

A-Engrossed
Senate Bill 316

Ordered by the Senate April 15
Including Senate Amendments dated April 15

Sponsored by Senator DEVLIN (Pre-session filed.)

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.

Requires health benefit plan to provide coverage of routine costs of care in qualifying clinical trials subject to copayment and other cost sharing requirements. Limits liability of insurers for adverse effects of clinical trial.

A BILL FOR AN ACT

1
2 Relating to clinical trials; creating new provisions; and amending ORS 750.055 and 750.333.

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

4 **SECTION 1. Section 2 of this 2009 Act is added to and made a part of ORS chapter 743A.**

5 **SECTION 2. (1) A health benefit plan, as defined in ORS 743.730, shall provide coverage**
6 **for the routine costs of the care of patients enrolled in and participating in qualifying clinical**
7 **trials.**

8 (2) As used in subsection (1) of this section, "routine costs":

9 (a) Means medically necessary conventional care, items or services covered by the health
10 benefit plan if typically provided absent a clinical trial.

11 (b) Does not include:

12 (A) The drug, device or service being tested in the clinical trial unless the drug, device
13 or service would be covered for that indication by the health benefit plan if provided outside
14 of a clinical trial;

15 (B) Items or services required solely for the provision of the drug device
16 or service being tested in the clinical trial;

17 (C) Items or services required solely for the clinically appropriate monitoring of the drug,
18 device or service being tested in the clinical trial;

19 (D) Items or services required solely for the prevention, diagnosis or treatment of com-
20 plications arising from the provision of the drug, device or service being tested in the clinical
21 trial;

22 (E) Items or services that are provided solely to satisfy data collection and analysis needs
23 and that are not used in the direct clinical management of the patient;

24 (F) Items or services customarily provided by a clinical trial sponsor free of charge to
25 any participant in the clinical trial; or

26 (G) Items or services that are not covered by the health plan if provided outside of the
27 clinical trial.

28 (3) As used in subsection (1) of this section, "qualifying clinical trial" means a clinical

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 **trial that is:**

2 (a) **Funded by the National Institutes of Health, the Centers for Disease Control and**
3 **Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and**
4 **Medicaid Services, the United States Department of Defense or the United States Depart-**
5 **ment of Veterans Affairs;**

6 (b) **Supported by a center or cooperative group that is funded by the National Institutes**
7 **of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Re-**
8 **search and Quality, the Centers for Medicare and Medicaid Services, the United States De-**
9 **partment of Defense or the United States Department of Veterans Affairs;**

10 (c) **Conducted as an investigational new drug application, an investigational device ex-**
11 **emption or a biologics license application subject to approval by the United States Food and**
12 **Drug Administration; or**

13 (d) **Exempt by federal law from the requirement to submit an investigational new drug**
14 **application to the United States Food and Drug Administration.**

15 (4) **The coverage required by this section may be subject to provisions of the health**
16 **benefit plan that apply to other benefits within the same category, including but not limited**
17 **to copayments, deductibles and coinsurance.**

18 (5) **An insurer that provides coverage required by this section is not, based upon that**
19 **coverage, liable for any adverse effects of the clinical trial.**

20 **SECTION 3.** ORS 750.055, as amended by section 5, chapter 22, Oregon Laws 2008, is amended
21 to read:

22 750.055. (1) The following provisions of the Insurance Code apply to health care service con-
23 tractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

24 (a) ORS 705.137, 705.139, 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386,
25 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.488, 731.504, 731.508, 731.509, 731.510,
26 731.511, 731.512, 731.574 to 731.620, 731.592, 731.594, 731.640 to 731.652, 731.730, 731.731, 731.735,
27 731.737, 731.750, 731.752, 731.804 and 731.844 to 731.992 and section 2, chapter 22, Oregon Laws 2008.

28 (b) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.592, not
29 including ORS 732.582.

30 (c) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695
31 to 733.780.

32 (d) ORS chapter 734.

33 (e) ORS 742.001 to 742.009, 742.013, 742.061, 742.065, 742.150 to 742.162, 742.400, 742.520 to
34 742.540, 743.010, 743.013, 743.018 to 743.030, 743.050, 743.100 to 743.109, 743.402, 743.472, 743.492,
35 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.527, 743.528, 743.529, 743.549 to 743.552,
36 743.560, 743.600 to 743.610, 743.650 to 743.664, 743.804, 743.807, 743.808, 743.814 to 743.839, 743.842,
37 743.845, 743.847, 743.854, 743.856, 743.857, 743.858, 743.859, 743.861, 743.862, 743.863, 743.864, 743.911,
38 743.913, 743A.010, 743A.012, 743A.036, 743A.048, 743A.062, 743A.064, 743A.066, 743A.068, 743A.070,
39 743A.080, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.110, 743A.140, 743A.148, 743A.160,
40 743A.164, 743A.168, 743A.184, 743A.188 and 743A.190 **and section 2 of this 2009 Act.**

41 (f) The provisions of ORS chapter 744 relating to the regulation of insurance producers.

