

House Bill 3421

Sponsored by Representatives GRAYBER, CHOTZEN

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced**. The statement includes a measure digest written in compliance with applicable readability standards.

Digest: This Act tells some health insurers and OHP to cover biomarker testing with some rules. (Flesch Readability Score: 67.5).

Requires certain policies and certificates of health insurance and medical assistance managed plans to cover biomarker testing with certain rules and requirements.

A BILL FOR AN ACT

1
2 Relating to biomarker testing coverage; creating new provisions; and amending ORS 414.761, 750.055
3 and 750.333.

4 **Be It Enacted by the People of the State of Oregon:**

5 **SECTION 1. Section 2 of this 2025 Act is added to and made a part of the Insurance Code.**

6 **SECTION 2. (1) As used in this section:**

7 (a) **“Biomarker” means a characteristic that is objectively measured and evaluated as**
8 **an indicator of normal biological processes, pathogenic processes or pharmacologic responses**
9 **to a specific therapeutic intervention, including known gene-drug interactions for**
10 **medications being considered for use or already being administered, such as gene mutations,**
11 **characteristics of genes or protein expression.**

12 (b) **“Biomarker testing” means the analysis of a patient’s tissue, blood or other**
13 **biospecimen for the presence of a biomarker, through procedures such as single-analyte**
14 **tests, multiplex panel tests, protein expression tests and whole exome, genome and**
15 **transcriptome sequencing.**

16 (c) **“Clinical practice guidelines” means guidelines that establish standards of care in-**
17 **formed by a systematic review of evidence and an assessment of the benefits and risks of**
18 **alternative care options with recommendations intended to optimize patient care.**

19 (d) **“Consensus statement” means a statement aimed at a specific clinical circumstance**
20 **that is developed by an independent, multidisciplinary panel of experts utilizing a transparent**
21 **methodology and reporting structure, that includes a conflict of interest policy and that is**
22 **for the purpose of using the best available evidence to optimize the outcome of clinical care.**

23 (e) **“Nationally recognized clinical practice guidelines” means clinical practice guidelines**
24 **that are developed by independent organizations or medical professional societies utilizing a**
25 **transparent methodology and reporting structure with a conflict of interest policy.**

26 (f) **“Prior authorization” has the meaning given the term in ORS 743B.001.**

27 (g) **“Utilization review” has the meaning given the term in ORS 743B.001.**

28 (2) **A policy or certificate of health insurance or health care services contract offered by**
29 **a health care service contractor, as defined in ORS 750.005, in this state that reimburses the**
30 **cost of laboratory services must include coverage of biomarker testing prescribed for the**

NOTE: Matter in **boldfaced** type in an amended section is new; matter *[italic and bracketed]* is existing law to be omitted. New sections are in **boldfaced** type.

1 **diagnosis, treatment, management or ongoing monitoring of a beneficiary's disease or con-**
2 **dition if the biomarker testing is supported by:**

3 **(a) Labeled indications for a United States Food and Drug Administration approved or**
4 **cleared test;**

5 **(b) Indicated tests for a United States Food and Drug Administration approved or cleared**
6 **drug;**

7 **(c) Warnings and precautions on United States Food and Drug Administration approved**
8 **drug labels;**

9 **(d) Centers for Medicare and Medicaid Services National Coverage Determinations or**
10 **Medicare Administrative Contractor Local Coverage Determinations; or**

11 **(e) Nationally recognized clinical practice guidelines and consensus statements.**

12 **(3) Coverage of biomarker testing as described in subsection (2) of this section must be**
13 **provided in a manner that limits disruptions in care including the need for multiple biopsies**
14 **or biospecimen samples.**

15 **(4) This section is exempt from ORS 743A.001.**

16 **SECTION 3.** ORS 414.761 is amended to read:

17 414.761. Notwithstanding ORS 414.065 and 414.690, a coordinated care organization and the
18 Oregon Health Authority shall provide to medical assistance recipients:

19 **(1) Who are 18 years of age or younger the devices and services described in ORS 743A.140 and**
20 **743A.141.**

21 **(2) Biomarker testing services and utilization review as described in section 2 of this 2025**
22 **Act.**

23 **SECTION 4.** ORS 750.055, as amended by section 3, chapter 24, Oregon Laws 2024, section 4,
24 chapter 35, Oregon Laws 2024, section 21, chapter 70, Oregon Laws 2024, and section 162, chapter
25 73, Oregon Laws 2024, is amended to read:

26 750.055. (1) The following provisions apply to health care service contractors to the extent not
27 inconsistent with the express provisions of ORS 750.005 to 750.095:

28 (a) ORS 705.137, 705.138 and 705.139.

