MEMORANDUM

Legislative Fiscal Office
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To: Capital Construction Subcommittee of the Joint Committee on Ways and Means

From: Kim To, Legislative Fiscal Office, 503-986-1830

Date: Friday, June 26, 2015

Subject: HB 2300 Relating to treatments for patients with terminal diseases
Work Session Recommendation

House Bill 2300 establishes a method to regulate the treatment of patients with terminal diseases with investigational products.

The measure previously had hearings in the House Committee on Health Care on 2/4/2015, and 3/30/2015; as well as Senate Committee on Health Care on 6/1/2015 and 6/3/2015.

The – A9 amendment, the original staff measure summary, and the fiscal impact statements are attached to this memo, and available on the Oregon Legislative Information System (OLIS).

Fiscal impact

Passage of this bill is anticipated to have minimal fiscal impact on the Oregon Health Authority (OHA) and the Department of Consumer and Business Services (DCBS). The Office of Health Analytics in OHA estimates that this new work will take an existing Operations and Policy Analyst 40 hours of work per year to complete, which may be accomplished through reprioritization of existing staff workload.

The –A9 amendment

The –A9 amendment replaces the original bill, and:

- Defines terms, and institutes a method by which attending physicians may refer a patient who has a terminal disease to a health care practitioner who is authorized to treat patients with investigational products.
- Establishes the parameters for health care practitioners and patients eligible for treatment with investigational products, including defining the provisions for qualifying for treatment and paying for payments
- Requires the physician who makes a referral, health care practitioner that administers treatment, and consulting physician to file a record with OHA. Records filed by the health

care practitioner that administers treatment must at least provide details that include adverse effects, positive outcomes, cost of treatment, and demographics.

The bill also requires OHA to:

- Adopt rules for the collection of information from physicians who makes a referral, health care practitioners that administers treatment, and consulting physicians.
- Review, annually, a sample of records of patients who have a terminal disease and receive treatment with an investigational product.
- Create an annual statistical report that is available to the public.
- Provide the annual to report to the Legislative Assembly on or before February 1 of every odd-numbered year.

The bill as amended is effective January 1, 2016, and sunsets on January 2, 2022.

Recommendation

LFO recommends moving the – A9 amendment into the bill.

Motion

Motion: Senator/Representative_____:

I move the dash A9 amendment into HB 2300.

Motion

Motion: Senator/Representative_____:

I move HB 2300 to the Full Committee with a "do pass" recommendation as amended.

Assignment of Carriers

Full: _____

Senate: _____

House: _____

HB 2300-A9
(LC 1942)
6/19/15 (MBM/ps)

PROPOSED AMENDMENTS TO
A-ENGROSSED HOUSE BILL 2300

On page 1 of the printed A-engrossed bill, delete lines 4 through 26 and delete pages 2 through 5 and insert:

"SECTION 1. As used in sections 1 to 14 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) 18 years of age or older.

"(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 six months.

"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 as 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;

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

"(d) 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 and that the investigational product may not be effective in treating the patient;

"(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 may be required to pay the costs of administering the treatment and the costs of, or the

costs associated with, manufacturing the investigational product as described in section 3 (1)(b) of this 2015 Act;

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

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

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

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

"(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.

"(3) If in the opinion of an attending physician a patient is suffering from a psychiatric or psychological disorder or depression causing impaired judgment, the attending physician shall refer the patient for counseling. Treatment may not be provided as described in section 3

of this 2015 Act until the person performing the counseling determines that the patient is not suffering from a psychiatric or psychological disorder or depression causing impaired judgment.

"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 costs of administering the treatment and the costs 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;

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

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

"(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 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.

"(3) If in the opinion of the health care practitioner a patient is suffering from a psychiatric or psychological disorder or depression causing impaired judgment, the health care practitioner shall refer the patient for counseling. Treatment may not be provided as described in this section until the person performing the counseling determines that the patient is not suffering from a psychiatric or psychological disorder or depression causing impaired judgment.

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

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

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

"(c) That the patient is qualified;

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

"(e) That the patient is informed:

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

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

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

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

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

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

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

"(2) A patient who has a terminal disease may demonstrate the patient's Oregon residency to the consulting 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.

"(3) If in the opinion of the consulting physician a patient is suffering from a psychiatric or psychological disorder or depression causing impaired judgment, the consulting physician shall refer the

patient for counseling. Treatment may not be provided as described in section 3 of this 2015 Act until the person performing the counseling determines that the patient is not suffering from a psychiatric or psychological disorder or depression causing impaired judgment.

"SECTION 5. Upon receiving an offer for treatment as 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) An individual 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 as 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 14 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 as described in section 3 of this 2015 Act if the administration of the treatment complies with sections 1 to 14 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 as 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 referred to in section 9 of this 2015 Act that the licensing board, health care facility, health care practitioner or professional organization or association otherwise may legally 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 14 of this 2015 Act do not require an insurer to reimburse any cost:

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

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

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

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

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

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

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

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

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

"(4) The authority shall adopt rules to facilitate the collection of information required to comply with sections 1 to 14 of this 2015 Act, including rules related to the submission of information required by this section. Except as otherwise provided by law, information collected by the authority under this section is not a public record and is not available for inspection by the public.

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

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

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

FISCAL IMPACT OF PROPOSED LEGISLATION **Measure: HB 2300 - A9**

Seventy-Eighth Oregon Legislative Assembly – 2015 Regular Session
Legislative Fiscal Office

Only Impacts on Original or Engrossed Versions are Considered Official

Prepared by: Kim To
Reviewed by: Matt Stayner, Linda Ames
Date: 6/24/2015

Measure Description:
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.