42 (g) 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 (h) ORS 743A.024, except in the case of group practice health maintenance organizations that
45 are federally qualified pursuant to Title XIII of the Public Health Service Act unless the patient is

1 referred by a physician associated with a group practice health maintenance organization.

2 (i) ORS 735.600 to 735.650.

3 (j) ORS 743.680 to 743.689.

4 (k) ORS 744.700 to 744.740.

5 (L) ORS 743.730 to 743.773.

6 (m) ORS 731.485, except in the case of a group practice health maintenance organization that
7 is federally qualified pursuant to Title XIII of the Public Health Service Act and that wholly owns
8 and operates an in-house drug outlet.

9 (2) For the purposes of this section, health care service contractors shall be deemed insurers.

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

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

16 **SECTION 4.** ORS 750.055, as amended by section 7, chapter 137, Oregon Laws 2003, section 3,
17 chapter 263, Oregon Laws 2003, sections 501 and 502, chapter 22, Oregon Laws 2005, sections 5 and
18 6, chapter 255, Oregon Laws 2005, section 5, chapter 418, Oregon Laws 2005, section 3, chapter 128,
19 Oregon Laws 2007, section 9, chapter 182, Oregon Laws 2007, section 6, chapter 313, Oregon Laws
20 2007, section 4, chapter 504, Oregon Laws 2007, section 4, chapter 566, Oregon Laws 2007, section
21 4, chapter 872, Oregon Laws 2007, and section 6, chapter 22, Oregon Laws 2008, is amended to read:

22 750.055. (1) The following provisions of the Insurance Code apply to health care service con-
23 tractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

24 (a) ORS 705.137, 705.139, 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386,
25 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.488, 731.504, 731.508, 731.509, 731.510,
26 731.511, 731.512, 731.574 to 731.620, 731.592, 731.594, 731.640 to 731.652, 731.730, 731.731, 731.735,
27 731.737, 731.750, 731.752, 731.804 and 731.844 to 731.992 and section 2, chapter 22, Oregon Laws 2008.

28 (b) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.592, not
29 including ORS 732.582.

30 (c) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695
31 to 733.780.

32 (d) ORS chapter 734.

33 (e) ORS 742.001 to 742.009, 742.013, 742.061, 742.065, 742.150 to 742.162, 742.400, 742.520 to
34 742.540, 743.010, 743.013, 743.018 to 743.030, 743.050, 743.100 to 743.109, 743.402, 743.472, 743.492,
35 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.527, 743.528, 743.529, 743.549 to 743.552,
36 743.560, 743.600 to 743.610, 743.650 to 743.656, 743.804, 743.807, 743.808, 743.814 to 743.839, 743.842,
37 743.845, 743.847, 743.854, 743.856, 743.857, 743.858, 743.859, 743.861, 743.862, 743.863, 743.864, 743.911,
38 743.913, 743A.010, 743A.012, 743A.036, 743A.048, 743A.062, 743A.064, 743A.066, 743A.068, 743A.070,
39 743A.080, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.110, 743A.140, 743A.148, 743A.160,
40 743A.164, 743A.168, 743A.184 and 743A.190 **and section 2 of this 2009 Act.**

41 (f) The provisions of ORS chapter 744 relating to the regulation of insurance producers.

42 (g) 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 (h) ORS 743A.024, except in the case of group practice health maintenance organizations that
45 are federally qualified pursuant to Title XIII of the Public Health Service Act unless the patient is

1 referred by a physician associated with a group practice health maintenance organization.

2 (i) ORS 735.600 to 735.650.

3 (j) ORS 743.680 to 743.689.

4 (k) ORS 744.700 to 744.740.

5 (L) ORS 743.730 to 743.773.

6 (m) ORS 731.485, except in the case of a group practice health maintenance organization that
7 is federally qualified pursuant to Title XIII of the Public Health Service Act and that wholly owns
8 and operates an in-house drug outlet.

9 (2) For the purposes of this section, health care service contractors shall be deemed insurers.

