HB 2300-6
(LC 1942)
3/25/15 (MBM/ps)

PROPOSED AMENDMENTS TO
HOUSE BILL 2300

On page 1 of the printed bill, line 4, delete "11" and insert "13".

Delete lines 16 through 22 and insert:

"(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.

"(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.".

Delete line 27 and insert:

"(b) The patient is qualified; and".

On page 2, line 1, delete "drug or device" and insert "investigational product".

In line 4, delete "and".

After line 4, insert:

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

In line 5, delete "(E)" and insert "(F)".

In line 16, delete "a drug or device" and insert "an investigational product".

Delete lines 21 through 23 and insert:

"(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;".

In line 24, delete "(e)" and insert "(f)".

In line 26, delete "(f)" and insert "(g)".

After line 35, insert:

"(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.".

In line 42, delete "drug or device" and insert "investigational product".

In line 45, delete "and".

After line 45, insert:

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

On page 3, line 1, delete "(c)" and insert "(d)".

In line 4, after "disease" delete the rest of the line.

In line 5, delete "of this state" and insert "and who is qualified".

In line 9, delete "drug or device" and insert "investigational product".

Delete lines 13 through 18 and insert "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".

In line 35, delete "(2)" and insert "(3)".

In line 40, delete "11" and insert "13".

After line 40, insert:

"(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.".

In line 41, delete "(2)" and insert "(3)".

On page 4, line 3, delete "11" and insert "13".

In line 8, delete the comma.

In line 9, after "practitioner" insert a period and delete the rest of the line and delete lines 10 through 15.

After line 29, insert:

"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.".