STATE OF OKLAHOMA

1st Session of the 58th Legislature (2021)

HOUSE BILL 2549 By: Virgin

AS INTRODUCED

An Act relating to pharmacy; defining terms; providing for the substitution of an interchangeable biological product for a prescribed biological product under certain conditions; requiring electronic notice of substitution; providing exceptions; directing State Board of Pharmacy to maintain link of all interchangeable biological products; 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 353.18B of Title 59, unless there is created a duplication in numbering, reads as follows:

A. As used in 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 United States Food and Drug Administration (FDA):

a. has licensed and determined it 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 FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

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

1. The substituted product has been determined by the FDA to be interchangeable with the prescribed biological product;

2. The prescribing physician has permitted substitution; and

3. The pharmacy informs the patient of the substitution.

C. Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The entry shall be conveyed in a manner electronically accessible by the prescriber 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 medical records system as described in subsection C of this section is presumed to provide notice to the prescriber. If the pharmacist is unable to comply with the provisions of subsection C of this section, 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 if:

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 State Board of Pharmacy shall maintain a link on its website to the current list of all biological products determined by the FDA to be interchangeable with a specific biological product.

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

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