

1 ENGROSSED SENATE
2 BILL NO. 4

By: Garvin of the Senate

and

Marti of the House

3
4
5
6 An Act relating to pharmacy; providing definitions;
7 allowing a pharmacist to substitute interchangeable
8 product for certain prescribed product under
9 specified conditions; requiring a pharmacist or
10 designee to make entry of provided products into an
11 electronic records system; specifying method of
12 certain communication; providing for notice to
13 prescriber; providing exemption for certain
14 communication; excluding dispensing pharmacist or
15 prescriber from certain requirement and certain
16 penalties; directing the State Board of Pharmacy to
17 maintain certain link on its website; providing
18 certain construction; providing for codification; and
19 providing an effective date.

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

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

24 A. For the purposes of this section:

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

2. "Interchangeable biological product" means a biological
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 if:

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

14 2. The prescribing health care provider does not express a
15 preference against substitution in writing, verbally or
16 electronically; and

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

18 C. The dispensing pharmacist or the pharmacist's designee shall
19 make an entry into an electronic records system of the specific
20 product provided to the patient including the name of the product
21 and the manufacturer. The communication shall be conveyed by making
22 an entry 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. If no electronic records system is in use by the
6 pharmacy, the pharmacist shall communicate the biological product
7 dispensed to the prescriber using facsimile, telephone, electronic
8 transmission or other prevailing means, except that communication
9 shall not be required where:

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

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

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

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

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

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

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

3 SECTION 2. This act shall become effective November 1, 2021.
4 Passed the Senate the 10th day of March, 2021.

5

6

Presiding Officer of the Senate

7

8 Passed the House of Representatives the ____ day of _____,
9 2021.

10

11

Presiding Officer of the House
of Representatives

12

13

14

15

16

17

18

19

20

21

22

23

24