

POLICY AND PROCEDURE

REACH for Tomorrow

Policy Title: Regulatory Compliance Policy (DEA, FDA, and State Board)

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 REACH for Tomorrow's medication-related practices are fully compliant with applicable federal, state, and accreditation requirements governing the prescribing, storage, dispensing, administration, and disposal of medications.

This policy provides the framework for adherence to DEA, FDA, and State of Ohio regulatory standards as required under CARF 2025 Section 2: Medication Use, ensuring medication safety, accountability, and legal compliance across all service settings.

II. Scope

This policy applies to all REACH for Tomorrow programs, locations, and personnel involved in medication management, including:

- Outpatient Mental Health and Substance Use Disorder (SUD) programs
- Integrated Primary Care/Behavioral Health services
- Partial Hospitalization (PHP) and Intensive Outpatient (IOP) programs
- Medication-Assisted Treatment (MAT) programs
- Any contracted or on-site laboratory and pharmacy-related activities

III. Policy Statement

REACH for Tomorrow maintains strict compliance with all federal and state laws governing medication use and storage.

The organization's medication management system adheres to regulations established by the Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), Ohio Board of Pharmacy, Ohio Board of Medicine, and Ohio Board of Nursing.

All prescribing, procurement, inventory, storage, administration, and disposal activities are monitored under the direction of the Director of Medical and Clinical Services and licensed prescribing staff.

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IV. Federal Compliance Standards

A. Drug Enforcement Administration (DEA)

1. REACH for Tomorrow and its licensed prescribers comply with all DEA requirements governing controlled substances, including registration, recordkeeping, prescribing, and security.
2. Each prescriber must:
 - Maintain an active DEA registration for controlled substance prescribing.
 - Utilize their own DEA number for all controlled substance prescriptions.
 - Review the Ohio Automated Rx Reporting System (OARRS) before issuing or renewing any controlled substance.
3. All controlled substances are stored in double-locked, secured cabinets with restricted access.
4. Controlled substances are inventoried and reconciled at least weekly, with logs maintained for a minimum of three years.
5. Lost, stolen, or diverted controlled substances must be reported immediately to the DEA, Ohio Board of Pharmacy, and Medical Director, using DEA Form 106 where required.
6. DEA Schedule II medications are prescribed only as clinically indicated, following state and federal refill and quantity limits.

B. Food and Drug Administration (FDA)

1. All medication procurement and administration practices follow FDA labeling, packaging, and storage requirements.
2. Sample medications must:
 - Be provided only by licensed representatives to prescribers with proper DEA and state licenses.
 - Be labeled clearly with name, strength, lot number, and expiration date.
 - Be stored securely and separately from patient-specific medications.
3. The organization participates in FDA recall monitoring; all medication recalls are logged and documented with removal or disposal confirmation.
4. Adverse reactions to any FDA-approved medication are documented, reported to the prescriber, and, when indicated, to the FDA MedWatch Program.

V. State of Ohio Compliance Standards

A. Ohio Board of Pharmacy

1. All medication storage, handling, destruction, and dispensing follow OAC 4729:5 standards.
2. Medications are stored in secured, temperature-controlled environments; temperature logs are reviewed daily.
3. Medication destruction must be witnessed by two authorized staff and documented on the Medication Destruction Log.

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4. The organization maintains a Terminal Distributor of Dangerous Drugs (TDDD) license when storing or administering medications requiring licensure.
5. Compliance inspections and audits are conducted at least annually, with corrective action taken for any deficiencies.

B. Ohio Board of Medicine

1. All prescribers maintain active licensure and follow all OAC 4731 requirements for prescribing and patient care.
2. Controlled substance prescribing is consistent with OAC 4731-11 standards, including documentation of medical necessity, diagnosis, and treatment rationale.
3. Prescribers ensure appropriate follow-up and documentation for ongoing medication management and monitoring of client response.

C. Ohio Board of Nursing

1. Nursing staff adhere to OAC 4723-4 and 4723-5 standards for medication administration and scope of practice.
2. Only licensed personnel may administer medications, and all administration must be documented in the client's health record.
3. Nurses and medical assistants receive ongoing training on medication safety, documentation, and controlled substance protocols.

VI. Oversight and Accountability

1. The Director of Medical and Clinical Services is responsible for ensuring compliance with all medication-related laws and standards.
2. The Director of Medical and Clinical Services oversees internal audits, ensuring documentation and corrective actions are completed.
3. The Medication Management Committee reviews compliance data, controlled-substance reports, and audit outcomes quarterly.
4. All incidents of potential noncompliance are reported to the Medical Director immediately and documented in the Risk Management System.
5. Findings and trends are reviewed under the Quality Improvement (QI) Program, with performance indicators tracked annually.

VII. Staff Training and Competency

1. All staff involved in medication handling receive training upon hire and annually thereafter, including:
 - DEA, FDA, and State Board requirements
 - Controlled substance handling and documentation
 - Infection control and disposal practices
 - Diversion prevention and reporting procedures

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2. Competency verification is documented in personnel files and reviewed during annual credentialing audits.

VIII. Documentation and Recordkeeping

1. All medication records (logs, inventories, disposal forms, OARRS checks, and prescriptions) are retained in accordance with DEA and OAC retention requirements (minimum of three years).
2. All documentation must be complete, legible, dated, and signed by authorized personnel.
3. Records are available for inspection by regulatory agencies and CARF surveyors upon request.

IX. Quality Improvement Integration

Findings from internal and external audits, DEA/OARRS reports, and incident reviews are incorporated into quarterly MMC meetings and the Annual Quality Improvement Plan. Corrective action plans are tracked and documented by the Director of Medical and Clinical Services.