

House Engrossed

health insurance coverage; biomarker testing

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

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)

1 Be it enacted by the Legislature of the State of Arizona:
2 Section 1. Title 20, chapter 4, article 3, Arizona Revised
3 Statutes, is amended by adding section 20-841.13, to read:
4 20-841.13. Biomarker testing; coverage; definitions
5 A. A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE CORPORATION
6 THAT ISSUES, AMENDS, DELIVERS OR RENEWS A SUBSCRIPTION CONTRACT ON OR
7 AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.
8 B. A SUBSCRIPTION CONTRACT SHALL COVER BIOMARKER TESTING FOR THE
9 PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING
10 MONITORING OF A SUBSCRIBER'S DISEASE OR CONDITION TO GUIDE TREATMENT
11 DECISIONS WHEN THE TEST IS SUPPORTED BY MEDICAL AND SCIENTIFIC EVIDENCE,
12 INCLUDING ANY OF THE FOLLOWING:
13 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
14 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
15 DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
16 2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE
17 DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE
18 DETERMINATIONS.
19 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
20 STATEMENTS.
21 C. A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE CORPORATION
22 MUST ENSURE THAT COVERAGE IS PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS
23 IN CARE, INCLUDING THE NEED FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.
24 D. THE SUBSCRIBER AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO
25 A CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION
26 TO A COVERAGE POLICY OF A HOSPITAL SERVICE CORPORATION OR MEDICAL SERVICE
27 CORPORATION. THE PROCESS SHALL BE READILY ACCESSIBLE ON THE HOSPITAL
28 SERVICE CORPORATION'S OR MEDICAL SERVICE CORPORATION'S WEBSITE. THIS
29 SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE HOSPITAL SERVICE
30 CORPORATION'S OR MEDICAL SERVICE CORPORATION'S EXISTING PROCESS COMPLIES
31 WITH THIS SUBSECTION.
32 E. FOR THE PURPOSES OF THIS SECTION:
33 1. "BIOMARKER":
34 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
35 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
36 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
37 INTERVENTION.
38 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.
39 2. "BIOMARKER TESTING":
40 (a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER
41 BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.
42 (b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE
43 GENOME SEQUENCING.

1 3. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:
2 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
3 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT
4 INCLUDES A CONFLICT OF INTEREST POLICY.
5 (b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
6 OPTIMIZING CLINICAL CARE OUTCOMES.
7 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.
8 4. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
9 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:
10 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
11 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
12 STRUCTURE AND A CONFLICT OF INTEREST POLICY.
13 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
14 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
15 ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO
16 OPTIMIZE PATIENT CARE.
17 Sec. 2. Title 20, chapter 4, article 9, Arizona Revised Statutes,
18 is amended by adding section 20-1057.19, to read:
19 20-1057.19. Biomarker testing; coverage; definitions
20 A. A HEALTH CARE SERVICES ORGANIZATION THAT ISSUES, AMENDS,
21 DELIVERS OR RENEWS AN EVIDENCE OF COVERAGE ON OR AFTER JANUARY 1, 2023
22 SHALL PROVIDE COVERAGE FOR BIOMARKER TESTING.
23 B. AN EVIDENCE OF COVERAGE SHALL COVER BIOMARKER TESTING FOR THE
24 PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING
25 MONITORING OF AN ENROLLEE'S DISEASE OR CONDITION TO GUIDE TREATMENT
26 DECISIONS WHEN THE TEST IS SUPPORTED BY MEDICAL AND SCIENTIFIC EVIDENCE,
27 INCLUDING ANY OF THE FOLLOWING:
28 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
29 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
30 DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
31 2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE
32 DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE
33 DETERMINATIONS.
34 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
35 STATEMENTS.
36 C. A HEALTH CARE SERVICES ORGANIZATION MUST ENSURE THAT COVERAGE IS
37 PROVIDED IN A MANNER THAT LIMITS DISRUPTIONS IN CARE, INCLUDING THE NEED
38 FOR MULTIPLE BIOPSIES OR BIOSPECIMEN SAMPLES.
39 D. THE ENROLLEE AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO A
40 CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION
41 TO A COVERAGE POLICY OF A HEALTH CARE SERVICES ORGANIZATION. THE PROCESS
42 SHALL BE READILY ACCESSIBLE ON HEALTH CARE SERVICES ORGANIZATION'S
43 WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF THE
44 HEALTH CARE SERVICES ORGANIZATION'S EXISTING PROCESS COMPLIES WITH THIS
45 SUBSECTION.

