20:51:21:01. Definitions. Terms used in this chapter mean:

(1) "Automated mechanical distribution device," see § 20:51:17:01 for definition and use;

(2) "Container," that which holds the drug and is or may be in direct contact with the drug without interacting chemically or physically affecting the drug placed in it so as to alter the strength, quality, or purity of the drug beyond the official compendium requirements;

(3) "Customized patient medication package," a package that contains two or more drugs per compartment;

(4) "Prepackage," to prepare a drug in a container for dispensing, prior to the receipt of an order. Such packaging may be in a unit dose, single dose, or unit of issue package for use in a unit dose dispensing system, in a container suitable for a traditional dispensing system, or in a customized patient medication package;

(5) "Repackage," to prepare a unit dose, single dose, unit of issue package, customized patient medication package, or traditional dispensing system package for dispensing pursuant to an existing order;

(6) "Sealed unit dose container," a container that holds the drug in a hermetically sealed compartment to reduce the drug's exposure to moisture, air, and tampering until the time of administration;

(7) "Traditional dispensing system," a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages;

(8) "Unit dose," a single dose of a drug in an individually sealed, labeled container ready for administration to a particular patient by the prescribed route at the prescribed time;

(9) "Unit dose distribution system," a drug distribution system that is in a pharmacy outlet, hospital, or other healthcare facility and uses unit dose packages, or unit of issue packages, labeled in accordance with § 20:51:21:05 and preserves the identity of the drug until the time of administration;

(10) "Unit dose package," an individual package that contains one single unit dose of a drug packaged by a manufacturer or a pharmacy and preserves the integrity and identity of the drug from the point of packaging to the point of administration; and

(11) "Unit of issue package," a package that provides multiple units of the same drug doses, each separated in a medication card or other specifically designed container.

Source: 8 SDR 5, effective July 26, 1981; 12 SDR 151, 12 SDR 155, effective July 1, 1986; definition of "unit dose packaging" transferred from § 20:51:21:02, 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.

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