WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

House Bill 4753

By Delegates Westfall, Barnhart, Riley, Hornbuckle,

W. Hall, Garcia, Jeffries, Hott, Cannon, Akers and

Young

[Introduced January 15, 2024; Referred

to the Committee Banking and Insurance then

Judiciary]

| 1 | A BILL to amend the code of West Virginia, 1931, by adding thereto a new section designated, §5- |
|---|--|
| 2 | 16-7h; to amend said code by adding thereto a new section designated §9-5-34; to amend |
| 3 | said code by adding thereto a new section designated §33-15-4x; to amend said code by |
| 4 | adding thereto a new section designated §33-16-3aa; to amend said code by adding |
| 5 | thereto a new section designated §33-24-7y; to amend said code by adding thereto a new |
| 6 | section designated §33-25-8v; and to amend said code by adding thereto a new section |
| 7 | designated §33-25A-8y, all relating to providing health insurance coverage concerning |
| 8 | biomarker testing. |

Be it enacted by the Legislature of West Virginia:

CHAPTER 5. GENERAL POWERS AND AUTHORITY OF THE GOVERNOR, SECRETARY OF STATE AND ATTORNEY GENERAL; BOARD OF PUBLIC WORKS; MISCELLANEOUS AGENCIES, COMMISSIONS, OFFICES, PROGRAMS, ETC.

| | ARTICLE 16. WEST VIRGINIA PUBLIC EMPLOYEES INSURANCE ACT. |
|---|---|
| | §5-16-7h. Biomarker testing. |
| 1 | (a) As used in this section: |
| 2 | (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an |
| 3 | indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a |
| 4 | specific therapeutic intervention, including known gene-drug interactions for medications being |
| 5 | considered for use or already being administered; and includes but is not limited to gene |
| 6 | mutations, characteristics of genes and protein expression; |
| 7 | (2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other |
| 8 | biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte |

9 tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole

| 10 | transcriptome sequencing; |
|----|--|
| 11 | (3) "Consensus statements" means statements that are: |
| 12 | (A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent |
| 13 | methodology and reporting structure with a conflict of interest policy; |
| 14 | (B) Aimed at specific clinical circumstances; and |
| 15 | (C) Based on the best available evidence for the purpose of optimizing the outcomes of |
| 16 | clinical care; |
| 17 | (4) "FDA" means the United States Food and Drug Administration; and |
| 18 | (5) "Nationally recognized clinical practice guidelines" means evidence-based clinical |
| 19 | practice guidelines that: |
| 20 | (A) Are developed by an independent organization or medical professional society utilizing |
| 21 | a transparent methodology and reporting structure with a conflict of interest policy and include |
| 22 | recommendations intended to optimize care; |
| 23 | (B) Establish standards of care informed by: |
| 24 | (i) A systematic review of evidence; and |
| 25 | (ii) An assessment of the benefits and risks of alternative care options. |
| 26 | (b) (1) The Public Employees Insurance Agency shall provide coverage for biomarker |
| 27 | testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring |
| 28 | of a covered person's disease or condition when supported by medical and scientific evidence, |
| 29 | including, but not limited to: |
| 30 | (A) Labeled indications for a test approved or cleared by the federal food and drug |
| 31 | administration; |
| 32 | (B) Indicated tests for a food and drug administration approved drug; |
| 33 | (C) Warnings and precautions on FDA-approved drug labels; |
| 34 | (D) Centers for Medicare and Medicaid Services national coverage determinations and |
| 35 | Medicare administrative contractor local coverage determinations; or |

