

B-Engrossed
House Bill 2300

Ordered by the Senate June 30
Including House Amendments dated April 2 and Senate Amendments
dated June 30

Introduced and printed pursuant to House Rule 12.00. Pre-session filed (at the request of House Interim Committee on Health Care)

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.

Creates method by which health care practitioner may offer to treat patient who has terminal disease with investigational product not approved by United States Food and Drug Administration. Provides protections, including waiver of liability, for health care practitioners, health care facilities, professional organizations or associations and manufacturers or suppliers of investigational products that comply with Act.

Sunsets Act on January 2, 2022.

A BILL FOR AN ACT

1
2 Relating to treatments for patients with terminal diseases.

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

4 **SECTION 1. As used in sections 1 to 14 of this 2015 Act:**

5 (1) **"Attending physician" means the physician who has primary responsibility for the**
6 **care of a patient.**

7 (2) **"Capable" means that, in the opinion of an attending physician, consulting physician**
8 **or other health care practitioner, a patient has the ability to make and communicate health**
9 **care decisions to health care practitioners, including the ability to communicate through**
10 **individuals familiar with the patient's manner of communicating.**

11 (3) **"Consulting physician" means a physician who is qualified by specialty or experience**
12 **to diagnose a patient who has a terminal disease and to make a prognosis for that patient.**

13 (4) **"Health care facility" has the meaning given that term in ORS 442.015.**

14 (5) **"Health care practitioner" means an individual who is licensed, certified or otherwise**
15 **authorized by the laws of this state to provide health care services or to dispense drugs.**

16 (6) **"Investigational product" means a drug, biological product or device that has suc-**
17 **cessfully completed Phase I and is currently in Phase II or a subsequent phase of an ap-**
18 **proved clinical trial, as defined in ORS 743A.192, assessing the safety of the drug, biological**
19 **product or device.**

20 (7) **"Physician" means a doctor of medicine or osteopathy licensed to practice medicine**
21 **under ORS chapter 677.**

22 (8) **"Qualified" means, with respect to a patient, that the patient is:**

23 (a) **Capable;**

24 (b) **A resident of this state; and**

25 (c) **18 years of age or older.**

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 (9) "Terminal disease" means an illness or a medical or surgical condition that in a
2 physician's reasonable medical judgment will result in the patient's death within six months.

3 **SECTION 2.** (1) The attending physician of a patient who has a terminal disease may re-
4 fer the patient to a health care practitioner who offers treatment as described in section 3
5 of this 2015 Act if:

6 (a) The treatment is being offered only for purposes related to the terminal disease;

7 (b) The patient is qualified;

8 (c) In the attending physician's judgment, the patient is acting voluntarily and is not
9 being coerced; and

10 (d) The attending physician informs the patient:

11 (A) That the patient has a terminal disease;

12 (B) Of the attending physician's prognosis for the patient;

13 (C) That the investigational product to be used in treating the patient is not approved
14 by the United States Food and Drug Administration and that the investigational product may
15 not be effective in treating the patient;

16 (D) Of each potential risk associated with receiving the treatment that is known to the
17 attending physician;

18 (E) That to receive the treatment, the patient may be required to pay the costs of ad-
19 ministering the treatment and the costs of, or the costs associated with, manufacturing the
20 investigational product as described in section 3 (1)(b) of this 2015 Act;

21 (F) That to receive the treatment, the patient must waive liability as described in section
22 5 (5) of this 2015 Act;

23 (G) That receiving the treatment relieves an insurer of reimbursing costs as described
24 in section 12 of this 2015 Act;

25 (H) Of feasible alternatives to receiving the treatment, including palliative care, hospice
26 care and pain control; and

27 (I) That expanded access to treating the patient's terminal disease may be provided pur-
28 suant to 21 C.F.R. 312.300 to 312.320 and may be an option for the patient, and, depending on
29 the type of coverage the patient's insurer provides, that a patient might not be required to
30 pay the costs of administering a treatment provided pursuant to 21 C.F.R. 312.300 to 312.320,
31 or the costs of, or the costs associated with, manufacturing an investigational product used
32 to treat a patient pursuant to 21 C.F.R. 312.300 to 312.320.

