HOUSE BILL 177

56TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2023

INTRODUCED BY

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AN ACT

RELATING TO DRUGS; AMENDING THE DRUG PRODUCT SELECTION ACT.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. Section 26-3-3 NMSA 1978 (being Laws 1976, Chapter 60, Section 4, as amended) is amended to read:

"26-3-3. DRUG AND BIOLOGICAL PRODUCT SELECTION PERMITTED--CONDITIONS--EXCEPTION FOR PROHIBITION--LABELING.--

A. Upon receipt of a prescription written by a licensed practitioner who may prescribe drugs or biological products for a drug or biological product for which one or more multiple-source drugs or interchangeable biological products are recognized, listed as final determinations and published in the federal register by the federal department of health and human services, a pharmacist may dispense any one of the drugs or interchangeable biological products that satisfies the final

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determinations so recognized and listed by the federal department of health and human services and is sold at a lower cost than the drug or biological product listed in the prescription.

B. Upon receipt of a prescription written by a licensed practitioner for a drug or biological product that appears on the federal food and drug administration's approved prescription drug products with therapeutic equivalence evaluation list as supplemented, or for a biological product that is listed as interchangeable on the lists of the federal food and drug administration's lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations, as supplemented, a pharmacist may dispense any of the listed therapeutically equivalent drugs or interchangeable biological products that is lower in cost to the patient than the prescribed drug or biological product.

C. Upon receipt of a prescription written by a licensed practitioner who may prescribe drugs or biological products, a pharmacist may substitute another drug in the same therapeutic class that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect, even though the substitute drug is not a therapeutically equivalent drug; provided that:

(1) the drug product is not:

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(a) a biological product;

(b) a compounded preparation;

(c) a controlled substance;

(d) a narrow therapeutic index drug;

(e) a psychotropic drug; or

(f) the subject of a risk evaluation and mitigation strategy;

(2) the drug product substitution is intended to ensure formulary compliance with the patient's health insurance plan or, in the case of a patient without insurance, to lower the cost to the patient while maintaining safety;

(3) the patient opts in to the drug product substitution, and the pharmacist clearly informs the patient of the differences in the drug products and specifies that the patient may refuse the substitution;

(4) the prescriber's directions are modified to allow for an equivalent amount of drug to be dispensed as prescribed; and

(5) the pharmacist documents the therapeutic substitution in the prescription record.

[~~C.~~] D. Drug and biological product selection shall be permitted only under circumstances and conditions set forth in Subsections A, [~~and~~] B and C of this section unless the licensed practitioner prescribing prohibits drug or biological product selection. A licensed practitioner shall prohibit drug

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or biological product selection by making an entry that is electronically accessible that includes the words "no substitution" or the diminution "no sub" on a prescription.

[~~D.~~] E. If drug or biological product selection or therapeutic substitution occurs as permitted in Subsections A, [~~and~~] B and C of this section, the pharmacist shall indicate on the label of the dispensed container the brand of drug or the specific biological product prescribed or the name of the drug prescribed in the case of therapeutic substitution and the name of the drug or interchangeable biological product dispensed.

[~~E.~~] F. A pharmacist who selects an interchangeable biological product shall inform the patient or the patient's representative.

[~~F.~~] G. A pharmacist shall not select a therapeutically equivalent drug or interchangeable biological product unless the substitution is in accordance with the provisions of Subsection A or B of this section.

[~~G.~~] H. Within five business days following the dispensing of a [~~biological product~~] therapeutically substituted drug, the dispensing pharmacist or the pharmacist's designee shall [~~make an entry~~] notify the prescriber 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 is electronically accessible to the prescriber through:~~

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~~(1) an interoperable electronic medical records system;~~

~~(2) an electronic prescribing technology;~~

~~(3) a pharmacy benefit management system; or~~

~~(4) a pharmacy record.~~

~~H. Entry into an electronic medical records system pursuant to Subsection G of this section is presumed to provide notice to the prescriber. Otherwise the pharmacist~~] product prescribed and the therapeutically substituted drug, including modified directions for use, if any, and maintain a record thereof.

I. Within five business days, the pharmacist or pharmacist's designee shall communicate to the prescriber what interchangeable biological product was dispensed, using [~~facsimile~~] telephone, electronic transmission or other prevailing means; provided that communication shall not be required when

[~~(1) there is no interchangeable biological product that has been approved by the federal food and drug administration for the product prescribed; or~~

~~(2)~~] a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

[~~I. The board shall maintain a link on its website to the current lists of all biological products that the federal food and drug administration has determined to be~~

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~~interchangeable biological products.~~]

J. For purposes of this section:

(1) "multiple-source drug" means a drug marketed or sold by two or more manufacturers, formulators or labelers; [~~and~~]

(2) "narrow therapeutic index drug" means a drug for which a small difference in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions;

(3) "therapeutic class" means a group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition; and

[~~(2)~~] (4) "therapeutically equivalent" means drug products that have the same amount of the active drug in the same dosage form that when administered can be expected to provide the same therapeutic effect."

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