| 36 | (E) Nationally recognized clinical practice guidelines such as, but not limited to, those of | | | | |
|----|---|------------|--|--|--|
| 37 | the national comprehensive cancer network or the American society of clinical oncology, and | | | | |
| 38 | consensus statements. | | | | |
| 39 | (2) The coverage shall be provided in a manner that shall limit disruptions in care includi | ng | | | |
| 40 | the need for multiple biopsies or biospecimen samples. | | | | |
| 41 | (3) The covered person and prescribing practitioner shall have access to a clear, read | ily | | | |
| 42 | accessible, and convenient process to request an exception to a coverage policy provid | ed | | | |
| 43 | pursuant to the provisions of this section. The process shall be made readily accessible on t | <u>he</u> | | | |
| 44 | website of the insur | <u>er.</u> | | | |
| | CHAPTER 9. HUMAN SERVICES. | | | | |
| | ARTICLE 5. MISCELLANEOUS PROVISION | S. | | | |
| | §9-5-34. Biomarker testin | <u>ig.</u> | | | |
| 1 | (a) As used in this section: | | | | |
| 2 | (1) "Biomarker": means a characteristic that is objectively measured and evaluated as | <u>an</u> | | | |
| 3 | indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to | <u>) a</u> | | | |
| 4 | specific therapeutic intervention, including known gene-drug interactions for medications being | | | | |
| 5 | considered for use or already being administered; and includes but is not limited to gene | | | | |
| 6 | mutations, characteristics of genes and protein expression; | | | | |
| 7 | (2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other | | | | |
| 8 | biospecimen for the presence of a biomarker; and includes but is not limited to single-analy | <u>/te</u> | | | |
| 9 | tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole | | | | |
| 10 | transcriptome sequencing; | | | | |
| 11 | (3) "Consensus statements" means statements that are: | | | | |
| 12 | (A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent | | | | |
| | (A) Developed by an independent, multidisciplinary panel of experts utilizing a transpare | | | | |

| 14 | (B) Aimed at specific clinical circumstances; and |
|----------|---|
| 15 | (C) Based on the best available evidence for the purpose of optimizing the outcomes of |
| 16 | clinical care; |
| 17 | (4) "FDA" means the United States Food and Drug Administration; and |
| 18 | (5) "Nationally recognized clinical practice guidelines" means evidence-based clinical |
| 19 | practice guidelines that: |
| 20 | (A) Are developed by an independent organization or medical professional society utilizing |
| 21 | a transparent methodology and reporting structure with a conflict of interest policy and include |
| 22 | recommendations intended to optimize care; |
| 23 | (B) Establish standards of care informed by: |
| 24 | (i) A systematic review of evidence; and |
| 25 | (ii) An assessment of the benefits and risks of alternative care options. |
| 26 | (b) (1) The Bureau for Medical Services shall provide coverage for biomarker testing for the |
| 27 | purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of a covered |
| 28 | person's disease or condition when supported by medical and scientific evidence, including, but |
| 29 | not limited to: |
| 30 | (A) Labeled indications for a test approved or cleared by the federal food and drug |
| 31 | administration; |
| 32 | (B) indicated tests for a food and drug administration approved drug; |
| 33 | (C) Warnings and precautions on FDA-approved drug labels; |
| 34 | (D) Centers for Medicare and Medicaid Services national coverage determinations and |
| 35 | Medicare administrative contractor local coverage determinations; or |
| 00 | |
| 36 | (E) Nationally recognized clinical practice guidelines such as, but not limited to, those of |
| 36 37 | (E) Nationally recognized clinical practice guidelines such as, but not limited to, those of the national comprehensive cancer network or the American society of clinical oncology, and |
| | |

40 the need for multiple biopsies or biospecimen samples.

| 41 | <u>(3)</u> Th | <u>ne covered person and pr</u> | escribing practitioner sha | Il have access to a clear, readily |
|----|----------------|------------------------------------|----------------------------|------------------------------------|
| 42 | accessible, a | nd convenient process | to request an exception | to a coverage policy provided |
| 43 | pursuant to th | <u>ne provisions of this secti</u> | on. The process shall be | made readily accessible on the |
| 44 | website | of | the | insurer. |

