HOUSE AMENDMENTS TO A-ENGROSSED HOUSE BILL 4110

By COMMITTEE ON RULES

February 20

On page 1 of the printed A-engrossed bill, line 2, before the period insert "; creating new provisions; amending ORS 689.522; and declaring an emergency".

After line 3, insert:

"**HEALTH PLAN COVERAGE OF PREADJUDICATED INMATES**".

On page 2, after line 14, insert:

"**WORK GROUP ON HEALTH INSURANCE COVERAGE EXCLUSIONS**

"**SECTION 3. (1) The Oregon Health Authority shall convene a work group consisting of individuals representing the interests of health insurers, health care providers, insureds, employers who provide health care coverage to employees, local law enforcement, prescription drug manufacturers, the division of the authority that administers the medical assistance program and other interests that the authority deems necessary for a comprehensive discussion of the public policy issues involved in limiting the utilization and scope of health care coverage.**

"(2) The work group shall study exclusions and other limitations applicable to the coverage of certain groups or certain health services in the health insurance market and self-insured health plans in this state.

"(3) A majority of the members of the work group constitutes a quorum for the transaction of business.

"(4) Official action by the work group requires the approval of a majority of the members of the work group.

"(5) The work group shall elect one of its members to serve as chairperson.

"(6) If there is a vacancy for any cause, the authority shall make an appointment to become immediately effective.

"(7) The work group shall meet at times and places specified by the call of the chairperson or of a majority of the members of the work group.

"(8) The work group may adopt rules necessary for the operation of the work group.

"(9) The work group shall submit a report in the manner provided in ORS 192.245, and may include recommendations for legislation, to the interim committees of the Legislative Assembly related to health as appropriate no later than September 15, 2014.

"(10) The authority shall provide staff support to the work group.

"(11) Members of the work group are not entitled to compensation.

"(12) All agencies of state government, as defined in ORS 174.111, are directed to assist the work group in the performance of its duties and, to the extent permitted by laws relating to confidentiality, to furnish such information and advice as the members of the work group consider necessary to perform their duties.

"**DISPENSING BIOLOGICAL PRODUCTS**

"**SECTION 4.** ORS 689.522 is amended to read:

"689.522. (1) As used in this section:

"(a) 'Biological product' means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

"(b) 'Biosimilar product' means a biological product [*licensed by*] **that** the United States Food and Drug Administration**, relying on a reference biological product:**

"(A) Licensed pursuant to 42 U.S.C. 262(k)(3)(A)(i)**; or**

"(B) Approved based on an application filed under 21 U.S.C. 355(b)(2).

"(c) 'Interchangeable' means[,]**:**

"(A) In reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4)**; or**

"(B) In reference to a biological product described in paragraph (b)(B) of this subsection, that the United States Food and Drug Administration has designated the product as therapeutically equivalent in the list of approved drug products with therapeutic evaluations.

"(d) 'Reference biological product' means the biological product licensed pursuant to 42 U.S.C. 262(a) **or approved based on an application filed under 21 U.S.C. 355(b)(1)** against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure **or approval** of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

"(2) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

"(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

"(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

"(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;

"(d) The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and

"(e) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

"(3) The State Board of Pharmacy shall post and regularly update on a website maintained by the board a list of biosimilar products determined by the United States Food and Drug Adminis-

tration to be interchangeable.

"**SECTION 5.** ORS 689.522, as amended by section 4, chapter 342, Oregon Laws 2013, is amended to read:

"689.522. (1) As used in this section:

"(a) 'Biological product' means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

"(b) 'Biosimilar product' means a biological product [*licensed by*] **that** the United States Food and Drug Administration**, relying on a reference biological product:**

"(A) Licensed pursuant to 42 U.S.C. 262(k)(3)(A)(i)**; or**

"(B) Approved based on an application filed under 21 U.S.C. 355(b)(2).

"(c) 'Interchangeable' means[,]**:**

"(A) In reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4)**; or**

"(B) In reference to a biological product described in paragraph (b)(B) of this subsection, that the United States Food and Drug Administration has designated the product as therapeutically equivalent in the list of approved drug products with therapeutic evaluations.

"(d) 'Reference biological product' means the biological product licensed pursuant to 42 U.S.C. 262(a) **or approved based on an application filed under 21 U.S.C. 355(b)(1)** against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure **or approval** of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

"(2) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

"(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

"(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

"(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product; and

"(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

"(3) The State Board of Pharmacy shall post and regularly update on a website maintained by the board a list of biosimilar products determined by the United States Food and Drug Administration to be interchangeable.

"**CAPTIONS**

"**SECTION 6. The unit captions used in this 2014 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2014 Act.**

"**OPERATIVE DATES AND APPLICABILITY DATES**".

In line 15, delete "3" and insert "7".

In line 16, after "after" delete the rest of the line and insert "January 1, 2015.

"**SECTION 8. Section 2 of this 2014 Act and the amendments to ORS 689.522 by section 4 of this 2014 Act become operative January 1, 2015.**

"**SECTION 9. Section 3 of this 2014 Act is repealed on the date of the convening of the 2015 regular session of the Legislative Assembly as specified in ORS 171.010.**

"**SECTION 10. This 2014 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2014 Act takes effect on its passage.**".