1	HOUSE BILL
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2	55TH LEGISLATURE - STATE OF NEW MEXICO - SECOND SESSION, 2022
3	INTRODUCED BY
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0 7	DISCUSSION DRAFT
8	FOR THE LEGISLATIVE HEALTH AND HUMAN SERVICES COMMITTEE
9 10	AN ACT
11	RELATING TO HEALTH INSURANCE COVERAGE; ENACTING SECTIONS OF THE
12	HEALTH CARE PURCHASING ACT, THE PUBLIC ASSISTANCE ACT, THE NEW
13	MEXICO INSURANCE CODE, THE HEALTH MAINTENANCE ORGANIZATION LAW
14	AND THE NONPROFIT HEALTH CARE PLAN LAW TO REQUIRE COVERAGE OF
15	BIOMARKER TESTING.
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17	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:
18	SECTION 1. A new section of the Health Care Purchasing
19	Act is enacted to read:
20	"[ <u>NEW MATERIAL</u> ] BIOMARKER TESTING INSURER COVERAGE
21	A. Group health coverage, including self-insurance,
22	offered, issued, amended, delivered or renewed under the Health
23	Care Purchasing Act shall provide coverage for insureds to
24	receive biomarker testing.
25	B. Coverage provided pursuant to this section
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1 shall be for the purposes of diagnosis, treatment, appropriate 2 management or ongoing monitoring of an insured's disease or 3 condition when the test is supported by medical and scientific evidence, including: 4 labeled indications for a United States 5 (1)food and drug administration-approved or -cleared test or 6 7 indicated tests for a United States food and drug administration-approved drug; 8 federal centers for medicare and medicaid 9 (2) services national coverage determinations and medicare 10 administrative contractor local coverage determinations; or 11 12 (3) nationally recognized clinical practice guidelines and consensus statements. 13 14 C. An insurer providing coverage for biomarker testing pursuant to this section shall ensure that: 15 (1) coverage is provided in a manner that 16 limits disruptions in care, including coverage for multiple 17 biopsies or biospecimen samples; and 18 19 (2) a patient and a practitioner who 20 prescribes biomarker testing have clear, accessible and convenient processes to request an exception to a coverage 21 policy of a health insurer and that those processes are 22 accessible on the insurer's website. 23 Coverage for biomarker testing may be subject to D. 24 deductibles and coinsurance consistent with those imposed on 25 .221342.3

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1 other benefits under the same group health care coverage, 2 including any form of self-insurance. As used in this section: 3 Ε. "biomarker" means a characteristic that is 4 (1)5 objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic 6 7 responses to a specific therapeutic intervention and includes 8 gene mutations or protein expressions; 9 (2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence 10 of a biomarker and includes single-analyte tests, multi-plex 11 12 panel tests and whole genome sequencing; "consensus statements" means statements (3) 13 14 that are: developed by an independent, (a) 15 multidisciplinary panel of experts using a transparent 16 methodology and reporting structure and with a conflict-of-17 interest policy; and 18 aimed at specific clinical 19 (b) 20 circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care; and 21 (4) "nationally recognized clinical practice 22 guidelines" means evidence-based clinical practice guidelines 23 that are: 24 developed by independent 25 (a) .221342.3 - 3 -

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1 organizations or medical professional societies using a 2 transparent methodology and reporting structure and with a 3 conflict-of-interest policy; and (b) used to establish standards of care 4 informed by a systematic review of evidence and an assessment 5 of the benefits and costs of alternative care options and 6 7 include recommendations intended to optimize patient care." SECTION 2. A new section of the Public Assistance Act is 8 9 enacted to read: 10 "[NEW MATERIAL] BIOMARKER TESTING COVERAGE.--In accordance with federal law, the secretary 11 Α. 12 shall adopt and promulgate rules that provide medical 13 assistance coverage for enrollees to receive biomarker testing. 14 B. A medical assistance plan providing coverage pursuant to this section shall be for the purposes of 15 diagnosis, treatment, appropriate management or ongoing 16 monitoring of an enrollee's disease or condition when the test 17 18 is supported by medical and scientific evidence, including: 19 (1)labeled indications for a United States 20 food and drug administration-approved or -cleared test or indicated tests for a United States food and drug 21 administration-approved drug; 22 federal centers for medicare and medicaid 23 (2) services national coverage determinations and medicare 24 25 administrative contractor local coverage determinations; or .221342.3 - 4 -

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1 nationally recognized clinical practice (3) 2 guidelines and consensus statements.