CHAPTER 33. INSURANCE.

| | ARTICLE | 15. | ACCIDENT | AND | SICKNESS | INSURANCE. |
|----|------------------------|---------------|----------------------------|------------------|--------------------------|---------------------------|
| | <u>§33-15-4x.</u> | | | Biomarker | | testing. |
| 1 | <u>(a) As</u> | used in this | section: | | | |
| 2 | <u>(1) "Bi</u> | omarker": r | neans a characteris | tic that is obje | ectively measured a | and evaluated as an |
| 3 | indicator of no | ormal biolog | <u>jic processes, path</u> | ogenic proces | ses, or pharmacolo | ogic responses to a |
| 4 | specific thera | peutic inter | vention, including k | nown gene-d | rug interactions for | medications being |
| 5 | considered for | or use or a | Iready being admi | nistered; and | includes but is r | not limited to gene |
| 6 | mutations, cha | aracteristics | of genes and prote | ein expression | | |
| 7 | <u>(2)</u> "B | liomarker to | esting": means the | e analysis of | <u>a patient's tissu</u> | <u>e, blood, or other</u> |
| 8 | biospecimen | for the pres | ence of a biomark | er; and incluc | les but is not limite | ed to single-analyte |
| 9 | <u>tests, multiple</u> | ex panel tes | sts, protein express | ion, and who | le exome, whole g | genome, and whole |
| 10 | transcriptome | sequencing | <u>a:</u> | | | |
| 11 | <u>(3) "Co</u> | onsensus st | atements" means s | tatements that | <u>t are:</u> | |
| 12 | <u>(A) De</u> | veloped by | <u>an independent, m</u> | ultidisciplinary | panel of experts ut | ilizing a transparent |
| 13 | methodology | and reportir | ng structure with a c | onflict of inter | est policy; | |
| 14 | <u>(B) Air</u> | ned at spec | ific clinical circums | ances; and | | |
| 15 | <u>(C) Ba</u> | ased on the | best available evid | ence for the p | ourpose of optimizi | ng the outcomes of |
| 16 | <u>clinical care;</u> | | | | | |
| 17 | <u>(4) "F[</u> | DA" means | the United States F | ood and Drug | Administration; an | <u>d</u> |

| 18 | (5) "Nationally recognized clinical practice guidelines" means evidence-based clinical |
|----|--|
| 19 | practice guidelines that: |
| 20 | (A) Are developed by an independent organization or medical professional society utilizing |
| 21 | a transparent methodology and reporting structure with a conflict of interest policy and include |
| 22 | recommendations intended to optimize care; |
| 23 | (B) Establish standards of care informed by: |
| 24 | (i) A systematic review of evidence; and |
| 25 | (ii) An assessment of the benefits and risks of alternative care options. |
| 26 | (b) (1) The health insurers shall provide coverage for biomarker testing for the purposes of |
| 27 | diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's |
| 28 | disease or condition when supported by medical and scientific evidence, including, but not limited |
| 29 | <u>to:</u> |
| 30 | (A) Labeled indications for a test approved or cleared by the federal food and drug |
| 31 | administration; |
| 32 | (B) indicated tests for a food and drug administration approved drug; |
| 33 | (C) Warnings and precautions on FDA-approved drug labels; |
| 34 | (D) Centers for Medicare and Medicaid Services national coverage determinations and |
| 35 | Medicare administrative contractor local coverage determinations; or |
| 36 | (E) Nationally recognized clinical practice guidelines such as, but not limited to, those of |
| 37 | the national comprehensive cancer network or the American society of clinical oncology, and |
| 38 | consensus statements. |
| 39 | (2) The coverage shall be provided in a manner that shall limit disruptions in care including |
| 40 | the need for multiple biopsies or biospecimen samples. |
| 41 | (3) The covered person and prescribing practitioner shall have access to a clear, readily |
| 42 | accessible, and convenient process to request an exception to a coverage policy provided |
| 43 | pursuant to the provisions of this section. The process shall be made readily accessible on the |