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

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

16 **SECTION 5.** ORS 750.333, as amended by section 7, chapter 22, Oregon Laws 2008, is amended
17 to read:

18 750.333. (1) The following provisions of the Insurance Code apply to trusts carrying out a mul-
19 tiple employer welfare arrangement:

20 (a) ORS 731.004 to 731.150, 731.162, 731.216 to 731.268, 731.296 to 731.316, 731.324, 731.328,
21 731.378, 731.386, 731.390, 731.398, 731.406, 731.410, 731.414, 731.418 to 731.434, 731.454, 731.484,
22 731.486, 731.488, 731.512, 731.574 to 731.620, 731.640 to 731.652 and 731.804 to 731.992.

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

24 (c) ORS chapter 734.

25 (d) ORS 742.001 to 742.009, 742.013, 742.061 and 742.400.

26 (e) ORS 743.028, 743.053, 743.524, 743.526, 743.527, 743.528, 743.529, 743.530, 743.560, 743.562,
27 743.600, 743.601, 743.602, 743.610, 743.730 to 743.773 (except 743.760 to 743.773), 743.801, 743.804,
28 743.807, 743.808, 743.814 to 743.839, 743.842, 743.845, 743.847, 743.854, 743.856, 743.857, 743.858,
29 743.859, 743.861, 743.862, 743.863, 743.864, 743A.012, 743A.064, 743A.080, 743A.100, 743A.104, 743A.110
30 and 743A.184 **and section 2 of this 2009 Act.**

31 (f) ORS 743A.010, 743A.014, 743A.024, 743A.028, 743A.032, 743A.036, 743A.040, 743A.044,
32 743A.048, 743A.066, 743A.068, 743A.084, 743A.088, 743A.090, 743A.140, 743A.148, 743A.168, 743A.180,
33 743A.188 and 743A.190. Multiple employer welfare arrangements to which ORS 743.730 to 743.773
34 apply are subject to the sections referred to in this paragraph only as provided in ORS 743.730 to
35 743.773.

36 (g) Provisions of ORS chapter 744 relating to the regulation of insurance producers and insur-
37 ance consultants, and ORS 744.700 to 744.740.

38 (h) ORS 746.005 to 746.140, 746.160 and 746.220 to 746.370.

39 (i) ORS 731.592 and 731.594.

40 (j) Section 2, chapter 22, Oregon Laws 2008.

41 (2) For the purposes of this section:

42 (a) A trust carrying out a multiple employer welfare arrangement shall be considered an insurer.

43 (b) References to certificates of authority shall be considered references to certificates of mul-
44 tiple employer welfare arrangement.

45 (c) Contributions shall be considered premiums.

1 (3) The provision of health benefits under ORS 750.301 to 750.341 shall be considered to be the
2 transaction of health insurance.

3 **SECTION 6.** ORS 750.333, as amended by section 4, chapter 263, Oregon Laws 2003, section 11,
4 chapter 182, Oregon Laws 2007, section 8, chapter 313, Oregon Laws 2007, section 6, chapter 504,
5 Oregon Laws 2007, section 6, chapter 566, Oregon Laws 2007, section 6, chapter 872, Oregon Laws
6 2007, and section 8, chapter 22, Oregon Laws 2008, is amended to read:

7 750.333. (1) The following provisions of the Insurance Code apply to trusts carrying out a mul-
8 tiple employer welfare arrangement:

9 (a) ORS 731.004 to 731.150, 731.162, 731.216 to 731.268, 731.296 to 731.316, 731.324, 731.328,
10 731.378, 731.386, 731.390, 731.398, 731.406, 731.410, 731.414, 731.418 to 731.434, 731.454, 731.484,
11 731.486, 731.488, 731.512, 731.574 to 731.620, 731.640 to 731.652 and 731.804 to 731.992.

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

13 (c) ORS chapter 734.

14 (d) ORS 742.001 to 742.009, 742.013, 742.061 and 742.400.

15 (e) ORS 743.028, 743.053, 743.524, 743.526, 743.527, 743.528, 743.529, 743.530, 743.560, 743.562,
16 743.600, 743.601, 743.602, 743.610, 743.730 to 743.773 (except 743.760 to 743.773), 743.801, 743.804,
17 743.807, 743.808, 743.814 to 743.839, 743.842, 743.845, 743.847, 743.854, 743.856, 743.857, 743.858,
18 743.859, 743.861, 743.862, 743.863, 743.864, 743A.012, 743A.064, 743A.080, 743A.100, 743A.104, 743A.110
19 and 743A.184 **and section 2 of this 2009 Act.**

20 (f) ORS 743A.010, 743A.014, 743A.024, 743A.028, 743A.032, 743A.036, 743A.040, 743A.044,
21 743A.048, 743A.066, 743A.068, 743A.084, 743A.088, 743A.090, 743A.140, 743A.148, 743A.168, 743A.180
22 and 743A.190. Multiple employer welfare arrangements to which ORS 743.730 to 743.773 apply are
23 subject to the sections referred to in this paragraph only as provided in ORS 743.730 to 743.773.

