

## **DRAFT RULES**

### **DIVISION 41**

#### **Definitions**

**855-041-1001**

#### **Definitions**

**(1) “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.**

**(2) “Biosimilar product” means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).**

**(3) “Interchangeable” means, 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).**

**(4) “Reference biological product” means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.**

Stat. Auth.: **ORS 689.205 & OL 2013, Ch 342**

Stats. Implemented: **ORS 689.155 & OL 2013, Ch 342**

## Prescriptions

**855-041-1105**

### Requirements for Prescriptions

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(2) Each pharmacy must document the following information:

(a) The name of the patient for whom or the owner of the animal and the species of the animal for which the drug is dispensed;

(b) The full name and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner or other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

(c) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(d) The directions for use, if given by the practitioner; and

(e) The date of filling, and the total number of refills authorized by the prescribing practitioner.

(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent shall clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions shall not be default values on the prescription.

~~(4) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.~~

**(4) 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.**

**(5) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.**

Stat. Auth.: ORS 689.205 **& OL 2013, Ch 342**

Stats. Implemented: ORS 689.505, ~~&689.515~~ **& OL 2013, Ch 342**