| 44 | website | | c | of | the | | insurer. |
|----|-------------------------|----------|----------------|-------------------------|---------------|-------------------------|--------------------------|
| | ARTICLE | 16. | GROUP | ACCIDENT | AND | SICKNESS | INSURANCE. |
| | <u>§33-16-3aa.</u> | | | Bioma | nrker | | testing. |
| 1 | <u>(a) As u</u> | ised in | this section: | | | | |
| 2 | <u>(1) "Bior</u> | marke | r": means a | characteristic that | t is objectiv | vely measured ar | nd evaluated as an |
| 3 | indicator of nor | mal bi | ologic proce | <u>sses, pathogenic</u> | processes | s, or pharmacolog | gic responses to a |
| 4 | specific therape | eutic ii | ntervention, i | ncluding known | gene-drug | interactions for I | medications being |
| 5 | considered for | use (| or already b | eing administere | d; and in | <u>cludes but is no</u> | ot limited to gene |
| 6 | mutations, char | racteris | stics of gene | s and protein exp | ression; | | |
| 7 | <u>(2) "Bio</u> | omarke | er testing": | means the anal | ysis of a | patient's tissue | <u>, blood, or other</u> |
| 8 | biospecimen fo | or the | presence of | a biomarker; and | l includes | but is not limited | <u>to single-analyte</u> |
| 9 | <u>tests, multiplex</u> | pane | l tests, prote | in expression, a | nd whole e | exome, whole ge | enome, and whole |
| 10 | transcriptome s | equer | icing; | | | | |
| 11 | <u>(3) "Con</u> | isensi | is statements | s" means stateme | ents that ar | <u>e:</u> | |
| 12 | <u>(A) Deve</u> | elopec | l by an indep | endent, multidisc | plinary pa | nel of experts utili | izing a transparent |
| 13 | methodology ar | nd rep | orting structu | re with a conflict | of interest | policy; | |
| 14 | <u>(B) Aime</u> | ed at s | pecific clinic | al circumstances; | and | | |
| 15 | <u>(C) Base</u> | ed on | the best ava | ilable evidence f | or the purp | oose of optimizing | g the outcomes of |
| 16 | <u>clinical care;</u> | | | | | | |
| 17 | <u>(4) "FDA</u> | A" mea | ans the Unite | d States Food an | d Drug Ad | ministration; and | |
| 18 | <u>(5)</u> "Nat | tionally | y recognized | clinical practice | guideline | s" means evider | nce-based clinical |
| 19 | practice guideli | nes th | <u>at:</u> | | | | |
| 20 | <u>(A) Are c</u> | develo | ped by an in | dependent organi | zation or n | nedical professior | nal society utilizing |
| 21 | <u>a transparent n</u> | nethoo | lology and re | eporting structure | with a co | nflict of interest | policy and include |
| 22 | recommendatio | ons inte | ended to opti | <u>mize care;</u> | | | |
| 23 | <u>(B) Esta</u> | ablish s | standards of | care informed by | _ | | |