33 (2) A patient who has a terminal disease may demonstrate the patient's Oregon residency
34 to the patient's attending physician by presenting:

35 (a) A driver license, driver permit or identification card issued to the patient by the De-
36 partment of Transportation;

37 (b) Evidence that the patient is registered to vote in this state;

38 (c) Evidence that the patient owns or leases property in this state; or

39 (d) A copy of the patient's Oregon individual tax return for the immediately preceding
40 tax year.

41 (3) If in the opinion of an attending physician a patient is suffering from a psychiatric
42 or psychological disorder or depression causing impaired judgment, the attending physician
43 shall refer the patient for counseling. Treatment may not be provided as described in section
44 3 of this 2015 Act until the person performing the counseling determines that the patient is
45 not suffering from a psychiatric or psychological disorder or depression causing impaired

1 judgment.

2 **SECTION 3.** (1) A health care practitioner may offer to treat a patient who has a ter-
3 minal disease with an investigational product not approved by the United States Food and
4 Drug Administration only if:

5 (a) The health care practitioner is authorized by the laws of this state to provide health
6 care services or to dispense drugs, and the health care practitioner is acting within the scope
7 of that authority;

8 (b) The treatment is provided to the patient for no more than the costs of administering
9 the treatment and the costs of, or the costs associated with, manufacturing the
10 investigational product;

11 (c) The patient is not compensated for receiving the treatment;

12 (d) The treatment is being offered only for purposes related to the terminal disease;

13 (e) The patient is qualified;

14 (f) The patient was referred to the health care practitioner by the patient's attending
15 physician under section 2 of this 2015 Act;

16 (g) The health care practitioner refers the patient to a consulting physician to confirm
17 the attending physician's diagnosis and prognosis; and

18 (h) In the health care practitioner's judgment, the patient is acting voluntarily and is not
19 being coerced.

20 (2) A patient who has a terminal disease may demonstrate the patient's Oregon residency
21 to the health care practitioner by presenting:

22 (a) A driver license, driver permit or identification card issued to the patient by the De-
23 partment of Transportation;

24 (b) Evidence that the patient is registered to vote in this state;

25 (c) Evidence that the patient owns or leases property in this state; or

26 (d) A copy of the patient's Oregon individual tax return for the immediately preceding
27 tax year.

28 (3) If in the opinion of the health care practitioner a patient is suffering from a psychi-
29 atric or psychological disorder or depression causing impaired judgment, the health care
30 practitioner shall refer the patient for counseling. Treatment may not be provided as de-
31 scribed in this section until the person performing the counseling determines that the pa-
32 tient is not suffering from a psychiatric or psychological disorder or depression causing
33 impaired judgment.

34 (4) If a patient accepts an offer for treatment under this section, and if the patient has
35 health insurance, the health care practitioner offering to treat the patient must notify the
36 insurer that the patient is receiving the treatment.

37 **SECTION 4.** (1) Before a patient may receive treatment as described in section 3 of this
38 2015 Act, a consulting physician must examine the patient and confirm, in writing:

39 (a) The attending physician's diagnosis that the patient has a terminal disease;

40 (b) The attending physician's prognosis for the patient;

41 (c) That the patient is qualified;

42 (d) That in the consulting physician's judgment the patient is acting voluntarily and is
43 not being coerced; and

44 (e) That the patient is informed:

45 (A) That the investigational product to be used in treating the patient is not approved

1 by the United States Food and Drug Administration and that the investigational product may
2 not be effective in treating the patient;

3 (B) Of each potential risk associated with receiving the treatment known to the con-
4 sulting physician;

5 (C) That to receive the treatment, the patient may be required to pay the costs of ad-
6 ministering the treatment and the costs of, or the costs associated with, manufacturing the
7 investigational product as described in section 3 (1)(b) of this 2015 Act;

8 (D) That to receive the treatment, the patient must waive liability as described in section
9 5 (5) of this 2015 Act;

10 (E) That receiving the treatment relieves an insurer of reimbursing costs as described
11 in section 12 of this 2015 Act;

12 (F) Of feasible alternatives to receiving the treatment, including palliative care, hospice
13 care and pain control; and

14 (G) That expanded access to treating the patient's terminal disease may be provided
15 pursuant to 21 C.F.R. 312.300 to 312.320 and may be an option for the patient, and, depending
16 on the type of coverage the patient's insurer provides, that a patient might not be required
17 to pay the costs of administering a treatment provided pursuant to 21 C.F.R. 312.300 to
18 312.320, or the costs of, or the costs associated with, manufacturing an investigational
19 product used to treat a patient pursuant to 21 C.F.R. 312.300 to 312.320.

