1 AN ACT 2 RELATING TO HEALTH INSURANCE COVERAGE; ENACTING SECTIONS OF 3 THE HEALTH CARE PURCHASING ACT, THE PUBLIC ASSISTANCE ACT, THE NEW MEXICO INSURANCE CODE, THE HEALTH MAINTENANCE 4 5 ORGANIZATION LAW AND THE NONPROFIT HEALTH CARE PLAN LAW TO 6 REQUIRE COVERAGE OF BIOMARKER TESTING. 7 8 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO: SECTION 1. A new section of the Health Care Purchasing 9 Act is enacted to read: 10 "BIOMARKER TESTING INSURER COVERAGE. --11 Group health coverage, including self-12 Α. insurance, offered, issued, amended, delivered or renewed 13 under the Health Care Purchasing Act shall provide coverage 14 15 for insureds to receive biomarker testing. 16 B. Coverage provided pursuant to this section shall be for the purposes of diagnosis, treatment, 17 appropriate management or ongoing monitoring of an insured's 18 disease or condition when the test is supported by medical 19 20 and scientific evidence, including: labeled indications for a United States (1)21 food and drug administration-approved or -cleared test; 22 (2)indicated tests for a United States food 23 and drug administration-approved drug; 24 (3) warnings and precautions on United 25 HCPAC/HB 73/a Page 1

1 States food and drug administration labels; (4) federal centers for medicare and 2 3 medicaid services national coverage determinations or medicare administrative contractor local coverage 4 5 determinations; or (5) nationally recognized clinical practice 6 guidelines. 7 8 C. An insurer providing coverage for biomarker testing pursuant to this section shall ensure that: 9 (1) coverage is provided in a manner that 10 limits disruptions in care, including coverage for multiple 11 biopsies or biospecimen samples; and 12 (2) a patient and a practitioner who 13 prescribes biomarker testing have clear, accessible and 14 convenient processes to request an appeal of a benefit denial 15 by the insurer and that those processes are accessible on the 16 insurer's website. 17 Coverage for biomarker testing may be subject D. 18 to deductibles and coinsurance consistent with those imposed 19 on other benefits under the same group health care coverage, 20 including any form of self-insurance. 21 Ε. The provisions of this section do not apply to 22 accident-only or limited or specified disease policies, plans 23 or certificates of health insurance. 24 F. As used in this section: 25

1 (1)"biomarker" means a characteristic that 2 is objectively measured and evaluated as an indicator of 3 normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic 4 intervention, including known gene-drug interactions for 5 medications being considered for use or already being 6 administered. "Biomarker" includes gene mutations, 7 characteristics of genes or protein expression; 8 "biomarker testing" means analysis of a (2) 9 patient's tissue, blood or other biospecimen for the presence 10 of a biomarker and includes single-analyte tests, multi-plex 11 panel tests, protein expression and whole exome, whole genome 12 and whole transcriptome sequencing; and 13 (3) "nationally recognized clinical practice 14 guidelines" means evidence-based clinical practice guidelines 15 that are: 16 (a) developed by independent 17 organizations or medical professional societies using a 18 transparent methodology and reporting structure and with a 19 conflict-of-interest policy; and 20 (b) used to establish standards of care 21 informed by a systematic review of evidence and an assessment 22 of the benefits and risks of alternative care options and 23 include recommendations intended to optimize patient care." 24 SECTION 2. A new section of the Public Assistance Act 25 HCPAC/HB 73/a Page 3

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is enacted to read:

"BIOMARKER TESTING COVERAGE.--

A. In accordance with federal law, the secretary shall adopt and promulgate rules that provide medical assistance coverage for enrollees to receive biomarker testing.

B. A medical assistance plan providing coverage
pursuant to this section shall be for the purposes of
diagnosis, treatment, appropriate management or ongoing
monitoring of an enrollee's disease or condition when the
test is supported by medical and scientific evidence,
including:

(1) labeled indications for a United Statesfood and drug administration-approved or -cleared test;

(2) indicated tests for a United States food and drug administration-approved drug;

7 (3) warnings and precautions on United
8 States food and drug administration labels;

19 (4) federal centers for medicare and 20 medicaid services national coverage determinations or 21 medicare administrative contractor local coverage 22 determinations; or

23 (5) nationally recognized clinical practice 24 guidelines.