| 24 | (i) A systematic review of evidence; and | | | | | | |
|----|--|--|--|--|--|--|--|
| 25 | (ii) An assessment of the benefits and risks of alternative care options. | | | | | | |
| 26 | (b) (1) The health insurers shall provide coverage for biomarker testing for the purposes of | | | | | | |
| 27 | diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's | | | | | | |
| 28 | disease or condition when supported by medical and scientific evidence, including, but not limited | | | | | | |
| 29 | <u>to:</u> | | | | | | |
| 30 | (A) Labeled indications for a test approved or cleared by the federal food and drug | | | | | | |
| 31 | administration; | | | | | | |
| 32 | (B) indicated tests for a food and drug administration approved drug; | | | | | | |
| 33 | (C) Warnings and precautions on FDA-approved drug labels; | | | | | | |
| 34 | (D) Centers for Medicare and Medicaid Services national coverage determinations and | | | | | | |
| 35 | Medicare administrative contractor local coverage determinations; or | | | | | | |
| 36 | (E) Nationally recognized clinical practice guidelines such as, but not limited to, those of | | | | | | |
| 37 | the national comprehensive cancer network or the American society of clinical oncology, and | | | | | | |
| 38 | consensus statements. | | | | | | |
| 39 | (2) The coverage shall be provided in a manner that shall limit disruptions in care including | | | | | | |
| 40 | the need for multiple biopsies or biospecimen samples. | | | | | | |
| 41 | (3) The covered person and prescribing practitioner shall have access to a clear, readily | | | | | | |
| 42 | accessible, and convenient process to request an exception to a coverage policy provided | | | | | | |
| 43 | pursuant to the provisions of this section. The process shall be made readily accessible on the | | | | | | |
| 44 | website of the insurer. | | | | | | |
| | ARTICLE 24. HOSPITAL SERVICE CORPORATIONS, MEDICAL SERVICE | | | | | | |
| | CORPORATIONS, DENTAL SERVICE CORPORATIONS, AND HEALTH | | | | | | |
| | SERVICE CORPORATIONS. | | | | | | |
| | §33-24-7y. Biomarker testing. | | | | | | |

| 1 | (a) As used in this section: |
|----|--|
| 2 | (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an |
| 3 | indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a |
| 4 | specific therapeutic intervention, including known gene-drug interactions for medications being |
| 5 | considered for use or already being administered; and includes but is not limited to gene |
| 6 | mutations, characteristics of genes and protein expression; |
| 7 | (2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other |
| 8 | biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte |
| 9 | tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole |
| 10 | transcriptome sequencing; |
| 11 | (3) "Consensus statements" means statements that are: |
| 12 | (A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent |
| 13 | methodology and reporting structure with a conflict of interest policy; |
| 14 | (B) Aimed at specific clinical circumstances; and |
| 15 | (C) Based on the best available evidence for the purpose of optimizing the outcomes of |
| 16 | clinical care; |
| 17 | (4) "FDA" means the United States Food and Drug Administration; and |
| 18 | (5) "Nationally recognized clinical practice guidelines" means evidence-based clinical |
| 19 | practice guidelines that: |
| 20 | (A) Are developed by an independent organization or medical professional society utilizing |
| 21 | a transparent methodology and reporting structure with a conflict of interest policy and include |
| 22 | recommendations intended to optimize care; |
| 23 | (B) Establish standards of care informed by: |
| 24 | (i) A systematic review of evidence; and |
| 25 | (ii) An assessment of the benefits and risks of alternative care options. |
| 26 | (b) (1) The health insurers shall provide coverage for biomarker testing for the purposes of |

