

1 STATE OF OKLAHOMA

2 1st Session of the 58th Legislature (2021)

3 SENATE BILL 4

By: McCortney

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5
6 AS INTRODUCED

7 An Act relating to pharmacy; providing definitions;
8 allowing a pharmacist to substitute certain
9 interchangeable product for certain prescribed
10 product if certain conditions are met; requiring a
11 pharmacist or designee to make entry of certain
12 product provided within certain time frame; providing
13 for method of certain communication; providing for
14 notice to certain prescriber; providing exemption for
15 certain communication; excluding dispensing
16 pharmacist or prescriber from certain requirement and
17 certain penalties; directing the State Board of
18 Pharmacy to maintain certain link on its website;
19 providing certain construction; providing for
20 codification; and providing an effective date.

21 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

22 SECTION 1. NEW LAW A new section of law to be codified
23 in the Oklahoma Statutes as Section 355.4 of Title 59, unless there
24 is created a duplication in numbering, reads as follows:

25 A. For the purposes of this section:

26 1. "Biological product" has the same meaning given to that term
27 in 42 U.S.C., Section 262; and

28 2. "Interchangeable biological product" means a biological
29 product that the U.S. Food and Drug Administration (FDA):

1 a. has licensed, and determined to meet the standards for
2 interchangeability pursuant to 42 U.S.C., Section
3 262(k)(4), or

4 b. has determined is therapeutically equivalent as set
5 forth in the latest edition of or supplement to the
6 United States Food and Drug Administration's (FDA)
7 Approved Drug Products with Therapeutic Equivalence
8 Evaluations.

9 B. A pharmacist may substitute an interchangeable biological
10 product for a prescribed biological product only if all of the
11 following conditions in this subsection are met:

12 1. The substituted product has been determined by FDA to be
13 interchangeable, as defined in subsection A of this section, with
14 the prescribed biological product;

15 2. The prescribing physician has permitted substitution; and

16 3. The pharmacy informs the patient of the substitution.

17 C. Within five (5) business days following the dispensing of a
18 biological product, the dispensing pharmacist or the pharmacist's
19 designee shall make an entry of the specific product provided to the
20 patient including the name of the product and the manufacturer. The
21 communication shall be conveyed by making an entry that can be
22 electronically accessed by the prescriber through:

23 1. An interoperable electronic medical records system;

24 2. An electronic prescribing technology;

1 3. A pharmacy benefit management system; or

2 4. A pharmacy record.

3 D. Entry into an electronic records system as described in
4 subsection C of this section is presumed to provide notice to the
5 prescriber. Otherwise, the pharmacist shall communicate the
6 biological product dispensed to the prescriber using facsimile,
7 telephone, electronic transmission or other prevailing means, except
8 that communication shall not be required where:

9 1. There is no FDA-approved interchangeable biological product
10 for the product prescribed; or

11 2. A refill prescription is not changed from the product
12 dispensed on the prior filling of the prescription.

13 E. The dispensing pharmacist or a prescriber shall not be:

14 1. Required to show proof that the prescriber has access to the
15 record in any type of payment audit conducted by a payer or pharmacy
16 benefit manager; or

17 2. Subject to disciplinary action or civil penalties for
18 failure to ensure that the record is accessible or for failure to
19 access the record.

20 F. The State Board of Pharmacy shall maintain a link on its
21 Internet website to the current list of all biological products
22 determined by the FDA to be interchangeable with a specific
23 biological product.

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G. Nothing in this section shall preclude existing approved brand and generic substitutions.

SECTION 2. This act shall become effective November 1, 2021.

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