A-Engrossed
House Bill 2300

Ordered by the House April 2
Including House Amendments dated April 2

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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 [*drug or device*] **investigational product** not approved by United States Food and Drug Administration. Provides protections, including waiver of liability, for health care practitioners, health care facilities [*and*]**,** professional organizations or associations **and manufacturers or suppliers of investigational products** that comply with Act.

A BILL FOR AN ACT

Relating to treatments for patients with terminal diseases.

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

SECTION 1. As used in sections 1 to 13 of this 2015 Act:

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

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

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

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

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

(6) "Investigational product" means a drug, biological product or device that has successfully completed Phase I and is currently in Phase II or a subsequent phase of an approved clinical trial, as defined in ORS 743A.192, assessing the safety of the drug, biological product or device.

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

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

(a) Capable;

(b) A resident of this state; and

(c) 15 years of age or older, provided that if the patient is 15, 16 or 17 years of age the patient is acting with the consent of the patient's parent or legal guardian.

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.

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

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

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

(b) The patient is qualified; and

(c) The attending physician informs the patient:

(A) That the patient has a terminal disease;

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

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

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

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

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

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

(a) A driver license, driver permit or identification card issued to the patient by the Department of Transportation;

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

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

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

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

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

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

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

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

(e) The patient is qualified;

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

(g) The health care practitioner refers the patient to a consulting physician to affirm the attending physician's diagnosis and prognosis.

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

(a) A driver license, driver permit or identification card issued to the patient by the De-

partment of Transportation;

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

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

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

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

SECTION 4. Before a patient may receive treatment described in section 3 of this 2015 Act, a consulting physician must examine the patient and confirm, in writing:

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

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

(3) That the patient is capable; and

(4) That the patient knows:

(a) That the investigational product to be used in treating the patient is not approved by the United States Food and Drug Administration;

(b) Of each potential risk associated with receiving the treatment known to the consulting physician;

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

(d) Of feasible alternatives to receiving the treatment, including palliative care, hospice care and pain control.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 8. (1) Except as provided in subsection (3) of this section, a health care practitioner who participates in administering a treatment described in section 3 of this 2015 Act, or a health care facility or professional organization or association involved in the administration of the treatment, is not subject to civil or criminal liability for acts or omissions of acts related to administering the treatment if the administration of the treatment complies with sections 1 to 13 of this 2015 Act.

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

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

SECTION 9. (1) Except as provided in subsection (2) of this section and sections 10 and 11 of this 2015 Act, a licensing board, health care facility, health care practitioner or professional organization or association may not subject a health care practitioner to discipline, including suspension, loss of license, loss of privileges, loss of membership or any other penalty, for participating in administering a treatment described in section 3 of this 2015 Act if the administration of the treatment complies with sections 1 to 13 of this 2015 Act.

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

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

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

(1) A licensing board, health care facility, health care practitioner or professional organization or association may impose upon the violating health care practitioner any form of discipline described in section 9 of this 2015 Act that the licensing board, health care facility, health care practitioner or professional organization or association otherwise may le-

gally impose; and

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

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

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

SECTION 12. Sections 1 to 13 of this 2015 Act do not require an insurer to reimburse any cost:

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

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

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