29 (b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398
30 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS
31 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652,
32 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

33 (c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not
34 including ORS 732.582, and ORS 732.650 to 732.689.

35 (d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695
36 to 733.780.

37 (e) ORS 734.014 to 734.440.

38 (f) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to
39 742.542.

40 (g) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.020, 743.022, 743.023, 743.025,
41 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406,
42 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650
43 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

44 (h) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044,
45 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066,

1 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105,
2 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.169,
3 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252, 743A.260, 743A.310
4 and 743A.315 and section 2, chapter 771, Oregon Laws 2013, and section 2, chapter 70, Oregon Laws
5 2024, and section 2 of this 2025 Act.

6 (i) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195, 743B.197, 743B.200,
7 743B.202, 743B.204, 743B.220, 743B.221, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253,
8 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310,
9 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403,
10 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505,
11 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 and section 2, chapter 24, Oregon Laws 2024,
12 and section 2, chapter 35, Oregon Laws 2024.

13 (j) The following provisions of ORS chapter 744:

14 (A) ORS 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance produc-
15 ers;

16 (B) ORS 744.602 to 744.665, relating to the regulation of insurance consultants; and

17 (C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

18 (k) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610,
19 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

20 (2) The following provisions of the Insurance Code apply to health care service contractors ex-
21 cept in the case of group practice health maintenance organizations that are federally qualified
22 pursuant to Title XIII of the Public Health Service Act:

23 (a) ORS 731.485, if the group practice health maintenance organization wholly owns and oper-
24 ates an in-house drug outlet.

25 (b) ORS 743A.024, unless the patient is referred by a physician, physician associate or nurse
26 practitioner associated with a group practice health maintenance organization.

27 (3) For the purposes of this section, health care service contractors are insurers.

28 (4) Any for-profit health care service contractor organized under the laws of any other state that
29 is not governed by the insurance laws of the other state is subject to all requirements of ORS
30 chapter 732.

31 (5)(a) A health care service contractor is a domestic insurance company for the purpose of de-
32 termining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

33 (b) A health care service contractor's classification as a domestic insurance company under
34 paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510
35 to 734.710.

36 (6) The Director of the Department of Consumer and Business Services may, after notice and
37 hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025
38 and 750.045 that are necessary for the proper administration of these provisions.

39 **SECTION 5.** ORS 750.055, as amended by section 21, chapter 771, Oregon Laws 2013, section
40 7, chapter 25, Oregon Laws 2014, section 82, chapter 45, Oregon Laws 2014, section 9, chapter 59,
41 Oregon Laws 2015, section 7, chapter 100, Oregon Laws 2015, section 7, chapter 224, Oregon Laws
42 2015, section 11, chapter 362, Oregon Laws 2015, section 10, chapter 470, Oregon Laws 2015, section
43 30, chapter 515, Oregon Laws 2015, section 10, chapter 206, Oregon Laws 2017, section 6, chapter
44 417, Oregon Laws 2017, section 22, chapter 479, Oregon Laws 2017, section 10, chapter 7, Oregon
45 Laws 2018, section 69, chapter 13, Oregon Laws 2019, section 38, chapter 151, Oregon Laws 2019,

1 section 5, chapter 441, Oregon Laws 2019, section 85, chapter 97, Oregon Laws 2021, section 12,
2 chapter 37, Oregon Laws 2022, section 5, chapter 111, Oregon Laws 2023, section 2, chapter 152,
3 Oregon Laws 2023, section 4, chapter 24, Oregon Laws 2024, section 5, chapter 35, Oregon Laws
4 2024, section 22, chapter 70, Oregon Laws 2024, and section 163, chapter 73, Oregon Laws 2024, is
5 amended to read:

6 750.055. (1) The following provisions apply to health care service contractors to the extent not
7 inconsistent with the express provisions of ORS 750.005 to 750.095:

8 (a) ORS 705.137, 705.138 and 705.139.

9 (b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398
10 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS
11 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652,
12 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

13 (c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not
14 including ORS 732.582, and ORS 732.650 to 732.689.

15 (d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695
16 to 733.780.

17 (e) ORS 734.014 to 734.440.

18 (f) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to
19 742.542.

20 (g) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.020, 743.022, 743.023, 743.025,
21 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406,
22 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650
23 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

24 (h) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044,
25 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066,
26 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105,
27 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.169,
28 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252, 743A.260, 743A.310
29 and 743A.315 and section 2, chapter 70, Oregon Laws 2024, **and section 2 of this 2025 Act.**

30 (i) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195, 743B.197, 743B.200,
31 743B.202, 743B.204, 743B.220, 743B.221, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253,
32 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310,
33 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403,
34 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505,
35 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 and section 2, chapter 24, Oregon Laws 2024,
36 and section 2, chapter 35, Oregon Laws 2024.

