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

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	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The Public Employees Insurance Agency shall provide coverage for biomarker
31	testing for the purposes of precision diagnosis, treatment, appropriate management, or ongoing
32	monitoring of a covered person's disease or condition when supported by medical and scientific
33	evidence, including, but not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;

35	(B) Indicated tests for an FDA-approved drug;			
36	(C) Warnings and precautions on FDA-approved drug labels;			
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and			
38	Medicare administ	rative contractor le	ocal coverage determinations; or	
39	(E) Nationa	Illy recognized cli	nical practice guidelines such as, bu	ut not limited to, those of
40	the National Comp	rehensive Cance	r Network or the American Society of	of Clinical Oncology, and
41	consensus stateme	ents: <i>Provided</i> , Th	hat any treatment provided in accord	dance with such practice
42	guidelines is limite	d to the use of dru	ugs and tests approved or cleared by	/ the FDA.
43	(2) Nothing	in this section sh	nall require coverage of biomarker to	esting for the purpose of
44	screening an indivi	dual prior to recei	ving a diagnosis of a disease or cond	lition for which biomarker
45	testing is appropria	<u>ite.</u>		
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including			
47	the need for multiple biopsies or biospecimen samples.			
48	(4) The Public Employees Insurance Agency may require that biomarker testing be subject			
49	to prior authorization in accordance with §33-16-3dd.			
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily			
51	accessible, and c	onvenient proces	ss to request an exception to a co	overage policy provided
52	pursuant to the provisions of this section. The process shall be made readily accessible on the			eadily accessible on the
53	website of the insu	rer.		
		CHAPT	ER 9. HUMAN SERVICES.	
	ARTICLE	5.	MISCELLANEOUS	PROVISIONS.
	<u>§9-5-34.</u>		Biomarker	testing.
1	(a) As used	I in this section:		
2	(1) "Biomarker": means a characteristic that is objectively measured and evaluated as a			
3	indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to			acologic 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	<u>clinical care;</u>
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	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.

30	(b)(1) The Bureau for Medical Services shall provide coverage for biomarker testing for the
31	purposes of precision diagnosis, treatment, appropriate management, or ongoing monitoring of a
32	covered person's disease or condition when supported by medical and scientific evidence,
33	including, but not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
41	consensus statements: Provided, That any treatment provided in accordance with such practice
42	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
45	testing is appropriate.
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including
47	the need for multiple biopsies or biospecimen samples.
48	(4) The Public Employees Insurance Agency may require that biomarker testing be subject
49	to prior authorization in accordance with §33-16-3dd.
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily
51	accessible, and convenient process to request an exception to a coverage policy provided
52	pursuant to the provisions of this section. The process shall be made readily accessible on the
53	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 thi	s section:			
2	<u>(1) "Bio</u>	omarker": r	means a characteris	tic that is obje	ectively measured a	nd evaluated as an
3	indicator of no	rmal biolo	gic processes, path	ogenic proces	sses, or pharmacolo	ogic responses to a
4	specific therap	peutic inter	vention, including k	nown gene-d	rug interactions for	medications being
5	considered fo	r use or	already being admi	nistered; and	l includes but is n	ot limited to gene
6	mutations, cha	aracteristic	s of genes and prote	ein expressior	<u>ı;</u>	
7	<u>(2) "B</u>	iomarker 1	testing": means the	e analysis o	f a patient's tissue	e, blood, or other
8	biospecimen f	or the pre	sence of a biomark	er; and includ	des but is not limite	ed to single-analyte
9	tests, multiple	x panel te	sts, protein express	sion, and who	ole exome, whole g	enome, and whole
10	transcriptome	<u>sequencin</u>	<u>g:</u>			
11	<u>(3) "Cc</u>	nsensus s	tatements" means s	tatements tha	at are:	
12	(A) De	veloped by	an independent, mu	ultidisciplinary	panel of experts uti	lizing a transparent
13	methodology a	and reporti	ng structure with a c	conflict of inte	rest policy;	
14	(B) Ain	ned at spe	cific clinical circumst	tances; and		
15	<u>(C) Ba</u>	sed on the	best available evid	ence for the	purpose of optimizir	ng the outcomes of
16	clinical care;					
17	<u>(4) "FD</u>	A" means	the United States F	ood and Drug	Administration; and	<u>d</u>
18	<u>(5) "Na</u>	ationally re	ecognized clinical p	ractice guide	lines" means evide	ence-based clinical
19	practice guide	lines that:				
20	(A) Are	develope	d by an independent	organization	or medical professio	onal society utilizing
21	a transparent	methodolo	ogy and reporting st	ructure with a	a conflict of interest	policy and include
22	recommendati	ions intend	led to optimize care;			
23	(B) Est	tablish star	ndards of care inforn	ned by:		
24	<u>(i) A sy</u>	stematic r	eview of evidence; a	<u>ınd</u>		

25	(ii) An assessment of the benefits and risks of alternative care options.
26	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
41	consensus statements: Provided, That any treatment provided in accordance with such practice
42	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
45	testing is appropriate.
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including
47	the need for multiple biopsies or biospecimen samples.
48	(4) The health insurers may require that biomarker testing be subject to prior authorization
49	in accordance with §33-16-3dd.

