STATE OF OKLAHOMA

2nd Session of the 57th Legislature (2020)

COMMITTEE SUBSTITUTE
FOR
HOUSE BILL NO. 3791 By: Marti

COMMITTEE SUBSTITUTE

An Act relating to pharmacy; defining terms; providing the substitution of an interchangeable biological product for a prescribed biological product under certain conditions; requiring electronic notice of substitution; providing that dispensing pharmacist shall not be required to show certain proof of access; providing exceptions; directing State Board of Pharmacy to maintain link of all interchangeable biological products; providing for approved brand and generic substitutions; 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 (USFDA):

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

b. has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the USFDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

B. A pharmacist may substitute an interchangeable biological product for a prescribed biological product only if all of the following conditions are met:

1. The substituted product has been determined by the USFDA to be interchangeable, as defined in subsection A of this section, 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 communication shall be conveyed by making an entry that can be electronically accessed 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. 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.

E. Entry into an electronic records system as described in subsection C of this section is presumed to provide notice to the prescriber. Otherwise, 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 when:

1. There is no USFDA-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.

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 USFDA 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, 2020.

57-2-11472 JW 02/26/20