Recall Procedures for Terminal Distributors of Dangerous Drugs

Updated 8/13/2024

Effective November 11, 2024, rule 4729:5-3-18 of the Administrative Code requires terminal distributors of dangerous drugs to develop and implement a written procedure to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee. Such procedures must be regularly updated as necessary and must be readily retrievable (e.g., produced within three business days) upon request.

For questions regarding this rule, please review the frequently asked questions in this document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Frequently Asked Questions

Q1) Does this apply to all terminal distributors of dangerous drugs?

A1) Yes. This applies to all licensed terminal distributors of dangerous drugs.

IMPORTANT: This applies to both human and veterinary drug recalls.

Q2) What is required to be included in our written procedures?

A2) The rule requires the adoption of written procedures that include all the following:

1. The terminal distributor must, where appropriate, contact patients to whom the recalled drug products have been dispensed or personally furnished.
2. The terminal distributor must 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 terminal distributor's responsible person or the responsible person's designee, and quarantined until proper disposal, destruction, or return of the drug.

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IMPORTANT: If a drug that is 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.

3. Maintaining all required documentation and records for activities taken by the terminal distributor in relation to a drug recall. **NOTE:** All records documenting recall activities shall be maintained for three years and shall be made readily retrievable.

Q3) Who is responsible for determining if a patient is notified?

A3) Patient notification is not required for all recalls. Rather, it is up to the terminal distributor's written procedure to determine when such notification is appropriate based on the risk to the patient and other factors surrounding recall.

Q4) Who must remove the recalled drugs from our stock?

A4) The terminal distributor through its responsible person or the responsible person's designee is responsible for removing a recalled drug from the terminal distributor's inventory.

Q5) What if we have a recalled drug that is housed in a container without a lot number?

A5) If the terminal distributor has the recalled drug in a container that does not have a lot number, the terminal distributor shall consider this drug part of the recall and must comply with the applicable requirements of the rule.

Q6) How often must recall procedures be reviewed and updated?

A6) There is no set timeframe for reviewing and updating written recall procedures. Rather, the rule requires the recall procedures to be updated as necessary.

Q7) How can I be alerted to drug recalls?

A7) The FDA currently lists all active drug recalls here: https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls

Licensees are encouraged to sign up for FDA's MedWatch Safety Alert: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/subscribe-medwatch-safety-alerts

Additionally, here are some resources from the FDA for handling drug recalls:

- Best Practices for Drug Product Recalls (Video Presentation)
- Industry Guidance For Recalls