50	(5) The covered person and prescribing practitioner shall have access to a clear, readily				
51	accessible, and convenient process to request an exception to a coverage policy provided				
52	pursuant to the provisions of this section. The process shall be made readily accessible on the				
53	website of the insurer				
	ARTICLE 16. GROUP ACCIDENT AND SICKNESS INSURANCE.				
	§33-16-3aa. 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	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
41	consensus statements: Provided, That any treatment provided in accordance with such practice
42	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
45	testing is appropriate.

16	(3) The coverage shall be provided in a manner that shall limit disruptions in care including			
17	the need for multiple biopsies or biospecimen samples.			
18	(4) The health insurers may require that biomarker testing be subject to prior authorization			
19	in accordance with §33-16-3dd.			
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily			
51	accessible, and convenient process to request an exception to a coverage policy provided			
52	pursuant to the provisions of this section. The process shall be made readily accessible on the			
53	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	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or

39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of				
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and				
41	consensus state	ements: <i>Provide</i>	ed, That any treatme	nt provided in acco	ordance with such practice
42	guidelines is lim	nited to the use o	of drugs and tests ap	proved or cleared	by the FDA.
43	(2) Noth	ing in this section	on shall require cove	erage of biomarker	testing for the purpose of
44	screening an inc	<u>dividual prior to r</u>	eceiving a diagnosis	of a disease or co	ndition for which biomarker
45	testing is appro	<u>priate.</u>			
46	(3) The	coverage shall b	e provided in a manı	ner that shall limit d	isruptions in care including
47	the need for mu	Itiple biopsies o	r biospecimen samp	<u>les.</u>	
48	(4) The health insurers may require that biomarker testing be subject to prior authorization				ubject to prior authorization
49	in accordance with §33-16-3dd.				
50	(5) The	covered person	and prescribing pra	ctitioner shall have	e access to a clear, readily
51	accessible, and	l convenient pr	ocess to request a	n exception to a	coverage policy provided
52	pursuant to the	provisions of th	nis section. The prod	ess shall be made	readily accessible on the
53	website		of	the	insurer.
	ARTICLE	25.	HEALTH	CARE	CORPORATIONS.
	§33-25-8v.		Bioma	ker	testing.
1	<u>(a) As u</u>	sed in this section	on:		
2	<u>(1) "Bior</u>	narker": means	a characteristic that	is objectively mea	sured 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, char	acteristics of ger	nes and protein exp	ression;	
7	(2) "Bio	marker testing"	': means the anal	sis of a patient's	s tissue, blood, or other
8	biospecimen fo	r the presence	of a biomarker; and	includes but is no	ot 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	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.
30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;

4	specific therape	eutic inter	vention, includi	ng known gene-drug	interactions for medicati	ons being
3	indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a					
2	(1) "Biomarker": means a characteristic that is objectively measured and evaluated as ar					
1	(a) As u	sed in this	s section:			
	§33-25A-8y.			Biomarker		testing.
	ARTICLE	25A.	HEALTH	MAINTENANCE	ORGANIZATION	ACT.
53	website		of		the	insurer.
52	pursuant to the provisions of this section. The process shall be made readily accessible on the				ble on the	
51	accessible, and convenient process to request an exception to a coverage policy provided					<u>provided</u>
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily					ar, readily
49	in accordance with §33-16-3dd.					
48	(4) The health insurers may require that biomarker testing be subject to prior authorization					thorization
47	the need for multiple biopsies or biospecimen samples.					
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including					e including
45	testing is appropriate.					
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarke					
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose o					
42	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.					
41	consensus statements: Provided, That any treatment provided in accordance with such practice					h practice
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, an					
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those					
38	Medicare administrative contractor local coverage determinations; or					
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and					ations and
36	(C) Warnings and precautions on FDA-approved drug labels;					
35	(B) Indicated tests for an FDA-approved drug;					

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	(6) "Precision diagnosis" means the use of biomarker testing after a covered individual has
27	received a medical diagnosis of a disease or condition for which biomarker testing is appropriate.
28	(7) "Prior authorization" means obtaining advanced approval from a health insurer about
29	the coverage of a service or medication.

30	(b)(1) The health insurers shall provide coverage for biomarker testing for the purposes of
31	precision diagnosis, treatment, appropriate management, or ongoing monitoring of a covered
32	person's disease or condition when supported by medical and scientific evidence, including, but
33	not limited to:
34	(A) Labeled indications for a test approved or cleared by the FDA;
35	(B) Indicated tests for an FDA-approved drug;
36	(C) Warnings and precautions on FDA-approved drug labels;
37	(D) Centers for Medicare and Medicaid Services national coverage determinations and
38	Medicare administrative contractor local coverage determinations; or
39	(E) Nationally recognized clinical practice guidelines such as, but not limited to, those of
40	the National Comprehensive Cancer Network or the American Society of Clinical Oncology, and
41	consensus statements: Provided, That any treatment provided in accordance with such practice
42	guidelines is limited to the use of drugs and tests approved or cleared by the FDA.
43	(2) Nothing in this section shall require coverage of biomarker testing for the purpose of
44	screening an individual prior to receiving a diagnosis of a disease or condition for which biomarker
45	testing is appropriate.
46	(3) The coverage shall be provided in a manner that shall limit disruptions in care including
47	the need for multiple biopsies or biospecimen samples.
48	(4) The health insurers may require that biomarker testing be subject to prior authorization
49	in accordance with §33-16-3dd.
50	(5) The covered person and prescribing practitioner shall have access to a clear, readily
51	accessible, and convenient process to request an exception to a coverage policy provided
52	pursuant to the provisions of this section. The process shall be made readily accessible on the
53	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.