WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Committee Substitute

for

House Bill 4753

By Delegates Westfall, Barnhart, Riley, Young,

Hornbuckle, W. Hall, Garcia, Jeffries, Hott, Cannon,

and Akers

[Originating in the Committee on the Judiciary;

Reported on February 21, 2024]

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

(a) As used in this section:

(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;

(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte

tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statements" means statements that are:

(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

(B) Aimed at specific clinical circumstances; and

(C) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "FDA" means the United States Food and Drug Administration; and

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy and include recommendations intended to optimize care;

(B) Establish standards of care informed by:

(i) A systematic review of evidence; and

(ii) An assessment of the benefits and risks of alternative care options.

(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

(7) "Prior authorization" means obtaining advanced approval from a health insurer about the coverage of a service or medication.

(b)(1) The Public Employees Insurance Agency shall provide coverage for biomarker testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when supported by medical and scientific evidence, including, but not limited to:

(A) Labeled indications for a test approved or cleared by the FDA;

(B) Indicated tests for an FDA-approved drug;

(C) Warnings and precautions on FDA-approved drug labels;

(D) Centers for Medicare and Medicaid Services national coverage determinations and Medicare administrative contractor local coverage determinations; or

(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 consensus statements: *Provided*, That any treatment provided in accordance with such practice guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

(2) Nothing in this section shall require coverage of biomarker testing for the purpose of screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker testing is appropriate.

(3) The coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The Public Employees Insurance Agency may require that biomarker testing be subject to prior authorization in accordance with §33-16-3dd.

(5) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. The process shall be made readily accessible on the website of the insurer.

CHAPTER 9. HUMAN SERVICES.

ARTICLE 5. MISCELLANEOUS PROVISIONS.

§9-5-34. Biomarker testing.

(a) As used in this section:

(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a

specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;

(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statements" means statements that are:

(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

(B) Aimed at specific clinical circumstances; and

(C) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "FDA" means the United States Food and Drug Administration; and

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy and include recommendations intended to optimize care;

(B) Establish standards of care informed by:

(i) A systematic review of evidence; and

(ii) An assessment of the benefits and risks of alternative care options.

(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

(7) "Prior authorization" means obtaining advanced approval from a health insurer about the coverage of a service or medication.

(b)(1) The Bureau for Medical Services shall provide coverage for biomarker testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when supported by medical and scientific evidence, including, but not limited to:

(A) Labeled indications for a test approved or cleared by the FDA;

(B) Indicated tests for an FDA-approved drug;

(C) Warnings and precautions on FDA-approved drug labels;

(D) Centers for Medicare and Medicaid Services national coverage determinations and Medicare administrative contractor local coverage determinations; or

(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 consensus statements: *Provided*, That any treatment provided in accordance with such practice guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

(2) Nothing in this section shall require coverage of biomarker testing for the purpose of screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker testing is appropriate.

(3) The coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The Public Employees Insurance Agency may require that biomarker testing be subject to prior authorization in accordance with §33-16-3dd.

(5) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. The process shall be made readily accessible on the website of the insurer.

CHAPTER 33. INSURANCE.

ARTICLE 15. ACCIDENT AND SICKNESS INSURANCE.

§33-15-4x. Biomarker testing.

(a) As used in this section:

(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;

(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statements" means statements that are:

(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

(B) Aimed at specific clinical circumstances; and

(C) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "FDA" means the United States Food and Drug Administration; and

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy and include recommendations intended to optimize care;

(B) Establish standards of care informed by:

(i) A systematic review of evidence; and

(ii) An assessment of the benefits and risks of alternative care options.

(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

(7) "Prior authorization" means obtaining advanced approval from a health insurer about the coverage of a service or medication.

(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when supported by medical and scientific evidence, including, but not limited to:

(A) Labeled indications for a test approved or cleared by the FDA;

(B) Indicated tests for an FDA-approved drug;

(C) Warnings and precautions on FDA-approved drug labels;

(D) Centers for Medicare and Medicaid Services national coverage determinations and Medicare administrative contractor local coverage determinations; or

(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 consensus statements: *Provided*, That any treatment provided in accordance with such practice guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

(2) Nothing in this section shall require coverage of biomarker testing for the purpose of screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker testing is appropriate.

(3) The coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The health insurers may require that biomarker testing be subject to prior authorization in accordance with §33-16-3dd.

(5) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. The process shall be made readily accessible on the website of the insurer.

ARTICLE 16. GROUP ACCIDENT AND SICKNESS INSURANCE.

§33-16-3aa. Biomarker testing.

(a) As used in this section:

(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;

(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statements" means statements that are:

(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

(B) Aimed at specific clinical circumstances; and

(C) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "FDA" means the United States Food and Drug Administration; and

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy and include recommendations intended to optimize care;

(B) Establish standards of care informed by:

(i) A systematic review of evidence; and

(ii) An assessment of the benefits and risks of alternative care options.

(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

(7) "Prior authorization" means obtaining advanced approval from a health insurer about the coverage of a service or medication.

(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when supported by medical and scientific evidence, including, but not limited to:

(A) Labeled indications for a test approved or cleared by the FDA;

(B) Indicated tests for an FDA-approved drug;

(C) Warnings and precautions on FDA-approved drug labels;

(D) Centers for Medicare and Medicaid Services national coverage determinations and Medicare administrative contractor local coverage determinations; or

(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 consensus statements: *Provided*, That any treatment provided in accordance with such practice guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

(2) Nothing in this section shall require coverage of biomarker testing for the purpose of screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker testing is appropriate.

