1 STATE OF OKLAHOMA 2 2nd Session of the 57th Legislature (2020) 3 SENATE BILL 1341 By: McCortney 4 5 6 AS INTRODUCED 7 An Act relating to pharmacy; providing definitions; allowing a pharmacist to substitute certain 8 interchangeable product for certain prescribed product if certain conditions are met; requiring a 9 pharmacist or designee to make entry of certain product provided within certain time frame; providing 10 for method of certain communication; providing for notice to certain prescriber; providing exemption for 11 certain communication; directing the State Board of Pharmacy to maintain certain link on its website; 12 providing for codification; and providing an effective date. 13 14 15 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA: 16 SECTION 1. NEW LAW A new section of law to be codified 17 in the Oklahoma Statutes as Section 353.18B of Title 59, unless 18 there is created a duplication in numbering, reads as follows: 19 For the purposes of this section: 20 "Biological product" has the same meaning given to that term 21 in 42 U.S.C., Section 262; and 22 "Interchangeable biological product" means a biological 23 product that the U.S. Food and Drug Administration (FDA): 24

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- 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 only if all of the following conditions in this subsection are met:
- 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 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;

1 A pharmacy benefit management system; or 2 4. A pharmacy record. 3 Entry into an electronic records system as described in D. 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 There is no FDA-approved interchangeable biological product 1. 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 The State Board of Pharmacy shall maintain a link on its Ε. 14 Internet website to the current list of all biological products 15 determined by the FDA to be interchangeable with a specific 16 biological product. 17 SECTION 2. This act shall become effective November 1, 2020. 18 19 57-2-3373 DC 1/13/2020 6:08:23 PM 20 21 22 23 24

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