HOUSE OF REPRESENTATIVES - FLOOR VERSION

STATE OF OKLAHOMA

1st Session of the 58th Legislature (2021)

ENGROSSED SENATE
BILL NO. 4 By: Garvin of the Senate

and

Marti of the House

An Act relating to pharmacy; providing definitions; allowing a pharmacist to substitute interchangeable product for certain prescribed product under specified conditions; requiring a pharmacist or designee to make entry of provided products into an electronic records system; specifying method of certain communication; providing for notice to prescriber; providing exemption for certain communication; excluding dispensing pharmacist or prescriber from certain requirement and certain penalties; directing the State Board of Pharmacy to maintain certain link on its website; providing certain construction; providing for codification; and providing an effective date.

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

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

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):

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

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

B. A pharmacist may substitute an interchangeable biological product for a prescribed biological product if:

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

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

3. The pharmacy informs the patient of the substitution.

C. The dispensing pharmacist or the pharmacist's designee shall make an entry into an electronic records system of the specific product provided to the patient including the name of the product and the manufacturer. The communication shall be conveyed by making an entry through:

1. An interoperable electronic medical records system;

2. An electronic prescribing technology;

3. A pharmacy benefit management system; or

4. A pharmacy record.

D. Entry into an electronic records system as described in subsection C of this section is presumed to provide notice to the prescriber. If no electronic records system is in use by the pharmacy, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, except that communication shall not be required where:

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

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

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

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

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

F. The State Board of Pharmacy shall maintain a link on its Internet website to the current list of all biological products

determined by the FDA to be interchangeable with a specific biological product.

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

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

COMMITTEE REPORT BY: COMMITTEE ON PUBLIC HEALTH, dated 03/31/2021 - DO PASS.