Injection and Biologic Administration Standard Operating Procedure (SOP)

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

Policy Statement
The organization shall ensure all injectable medications and biologic agents are prepared, administered, and documented by qualified staff following evidence-based clinical standards and manufacturer guidance. All procedures must prioritize client safety, proper technique, infection control, and accurate documentation. Only trained and credentialed staff may administer injections or biologics, and each administration must occur under the order and supervision of a licensed prescriber.

Purpose
To establish standardized procedures for the preparation, administration, monitoring, and documentation of injectable medications and biologic therapies. This SOP ensures safe and effective care, minimizes risk of infection or adverse reactions, and maintains regulatory compliance.

Scope
This SOP applies to all physicians, nurse practitioners, nurses, and designated clinical staff responsible for administering injections and biologics within REACH for Tomorrow's integrated care programs.

Procedures

1. Authorized Personnel
- Only licensed medical professionals (MA, RN, LPN, NP, or MD/DO) with documented training and competency in injection administration may perform these procedures.
- Medical assistants may assist with preparation under direct supervision of a licensed nurse or provider but may not independently administer injectable medications unless permitted by Ohio law and organizational policy.

2. Provider Orders
- All injectable and biologic administrations must be based on a written or electronic order from a licensed prescriber that includes:
  - Client's full name and date of birth
  - Medication or biologic name

- Dose, route, and frequency
- Administration site and any specific instructions
- Prescriber's name, credentials, and signature
- Verbal or telephone orders must be documented and signed by the prescriber within 72 hours.
- The order must be verified prior to every administration.

3. Storage and Preparation
- All injectable medications and biologics shall be stored per manufacturer's instructions (refrigeration, light protection, etc.).
- Refrigerated items must be kept at 36°F–46°F (2°C–8°C) with daily temperature logs.
- Before preparation:
  - Verify medication label, expiration date, and lot number.
  - Check for discoloration, particulate matter, or damage to vials/syringes.
  - Wash hands and don clean gloves.
  - Use aseptic (sterile) technique when drawing or reconstituting medication.
- Multi-dose vials must be dated upon first use and discarded after 28 days unless otherwise specified.
- Each syringe and needle must be sterile and single-use only.

4. Verification Prior to Administration
Before administration, staff shall verify:
1. Right client – Confirm two identifiers (name and date of birth).
2. Right medication – Match order and label.
3. Right dose – Confirm dosage accuracy.
4. Right route – Confirm intramuscular (IM), subcutaneous (SC), or intradermal (ID).
5. Right time – Ensure correct timing and schedule.
6. Right documentation – Record administration promptly after completion.
Allergy status must be reviewed and confirmed prior to every injection.

5. Administration Techniques
a. Intramuscular (IM) Injection
- Common sites: Deltoid (≤1 mL), Vastus lateralis (thigh), Ventrogluteal (hip)
- Use appropriate needle size (typically 1–1.5 inches, 22–25 gauge).
- Clean injection site with alcohol swab for at least 30 seconds and allow to dry.
- Insert needle at 90° angle in a swift motion.
- Aspirate only if per manufacturer instructions (most vaccines/biologics do not require aspiration).
- Inject medication slowly and withdraw needle smoothly.
- Apply gentle pressure with sterile gauze and observe for bleeding or discomfort.

b. Subcutaneous (SC) Injection
- Common sites: upper outer arm, abdomen (2 inches from umbilicus), or thigh.

- Use short needle (3/8–5/8 inch, 25–30 gauge).
- Pinch skin fold, insert at 45–90° angle, and inject slowly.
- Do not aspirate.
- Apply light pressure afterward.

c. Intradermal (ID) Injection
- Typically used for TB testing or allergy screening.
- Use 1 mL syringe with 26–27 gauge needle.
- Insert at 10–15° angle with bevel up to form a small wheal.
- Do not massage the site post-injection.

d. Biologic Administration
- Follow manufacturer-specific reconstitution and dilution protocols exactly.
- Allow refrigerated biologics to reach room temperature before administration.
- Rotate injection sites to minimize tissue irritation.
- Dispose of any reconstituted but unused portions per manufacturer and DEA/OSHA guidelines.

6. Observation and Monitoring
- Clients receiving injections or biologics must be observed for a minimum of 15 minutes post-administration (30 minutes for first-time biologic doses or high-risk injections).
- Observe for: Allergic reaction (rash, swelling, wheezing, anaphylaxis), Dizziness, fainting, or distress, Local reaction (pain, redness, swelling).
- Emergency supplies (e.g., epinephrine, antihistamines, oxygen) must be available at all times.
- Adverse events must be documented and reported immediately to the prescriber and Clinical Director.

7. Documentation Requirements
All administrations must be recorded in the Medication Administration Record (MAR) or EHR, including:
- Date and time of administration
- Medication/biologic name, dose, and lot number
- Route and injection site
- Name and credentials of staff administering
- Any observed reactions or complications
- Patient education provided
- Follow-up or next scheduled dose
- Signatures of both administering and witnessing staff (if applicable for high-risk medications)

8. Disposal of Materials
- All syringes, needles, and sharps must be disposed of immediately after use in approved

sharps containers.
- Containers must never be overfilled and must be replaced when two-thirds full.
- Used vials and biologic waste must be discarded following OSHA and EPA biomedical waste regulations.

9. Adverse Reactions and Incident Reporting
- Any unexpected reaction, error, or near-miss must be reported to the prescriber immediately and documented in the incident reporting system within 24 hours.
- For severe allergic or anaphylactic reactions:
  - Activate emergency medical response (911).
  - Administer epinephrine per standing orders.
  - Monitor vital signs and airway continuously.
- The Clinical Director and Quality Improvement Committee will review all injection-related incidents to identify corrective actions and ensure quality assurance.

10. Staff Training and Competency
- All staff performing injections must complete initial training and demonstrate annual competency in:
  - Injection techniques and site selection
  - Infection control and aseptic preparation
  - Recognition and management of adverse reactions
  - Safe disposal and documentation standards
- Competency will be validated by a qualified clinical supervisor or nurse educator.

11. Quality Assurance and Review
- The Quality Improvement (QI) Committee shall:
  - Review injection records and incident reports quarterly;
  - Verify staff credentialing and training compliance;
  - Audit biologic inventory for expiration, storage, and documentation accuracy.
- Corrective actions will be implemented when deficiencies are identified.

Performance Indicators
- 100% of injections documented accurately in EHR/MAR.
- Zero expired or improperly stored injectable medications.
- 100% of staff performing injections have current competency verification.
- Zero unaddressed adverse events related to injection administration.

Review and Revision
This SOP shall be reviewed annually and revised as needed to ensure compliance with CARF, SAMHSA, CDC, and Ohio Board of Nursing regulations, and to reflect best practices in safe injection and biologic administration.