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| 27 | diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's | | | | | | |
|----|---|--|---------------------------------|--|--|--|--|
| 28 | 8 <u>disease or condition when supported by medic</u> | disease or condition when supported by medical and scientific evidence, including, but not limited | | | | | |
| 29 | 9 <u>to:</u> | | | | | | |
| 30 | 0 (A) Labeled indications for a test ap | proved or cleared by the | federal food and drug | | | | |
| 31 | 1 <u>administration;</u> | | | | | | |
| 32 | 2 (B) indicated tests for a food and drug | administration approved dr | ug; | | | | |
| 33 | 3 (C) Warnings and precautions on FDA | approved drug labels; | | | | | |
| 34 | 4 (D) Centers for Medicare and Medica | id Services national covera | age determinations and | | | | |
| 35 | 5 Medicare administrative contractor local cover | age determinations; or | | | | | |
| 36 | 6 (E) Nationally recognized clinical prac | <u>tice guidelines such as, bu</u> | t not limited to, those of | | | | |
| 37 | 7 the national comprehensive cancer network | <u>or the American society o</u> | <u>f clinical oncology, and</u> | | | | |
| 38 | 8 <u>consensus statements.</u> | | | | | | |
| 39 | 9 (2) The coverage shall be provided in a | (2) The coverage shall be provided in a manner that shall limit disruptions in care including | | | | | |
| 40 | 0 the need for multiple biopsies or biospecimen | the need for multiple biopsies or biospecimen samples. | | | | | |
| 41 | 1 (3) The covered person and prescribin | ng practitioner shall have a | ccess to a clear, readily | | | | |
| 42 | 2 accessible, and convenient process to requ | <u>est an exception to a co</u> | verage policy provided | | | | |
| 43 | 3 pursuant to the provisions of this section. The | process shall be made re | adily accessible on the | | | | |
| 44 | 4 <u>website</u> of | the | insurer. | | | | |
| | ARTICLE 25. HEALTH | CARE | CORPORATIONS. | | | | |
| | <u>§33-25-8v.</u> Bi | omarker | testing. | | | | |
| 1 | 1 (a) As used in this section: | | | | | | |
| 2 | 2 (1) "Biomarker": means a characteristi | (1) "Biomarker": means a characteristic that is objectively measured and evaluated as an | | | | | |
| 3 | indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a | | | | | | |
| 4 | 4 specific therapeutic intervention, including kn | specific therapeutic intervention, including known gene-drug interactions for medications being | | | | | |
| 5 | considered for use or already being administered; and includes but is not limited to gene | | | | | | |
| 6 | mutations, characteristics of genes and protein expression; | | | | | | |

| 7 | (2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other | | | |
|----|--|--|--|--|
| 8 | biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte | | | |
| 9 | tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole | | | |
| 10 | transcriptome sequencing; | | | |
| 11 | (3) "Consensus statements" means statements that are: | | | |
| 12 | (A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent | | | |
| 13 | methodology and reporting structure with a conflict of interest policy; | | | |
| 14 | (B) Aimed at specific clinical circumstances; and | | | |
| 15 | (C) Based on the best available evidence for the purpose of optimizing the outcomes of | | | |
| 16 | clinical care; | | | |
| 17 | (4) "FDA" means the United States Food and Drug Administration; and | | | |
| 18 | (5) "Nationally recognized clinical practice guidelines" means evidence-based clinical | | | |
| 19 | practice guidelines that: | | | |
| 20 | (A) Are developed by an independent organization or medical professional society utilizing | | | |
| 21 | a transparent methodology and reporting structure with a conflict of interest policy and include | | | |
| 22 | recommendations intended to optimize care; | | | |
| 23 | (B) Establish standards of care informed by: | | | |
| 24 | (i) A systematic review of evidence; and | | | |
| 25 | (ii) An assessment of the benefits and risks of alternative care options. | | | |
| 26 | (b) (1) The health insurers shall provide coverage for biomarker testing for the purposes of | | | |
| 27 | diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's | | | |
| 28 | disease or condition when supported by medical and scientific evidence, including, but not limited | | | |
| 29 | <u>to:</u> | | | |
| 30 | (A) Labeled indications for a test approved or cleared by the federal food and drug | | | |
| 31 | administration; | | | |
| 32 | (B) indicated tests for a food and drug administration approved drug; | | | |

