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Date: (Filing No. H-)

HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

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**STATE OF MAINE
HOUSE OF REPRESENTATIVES
132ND LEGISLATURE
FIRST SPECIAL SESSION**

COMMITTEE AMENDMENT “ ” to H.P. 72, L.D. 107, “An Act to Require Health Insurance Coverage for Biomarker Testing”

Amend the bill in section 1 in §3174-PPP in subsection 1 by striking out all of paragraph C (page 1, lines 16 to 22 in L.D.) and inserting the following:

'C. "Clinical utility" means, in the context of biomarker testing, that the use of biomarker testing is expected to provide meaningful information to guide decisions for the treatment of a disease or condition to improve net health outcomes, quality of life or survival of a patient, even if the results of biomarker testing are not immediately actionable in the course of a patient's treatment.'

Amend the bill in section 1 in §3174-PPP in subsection 2 in the 3rd line (page 1, line 33 in L.D.) by striking out the following: "is supported" and inserting the following: 'provides clinical utility as demonstrated'

Amend the bill in section 1 in §3174-PPP in subsection 2 in paragraph D in the last 2 lines (page 2, lines 2 and 3 in L.D.) by striking out the following: "Medicare administrative contractor local coverage determination" and inserting the following: 'a Medicare administrative contractor local coverage determination that is explicitly applicable in this State'

Amend the bill in section 1 in §3174-PPP in subsection 2 in paragraph E in the first line (page 2, line 4 in L.D.) by striking out the following: "or consensus statement"

Amend the bill in section 1 in §3174-PPP by inserting after subsection 2 the following:

3. Prior authorization. Before providing coverage for biomarker testing as required by subsection 2, the department may require prior authorization. If prior authorization is required prior to biomarker testing, the department or any 3rd party acting on behalf of the department must approve or deny a prior authorization request and notify the MaineCare member and the MaineCare member's health care provider and any entity requesting authorization of the service within 72 hours for requests that are not urgent or within 24 hours for urgent requests.

COMMITTEE AMENDMENT

1 **4. No biomarker testing for asymptomatic screening.** This section may not be
2 construed to require coverage for biomarker testing for the purposes of asymptomatic
3 screening.'

4 Amend the bill in section 3 in §2745-H in subsection 1 by striking out all of paragraph
5 C (page 2, lines 25 to 31 in L.D.) and inserting the following:

6 'C. "Clinical utility" means, in the context of biomarker testing, that the use of
7 biomarker testing is expected to provide meaningful information to guide decisions for
8 the treatment of a disease or condition to improve net health outcomes, quality of life
9 or survival of a patient, even if the results of biomarker testing are not immediately
10 actionable in the course of a patient's treatment.'

11 Amend the bill in section 3 in §2745-H in subsection 2 in the 4th line (page 3, line 4 in
12 L.D.) by striking out the following: "is supported" and inserting the following: 'provides
13 clinical utility as demonstrated'

14 Amend the bill in section 3 in §2745-H in subsection 2 in paragraph D in the last line
15 (page 3, line 12 in L.D.) by inserting after the following: "determination" the following:
16 'that is explicitly applicable in this State'

17 Amend the bill in section 3 in §2745-H in subsection 2 in paragraph E in the first line
18 (page 3, line 13 in L.D.) by striking out the following: "or consensus statement"

19 Amend the bill in section 3 in §2745-H in subsection 3 in the last 3 lines (page 3, lines
20 22 to 24 in L.D.) by striking out the following: "and notify the person covered by the policy,
21 the person's health care provider and any entity requesting authorization of the service
22 within 72 hours for nonurgent requests or within 24 hours for urgent requests" and inserting
23 the following: 'in accordance with the requirements in section 4304'

24 Amend the bill in section 3 in §2745-H by inserting after subsection 3 the following:

25 '**4. No biomarker testing for asymptomatic screening.** This section may not be
26 construed to require coverage for biomarker testing for the purposes of asymptomatic
27 screening.'

28 Amend the bill in section 4 in §2837-I in subsection 1 by striking out all of paragraph
29 C (page 3, lines 39 to 42 and page 4, lines 1 to 3 in L.D.) and inserting the following:

30 'C. "Clinical utility" means, in the context of biomarker testing, that the use of
31 biomarker testing is expected to provide meaningful information to guide decisions for
32 the treatment of a disease or condition to improve net health outcomes, quality of life
33 or survival of a patient, even if the results of biomarker testing are not immediately
34 actionable in the course of a patient's treatment.'

