

§8731. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 2019, c. 470, §8 (NEW).]

1. Brand-name drug. "Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product. [PL 2019, c. 470, §8 (NEW).]

1-A. Drug product family. "Drug product family" means a group of one or more prescription drugs that share a unique generic drug description and drug form. [PL 2021, c. 305, §1 (NEW).]

2. Generic drug. "Generic drug" means a prescription drug, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand-name drug and is therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance and intended use. "Generic drug" includes a biosimilar product. [PL 2019, c. 470, §8 (NEW).]

3. Manufacturer. "Manufacturer" means an entity that manufactures or repackages, and sets the wholesale acquisition cost for, prescription drugs that are distributed in the State. [PL 2021, c. 305, §2 (AMD).]

3-A. Prescription drug. "Prescription drug" means a drug, as defined in 21 United States Code, Section 321(g) or a biological product as defined in 42 United States Code, Section 262(i)(1) that:

A. Is intended for human use; [PL 2021, c. 305, §3 (NEW).]

B. Is not a device within the meaning of 21 United States Code, Section 321(h); and [PL 2021, c. 305, §3 (NEW).]

C. By federal or state law, can be lawfully dispensed or administered only on prescription by a licensed health care professional. [PL 2021, c. 305, §3 (NEW).]
[PL 2021, c. 305, §3 (NEW).]

4. Pricing component data. "Pricing component data" means data unique to each manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter that evidences the cost to each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers and the payments received by each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers, taking into account any price concessions, and that is measured uniformly among the entities, as determined by rules adopted by the organization pursuant to section 8737. [PL 2019, c. 470, §8 (NEW).]

5. Pricing unit. "Pricing unit" means the smallest dispensable amount of a prescription drug that could be dispensed. [PL 2019, c. 470, §8 (NEW).]

6. Wholesale acquisition cost. "Wholesale acquisition cost" means a manufacturer's listed price for sale to a wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions. [PL 2019, c. 470, §8 (NEW).]

SECTION HISTORY

PL 2019, c. 470, §8 (NEW). PL 2021, c. 305, §§1-3 (AMD).

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