Medicaid contractors delivering services to 3 C. enrollees shall provide biomarker testing at the same scope, 4 duration and frequency as the medical assistance plan otherwise 5 provides to enrollees. 6

D. A medical assistance plan providing coverage for biomarker testing pursuant to this section shall ensure that:

9 (1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple 10 biopsies or biospecimen samples; and 11

12 (2) a patient and a practitioner who prescribes biomarker testing have clear, readily accessible and convenient processes to request an exception to a coverage policy of a health insurer and that those processes are accessible on the medical assistance division of the department's website.

> As used in this section: Ε.

"biomarker" means a characteristic that is (1)objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention, including gene mutations or protein expressions;

"biomarker testing" means analysis of a (2) patient's tissue, blood or other biospecimen for the presence .221342.3 - 5 -

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1	of a biomarker and includes single-analyte tests, multi-plex
2	panel tests and whole genome sequencing;
3	(3) "consensus statements" means statements
4	that are:
5	(a) developed by an independent,
6	multidisciplinary panel of experts using a transparent
7	methodology and reporting structure and with a conflict-of-
8	interest policy; and
9	(b) aimed at specific clinical
10	circumstances and based on the best available evidence for the
11	purpose of optimizing the outcomes of clinical care; and
12	(4) "nationally recognized clinical practice
13	guidelines" means evidence-based clinical practice guidelines
14	that are:
15	(a) developed by independent
16	organizations or medical professional societies using a
17	transparent methodology and reporting structure and with a
18	conflict-of-interest policy; and
19	(b) used to establish standards of care
20	informed by a systematic review of evidence and an assessment
21	of the benefits and costs of alternative care options and
22	include recommendations intended to optimize patient care."
23	SECTION 3. A new section of Chapter 59A, Article 23 NMSA
24	1978 is enacted to read:
25	"[ <u>NEW MATERIAL</u> ] BIOMARKER TESTING COVERAGE
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1 A blanket or group health insurance policy, Α. 2 health care plan or certificate of health insurance that is 3 delivered, issued for delivery or renewed in this state shall provide coverage for insureds to receive biomarker testing. 4 5 Β. Coverage provided pursuant to this section shall be for the purposes of diagnosis, treatment, appropriate 6 7 management or ongoing monitoring of an insured's disease or condition when the test is supported by medical and scientific 8 9 evidence, including: labeled indications for a United States 10 (1)food and drug administration-approved or -cleared test or 11 12 indicated tests for a United States food and drug administration-approved drug; 13 federal centers for medicare and medicaid 14 (2) services national coverage determinations and medicare 15 administrative contractor local coverage determinations; or 16 (3) nationally recognized clinical practice 17 guidelines and consensus statements. 18 C. 19 A blanket or group health policy, health care 20 plan or certificate of health insurance providing coverage for biomarker testing pursuant to this section shall ensure that: 21 coverage is provided in a manner that (1)22 limits disruptions in care, including coverage for multiple 23 biopsies or biospecimen samples; and 24 a patient and a practitioner who 25 (2) .221342.3 - 7 -

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prescribes biomarker testing have clear, accessible and convenient processes to request an exception to a coverage policy of a health insurer and that those processes are accessible on the insurer's website.

D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same policy, plan or certificate.

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E. As used in this section:

9 (1) "biomarker" means a characteristic that is
10 objectively measured and evaluated as an indicator of normal
11 biological processes, pathogenic processes or pharmacologic
12 responses to a specific therapeutic intervention and includes
13 gene mutations or protein expressions;

(2) "biomarker testing" means analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex panel tests and whole genome sequencing;

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

(a) developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict-ofinterest policy; and

(b) aimed at specific clinical circumstances and based on the best available evidence for the .221342.3

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1	purpose of optimizing the outcomes of clinical care; and
2	(4) "nationally recognized clinical practice
3	guidelines" means evidence-based clinical practice guidelines
4	that are:
5	(a) developed by independent
6	organizations or medical professional societies using a
7	transparent methodology and reporting structure and with a
8	conflict-of-interest policy; and
9	(b) used to establish standards of care
10	informed by a systematic review of evidence and an assessment
11	of the benefits and costs of alternative care options and
12	include recommendations intended to optimize patient care."
13	SECTION 4. A new section of the Health Maintenance
14	Organization Law is enacted to read:
15	"[ <u>NEW MATERIAL</u> ] BIOMARKER TESTING COVERAGE
16	A. An individual or group health maintenance
17	organization contract that is delivered, issued for delivery or
18	renewed in this state shall provide coverage for eligible
19	enrollees to receive biomarker testing.
20	B. Coverage provided pursuant to this section
21	shall be for the purposes of diagnosis, treatment, appropriate
22	management or ongoing monitoring of an enrollee's disease or
23	condition when the test is supported by medical and scientific
24	evidence, including:
25	(1) labeled indications for a United States
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1 food and drug administration-approved or -cleared test or 2 indicated tests for a United States food and drug 3 administration-approved drug; federal centers for medicare and medicaid 4 (2) 5 services national coverage determinations and medicare administrative contractor local coverage determinations; or 6 7 (3) nationally recognized clinical practice guidelines and consensus statements. 8 9 C. A health maintenance organization contract providing coverage for biomarker testing pursuant to this 10 section shall ensure that: 11 12 (1) coverage is provided in a manner that limits disruptions in care, including coverage for multiple 13 14 biopsies or biospecimen samples; and a patient and a practitioner who 15 (2) prescribes biomarker testing have clear, accessible and 16 convenient processes to request an exception to a coverage 17 policy of a carrier and that those processes are accessible on 18 the carrier's website. 19 20 D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on 21 other benefits under the same contract. 22 Ε. As used in this section: 23 "biomarker" means a characteristic that is (1)24 objectively measured and evaluated as an indicator of normal 25 .221342.3 - 10 -

