PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17755 Dispensing lower cost generically equivalent drug product or interchangeable biological drug product; notice; contents of prescription label; limitation; restrictions; limitation on total charge; communication to be provided prescriber; exception; link on website to Purple Book; report; definitions.

Sec. 17755. (1) Except as provided in subsection (3), when a pharmacist receives a prescription for a brand name drug product or biological drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product or interchangeable biological drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product or interchangeable biological drug product if available in the pharmacy. If a drug or biological drug product is dispensed that is not the prescribed brand, the purchaser must be notified and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. Except as otherwise provided in section 17756, if the dispensed drug or biological drug product does not have a brand name, the prescription label must indicate the generic name of the drug dispensed or the proprietary name of the biological drug product dispensed.

(2) If a pharmacist substitutes a lower cost generically equivalent drug product or interchangeable biological drug product to a purchaser who is not submitting a claim to a third-party payment source, the pharmacist shall charge the purchaser not more than the current selling price for the lower cost drug product.

(3) The pharmacist shall not dispense a generically equivalent drug product or interchangeable biological drug product under subsection (1) if any of the following apply:

(a) The prescriber, in the case of a prescription in writing signed by the prescriber, writes in his or her own handwriting "dispense as written" or "d.a.w." on the prescription.

(b) The prescriber, having preprinted on his or her prescription blanks the statement "another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed d.a.w.", writes in his or her own handwriting the initials "d.a.w." in a space, box, or square adjacent to the statement.

(c) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates that the prescription is to be dispensed as communicated.

(4) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser.

(5) Except as otherwise provided in subsection (6), within 5 days after dispensing an interchangeable biological drug product, the dispensing pharmacist or his or her designee shall communicate to the prescriber the specific interchangeable biological drug product provided to the patient, including the name of the interchangeable biological drug product and its manufacturer. The communication required under this subsection must be made as follows:

(a) By making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, a health information exchange, or a pharmacy record. An entry made as described in this subdivision is presumed to provide notice to the prescriber.

(b) If the methods described in subdivision (a) are not available, then by facsimile, telephone, electronic transmission, or other prevailing means.

(6) Subsection (5) does not apply if either of the following occurs:

(a) There is no FDA-licensed interchangeable biological drug product for the product prescribed.

(b) A refill authorization does not change the product that was dispensed on the prior filling of the prescription.

(7) The board shall maintain a link on its website to the current Purple Book.

(8) Beginning June 1, 2018 and annually thereafter, the department shall submit a report on all of the following to the house and senate standing committees on health policy, the speaker of the house of representatives, and the senate majority leader:

(a) A list of each biological drug product that the FDA had previously determined to be therapeutically equivalent as set forth in the Orange Book that is now included in the Purple Book.

(b) The anticipated date that every biological drug product that the FDA has determined to be therapeutically equivalent as set forth in the Orange Book will be included in the Purple Book.

(9) As used in this section:

(a) "Orange Book" means "Approved Drug Products with Therapeutic Equivalence Evaluations", an FDA publication that is commonly referred to as the "Orange Book".

(b) "Purple Book" means "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations", an FDA publication that is commonly referred to as the "Purple Book".

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2018, Act 41, Eff. May 29, 2018;—Am. 2018, Act 246, Eff. Sept. 26, 2018.

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