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C. Medicaid contractors delivering services to

1 enrollees shall provide biomarker testing at the same scope, 2 duration and frequency as the medical assistance plan 3 otherwise provides to enrollees.

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

(1) coverage is provided in a manner that 7 8 limits disruptions in care, including coverage for multiple biopsies or biospecimen samples; and 9

(2) a patient and a practitioner who 10 prescribes biomarker testing have clear, readily accessible 11 and convenient processes to request an appeal of a benefit 12 denial by the insurer and that those processes are accessible 13 on the medical assistance division of the department's 14 website. 15

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E. As used in this section:

"biomarker" means a characteristic that (1)17 is objectively measured and evaluated as an indicator of 18 normal biological processes, pathogenic processes or 19 pharmacologic responses to a specific therapeutic 20 intervention, including known gene-drug interactions for 21 medications being considered for use or already being 22 administered. "Biomarker" includes gene mutations, 23 characteristics of genes or protein expression; 24 "biomarker testing" means analysis of a (2)

1 patient's tissue, blood or other biospecimen for the presence 2 of a biomarker and includes single-analyte tests, multi-plex 3 panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing; and 4 "nationally recognized clinical practice 5 (3) guidelines" means evidence-based clinical practice guidelines 6 that are: 7 8 (a) developed by independent organizations or medical professional societies using a 9 transparent methodology and reporting structure and with a 10 conflict-of-interest policy; and 11 (b) used to establish standards of care 12 informed by a systematic review of evidence and an assessment 13 of the benefits and risks of alternative care options and 14 include recommendations intended to optimize patient care." 15 SECTION 3. A new section of Chapter 59A, Article 22 16 NMSA 1978 is enacted to read: 17 "BIOMARKER TESTING COVERAGE. --18 A. An individual or group health insurance policy, 19 health care plan or certificate of health insurance that is 20 delivered, issued for delivery or renewed in this state shall 21 provide coverage for insureds to receive biomarker testing 22 for the purposes of diagnosis, treatment, appropriate 23 management or ongoing monitoring of an insured's disease or 24 condition when the test is supported by medical and 25

1 scientific evidence.

2 B. Coverage provided pursuant to this section 3 shall be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's 4 disease or condition when the test is supported by medical 5 and scientific evidence, including: 6 labeled indications for a United States (1)7 8 food and drug administration-approved or -cleared test; (2) indicated tests for a United States food 9 and drug administration-approved drug; 10 (3) warnings and precautions on United 11 States food and drug administration labels; 12 (4) federal centers for medicare and 13 medicaid services national coverage determinations or 14 medicare administrative contractor local coverage 15 determinations; or 16 (5) nationally recognized clinical practice 17 guidelines. 18 C. An individual or group health policy, health 19 care plan or certificate of health insurance providing 20 coverage for biomarker testing pursuant to this section shall 21 ensure that: 22 (1) coverage is provided in a manner that 23 limits disruptions in care, including coverage for multiple 24 biopsies or biospecimen samples; and 25

1 a patient and a practitioner who (2) 2 prescribe biomarker testing have clear, accessible and 3 convenient processes to request an appeal of a benefit denial by the insurer and that those processes are accessible on the 4 insurer's website. 5 D. Coverage for biomarker testing may be subject 6 to deductibles and coinsurance consistent with those imposed 7 on other benefits under the same policy, plan or certificate. 8 The provisions of this section do not apply to Ε. 9 short-term travel, accident-only or limited or specified 10 disease policies, plans or certificates of health insurance. 11 F. As used in this section: 12 "biomarker" means a characteristic that (1)13 is objectively measured and evaluated as an indicator of 14 normal biological processes, pathogenic processes or 15 pharmacologic responses to a specific therapeutic 16 intervention, including known gene-drug interactions for 17 medications being considered for use or already being 18 administered. "Biomarker" includes gene mutations, 19 characteristics of genes or protein expression; 20 "biomarker testing" means analysis of a (2) 21 patient's tissue, blood or other biospecimen for the presence 22 of a biomarker and includes single-analyte tests, multi-plex 23 panel tests, protein expression and whole exome, whole genome 24 and whole transcriptome sequencing; and 25