1 E. FOR THE PURPOSES OF THIS SECTION:
2 1. "BIOMARKER":
3 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
4 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
5 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
6 INTERVENTION.
7 (b) INCLUDE GENE MUTATIONS OR PROTEIN EXPRESSION.
8 2. "BIOMARKER TESTING":
9 (a) MEANS THE ANALYSIS OF A PATIENT'S TISSUE, BLOOD OR OTHER
10 BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.
11 (b) INCLUDES SINGLE-ANALYTE TESTS, MULTIPLEX PANEL TESTS AND WHOLE
12 GENOME SEQUENCING.
13 3. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT BOTH:
14 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
15 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE THAT
16 INCLUDES A CONFLICT OF INTEREST POLICY.
17 (b) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
18 OPTIMIZING CLINICAL CARE OUTCOMES.
19 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.
20 4. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
21 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:
22 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
23 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
24 STRUCTURE AND A CONFLICT OF INTEREST POLICY.
25 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
26 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
27 ALTERNATIVE CARE OPTIONS THAT INCLUDES RECOMMENDATIONS INTENDED TO
28 OPTIMIZE PATIENT CARE.
29 Sec. 3. Title 20, chapter 6, article 4, Arizona Revised Statutes,
30 is amended by adding section 20-1376.10, to read:
31 20-1376.10. Biomarker testing; coverage; definitions
32 A. A DISABILITY INSURER THAT ISSUES, AMENDS, DELIVERS OR RENEWS A
33 POLICY ON OR AFTER JANUARY 1, 2023 SHALL PROVIDE COVERAGE FOR BIOMARKER
34 TESTING.
35 B. A POLICY SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF
36 DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF AN
37 INSURED'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE TEST
38 IS SUPPORTED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE
39 FOLLOWING:
40 1. LABELED INDICATIONS FOR TESTS THAT ARE APPROVED OR CLEARED BY
41 THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR INDICATED TESTS FOR A
42 DRUG THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
43 2. CENTERS FOR MEDICARE AND MEDICAID SERVICES NATIONAL COVERAGE
44 DETERMINATIONS OR MEDICARE ADMINISTRATIVE CONTRACTOR LOCAL COVERAGE
45 DETERMINATIONS.

1 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
2 STATEMENTS.

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

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

12 E. FOR THE PURPOSES OF THIS SECTION:

13 1. "BIOMARKER":

14 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
15 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
16 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
17 INTERVENTION.

18 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

19 2. "BIOMARKER TESTING":

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

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

24 3. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

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

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

30 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

31 4. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
32 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

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

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

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

42 20-1406.10. Biomarker testing; coverage; definitions

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

1 B. A POLICY SHALL COVER BIOMARKER TESTING FOR THE PURPOSES OF
2 DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF A
3 SUBSCRIBER'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS WHEN THE
4 TEST IS SUPPORTED BY MEDICAL AND SCIENTIFIC EVIDENCE, INCLUDING ANY OF THE
5 FOLLOWING:

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

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

12 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
13 STATEMENTS.

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

17 D. THE SUBSCRIBER AND PRESCRIBING PRACTITIONER MUST HAVE ACCESS TO
18 A CLEAR, READILY ACCESSIBLE AND CONVENIENT PROCESS TO REQUEST AN EXCEPTION
19 TO A COVERAGE POLICY OF A GROUP OR BLANKET DISABILITY INSURER. THE
20 PROCESS SHALL BE READILY ACCESSIBLE ON A GROUP OR BLANKET DISABILITY
21 INSURER'S WEBSITE. THIS SUBSECTION DOES NOT REQUIRE A SEPARATE PROCESS IF
22 THE GROUP OR BLANKET DISABILITY INSURER'S EXISTING PROCESS COMPLIES WITH
23 THIS SUBSECTION.

24 E. FOR THE PURPOSES OF THIS SECTION:

25 1. "BIOMARKER":

26 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
27 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
28 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
29 INTERVENTION.

30 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

31 2. "BIOMARKER TESTING":

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

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

36 3. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:

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

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

42 (c) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.

43 4. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
44 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:

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

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

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

10 36-2907.03. Biomarker testing; coverage; definitions

11 A. THE ADMINISTRATION AND ITS CONTRACTORS SHALL PROVIDE BIOMARKER
12 TESTING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT
13 OR ONGOING MONITORING OF A MEMBER'S DISEASE OR CONDITION TO GUIDE
14 TREATMENT DECISIONS WHEN THE TEST IS SUPPORTED BY MEDICAL AND SCIENTIFIC
15 EVIDENCE, INCLUDING ANY OF THE FOLLOWING:

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

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

22 3. NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES AND CONSENSUS
23 STATEMENTS.

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

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

34 D. FOR THE PURPOSES OF THIS SECTION:

35 1. "BIOMARKER":

36 (a) MEANS A CHARACTERISTIC THAT IS OBJECTIVELY MEASURED AND
37 EVALUATED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC
38 PROCESSES OR PHARMACOLOGIC RESPONSES TO A SPECIFIC THERAPEUTIC
39 INTERVENTION.

40 (b) INCLUDES GENE MUTATIONS OR PROTEIN EXPRESSION.

41 2. "BIOMARKER TESTING":

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

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

- 1 3. "CONSENSUS STATEMENTS" MEANS STATEMENTS THAT:
2 (a) ARE DEVELOPED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF
3 EXPERTS USING A TRANSPARENT METHODOLOGY AND REPORTING STRUCTURE AND WITH A
4 CONFLICT OF INTEREST POLICY.
5 (b) ARE AIMED AT SPECIFIC CLINICAL CIRCUMSTANCES.
6 (c) ARE BASED ON THE BEST AVAILABLE EVIDENCE FOR THE PURPOSE OF
7 OPTIMIZING THE OUTCOMES OF CLINICAL CARE.
- 8 4. "NATIONALLY RECOGNIZED CLINICAL PRACTICE GUIDELINES" MEANS
9 EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES THAT BOTH:
10 (a) ARE DEVELOPED BY INDEPENDENT ORGANIZATIONS OR MEDICAL
11 PROFESSIONAL SOCIETIES USING A TRANSPARENT METHODOLOGY AND REPORTING
12 STRUCTURE AND WITH A CONFLICT OF INTEREST POLICY.
13 (b) ESTABLISH STANDARDS OF CARE THAT ARE INFORMED BY A SYSTEMATIC
14 REVIEW OF EVIDENCE AND AN ASSESSMENT OF THE BENEFITS AND COSTS OF
15 ALTERNATIVE CARE OPTIONS AND INCLUDE RECOMMENDATIONS INTENDED TO OPTIMIZE
16 PATIENT CARE.