State of Arizona
House of Representatives
Fifty-fifth Legislature
Second Regular Session
2022

CHAPTER 219

HOUSE BILL 2144

AN ACT

AMENDING TITLE 20, CHAPTER 4, ARTICLE 3, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-841.13; AMENDING TITLE 20, CHAPTER 4, ARTICLE 9, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-1057.19; AMENDING TITLE 20, CHAPTER 6, ARTICLE 4, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-1376.10; AMENDING TITLE 20, CHAPTER 6, ARTICLE 5, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-1406.10; AMENDING TITLE 36, CHAPTER 29, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING SECTION 36-2907.03; RELATING TO HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Title 20, chapter 4, article 3, Arizona Revised Statutes, is amended by adding section 20-841.13, to read:

20-841.13. Biomarker testing; coverage; definitions

A. A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE CORPORATION THAT ISSUES, AMENDS, DELIVERS OR RENEWS A SUBSCRIPTION CONTRACT ON OR AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.

B. A SUBSCRIPTION CONTRACT SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF A SUBSCRIBER'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATIONS.

3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS STATEMENTS.

C. A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE CORPORATION MUST ENSURE THAT COVERAGE IS PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

D. THE SUBSCRIBER AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION TO A COVERAGE POLICY OF A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE CORPORATION. THE PROCESS SHALL BE READILY ACCESSIBLE ON THE HOSPITAL SERVICE CORPORATION'S OR MEDICAL SERVICE CORPORATION'S WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE HOSPITAL SERVICE CORPORATION'S OR MEDICAL SERVICE CORPORATION'S EXISTING PROCESS COMPLIES WITH THIS SUBSECTION.

E. FOR THE PURPOSES OF THIS SECTION:

1. "BIOMARKER":

(a) 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.

(b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

2. "BIOMARKER TESTING":

(a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

(b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE GENOME SEQUENCING.

3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A CLINICAL DECISION.

4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

(a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT INCLUDES A CONFLICT OF INTEREST POLICY.

(b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING CLINICAL CARE OUTCOMES.

(c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

(a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND A CONFLICT OF INTEREST POLICY.

(b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT CARE.

Sec. 2. Title 20, chapter 4, article 9, Arizona Revised Statutes, is amended by adding section 20-1057.19, to read:

20-1057.19. Biomarker testing; coverage; definitions

A. A HEALTH CARE SERVICES ORGANIZATION THAT ISSUES, AMENDS, DELIVERS OR RENEWS AN EVIDENCE OF COVERAGE ON OR AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.

B. AN EVIDENCE OF COVERAGE SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF AN ENROLLEE'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATIONS.

3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS STATEMENTS.

C. A HEALTH CARE SERVICES ORGANIZATION MUST ENSURE THAT COVERAGE IS PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

D. THE ENROLLEE AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION TO A COVERAGE POLICY OF A HEALTH CARE SERVICES ORGANIZATION. THE PROCESS SHALL BE READILY ACCESSIBLE ON THE HEALTH CARE SERVICES ORGANIZATION'S WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE HEALTH CARE SERVICES ORGANIZATION'S EXISTING PROCESS COMPLIES WITH THIS SUBSECTION.

E. FOR THE PURPOSES OF THIS SECTION:

1. "BIOMARKER":

(a) 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.

(b) INCLUDE GENE MUTATIONS OR PROTEIN EXPRESSION.

2. "BIOMARKER TESTING":

(a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

(b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE GENOME SEQUENCING.

3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A CLINICAL DECISION.

4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT BOTH:

(a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT INCLUDES A CONFLICT OF INTEREST POLICY.

(b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING CLINICAL CARE OUTCOMES.

(c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

(a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND A CONFLICT OF INTEREST POLICY.

(b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT CARE.

Sec. 3. Title 20, chapter 6, article 4, Arizona Revised Statutes, is amended by adding section 20-1376.10, to read:

20-1376.10. Biomarker testing; coverage; definitions

A. A DISABILITY INSURER THAT ISSUES, AMENDS, DELIVERS OR RENEWS A POLICY ON OR AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.

B. A POLICY SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF AN INSURED'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATIONS.

3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS STATEMENTS.

C. A DISABILITY INSURER MUST ENSURE THAT COVERAGE IS PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

D. THE INSURED AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION TO A COVERAGE POLICY OF A DISABILITY INSURER. THE PROCESS SHALL BE READILY ACCESSIBLE ON THE DISABILITY INSURER'S WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE DISABILITY INSURER'S EXISTING PROCESS COMPLIES WITH THIS SUBSECTION.