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| 33 | <u>(C) Warnings an</u> | d precautions or | n FDA-approved drug lat | <u>pels;</u> | |
|--------------------------------------|---|---|--|--|---|
| 34 | (D) Centers for | Medicare and N | ledicaid Services nation | nal coverage determina | <u>tions and</u> |
| 35 | Medicare administrative | contractor local | coverage determination | <u>s; or</u> | |
| 36 | (E) Nationally re | cognized clinica | al practice guidelines su | ch as, but not limited to | <u>, those of</u> |
| 37 | the national comprehen | sive cancer net | twork or the American | society of clinical onco | logy, and |
| 38 | consensus statements. | | | | |
| 39 | (2) The coverage | e shall be provid | ed in a manner that shall | limit disruptions in care | including |
| 40 | the need for multiple bio | psies or biospe | cimen samples. | | |
| 41 | (3) The covered | person and pre | escribing practitioner sha | Il have access to a clea | ar, readily |
| 42 | accessible, and conver | nient process to | <u>request an exception</u> | to a coverage policy | provided |
| 43 | pursuant to the provisio | ns of this sectio | n. The process shall be | made readily accessib | ole on the |
| 44 | website | of | the | | insurer. |
| | | | | | |
| | ARTICLE 25A. | HEALTH | MAINTENANCE | ORGANIZATION | ACT. |
| | ARTICLE 25A. <u>§33-25A-8y.</u> | HEALTH | MAINTENANCE Biomarker | ORGANIZATION | ACT. testing. |
| 1 | | | | ORGANIZATION | |
| 1 2 | <u>§33-25A-8y.</u> (a) As used in th | is section: | | | <u>testing.</u> |
| | <u>§33-25A-8y.</u> (a) As used in th | is section: means a charac | Biomarker | y measured and evalua | testing. ted as an |
| 2 | §33-25A-8y. (a) As used in th <u>(1) "Biomarker":</u> | is section: means a charac ogic processes, | Biomarker cteristic that is objectivel pathogenic processes, c | y measured and evalua | <u>testing.</u> ted as an nses to a |
| 2 3 | <u>§33-25A-8y.</u> (a) As used in th (1) "Biomarker": indicator of normal biolo | is section: means a charac ogic processes, rvention, includi | Biomarker cteristic that is objectivel pathogenic processes, c ing known gene-drug in | y measured and evalua or pharmacologic respo teractions for medicatio | testing. ted as an nses to a ons being |
| 2 3 4 | §33-25A-8y. (a) As used in th (1) "Biomarker": indicator of normal bioloc specific therapeutic inte | is section: means a charac gic processes, rvention, includi already being | Biomarker cteristic that is objectivel pathogenic processes, of ing known gene-drug in administered; and inclu | y measured and evalua or pharmacologic respo teractions for medicatio | testing. ted as an nses to a ons being |
| 2 3 4 5 | §33-25A-8y. (a) As used in th (1) "Biomarker": indicator of normal bioloc specific therapeutic inter considered for use or mutations, characteristic | is section: means a charac ogic processes, rvention, includi already being as of genes and | Biomarker cteristic that is objectivel pathogenic processes, of ing known gene-drug in administered; and inclu | y measured and evalua or pharmacologic respo teractions for medicatio des but is not limited | testing. ted as an nses to a ons being to gene |
| 2 3 4 5 6 | §33-25A-8y. (a) As used in th (1) "Biomarker": indicator of normal bioloc specific therapeutic inter considered for use or mutations, characteristic | is section: means a charac ogic processes, rvention, includi already being a cs of genes and testing": means | Biomarker cteristic that is objectivel pathogenic processes, of ing known gene-drug in administered; and inclu protein expression; s the analysis of a pa | y measured and evalua or pharmacologic respo teractions for medicatic des but is not limited atient's tissue, blood, | testing. ted as an nses to a ons being to gene or other |
| 2 3 4 5 6 7 | §33-25A-8y. (a) As used in th (1) "Biomarker": indicator of normal biolo specific therapeutic inter considered for use or mutations, characteristic (2) "Biomarker | is section: means a charac ogic processes, rvention, includi already being as of genes and testing": means esence of a bior | Biomarker cteristic that is objectivel pathogenic processes, of ing known gene-drug in administered; and inclu protein expression; s the analysis of a para marker; and includes bu | y measured and evalua or pharmacologic respo teractions for medicatio des but is not limited atient's tissue, blood, it is not limited to singl | testing. ted as an nses to a ons being to gene or other e-analyte |
| 2 3 4 5 6 7 8 | §33-25A-8y. (a) As used in the (1) "Biomarker": indicator of normal bioloce specific therapeutic inter considered for use or mutations, characteristice (2) "Biomarker biospecimen for the present | is section: means a charac ogic processes, rvention, includi already being as of genes and testing": means esence of a bior ests, protein exp | Biomarker cteristic that is objectivel pathogenic processes, of ing known gene-drug in administered; and inclu protein expression; s the analysis of a para marker; and includes bu | y measured and evalua or pharmacologic respo teractions for medicatio des but is not limited atient's tissue, blood, it is not limited to singl | testing. ted as an nses to a ons being to gene or other e-analyte |
| 2 3 4 5 6 7 8 9 | §33-25A-8y. (a) As used in the (1) "Biomarker": indicator of normal biolog specific therapeutic integendent considered for use or mutations, characteristic (2) "Biomarker biospecimen for the presenter tests, multiplex panel test transcriptome sequencing | is section: means a charac ogic processes, rvention, includi already being as of genes and testing": means esence of a bior ests, protein exp | Biomarker cteristic that is objectivel pathogenic processes, of ing known gene-drug in administered; and inclu protein expression; s the analysis of a para marker; and includes bu | y measured and evalua or pharmacologic respo teractions for medicatio des but is not limited atient's tissue, blood, it is not limited to singl | testing. ted as an nses to a ons being to gene or other e-analyte |

