B-Engrossed House Bill 4110

Ordered by the House February 20 Including House Amendments dated February 14 and February 20

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.

Prohibits insurer from denying reimbursement under health benefit plan for covered services provided to person in custody of county sheriff, if person is in custody pending disposition of charges. Requires insurer to reimburse county sheriff for covered services at no less than out-of-network provider rate.

Requires Oregon Health Authority to convene temporary work group of interested persons to study private health insurance and self-insured health plan exclusions and other limitations on coverage of groups of individuals or health services.

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Expands definition of "biosimilar product" for purpose of substitution by pharmacist of prescribed biological product for another biological product.

Declares emergency, effective on passage.

1 A BILL FOR AN ACT

- Relating to health care; creating new provisions; amending ORS 689.522; and declaring an emergency.
- Be It Enacted by the People of the State of Oregon:

HEALTH PLAN COVERAGE OF PREADJUDICATED INMATES

SECTION 1. Section 2 of this 2014 Act is added to and made a part of the Insurance Code.

SECTION 2. (1) As used in this section, "health benefit plan" has the meaning given that term in ORS 743.730.

- (2) Except as provided in subsection (4) of this section, an insurer offering a health benefit plan may not deny reimbursement for any service or supply covered by the plan or cancel the coverage of an insured under the plan on the basis that:
- (a) The insured is in the custody of a county sheriff's office, if the insured is in custody pending the disposition of charges;
- (b) The insured receives publicly funded medical care while in the custody of a county sheriff's office; or
- (c) The care was provided to the insured by an employee or contractor of a county who is qualified to receive reimbursement under the health benefit plan.
- (3) An insurer shall reimburse a county for the costs of covered services or supplies provided to an insured who is in the custody of the county sheriff's office, pending the disposition of charges, in an amount that is no less than the amount paid under the insured's health benefit plan to other out-of-network providers for the same services or supplies.

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.

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- (4) An insurer offering a health benefit plan may:
- (a) Deny coverage for the treatment of injuries resulting from a violation of law;
- (b) Exclude from any requirements for reporting quality outcomes or performance, any covered services provided to an insured in the custody of a county sheriff's office;
- (c) Impose utilization controls under the health benefit plan that apply to services provided to insureds who are not in custody by out-of-network providers, including a requirement for prior authorization;
- (d) Impose the requirements for billing and medical coding for covered services provided to an insured in the custody of a county sheriff's office that the insurer imposes on other providers; and
- (e) Deny coverage of diagnostic tests or health evaluations required, as a matter of course, for all individuals who are in the custody of the county sheriff's office pending the disposition of charges.
 - (5) This section does not:
- (a) Impair any right of an employer to remove an employee from coverage under a health benefit plan;
- (b) Release carriers from the requirement to coordinate benefits for persons who are insured by more than one carrier; or
 - (c) Limit an insurer's right to rescind coverage in accordance with ORS 743.894.
- (6) A public body, as defined in ORS 174.109, may not pay health benefit plan premiums on behalf of a person who is in the custody of a county sheriff's office.

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 Administration 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.

44 CAPTIONS

| SECTION 6. The unit captions used in this 2014 Act are provided only for the convenience |
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| of the reader and do not become part of the statutory law of this state or express any leg- |
| islative intent in the enactment of this 2014 Act. |
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| OPERATIVE DATES AND APPLICABILITY DATES |
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| SECTION 7. Section 2 of this 2014 Act applies to claims for reimbursement of health |
| services that are provided on or after 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. |
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