Policy Title: Medication Recall Notification and Removal of Affected Medications

Effective Date: 08/15/2025

Approved By: Director of Medical and Clinical Services

Review Schedule: Annually or as Needed

Applies To: All Programs — Outpatient MH/SUD, IOP, PHP, and Integrated Primary Care/Behavioral Health

I. Purpose

To ensure a prompt, safe, and organized response to medication recalls, including notification, identification, removal, and appropriate disposition of affected medications, in compliance with CARF, FDA, DEA, and Ohio Board of Pharmacy regulations.

II. Scope

Applies to all REACH for Tomorrow locations and staff involved in medication procurement, prescribing, dispensing, administration, and oversight.

III. Policy Statement

REACH for Tomorrow will promptly respond to all recall notifications by identifying, removing, and securing affected medications, notifying prescribers and clients as appropriate, and documenting all actions in compliance with CARF Section 2.F and regulatory standards.

IV. Definitions

- Medication Recall: Action to remove a drug product from the market due to safety or regulatory concerns.
- Class I: Serious or life-threatening health risk.
- Class II: Temporary or reversible adverse effects.
- Class III: Violates labeling or manufacturing standards with minimal health risk.
- Recall Coordinator: Director of Medical and Clinical Services responsible for managing recall actions.

V. Responsibilities

- Director of Medical and Clinical Services: Serves as Recall Coordinator, manages recall response, ensures compliance, and documentation.
- Site Leads/Nurse Leads: Conduct on-site searches, remove affected stock, complete recall logs.
- Prescribers: Review client exposure, provide clinical guidance, and document follow-up.
- All Staff: Report recall notices immediately to the Recall Coordinator.

VI. Procedure

A. Receipt of Recall Notification

1. Recall Coordinator reviews recall details (drug name, strength, NDC, lot, expiration, recall class). If the lot number is not found, it is considered affected by the recall and must be included in segregation and destruction.
2. Records notice in the Medication Recall Action Log.
3. Issues written/electronic notification to all sites with recall details and instructions.

B. Identification of Affected Stock

Site Leads perform a full inventory search (med rooms, fridges, sample closets).
Findings are reported to the Recall Coordinator and logged, including "none found" if applicable. This will be done by the end of the next business day.

C. Removal and Segregation

Affected medications are immediately removed, labeled "RECALLED – DO NOT USE," and secured in a locked location until final disposition.

D. Disposition

Medications are returned to the manufacturer/distributor or destroyed per the Medication Return and Destruction Policy.
Controlled substances follow DEA and OAC destruction requirements (including DEA Form 41 when applicable).

E. Notification of Prescribers and Clients

1. Prescribers are notified to identify and review clients prescribed the affected medication.
2. For Class I and relevant Class II recalls, clients/guardians are contacted, advised on next steps, and follow-up actions documented in the EHR.

F. Documentation and Tracking

The Recall Coordinator maintains a Medication Recall Action Log including recall details, findings, quantities removed, actions taken, and resolution. Records are retained for at least three (3) years.

G. Oversight and Quality Improvement

The Medication Management Committee reviews all recall activities quarterly to ensure timeliness, completeness, and staff compliance.