

LEGACY HEALTH

OPERATIONAL

Origination Date: NOV 2025

Last Review Date: NOV 2025

SECTION: PHARMACY SERVICES

TITLE: Pharmacy Standard Operating Procedures for Dispensing Subcutaneous Buprenorphine Extended-Release (Brixadi) for Adult Inpatients for Compliance with REMS Program Requirements

FACILITY:

- ☒ Legacy Emanuel Hospital and Health Center (as applicable: ☒ LEMC only ☐ RCH only ☐ Unity only)
- | | |
|---|--|
| <input type="checkbox"/> Legacy Good Samaritan Medical Center | <input type="checkbox"/> Legacy Medical Group |
| <input type="checkbox"/> Legacy Meridian Park Medical Center | <input type="checkbox"/> Legacy Urgent Care |
| <input type="checkbox"/> Legacy Mount Hood Medical Center | <input type="checkbox"/> Legacy Visiting Nurse Association (Hospice) |
| <input type="checkbox"/> Legacy Salmon Creek Medical Center | <input type="checkbox"/> Legacy Lab Services |
| <input type="checkbox"/> Legacy Silverton Medical Center | <input type="checkbox"/> Legacy Research Institute |
| <input type="checkbox"/> Administrative / System Support Services | <input type="checkbox"/> Other: |
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PURPOSE:

To ensure full compliance with subcutaneous buprenorphine extended-release (Brixadi) Risk Evaluation and Mitigation Strategy (Brixadi REMS) program requirements for the safe dispensing of Brixadi. This standard operating procedure outlines the REMS certification process and workflow, including staff training, standard verification and dispensing processes, maintenance of compliance documentation, and cooperation with audits as required by the Brixadi REMS program.

RESPONSIBLE STAFF:

Pharmacy Manager: Serves as the Authorized Representative (AR) and oversees REMS certification, implementation of processes, and compliance monitoring.

Pharmacists: Directs and complies with standards for order verification and dispensing.

Pharmacy Technicians / Support Staff: Assists in standards for storage and dispensing.

Physicians: Licensed Independent Provider licensed and trained to order and administer Brixadi.

PROCEDURE:

1. Certification in the Brixadi REMS by Authorized Representative (Pharmacy Manager)

- Complete the Healthcare Setting and Pharmacy Enrollment Form.
- Submit the completed form to the Brixadi REMS via the designated portal or mailing address.
- Maintain a copy of the submitted form in the REMS electronic shared drive.

2. Staff Training

- All pharmacy staff involved in verifying and dispensing must complete Brixadi REMS training.
- Document completion of training in E+.

3. Inventory Management, Ordering, Verification, Dispensing, and Administration

- Inventory Management
 - Brixadi shall be ordered from an Authorized Distributor.
 - Brixadi shall be received and added into inventory via our standard controlled substance procedures.
 - Brixadi will be stored at room temperature at 20 degrees to 25 degrees C (68 degrees to 77 degrees F), with excursions permitted at 15 degrees to 30 degrees C (59 degrees to 86 degrees F).
- Ordering:
 - Providers participating in the pilot program shall order Brixadi via the electronic medical record.

- ii. Only specific providers have access to Brixadi in their preference list.
- c. Order Verification:
 - i. Upon receiving a Brixadi order in the verification queue, the pharmacist will verify that the order is complete and appropriate for indication, dose, and drug interactions.
 - ii. Ensure that the dose ordered is available for dispensing.
 - iii. Change the dispense code to "Patient Own Med" in the verification queue to prevent charge generation.
- d. Dispensing:
 - i. Dispense Brixadi only to a licensed healthcare provider (nurse or provider) or to the ADC Patient-Specific Controlled Bin.
 - ii. **Do not dispense Brixadi directly to patients under any circumstances.**
- e. Administration:
 - i. Brixadi shall be administered by a licensed health professional. Under no circumstances will Brixadi be self-administered by the patient.
 - ii. After administration, used syringes shall be properly disposed per standard waste procedures for controlled substances per applicable federal, state, and local regulations.

4. Healthcare Provider Notifications

- a. Ensure that healthcare providers understand that Brixadi must not be dispensed directly to patients.
 - i. The electronic health record will include product labeling in the Medication Administration Record (MAR) stating: "Patient self administration is not allowed. Brixadi must be administered on site by licensed staff."

5. Prohibition of Distribution, Transfer, Loan, or Sale

- a. Do not distribute, transfer, loan, or sell Brixadi outside the certified dispensing site.
- b. Report any potential breaches immediately to the Authorized Representative.

6. Recordkeeping

- a. Maintain documentation of:
 - i. REMS certification.
 - ii. Staff training records.
 - iii. Controlled substance records.
- b. Records will be stored via electronic file system for at least 3 years.

7. Audit Compliance

- a. Cooperate fully with audits conducted by Braeburn or their third-party representatives.
- b. Provide requested records promptly and allow inspection of processes and procedures.
- c. Document all audit communications and outcomes.

References:

Reviewed/Approval:

Originators: LEMC/RCH/UBH Pharmacy Managers

Owner: LEMC/RCH/UBH Pharmacy Director & Managers