1 "nationally recognized clinical practice (3) 2 guidelines" means evidence-based clinical practice guidelines 3 that are: (a) developed by independent 4 organizations or medical professional societies using a 5 transparent methodology and reporting structure and with a 6 conflict-of-interest policy; and 7 8 (b) used to establish standards of care informed by a systematic review of evidence and an assessment 9 of the benefits and risks of alternative care options and 10 include recommendations intended to optimize patient care." 11 SECTION 4. A new section of Chapter 59A, Article 23 12 NMSA 1978 is enacted to read: 13 "BIOMARKER TESTING COVERAGE. --14 A. A blanket or group health insurance policy, 15 health care plan or certificate of health insurance that is 16 delivered, issued for delivery or renewed in this state shall 17 provide coverage for insureds to receive biomarker testing. 18 B. Coverage provided pursuant to this section 19 shall be for the purposes of diagnosis, treatment, 20 appropriate management or ongoing monitoring of an insured's 21 disease or condition when the test is supported by medical 22 and scientific evidence, including: 23 labeled indications for a United States (1)24 food and drug administration-approved or -cleared test; 25

indicated tests for a United States food 1 (2)2 and drug administration-approved drug; 3 (3) warnings and precautions on United States food and drug administration labels; 4 (4) federal centers for medicare and 5 medicaid services national coverage determinations or 6 medicare administrative contractor local coverage 7 8 determinations; or (5) nationally recognized clinical practice 9 guidelines. 10 C. A blanket or group health policy, health care 11 plan or certificate of health insurance providing coverage 12 for biomarker testing pursuant to this section shall ensure 13 that: 14 (1) coverage is provided in a manner that 15 limits disruptions in care, including coverage for multiple 16 biopsies or biospecimen samples; and 17 a patient and a practitioner who (2) 18 prescribes biomarker testing have clear, accessible and 19 convenient processes to request an appeal of a benefit denial 20 by the insurer and that those processes are accessible on the 21 insurer's website. 22 D. Coverage for biomarker testing may be subject 23 to deductibles and coinsurance consistent with those imposed 24 on other benefits under the same policy, plan or certificate. 25 HCPAC/HB 73/a

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1 Ε. The provisions of this section do not apply to 2 accident-only or limited or specified disease policies, plans 3 or certificates of health insurance. F. As used in this section: 4 "biomarker" means a characteristic that 5 (1)is objectively measured and evaluated as an indicator of 6 normal biological processes, pathogenic processes or 7 pharmacologic responses to a specific therapeutic 8 intervention, including known gene-drug interactions for 9 medications being considered for use or already being 10 "Biomarker" includes gene mutations, administered. 11 characteristics of genes or protein expression; 12 "biomarker testing" means analysis of a (2) 13 patient's tissue, blood or other biospecimen for the presence 14 of a biomarker and includes single-analyte tests, multi-plex 15 panel tests, protein expression and whole exome, whole genome 16 and whole transcriptome sequencing; and 17 "nationally recognized clinical practice (3) 18 guidelines" means evidence-based clinical practice guidelines 19 that are: 20 (a) developed by independent 21 organizations or medical professional societies using a 22 transparent methodology and reporting structure and with a 23 conflict-of-interest policy; and 24 (b) used to establish standards of care  $_{\rm HCPAC/HB}$  73/a 25 Page 11

informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care."

**SECTION 5.** A new section of the Health Maintenance Organization Law is enacted to read:

"BIOMARKER TESTING COVERAGE.--

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A. An individual or group health maintenance 8 organization contract that is delivered, issued for delivery or renewed in this state shall provide coverage for eligible enrollees to receive biomarker testing.

Β. Coverage provided pursuant to this section 11 shall be for the purposes of diagnosis, treatment, 12 appropriate management or ongoing monitoring of an enrollee's 13 disease or condition when the test is supported by medical 14 and scientific evidence, including: 15

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

indicated tests for a United States food (2) 18 and drug administration-approved drug; 19

(3) warnings and precautions on United 20 States food and drug administration labels; 21

(4) federal centers for medicare and 22 medicaid services national coverage determinations or 23 medicare administrative contractor local coverage 24 determinations; or 25

1 (5) nationally recognized clinical practice
2 guidelines.