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1 biological processes, pathogenic processes or pharmacologic 2 responses to a specific therapeutic intervention and includes 3 gene mutations or protein expression; (2) "biomarker testing" means analysis of a 4 5 patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex 6 7 panel tests and whole genome sequencing; "consensus statements" means statements 8 (3) 9 that are: developed by an independent, 10 (a) multidisciplinary panel of experts using a transparent 11 12 methodology and reporting structure and with a conflict-ofinterest policy; and 13 aimed at specific clinical 14 (b) circumstances and based on the best available evidence for the 15 purpose of optimizing the outcomes of clinical care; and 16 "nationally recognized clinical practice 17 (4) guidelines" means evidence-based clinical practice guidelines 18 19 that are: 20 (a) developed by independent organizations or medical professional societies using a 21 transparent methodology and reporting structure and with a 22 conflict-of-interest policy; and 23 (b) used to establish standards of care 24 informed by a systematic review of evidence and an assessment 25 .221342.3 - 11 -

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of the benefits and costs of alternative care options and include recommendations intended to optimize patient care."

SECTION 5. A new section of the Nonprofit Health Care Plan Law is enacted to read:

"[<u>NEW MATERIAL</u>] BIOMARKER TESTING COVERAGE .--

A. An individual or group health care plan that is delivered, issued for delivery or renewed in this state shall provide coverage for subscribers to receive biomarker testing.

B. Coverage provided pursuant to this section shall be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a subscriber's disease or condition when the test is supported by medical and scientific evidence, including:

(1) labeled indications for a United States food and drug administration-approved or -cleared test or indicated tests for a United States food and drug administration-approved drug;

(2) federal centers for medicare and medicaid services national coverage determinations and medicare administrative contractor local coverage determinations; or

(3) nationally recognized clinical practice guidelines and consensus statements.

C. Health care plans providing coverage for biomarker testing pursuant to this section shall ensure that:

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(1) coverage is provided in a manner that

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1 limits disruptions in care, including coverage for multiple 2 biopsies or biospecimen samples; and 3 a patient and a practitioner who (2) prescribes biomarker testing have clear, accessible and 4 5 convenient processes to request an exception to a coverage policy of a health care plan and that those processes are 6 7 accessible on the health care plan's website. 8 D. Coverage for biomarker testing may be subject to 9 deductibles and coinsurance consistent with those imposed on other benefits under the same policy, plan or certificate. 10 As used in this section: Ε. 11 12 (1)"biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal 13 14 biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention and includes 15 gene mutations or protein expressions; 16 "biomarker testing" means analysis of a 17 (2) patient's tissue, blood or other biospecimen for the presence 18 of a biomarker and includes single-analyte tests, multi-plex 19 20 panel tests and whole genome sequencing; "consensus statements" means statements (3) 21 that are: 22 (a) developed by an independent, 23 multidisciplinary panel of experts using a transparent 24 methodology and reporting structure and with a conflict-of-25 .221342.3 - 13 -

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1	interest policy; and
2	(b) aimed at specific clinical
3	circumstances and based on the best available evidence for the
4	purpose of optimizing the outcomes of clinical care; and
5	(4) "nationally recognized clinical practice
6	guidelines" means evidence-based clinical practice guidelines
7	that are:
8	(a) developed by independent
9	organizations or medical professional societies using a
10	transparent methodology and reporting structure and with a
11	conflict-of-interest policy; and
12	(b) used to establish standards of care
13	informed by a systematic review of evidence and an assessment
14	of the benefits and costs of alternative care options and
15	include recommendations intended to optimize patient care."
16	SECTION 6. APPLICABILITYThe provisions of this act
17	apply to health insurance policies, health care plans,
18	certificates of health insurance or health maintenance
19	organization contracts that are delivered, issued for delivery
20	or renewed in this state on or after January 1, 2023.
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