35 Amend the bill in section 4 in §2837-I in subsection 2 in the 4th line (page 4, line 15
36 in L.D.) by striking out the following: "is supported" and inserting the following: 'provides
37 clinical utility as demonstrated'

38 Amend the bill in section 4 in §2837-I in subsection 2 in paragraph D in the last 2 lines
39 (page 4, lines 23 and 24 in L.D.) by striking out the following: "Medicare administrative
40 contractor local coverage determination" and inserting the following: 'a Medicare
41 administrative contractor local coverage determination that is explicitly applicable in this
42 State'

1 Amend the bill in section 4 in §2837-I in subsection 2 in paragraph E in the first line
2 (page 4, line 25 in L.D.) by striking out the following: "or consensus statement"

3 Amend the bill in section 4 in §2837-I in subsection 3 in the last 4 lines (page 4, lines
4 34 to 37 in L.D.) by striking out the following: "and notify the insured person or subscriber
5 covered by that policy, the insured person's or subscriber's health care provider and any
6 entity requesting authorization of the service within 72 hours for nonurgent requests or
7 within 24 hours for urgent requests" and inserting the following: 'in accordance with the
8 requirements in section 4304'

9 Amend the bill in section 4 in §2837-I by inserting after subsection 3 the following:

10 **'4. No biomarker testing for asymptomatic screening.** This section may not be
11 construed to require coverage for biomarker testing for the purposes of asymptomatic
12 screening.'

13 Amend the bill in section 5 in §4237-B in subsection 1 by striking out all of paragraph
14 C (page 5, lines 11 to 17 in L.D.) and inserting the following:

15 'C. "Clinical utility" means, in the context of biomarker testing, that the use of a
16 biomarker test is expected to provide meaningful information to guide decisions for the
17 treatment of a disease or condition to improve net health outcomes, quality of life or
18 survival of a patient, even if the results of a biomarker test are not immediately
19 actionable in the course of a patient's treatment.'

20 Amend the bill in section 5 in §4237-B in subsection 2 in the 4th line (page 5, line 29
21 in L.D.) by striking out the following: "is supported" and inserting the following: 'provides
22 clinical utility as demonstrated'

23 Amend the bill in section 5 in §4237-B in subsection 2 in paragraph D in the last 2 lines
24 (page 5, lines 37 and 38 in L.D.) by striking out the following: "Medicare administrative
25 contractor local coverage determination" and inserting the following: 'a Medicare
26 administrative contractor local coverage determination that is explicitly applicable in this
27 State'

28 Amend the bill in section 5 in §4237-B in subsection 2 in paragraph E in the first line
29 (page 5, line 39 in L.D.) by striking out the following: "or consensus statement"

30 Amend the bill in section 5 in §4237-B in subsection 3 in the last 4 lines (page 6, lines
31 9 to 12 in L.D.) by striking out the following: "and notify the insured person or subscriber
32 covered by that policy, the insured person's or subscriber's health care provider and any
33 entity requesting authorization of the service within 72 hours for nonurgent requests or
34 within 24 hours for urgent requests" and inserting the following: 'in accordance with the
35 requirements in section 4304'

36 Amend the bill in section 5 in §4237-B by inserting after subsection 3 the following:

37 **'4. No biomarker testing for asymptomatic screening.** This section may not be
38 construed to require coverage for biomarker testing for the purposes of asymptomatic
39 screening.'

40 Amend the bill in section 6 in the last line (page 6, line 16 in L.D.) by striking out the
41 following: "2026" and inserting the following: '2027'

42 Amend the bill by inserting after section 6 the following:

1 **Sec. 7. Exempt from mandate review.** Notwithstanding the Maine Revised
 2 Statutes, Title 24-A, section 2752, this Act is enacted without review and evaluation by the
 3 Department of Professional and Financial Regulation, Bureau of Insurance.

4 **Sec. 8. Appropriations and allocations.** The following appropriations and
 5 allocations are made.

6 **ADMINISTRATIVE AND FINANCIAL SERVICES, DEPARTMENT OF**
 7 **State Benefit Mandate Defrayal Z373**

8 Initiative: Provides ongoing funding for the cost of the benefit mandate providing coverage,
 9 including coverage in the MaineCare program, for biomarker testing, beginning January 1,
 10 2027.

