**217.822 Substitution of equivalent drug or interchangeable biological product -- Substitute must be lower in price than prescribed drug or biological product -- Selection by pharmacist not practice of medicine -- Liability of pharmacist -- Pharmacist to communicate to prescribing practitioner the specific biological product dispensed.**

(1) When a pharmacist receives a prescription for a brand name drug which is not listed by generic name in the nonequivalent drug product formulary prepared by the board, the pharmacist shall select a lower-priced therapeutically equivalent drug which the pharmacist has in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's practitioner. If a lower-priced selection is made, the label on the container of the drug shall show the name of the drug dispensed.

(2) When a pharmacist receives a prescription for a brand name biological product which is not listed by name in the nonequivalent drug product formulary prepared by the board, the pharmacist shall dispense a lower-priced interchangeable biological product, if there is one in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's prescribing practitioner. If an interchangeable product is selected, the label on the container shall show the name of the biological product dispensed.

(3) When an equivalent drug product or interchangeable biological product is dispensed in lieu of a brand name drug prescribed, the price of the equivalent drug or interchangeable biological product dispensed shall be lower in price to the purchaser than the drug product prescribed.

(4) If, in the opinion of a practitioner, it is to the best interest of the practitioner's patient that an equivalent drug or interchangeable biological product should not be dispensed, the practitioner may indicate in the manner of his or her choice on the prescription "Do Not Substitute," except that the indication shall not be preprinted on a prescription.

(5) The selection of any drug or interchangeable biological product by a pharmacist under the provisions of this section shall not constitute the practice of medicine.

(6) A pharmacist who selects an equivalent drug product or interchangeable biological product pursuant to KRS 217.815 to 217.826 assumes no greater liability for selecting the dispensed drug product than would be incurred in dispensing a prescription for a drug product or biological product prescribed by its generic, nonbrand, or proper name.

(7) When a pharmacist receives a generically written prescription for a multiple source drug product, he or she shall dispense an equivalent drug product in accordance with the provisions of KRS 217.815 to 217.826.

(8) When a pharmacist receives a prescription for a biological product written by nonbrand or proper name, he or she shall dispense an interchangeable biological product in accordance with the provisions of KRS 217.814 to 217.826, provided that the interchangeable product has been deemed by the United States Food and Drug Administration to be interchangeable with that specific reference product as identified by the nonbrand or proper name.

(9) A pharmacist shall not substitute a biological product for a prescribed biological product unless the substituted product is an interchangeable biological product for the prescribed biological product.

(10) (a) Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer.

(b) Communication shall be conveyed by making an entry that is electronically accessible to the prescribing practitioner through:

1. An interoperable electronic medical records system;
2. An electronic prescribing technology;
3. A pharmacy benefit management system; or
4. A pharmacy record.

(c) Communication entries into an electronic records system as described in this subsection are presumed to provide notice to the prescribing practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescribing practitioner using facsimile, telephone, electronic transmission, or other prevailing means. Communication to the prescribing practitioner, or the prescribing practitioner's office personnel, using facsimile, telephone, electronic transmission, or other prevailing means shall be presumed to provide notice to the prescribing practitioner.

(d) Communication shall not be required where:

1. There is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed;
2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or
3. The prescribing practitioner indicates "Do Not Substitute" on the prescription.

(e) Communication received by the prescribing practitioner from the dispensing pharmacist or the pharmacist's designee shall be treated in accordance with the standards of acceptable and prevailing practice of the prescribing practitioner within the Commonwealth of Kentucky and the following as they relate to patient records:

1. The principles of ethics of the American Medical Association;
2. The code of ethics of the American Osteopathic Association;
3. The principles of ethics and code of professional conduct of the American Dental Association;
4. The code of ethics of the American Chiropractic Association;
5. The principles of veterinary medical ethics of the American Veterinary Medical Association;
6. The code of ethics of the American Optometric Association; or

7. The code of ethics for nurses of the American Nurses Association.

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