Government Unit(s) Affected:
Oregon Health Authority (OHA), Department of Consumer and Business Services (DCBS)

Analysis:

The proposed legislation has been determined to have

MINIMAL EXPENDITURE IMPACT

on state or local government.

While this individual measure has a "Minimal" fiscal impact, an agency may incur a net fiscal impact greater than minimal depending on the cumulative impact of all measures enacted into law that affect the agency.

Seventy-Eighth Oregon Legislative Assembly - 2015 Regular Session **MEASURE: HB 2300 A**

STAFF MEASURE SUMMARY

Senate Committee On Health Care

Fiscal: No Fiscal Impact
Revenue: No Revenue Impact

Action Date: 06/03/15
Action: Do Pass The A-Eng Bill. Refer To Ways And Means.
Meeting Dates: 06/01, 06/03
Vote:
Yeas: 5 - Knopp, Kruse, Monnes Anderson, Shields, Steiner Hayward
Prepared By: Zena Rockowitz, Committee Administrator

WHAT THE MEASURE DOES:

Creates and specifies providers, methods and criteria by which a health care practitioner may offer to treat patient who has a terminal illness with an investigational product that is not approved by the United States Food and Drug Administration. Defines "terminal disease." States that insurers are not required to reimburse any cost associated with the treatment. Specifies that hospice care must be determined on a patient's overall prognosis, care or treatment goals. Specifies protections of waiver of liability for health care practitioners, health care facilities, professional organizations or associations and manufacturers or suppliers of investigational products that comply with the measure.

ISSUES DISCUSSED:

- Time to develop, test and receive approval by U.S. Food and Drug Administration (FDA) for drugs
- Time to process paperwork when requesting non-FDA-approved drugs
- Compromise of clinical integrity
- Pursuit of non-FDA-approved drugs through investigational clinical studies or compassionate use
- Patient access to medication based on socioeconomic factors
- Ethical challenges for physicians
- Side effects of non-FDA-approved drugs
- Hope for patients with terminal illnesses

EFFECT OF COMMITTEE AMENDMENT:

No amendment.

BACKGROUND:

Arizona, Colorado, Louisiana, Michigan and Missouri enacted Right-to-Try laws in 2014. Right-to-Try laws generally permit a patient to have access to an experimental drug after it has passed through Phase 1 of a clinical trial, which is the initial trial testing where a drug is given to a small group of people to evaluate its safety and side effects. Proponents state that only about three percent of the sickest Americans qualify for or have access to clinical drug trials approved by the United States Food and Drug Administration. Right-to-Try legislation that has been developed by the Goldwater Institute states that insurers are not required to cover the costs of the drug or other services related to its use.

Seventy-Eighth Oregon Legislative Assembly - 2015 Regular Session **MEASURE: HB 2300 A**
STAFF MEASURE SUMMARY **CARRIER: Rep. Buehler**
House Committee On Health Care

Fiscal: No Fiscal Impact
Revenue: No Revenue Impact

Action Date: 03/30/15
Action: Do Pass As Amended And Be Printed Engrossed.
Meeting Dates: 02/04, 03/30
Vote:
Yeas: 9 - Buehler, Clem, Greenlick, Hayden, Kennemer, Keny-Guyer, Lively, Nosse, Weidner
Prepared By: Sandy Thiele-Cirka, Committee Administrator

WHAT THE MEASURE DOES:
Creates and specifies providers, methods and criteria by which a health care practitioner may offer to treat patient who has a terminal illness with an investigational product that is not approved by the United States Food and Drug Administration. Defines "terminal disease." States that insurers are not required to reimburse any cost associated with the treatment. Specifies that hospice care must be determined on a patient's overall prognosis, care or treatment goals. Specifies protections of waiver of liability for health care practitioners, health care facilities and professional organizations or associations that comply with the measure.

ISSUES DISCUSSED:

- Patient choices for terminal disease treatment
- Other states that have enacted Right-to-Try laws
- Current drug approval process
- Barriers to the use of effective drugs
- Concerns associated with drug misuse
- Current clinical trial processes and procedures
- Handling of costs to clinicians and patients
- Legislative Counsel's opinion
- Review of amendment

EFFECT OF COMMITTEE AMENDMENT:
Replaces term "drug or device" with "investigational product(s)." Specifies that the patient must be 15 years of age or older and, if 15, 16 or 17 years of age, that parental consent is required. Defines "terminal disease" as death expected to result in one year. States that insurers are not required to reimburse any cost associated with the treatment. Specifies that hospice care must be determined on a patient's overall prognosis, care or treatment goals.

BACKGROUND:
Arizona, Colorado, Louisiana, Michigan and Missouri enacted Right-to-Try laws in 2014. Right-to-Try laws generally permit a patient to have access to an experimental drug after it has passed through Phase 1 of a clinical trial, which is the initial trial testing where a drug is given to a small group of people to evaluate its safety and side effects. Proponents state that only about three percent of the sickest Americans qualify for or have access to clinical drug trials approved by the United States Food and Drug Administration.

Right-to-Try legislation that has been developed by the Goldwater Institute states that insurers are not required to cover the costs of the drug or other services related to its use.

A-Engrossed
House Bill 2300

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

Introduced and printed pursuant to House Rule 12.00. Presession 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 [*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.