11	GENERAL FUND	2025-26	2026-27
12	All Other	\$0	\$170,000
13			
14	GENERAL FUND TOTAL	\$0	\$170,000

15			
16	ADMINISTRATIVE AND FINANCIAL		
17	SERVICES, DEPARTMENT OF		
18	DEPARTMENT TOTALS	2025-26	2026-27

19			
20	GENERAL FUND	\$0	\$170,000
21			
22	DEPARTMENT TOTAL - ALL FUNDS	\$0	\$170,000

23 **HEALTH AND HUMAN SERVICES, DEPARTMENT OF**
 24 **Medical Care - Payments to Providers 0147**

25 Initiative: Provides funding for MaineCare coverage of biomarker testing.

26	GENERAL FUND	2025-26	2026-27
27	All Other	\$0	\$935,162
28			
29	GENERAL FUND TOTAL	\$0	\$935,162

30			
31	FEDERAL EXPENDITURES FUND	2025-26	2026-27
32	All Other	\$0	\$2,098,754
33			
34	FEDERAL EXPENDITURES FUND TOTAL	\$0	\$2,098,754

35			
36	FEDERAL BLOCK GRANT FUND	2025-26	2026-27
37	All Other	\$0	\$12,773
38			
39	FEDERAL BLOCK GRANT FUND TOTAL	\$0	\$12,773

40 **Office of MaineCare Services 0129**

1 Initiative: Establishes one Health Services Consultant position funded 50% General Fund
 2 and 50% Federal Expenditures Fund in the Office of MaineCare Services to conduct prior
 3 authorization work and provides funding for related All Other costs.

4	GENERAL FUND	2025-26	2026-27
5	POSITIONS - LEGISLATIVE COUNT	0.000	1.000
6	Personal Services	\$0	\$54,559
7	All Other	\$0	\$3,628
8			
9	GENERAL FUND TOTAL	\$0	\$58,187

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11	FEDERAL EXPENDITURES FUND	2025-26	2026-27
12	POSITIONS - LEGISLATIVE COUNT	0.000	1.000
13	Personal Services	\$0	\$54,559
14	All Other	\$0	\$4,978
15			
16	FEDERAL EXPENDITURES FUND TOTAL	\$0	\$59,537

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18	HEALTH AND HUMAN SERVICES,		
19	DEPARTMENT OF		
20	DEPARTMENT TOTALS	2025-26	2026-27
21			
22	GENERAL FUND	\$0	\$993,349
23	FEDERAL EXPENDITURES FUND	\$0	\$2,158,291
24	FEDERAL BLOCK GRANT FUND	\$0	\$12,773
25			
26	DEPARTMENT TOTAL - ALL FUNDS	\$0	\$3,164,413

27

28	SECTION TOTALS	2025-26	2026-27
29			
30	GENERAL FUND	\$0	\$1,163,349
31	FEDERAL EXPENDITURES FUND	\$0	\$2,158,291
32	FEDERAL BLOCK GRANT FUND	\$0	\$12,773
33			
34	SECTION TOTAL - ALL FUNDS	\$0	\$3,334,413

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36 Amend the bill by relettering or renumbering any nonconsecutive Part letter or section
 37 number to read consecutively.

38

SUMMARY

39 As drafted, the bill requires insurance coverage, including coverage in the MaineCare
 40 program, for biomarker testing. This amendment proposes to make the following changes
 41 to the bill. The amendment:

COMMITTEE AMENDMENT

1 1. Eliminates "consensus statement" as a source of evidence by removing the definition
2 and all uses of the term in the bill;

3 2. Adds a definition of "clinical utility" in the context of biomarker testing that means
4 that the use of biomarker testing will provide meaningful information that affects treatment
5 decisions and guides improvement of net health outcomes, including an improved quality
6 of life or longer survival. The most appropriate test may include some information that is
7 not immediately actionable;

8 3. Expressly states that no coverage is required for biomarker testing for the purposes
9 of asymptomatic screening;

10 4. Adds that coverage for a Medicare administrative contractor local coverage
11 determination is only required when applicable to Maine;

12 5. Clarifies testing is done to guide treatment decisions;

13 6. Expressly permits the MaineCare program to require prior authorization for
14 biomarker testing;

15 7. Clarifies that prior authorization determinations by health insurance carriers must be
16 done in accordance with the requirements of current law in the Maine Revised Statutes,
17 Title 24-A, section 4304;

18 8. Extends the application date from January 1, 2026 to January 1, 2027;

19 9. Adds language exempting the proposal from review and evaluation by the
20 Department of Professional and Financial Regulation, Bureau of Insurance; and

21 10. Adds an appropriations and allocations section.

22 **FISCAL NOTE REQUIRED**

23 **(See attached)**