

18 procedure used to repackage, label, transfer, restock, re-dispense,
19 and credit any unit dose drugs returned to the pharmacy;

20 (c) The drugs are provided in the manufacturer's unit dose pack-
21 aging or are repackaged by the pharmacy in a hermetically sealed
22 single unit dose container that meets Class A or Class B standards
23 on pages 1937 and 1938 of the United States Pharmacopeia;

24 (d) The unit dose package is labeled by the manufacturer with the
25 drug lot number and expiration date;

26 (e) If the drug is repackaged by the pharmacy, each single unit
27 dose prepackaged or repackaged container must be labeled in accor-
28 dance with this regulation. Labeling must include the following:—

29 i.) Name and strength of the medication;

30 ii.) A suitable expiration date which shall not be later than the
31 expiration date on the manufacturer's container, or one year max-
32 imum from the date the drug is prepackaged or repackaged;

33 iii.) The date the product was prepackaged or repackaged;

34 iv.) The manufacturer's lot number, expiration date, and identity;

35 v.) The identity of the pharmacist responsible for prepackaging or
36 repackaging;

37 If the requirements of subsections (e)(iv) and (e)(v) are main-
38 tained in the internal records of the drug outlet, those requirements
39 may be omitted from the labeling.

40 (f) The drug's packaging is tamper resistant and shows no evi-
41 dence of contamination, such as an opened or stained container;

42 (g) The unit dose drugs have not reached the expiration date;

43 (h) The drugs have not been dispensed in packaging that intermin-
44 gles different drugs in a single compartment; and

45 (i) The drugs are not controlled drugs.

1 SECTION 2. Unused unit dose drugs that are returned under this
2 section may be re-dispensed if the drug is in:—

3 (a) Its original dispensed, unopened, untampered multiple dose
4 container or unopened, untampered single user unit; or an in-use
5 multiple dose container subject to appropriate safeguards as defined
6 in rules for public health or operational considerations;

7 (b) Has remained at all times under the control or direction of a
8 person in the institutional facility or the pharmacy trained and
9 knowledgeable in the storage of drugs, including periods in transit

- 10 by any carrier for hire or person or entity hired solely to transport
11 prescription drugs;
- 12 (c) Is not adulterated or misbranded;
- 13 (d) Has been stored under conditions meeting United States Phar-
14 macopoeia standards;
- 15 (e) Is returned and redispensed or redistributed before the expira-
16 tion date or use by date on the multiple dose container or single user
17 unit;
- 18 (f) Has not been in the possession of an individual member of the
19 public; and
- 20 (g) Is not included within the classification of controlled sub-
21 stances, as defined in applicable federal and state laws.