CHAPTER 238
FORMERLY
SENATE SUBSTITUTE NO. 1 FOR
SENATE BILL NO. 118
AS AMENDED BY
HOUSE AMENDMENT NO. 2

AN ACT TO AMEND TITLE 24 OF THE DELAWARE CODE RELATING TO PHARMACISTS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 25, Subchapter VI, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows and redesignating accordingly:

CHAPTER 25. PHARMACY

Subchapter I. Objectives; Definitions; Board of Pharmacy

§ 2502. Definitions.

The following words, terms, and phrases when used in this chapter have the meanings ascribed to them in this section, except where the context clearly indicates a different meaning.

"Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act 42 U.S.C. § 262(i)).

"Interchangeable" means a biological product licensed by the Federal Food and Drug Administration pursuant to 42 U.S.C. § 262(k)(4).

"Reference Product" means a product as defined by the Federal Food and Drug Administration pursuant to 42 U.S.C. § 262.

"Substitution" or "substitute" means pharmacists selection of prescriber authorized generic or therapeutically equivalent prescription medications or, in the case of biologicals, pharmacist selection of an interchangeable biological product in place of the prescribed product. Generic substitution means a drug that is the same active ingredient, equivalent in strength to the strength written on the prescription and which is classified as being therapeutically equivalent to another drug in the latest edition or supplement of the Federal Food and Drug Administration (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations, sometimes referred to as the "Orange Book."

§ 2549A. Dispensing and Substitution of Biological Products

(a) A pharmacist may substitute for a prescribed biological product only if:

(1) the practitioner has not expressly prohibited substitution in a manner specified in §2549;

(2) the product to be substituted has been designated by the Federal Food and Drug Administration as interchangeable with or therapeutically equivalent to the prescribed product;

(3) the pharmacist informs the patient or the patient's adult representative that an interchangeable biological product has been dispensed; and

(4) the pharmacist indicates on the prescription and on the prescription label the name of the manufacturer of the interchangeable biological product substituted unless the practitioner indicates otherwise.

(b) If a biological product is dispensed, the pharmacist or the pharmacist's designee shall, within a reasonable time but not to exceed ten days following dispensing, communicate to the practitioner the name and manufacturer of the biological product dispensed, by:

(1) recording such information in an interoperable electronic health records system shared with the prescribing practitioner, to the extent such a system is in place between a pharmacist and practitioner; or

(2) in the case where electronic health records are not in place between a pharmacist and a practitioner, communicating such information to the practitioner using any prevailing means available. No communication is required under this subsection where there is no interchangeable or therapeutically equivalent biological product for the prescribed biological product, or where a refill prescription is not changed from the biological product originally dispensed.

(c) The pharmacy shall maintain a record of the biological product dispensed as required in §2532.

(d) The Board of Pharmacy shall maintain a link on its web site to the current list of all biological products determined by the Federal Food and Drug Administration to be interchangeable with a specific biological product.

(e) Hospital pharmacies shall be exempt from the requirements of subsection (b) of this section.

Approved May 28, 2014