C. A health maintenance organization contract providing coverage for biomarker testing pursuant to this section shall ensure that:

(1) coverage is provided in a manner thatlimits disruptions in care, including coverage for multiplebiopsies or biospecimen samples; and

9 (2) a patient and a practitioner who
10 prescribes biomarker testing have clear, accessible and
11 convenient processes to request an appeal of a benefit denial
12 by the carrier and that those processes are accessible on the
13 carrier's website.

D. Coverage for biomarker testing may be subject to deductibles and coinsurance consistent with those imposed on other benefits under the same contract.

E. The provisions of this section do not apply to accident-only or limited or specified disease policies, plans or certificates of health insurance.

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F. As used in this section:

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

1 medications being considered for use or already being 2 administered. "Biomarker" includes gene mutations, 3 characteristics of genes or protein expression; "biomarker testing" means analysis of a (2) 4 5 patient's tissue, blood or other biospecimen for the presence of a biomarker and includes single-analyte tests, multi-plex 6 panel tests, protein expression and whole exome, whole genome 7 and whole transcriptome sequencing; and 8 "nationally recognized clinical practice (3) 9 guidelines" means evidence-based clinical practice guidelines 10 that are: 11 (a) developed by independent 12 organizations or medical professional societies using a 13 transparent methodology and reporting structure and with a 14 conflict-of-interest policy; and 15 (b) used to establish standards of care 16 informed by a systematic review of evidence and an assessment 17 of the benefits and risks of alternative care options and 18 include recommendations intended to optimize patient care." 19 SECTION 6. A new section of the Nonprofit Health Care 20 Plan Law is enacted to read: 21 "BIOMARKER TESTING COVERAGE. --22 Α. An individual or group health care plan that is 23 delivered, issued for delivery or renewed in this state shall 24 provide coverage for subscribers to receive biomarker 25 HCPAC/HB 73/a Page 14

testing.

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2 Coverage provided pursuant to this section Β. 3 shall be for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a 4 subscriber's disease or condition when the test is supported 5 by medical and scientific evidence, including: 6 labeled indications for a United States (1)7 8 food and drug administration-approved or -cleared test; (2) indicated tests for a United States food 9 and drug administration-approved drug; 10 (3) warnings and precautions on United 11 States food and drug administration labels; 12 (4) federal centers for medicare and 13 medicaid services national coverage determinations or 14 medicare administrative contractor local coverage 15 determinations; or 16 (5) nationally recognized clinical practice 17 guidelines. 18 C. Health care plans providing coverage for 19 biomarker testing pursuant to this section shall ensure that: 20 (1) coverage is provided in a manner that 21 limits disruptions in care, including coverage for multiple 22 biopsies or biospecimen samples; and 23 a patient and a practitioner who (2) 24 prescribes biomarker testing have clear, accessible and 25

convenient processes to request an appeal of a benefit denial by the health care plan and that those processes are accessible on the health care plan's website.

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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.

E. The provisions of this section do not apply to short-term travel, accident-only or limited or specified disease policies, plans or certificates of health insurance.

F. As used in this section:

"biomarker" means a characteristic that (1)11 is objectively measured and evaluated as an indicator of 12 normal biological processes, pathogenic processes or 13 pharmacologic responses to a specific therapeutic 14 intervention, including known gene-drug interactions for 15 medications being considered for use or already being 16 administered. "Biomarker" includes gene mutations, 17 characteristics of genes or protein expression; 18

(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, protein expression and whole exome, whole genome
and whole transcriptome sequencing; and

(3) "nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines

1	that are:	
2	(a) developed by independent	
3	organizations or medical professional societies using a	
4	transparent methodology and reporting structure and with a	
5	conflict-of-interest policy; and	
6	(b) used to establish standards of care	
7	informed by a systematic review of evidence and an assessment	
8	of the benefits and risks of alternative care options and	
9	include recommendations intended to optimize patient care."	
10	SECTION 7. APPLICABILITYThe provisions of this act	
11	apply to health insurance policies, health care plans,	
12	certificates of health insurance or health maintenance	
13	organization contracts that are delivered, issued for delivery	
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14	or renewed in this state on or after January 1, 2024 H	HCPAC/HB 73/a
	or renewed in this state on or after January 1, 2024 H	HCPAC/HB 73/a Page 17
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