20 (2) A patient who has a terminal disease may demonstrate the patient's Oregon residency
21 to the consulting physician by presenting:

22 (a) A driver license, driver permit or identification card issued to the patient by the De-
23 partment of Transportation;

24 (b) Evidence that the patient is registered to vote in this state;

25 (c) Evidence that the patient owns or leases property in this state; or

26 (d) A copy of the patient's Oregon individual tax return for the immediately preceding
27 tax year.

28 (3) If in the opinion of the consulting physician a patient is suffering from a psychiatric
29 or psychological disorder or depression causing impaired judgment, the consulting physician
30 shall refer the patient for counseling. Treatment may not be provided as described in section
31 3 of this 2015 Act until the person performing the counseling determines that the patient is
32 not suffering from a psychiatric or psychological disorder or depression causing impaired
33 judgment.

34 **SECTION 5.** Upon receiving an offer for treatment as described in section 3 of this 2015
35 Act, a patient who has a terminal disease and who is qualified may elect to receive that
36 treatment by signing and dating a form attesting to the election in the presence of two wit-
37 nesses. A form attesting to an election must include:

38 (1) The attending physician's diagnosis for the patient;

39 (2) The attending physician's prognosis for the patient;

40 (3) A statement that the investigational product to be used in treating the patient is not
41 approved by the United States Food and Drug Administration;

42 (4) A description of each potential risk that is associated with receiving the treatment;

43 (5) A waiver of liability for any act or omission of an act related to administering the
44 treatment or manufacturing or distributing the investigational product that does not con-
45 stitute gross negligence for:

1 (a) Any health care practitioner who participates in administering the treatment, to
2 whom a health care practitioner who participates in administering the treatment refers the
3 patient or with whom a health care practitioner who participates in administering the
4 treatment consults;

5 (b) Any health care facility or professional organization or association involved in the
6 administration of the treatment; or

7 (c) Any person that participates in manufacturing or distributing the investigational
8 product used to treat the patient;

9 (6) A provision authorizing any information obtained during the treatment to be used:

10 (a) By the inventor, manufacturer or supplier of any investigational product used in
11 treating the patient for research, analytical or marketing purposes; and

12 (b) By any health care practitioner who participates in administering the treatment for
13 research or analytical purposes; and

14 (7) A statement signed and dated by both witnesses attesting that the patient, to the best
15 of the witnesses' knowledge, is capable and acting voluntarily.

16 **SECTION 6.** (1) Of the witnesses described in section 5 of this 2015 Act, one must be an
17 individual who is not:

18 (a) A relative of the patient by blood, marriage or adoption;

19 (b) An individual who, at the time the form is signed, would be entitled to any portion
20 of the estate of the patient upon the patient's death under any will or by operation of law;
21 or

22 (c) An owner, operator or employee of a health care facility where the patient resides
23 or receives health care services.

24 (2) Neither witness described in section 5 of this 2015 Act may be the attending physician
25 of the patient.

26 **SECTION 7.** A waiver of liability required by section 5 (5) of this 2015 Act must be written
27 in plain and simple language.

28 **SECTION 8.** (1) Except as provided in subsection (3) of this section, a health care prac-
29 titioner who participates in administering a treatment as described in section 3 of this 2015
30 Act, or a health care facility or professional organization or association involved in the ad-
31 ministration of the treatment, is not subject to civil or criminal liability for acts or omis-
32 sions of acts related to administering the treatment if the administration of the treatment
33 complies with sections 1 to 14 of this 2015 Act.

34 (2) Except as provided in subsection (3) of this section, a manufacturer or distributor of
35 an investigational product used to treat a patient pursuant to section 3 of this 2015 Act is
36 not subject to civil or criminal liability for acts or omissions of acts related to the adminis-
37 tration of the investigational product.

