

4729:5-3-18

**Dangerous drug recall procedures.**

- (A) A terminal distributor of dangerous drugs shall develop and implement a written procedure for the management of recalls by the manufacturer for dangerous drugs stocked by the terminal distributor. Such procedures shall include, where appropriate, contacting patients to whom the recalled drug products have been dispensed or personally furnished.
- (B) The written procedure shall include, but not be limited to, the following:
- (1) The terminal distributor shall make a reasonable attempt to ensure that a recalled drug has been removed from inventory no later than the next business day after receipt of the recall notice by the responsible person or the responsible person's designee, and quarantined until proper disposal, destruction, or return of the drug;
  - (2) If the drug that is the subject to a recall is maintained by the terminal distributor in a container without a lot number, the terminal distributor shall consider this drug included in the recall; and
  - (3) Maintaining records for activities taken by the terminal distributor in relation to a drug recall.
- (C) The written procedures shall be updated as necessary and maintained in a readily retrievable manner. All records documenting recall activities shall be maintained for three years and shall be made readily retrievable.

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Five Year Review (FYR) Dates: 11/11/2029

CERTIFIED ELECTRONICALLY

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Certification

08/09/2024

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Date

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