12 (A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent

| 13 | methodology and reporting structure with a conflict of interest policy; | | | |
|----|--|--|--|--|
| 14 | (B) Aimed at specific clinical circumstances; and | | | |
| 15 | (C) Based on the best available evidence for the purpose of optimizing the outcomes of | | | |
| 16 | clinical care; | | | |
| 17 | (4) "FDA" means the United States Food and Drug Administration; and | | | |
| 18 | (5) "Nationally recognized clinical practice guidelines" means evidence-based clinical | | | |
| 19 | practice guidelines that: | | | |
| 20 | (A) Are developed by an independent organization or medical professional society utilizing | | | |
| 21 | a transparent methodology and reporting structure with a conflict of interest policy and include | | | |
| 22 | recommendations intended to optimize care; | | | |
| 23 | (B) Establish standards of care informed by: | | | |
| 24 | (i) A systematic review of evidence; and | | | |
| 25 | (ii) An assessment of the benefits and risks of alternative care options. | | | |
| 26 | (b) (1) The health insurers shall provide coverage for biomarker testing for the purposes of | | | |
| 27 | diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's | | | |
| 28 | disease or condition when supported by medical and scientific evidence, including, but not limited | | | |
| 29 | <u>to:</u> | | | |
| 30 | (A) Labeled indications for a test approved or cleared by the federal food and drug | | | |
| 31 | administration; | | | |
| 32 | (B) indicated tests for a food and drug administration approved drug; | | | |
| 33 | (C) Warnings and precautions on FDA-approved drug labels; | | | |
| 34 | (D) Centers for Medicare and Medicaid Services national coverage determinations and | | | |
| 35 | Medicare administrative contractor local coverage determinations; or | | | |
| 36 | (E) Nationally recognized clinical practice guidelines such as, but not limited to, those of | | | |
| 37 | the national comprehensive cancer network or the American society of clinical oncology, and | | | |
| 38 | consensus statements. | | | |

- 39 (2) The coverage shall be provided in a manner that shall limit disruptions in care including
- 40 the need for multiple biopsies or biospecimen samples.
- 41 (3) The covered person and prescribing practitioner shall have access to a clear, readily
- 42 accessible, and convenient process to request an exception to a coverage policy provided
- 43 pursuant to the provisions of this section. The process shall be made readily accessible on the
- 44 website of the insurer.

NOTE: The purpose of this bill is to require insurance coverage for biomarker testing.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.