38 (3) This section does not apply to acts or omissions of acts that constitute gross
39 negligence.

40 **SECTION 9.** (1) Except as provided in subsection (2) of this section and sections 10 and
41 11 of this 2015 Act, a licensing board, health care facility, health care practitioner or pro-
42 fessional organization or association may not subject a health care practitioner to discipline,
43 including suspension, loss of license, loss of privileges, loss of membership or any other
44 penalty, for participating in administering a treatment as described in section 3 of this 2015
45 Act if the administration of the treatment complies with sections 1 to 14 of this 2015 Act.

1 (2) This section does not apply to acts or omissions of acts that constitute gross
2 negligence.

3 **SECTION 10.** A health care facility or health care practitioner may prohibit another
4 health care practitioner from participating in administering a treatment as described in
5 section 3 of this 2015 Act at the health care facility or on premises owned or controlled by
6 the prohibiting health care practitioner.

7 **SECTION 11.** If a health care practitioner violates a prohibition authorized by section 10
8 of this 2015 Act:

9 (1) A licensing board, health care facility, health care practitioner or professional or-
10 ganization or association may impose upon the violating health care practitioner any form
11 of discipline referred to in section 9 of this 2015 Act that the licensing board, health care
12 facility, health care practitioner or professional organization or association otherwise may
13 legally impose; and

14 (2) The health care facility or prohibiting health care practitioner may:

15 (a) Terminate any lease or other property contract entered into with the violating health
16 care practitioner and subject the violating health care practitioner to any other nonmonetary
17 remedies provided by such a contract; or

18 (b) Terminate any contract for the provision of services entered into with the violating
19 health care practitioner and subject the violating health care practitioner to any other non-
20 monetary remedies provided by such a contract.

21 **SECTION 12.** Sections 1 to 14 of this 2015 Act do not require an insurer to reimburse any
22 cost:

23 (1) Associated with undergoing a treatment as described in section 3 of this 2015 Act; or

24 (2) Demonstrated to be associated with an adverse effect that is a result of undergoing
25 a treatment as described in section 3 of this 2015 Act.

26 **SECTION 13.** Eligibility for hospice care must be determined on the basis of a patient's
27 overall prognosis and care or treatment goals as determined by the patient's attending phy-
28 sician and may not be determined on the basis of whether a patient is undergoing or has
29 undergone a treatment as described in section 3 of this 2015 Act.

30 **SECTION 14.** (1) The Oregon Health Authority shall annually review a sample of records
31 maintained pursuant to sections 1 to 14 of this 2015 Act.

32 (2) An attending physician who makes a referral under section 2 of this 2015 Act, a health
33 care practitioner who administers treatment as described in section 3 of this 2015 Act and
34 a consulting physician who provides written confirmation as described in section 4 of this
35 2015 Act must file with the authority a record, in a form and manner prescribed by the au-
36 thority, of the findings of the attending physician, health care practitioner or consulting
37 physician.

38 (3) At a minimum, the authority shall require that a record filed by a health care prac-
39 titioner who administers treatment as described in section 3 of this 2015 Act must include:

40 (a) The adverse effects of the treatment, if any;

41 (b) The positive outcomes of the treatment, if any;

42 (c) The cost of the treatment to the patient; and

43 (d) The demographics of the patients to whom the treatment is administered.

44 (4) The authority shall adopt rules to facilitate the collection of information required to
45 comply with sections 1 to 14 of this 2015 Act, including rules related to the submission of

1 **information required by this section. Except as otherwise provided by law, information col-**
2 **lected by the authority under this section is not a public record and is not available for in-**
3 **spection by the public.**

4 **(5) The authority shall generate and make available to the public an annual statistical**
5 **report of information collected by the authority pursuant to this section and of patients who**
6 **receive treatment provided pursuant to 21 C.F.R. 312.300 to 312.320.**

7 **(6) The authority shall make the annual report generated under subsection (5) of this**
8 **section available to the Legislative Assembly, in the manner required by ORS 192.245, on or**
9 **before February 1 of each odd-numbered year.**

10 **SECTION 15. This 2015 Act is repealed on January 2, 2022.**

11