24 (g) Provisions of ORS chapter 744 relating to the regulation of insurance producers and insur-
25 ance consultants, and ORS 744.700 to 744.740.

26 (h) ORS 746.005 to 746.140, 746.160 and 746.220 to 746.370.

27 (i) ORS 731.592 and 731.594.

28 (j) Section 2, chapter 22, Oregon Laws 2008.

29 (2) For the purposes of this section:

30 (a) A trust carrying out a multiple employer welfare arrangement shall be considered an insurer.

31 (b) References to certificates of authority shall be considered references to certificates of mul-
32 tiple employer welfare arrangement.

33 (c) Contributions shall be considered premiums.

34 (3) The provision of health benefits under ORS 750.301 to 750.341 shall be considered to be the
35 transaction of health insurance.

36 **SECTION 7.** ORS 750.333, as amended by section 8, chapter 137, Oregon Laws 2003, section 4,
37 chapter 263, Oregon Laws 2003, section 3, chapter 446, Oregon Laws 2003, section 6, chapter 418,
38 Oregon Laws 2005, section 12, chapter 182, Oregon Laws 2007, section 9, chapter 313, Oregon Laws
39 2007, section 7, chapter 504, Oregon Laws 2007, section 7, chapter 566, Oregon Laws 2007, section
40 7, chapter 872, Oregon Laws 2007, and section 9, chapter 22, Oregon Laws 2008, is amended to read:

41 750.333. (1) The following provisions of the Insurance Code apply to trusts carrying out a mul-
42 tiple employer welfare arrangement:

43 (a) ORS 731.004 to 731.150, 731.162, 731.216 to 731.268, 731.296 to 731.316, 731.324, 731.328,
44 731.378, 731.386, 731.390, 731.398, 731.406, 731.410, 731.414, 731.418 to 731.434, 731.454, 731.484,
45 731.486, 731.488, 731.512, 731.574 to 731.620, 731.640 to 731.652 and 731.804 to 731.992.

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

2 (c) ORS chapter 734.

3 (d) ORS 742.001 to 742.009, 742.013, 742.061 and 742.400.

4 (e) ORS 743.028, 743.053, 743.524, 743.526, 743.527, 743.528, 743.529, 743.530, 743.560, 743.562,
5 743.600, 743.601, 743.602, 743.610, 743.730 to 743.773 (except 743.760 to 743.773), 743.801, 743.804,
6 743.807, 743.808, 743.814 to 743.839, 743.842, 743.845, 743.847, 743.854, 743.856, 743.857, 743.858,
7 743.859, 743.861, 743.862, 743.863, 743.864, 743A.012, 743A.064, 743A.080, 743A.100, 743A.104, 743A.110
8 and 743A.184 **and section 2 of this 2009 Act.**

9 (f) ORS 743A.010, 743A.014, 743A.024, 743A.028, 743A.032, 743A.036, 743A.040, 743A.048,
10 743A.066, 743A.068, 743A.084, 743A.088, 743A.090, 743A.140, 743A.148, 743A.168, 743A.180 and
11 743A.190. Multiple employer welfare arrangements to which ORS 743.730 to 743.773 apply are sub-
12 ject to the sections referred to in this paragraph only as provided in ORS 743.730 to 743.773.

13 (g) Provisions of ORS chapter 744 relating to the regulation of insurance producers and insur-
14 ance consultants, and ORS 744.700 to 744.740.

15 (h) ORS 746.005 to 746.140, 746.160 and 746.220 to 746.370.

16 (i) ORS 731.592 and 731.594.

17 (j) Section 2, chapter 22, Oregon Laws 2008.

18 (2) For the purposes of this section:

19 (a) A trust carrying out a multiple employer welfare arrangement shall be considered an insurer.

20 (b) References to certificates of authority shall be considered references to certificates of mul-
21 tiple employer welfare arrangement.

22 (c) Contributions shall be considered premiums.

23 (3) The provision of health benefits under ORS 750.301 to 750.341 shall be considered to be the
24 transaction of health insurance.

25 **SECTION 8. Section 2 of this 2009 Act and the amendments to ORS 750.055 and 750.333**
26 **by sections 3 to 7 of this 2009 Act apply to benefits of individuals who enroll or renew an**
27 **enrollment in a health benefit plan on or after the effective date of this 2009 Act.**

28