37 (j) The following provisions of ORS chapter 744:

38 (A) ORS 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance produc-
39 ers;

40 (B) ORS 744.602 to 744.665, relating to the regulation of insurance consultants; and

41 (C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

42 (k) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610,
43 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

44 (2) The following provisions of the Insurance Code apply to health care service contractors ex-
45 cept in the case of group practice health maintenance organizations that are federally qualified

1 pursuant to Title XIII of the Public Health Service Act:

2 (a) ORS 731.485, if the group practice health maintenance organization wholly owns and oper-
 3 ates an in-house drug outlet.

4 (b) ORS 743A.024, unless the patient is referred by a physician, physician associate or nurse
 5 practitioner associated with a group practice health maintenance organization.

6 (3) For the purposes of this section, health care service contractors are insurers.

7 (4) Any for-profit health care service contractor organized under the laws of any other state that
 8 is not governed by the insurance laws of the other state is subject to all requirements of ORS
 9 chapter 732.

10 (5)(a) A health care service contractor is a domestic insurance company for the purpose of de-
 11 termining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

12 (b) A health care service contractor's classification as a domestic insurance company under
 13 paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510
 14 to 734.710.

15 (6) The Director of the Department of Consumer and Business Services may, after notice and
 16 hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025
 17 and 750.045 that are necessary for the proper administration of these provisions.

18 **SECTION 6.** ORS 750.333, as amended by section 5, chapter 24, Oregon Laws 2024, and section
 19 23, chapter 70, Oregon Laws 2024, is amended to read:

20 750.333. (1) The following provisions apply to trusts carrying out a multiple employer welfare
 21 arrangement:

22 (a) ORS 705.137, 705.138 and 705.139.

23 (b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.268, 731.296 to 731.316, 731.324, 731.328,
 24 731.378, 731.386, 731.390, 731.398, 731.406, 731.410, 731.414, 731.418 to 731.434, 731.454, 731.484,
 25 731.486, 731.488, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.804, 731.808 and 731.844 to
 26 731.992.

27 (c) ORS 733.010 to 733.050, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

28 (d) ORS 734.014 to 734.440.

29 (e) ORS 742.001 to 742.009, 742.013, 742.016, 742.061 and 742.065.

30 (f) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.020, 743.023, 743.028, 743.029,
 31 743.053, 743.405, 743.406, 743.524, 743.526, 743.535 and 743B.221.

32 (g) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.024, 743A.034, 743A.036, 743A.040,
 33 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066,
 34 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105,
 35 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.169,
 36 743A.170, 743A.175, 743A.180, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252, 743A.260
 37 and 743A.310 and section 2, chapter 70, Oregon Laws 2024, **and section 2 of this 2025 Act.**

38 (h) ORS 743B.001, 743B.003 to 743B.127 (except 743B.125 to 743B.127), 743B.195, 743B.197,
 39 743B.200, 743B.202, 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253,
 40 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.310, 743B.320, 743B.321, 743B.330, 743B.340,
 41 743B.341, 743B.342, 743B.343, 743B.344, 743B.345, 743B.347, 743B.400, 743B.403, 743B.407, 743B.420,
 42 743B.423, 743B.451, 743B.453, 743B.470, 743B.505, 743B.550, 743B.555 and 743B.601 and section 2,
 43 chapter 24, Oregon Laws 2024.

44 (i) The following provisions of ORS chapter 744:

45 (A) ORS 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance produc-

1 ers;

2 (B) ORS 744.602 to 744.665, relating to the regulation of insurance consultants; and

3 (C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

4 (j) ORS 746.005 to 746.140, 746.160 and 746.220 to 746.370.

5 (2) For the purposes of this section:

6 (a) A trust carrying out a multiple employer welfare arrangement is an insurer.

7 (b) References to certificates of authority are references to certificates of multiple employer
8 welfare arrangement.

9 (c) Contributions are premiums.

10 (3) The provision of health benefits under ORS 750.301 to 750.341 is the transaction of health
11 insurance.

12 (4) The Department of Consumer and Business Services may adopt rules that are necessary to
13 implement the provisions of ORS 750.301 to 750.341.

14 **SECTION 7. (1) Section 2 of this 2025 Act and the amendments to ORS 750.055 and 750.333**
15 **by sections 4 to 6 of this 2025 Act apply to policies or certificates of health insurance or**
16 **health care service contracts offered, renewed or extended on or after the effective date of**
17 **this 2025 Act.**

18 **(2) The amendments to ORS 414.761 by section 3 of this 2025 Act apply to medical as-**
19 **sistance provided and to contracts with coordinated care organizations for periods beginning**
20 **on or after the effective date of this 2025 Act.**

21