the Department of Human Services shall ensure that  
14 expenses incurred for biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be  
15 provided with no cost-sharing to persons served under the Medicaid  
16 program, established pursuant to P.L.1968, c.413 (C.30:4D-  
17 1 et seq.).

18 b. Biomarker <sup>2</sup>precision medical<sup>2</sup> testing shall be covered for  
19 the purposes of diagnosis, treatment, appropriate management, or  
20 ongoing monitoring of a disease or condition<sup>2</sup>, excluding  
21 asymptomatic screening, to guide treatment decisions<sup>2</sup> of an  
22 individual when the <sup>2</sup>【test is supported by medical and scientific  
23 evidence, including, but not limited to】 efficacy and appropriateness  
24 of biomarker precision medical testing for the diagnosis, treatment,  
25 appropriate management, or guiding treatment decisions for an  
26 individual’s disease or condition is recognized by<sup>2</sup>:

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

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

29 (3) <sup>2</sup>actions to address<sup>2</sup> warnings and precautions on FDA-  
30 approved drug labels;

31 (4) Centers for Medicare and Medicaid Services National  
32 Coverage Determinations or Medicare Administrative Contractor  
33 Local Coverage Determinations; or

34 (5) nationally-recognized clinical practice guidelines <sup>2</sup>【and  
35 consensus statements】<sup>2</sup>.

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

39 d. If the Division of Medical Assistance and Health Services in  
40 the Department of Human Services contracts with a third-party  
41 entity to deliver biomarker <sup>2</sup>precision medical<sup>2</sup> testing services  
42 pursuant to this section to beneficiaries under the Medicaid  
43 program, the third-party entity shall provide biomarker <sup>2</sup>precision  
44 medical<sup>2</sup> testing at the same scope, duration and frequency as the  
45 Medicaid program otherwise provides to individuals.

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

10 (2) The individual and the treating health care provider or  
11 treating health care entity prescribing biomarker <sup>2</sup>precision medical<sup>2</sup>  
12 testing for the individual shall have access to clear, readily  
13 accessible, and conspicuous information on the process to submit an  
14 appeal to an adverse determination.

15 f. As used in this section:

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

23 “Biomarker <sup>2</sup>precision medical<sup>2</sup> testing” means the analysis of  
24 tissue, blood, or other biospecimen for the presence of a biomarker.  
25 Biomarker <sup>2</sup>precision medical<sup>2</sup> testing includes<sup>2,2</sup> but is not limited  
26 to, single-analyte tests, multiplex panel tests, protein expression,  
27 and whole exome, whole genome, and whole transcriptome  
28 sequencing.

29

30 12. This act shall take effect on the 90th day next following  
31 enactment and shall apply to policies and contracts issued or  
32 renewed on or after the effective date.