(3) The coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The health insurers may require that biomarker testing be subject to prior authorization in accordance with §33-16-3dd.

(5) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. The process shall be made readily accessible on the website of the insurer.

ARTICLE 24. HOSPITAL SERVICE CORPORATIONS, MEDICAL SERVICE CORPORATIONS, DENTAL SERVICE CORPORATIONS, AND HEALTH SERVICE CORPORATIONS.

§33-24-7y. Biomarker testing.

(a) As used in this section:

(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;

(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statements" means statements that are:

(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

(B) Aimed at specific clinical circumstances; and

(C) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "FDA" means the United States Food and Drug Administration; and

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy and include recommendations intended to optimize care;

(B) Establish standards of care informed by:

(i) A systematic review of evidence; and

(ii) An assessment of the benefits and risks of alternative care options.

(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

(7) "Prior authorization" means obtaining advanced approval from a health insurer about the coverage of a service or medication.

(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when supported by medical and scientific evidence, including, but not limited to:

(A) Labeled indications for a test approved or cleared by the FDA;

(B) Indicated tests for an FDA-approved drug;

(C) Warnings and precautions on FDA-approved drug labels;

(D) Centers for Medicare and Medicaid Services national coverage determinations and Medicare administrative contractor local coverage determinations; or

(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 consensus statements: *Provided*, That any treatment provided in accordance with such practice guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

(2) Nothing in this section shall require coverage of biomarker testing for the purpose of screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker testing is appropriate.

(3) The coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The health insurers may require that biomarker testing be subject to prior authorization in accordance with §33-16-3dd.

(5) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. The process shall be made readily accessible on the website of the insurer.

ARTICLE 25. HEALTH CARE CORPORATIONS.

§33-25-8v. Biomarker testing.

(a) As used in this section:

(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;

(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte

tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statements" means statements that are:

(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

(B) Aimed at specific clinical circumstances; and

(C) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "FDA" means the United States Food and Drug Administration; and

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy and include recommendations intended to optimize care;

(B) Establish standards of care informed by:

(i) A systematic review of evidence; and

(ii) An assessment of the benefits and risks of alternative care options.

(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

(7) "Prior authorization" means obtaining advanced approval from a health insurer about the coverage of a service or medication.

(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when supported by medical and scientific evidence, including, but not limited to:

(A) Labeled indications for a test approved or cleared by the FDA;

(B) Indicated tests for an FDA-approved drug;

(C) Warnings and precautions on FDA-approved drug labels;

(D) Centers for Medicare and Medicaid Services national coverage determinations and Medicare administrative contractor local coverage determinations; or

(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 consensus statements: *Provided*, That any treatment provided in accordance with such practice guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

(2) Nothing in this section shall require coverage of biomarker testing for the purpose of screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker testing is appropriate.

(3) The coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The health insurers may require that biomarker testing be subject to prior authorization in accordance with §33-16-3dd.

(5) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. The process shall be made readily accessible on the website of the insurer.

ARTICLE 25A. HEALTH MAINTENANCE ORGANIZATION ACT.

§33-25A-8y. Biomarker testing.

(a) As used in this section:

(1) "Biomarker": means a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being

considered for use or already being administered; and includes but is not limited to gene mutations, characteristics of genes and protein expression;

(2) "Biomarker testing": means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker; and includes but is not limited to single-analyte tests, multiplex panel tests, protein expression, and whole exome, whole genome, and whole transcriptome sequencing;

(3) "Consensus statements" means statements that are:

(A) Developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure with a conflict of interest policy;

(B) Aimed at specific clinical circumstances; and

(C) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care;

(4) "FDA" means the United States Food and Drug Administration; and

(5) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

(A) Are developed by an independent organization or medical professional society utilizing a transparent methodology and reporting structure with a conflict of interest policy and include recommendations intended to optimize care;

(B) Establish standards of care informed by:

(i) A systematic review of evidence; and

(ii) An assessment of the benefits and risks of alternative care options.

(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.

(7) "Prior authorization" means obtaining advanced approval from a health insurer about the coverage of a service or medication.

(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when supported by medical and scientific evidence, including, but not limited to:

(A) Labeled indications for a test approved or cleared by the FDA;

(B) Indicated tests for an FDA-approved drug;

(C) Warnings and precautions on FDA-approved drug labels;

(D) Centers for Medicare and Medicaid Services national coverage determinations and Medicare administrative contractor local coverage determinations; or

(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 consensus statements: *Provided*, That any treatment provided in accordance with such practice guidelines is limited to the use of drugs and tests approved or cleared by the FDA.

(2) Nothing in this section shall require coverage of biomarker testing for the purpose of screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker testing is appropriate.

(3) The coverage shall be provided in a manner that shall limit disruptions in care including the need for multiple biopsies or biospecimen samples.

(4) The health insurers may require that biomarker testing be subject to prior authorization in accordance with §33-16-3dd.

(5) The covered person and prescribing practitioner shall have access to a clear, readily accessible, and convenient process to request an exception to a coverage policy provided pursuant to the provisions of this section. The process shall be made readily accessible on the 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.