E. FOR THE PURPOSES OF THIS SECTION:

1. "BIOMARKER":

(a) 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.

(b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

2. "BIOMARKER TESTING":

(a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

(b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE GENOME SEQUENCING.

3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME

INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A CLINICAL DECISION.

4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

(a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT INCLUDES A CONFLICT OF INTEREST POLICY.

(b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING CLINICAL CARE OUTCOMES.

(c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

(a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND A CONFLICT OF INTEREST POLICY.

(b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT CARE.

Sec. 4. Title 20, chapter 6, article 5, Arizona Revised Statutes, is amended by adding section 20-1406.10, to read:

20-1406.10. Biomarker testing; coverage; definitions

A. A GROUP OR BLANKET DISABILITY INSURER THAT ISSUES, AMENDS, DELIVERS OR RENEWS A POLICY ON OR AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.

B. A POLICY SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF AN INSURED'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATIONS.

3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS STATEMENTS.

C. A GROUP OR BLANKET DISABILITY INSURER MUST ENSURE COVERAGE IS PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.

D. THE INSURED AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION TO A COVERAGE POLICY OF A GROUP OR BLANKET DISABILITY INSURER. THE PROCESS SHALL BE READILY ACCESSIBLE ON A GROUP OR BLANKET DISABILITY INSURER'S WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF

THE GROUP OR BLANKET DISABILITY INSURER'S EXISTING PROCESS COMPLIES WITH THIS SUBSECTION.

E. FOR THE PURPOSES OF THIS SECTION:

1. "BIOMARKER":

(a) 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.

(b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

2. "BIOMARKER TESTING":

(a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

(b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE GENOME SEQUENCING.

3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT INFORMS A PATIENT'S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A CLINICAL DECISION.

4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

(a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT INCLUDES A CONFLICT OF INTEREST POLICY.

(b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING CLINICAL CARE OUTCOMES.

(c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

(a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND A CONFLICT OF INTEREST POLICY.

(b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT CARE.

Sec. 5. Title 36, chapter 29, article 1, Arizona Revised Statutes, is amended by adding section 36-2907.03, to read:

36-2907.03. Biomarker testing; coverage; definitions

A. THE ADMINISTRATION AND ITS CONTRACTORS SHALL PROVIDE BIOMARKER TESTING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF A MEMBER'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST PROVIDES CLINICAL UTILITY AS DEMONSTRATED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE DETERMINATIONS.

3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS STATEMENTS.

B. THE ADMINISTRATION AND ITS CONTRACTORS SHALL PROVIDE BIOMARKER TESTING WITH THE SAME SCOPE, DURATION AND FREQUENCY AS THE SYSTEM OTHERWISE PROVIDES TO MEMBERS PURSUANT TO THIS ARTICLE.

C. THE MEMBER AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A CLEAR, READILY ACCESSIBLE AND CONVENIENT ONLINE PROCESS TO REQUEST AN EXCEPTION TO A COVERAGE POLICY OF THE SYSTEM. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE ADMINISTRATION'S AND ITS CONTRACTOR'S EXISTING PROCESS COMPLIES WITH THIS SUBSECTION. ANY REQUEST FOR A COVERAGE EXCEPTION SHALL BE SUBMITTED ELECTRONICALLY BY THE PRESCRIBING PRACTITIONER.

D. FOR THE PURPOSES OF THIS SECTION:

1. "BIOMARKER":

(a) 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.

(b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

2. "BIOMARKER TESTING":

(a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

(b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE GENOME SEQUENCING.

3. "CLINICAL UTILITY" MEANS THE TEST RESULT PROVIDES INFORMATION THAT IS USED IN THE FORMULATION OF A TREATMENT OR MONITORING STRATEGY THAT INFORMS A PATIENT’S OUTCOME AND IMPACTS THE CLINICAL DECISION. THE MOST APPROPRIATE TEST MAY INCLUDE BOTH INFORMATION THAT IS ACTIONABLE AND SOME INFORMATION THAT CANNOT BE IMMEDIATELY USED IN THE FORMULATION OF A CLINICAL DECISION.

4. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

(a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT INCLUDES A CONFLICT OF INTEREST POLICY.

(b) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

(c) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF OPTIMIZING CLINICAL CARE OUTCOMES.

5. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

(a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND A CONFLICT OF INTEREST POLICY.

(b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO OPTIMIZE PATIENT CARE.

APPROVED BY THE GOVERNOR MAY 6, 2022.

FILED IN THE OFFICE OF THE SECRETARY OF STATE MAY 6, 2022.