96060 Definitions

For the purposes of this chapter, the following definitions apply:

(a)

"Department" means the Department of Health Care Access and Information.

(b)

"Drug product" means the finished dosage form of a prescription drug that contains a drug substance, generally, but not necessarily, in association with other active or inactive ingredients, and that has a unique NDC.

(c)

"Introduced to market" means made available for purchase in California.

(d)

"Manufacturer" means an entity that (1) holds the NDC for a prescription drug; and (2) Is described in Health and Safety Code Section 127675.

(1)

holds the NDC for a prescription drug; and

(2)

Is described in Health and Safety Code Section 127675.

(e)

"National Drug Code (NDC)" refers to a three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit

format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one "0" has been added to the front of each segment containing less than the specified amount of digits such that each segment contains the specified amount of digits.

(f)

"New prescription drug" means a drug receiving initial approval under an original new drug application under Section 355(b) of Title 21 of the United States Code, under an abbreviated new drug application under Section 355(j) of Title 21 of the United States Code, or under a biologics license application under Section 262 of Title 42 of the United States Code. Each product listed on the application shall be considered a new prescription drug.

(g)

"Prescription drug" means a drug, as defined in Section 321(g) of Title 21 of the United States Code, or a biological product as defined in Section of Title 42262(i)(1) of Title 42 of the United States Code, that (1) is intended for human use; (2) is not a device within the meaning of Section 321(h) of Title 21 of the United States Code; (3) by federal or state law, can be lawfully dispensed only on prescription by a licensed healthcare professional; and (4) is purchased or reimbursed by an entity described in subdivision (a) of Health and Safety Code Section 127675.

(1)

is intended for human use;

(2)

is not a device within the meaning of Section 321(h) of Title 21 of the United States Code;

(3)

by federal or state law, can be lawfully dispensed only on prescription by a licensed healthcare professional; and

(4)

is purchased or reimbursed by an entity described in subdivision (a) of Health and Safety Code Section 127675.

(h)

"Registered purchaser" means an organization described in subdivision (a) of Health and Safety Code Section 127675 and that has registered with the Department pursuant to Section 96061.

(i)

"Wholesale Acquisition Cost" means a manufacturer's published list price for a prescription drug product with a unique NDC.

(j)

"Date" means calendar date; month, day and year shall be reported in numeric format separated by "/". For example, 3/12/2009.

(k)

"Cost" or "price" means a monetary amount in United States currency, which shall be reported in dollars to the cent level.