

LEGACY HEALTH

PATIENT CARE

Policy: 916.3002
Origination Date: APR 2026
Last Review Date: APR 2026

SECTION: PHARMACY SERVICES
TITLE: REMS (RISK EVALUATION AND MITIGATION STRATEGY) DRUGS

FACILITY:

Legacy Emanuel Hospital and Health Center (as applicable: LEMC only RCH only Unity only)
 Legacy Good Samaritan Medical Center Legacy Medical Group
 Legacy Meridian Park Medical Center Legacy Urgent Care
 Legacy Mount Hood Medical Center Legacy Visiting Nurse Association (Hospice)
 Legacy Salmon Creek Medical Center Legacy Lab Services
 Legacy Silverton Medical Center Legacy Research Institute
 Administrative / System Support Services Other:

POPULATION: X Adult X Pediatric X Neonate
(Adult >18 years of age; Pediatric 0-18 and adult patients under care of a pediatric specialty physician at RCH;
Neonate 0-28 days and continued hospitalization in the NICU)

PURPOSE:

To identify the standard practices and procedures related to the management of Risk Evaluation and Mitigation Strategy (REMS) programs. This includes ensuring patient safety, compliance with regulatory requirements, and effective management of medications subject to REMS.

RESPONSIBLE STAFF:

Licensed independent practitioners (LIP), nurses, pharmacists, pharmacy technicians

DEFINITIONS:

- EHR: Electronic health record (Epic)
- FDA: US Food and Drug Administration
- REMS: Risk Evaluation and Mitigation Strategy, an FDA-required program designed to ensure the safe use of a specific medication
- REMS medications: medications that have been assigned a REMS program due to safety concerns
- REMS authorized representative (AR): a designated individual (e.g., LIP, pharmacist) acting on behalf of the pharmacy or healthcare setting to fulfill REMS requirements, including enrollment, certification and ensuring compliance with the program's safety measures.
- REMS requirements: specific requirements for prescribing, dispensing, administering and monitoring medications subject to REMS

POLICY:

1. Legacy Health and the REMS authorized representative (AR) will adhere to all required elements of a REMS program when prescribing, dispensing, administering or storing a medication subject to REMS.
 - a. Medications requiring REMS are identified and monitored according to policy.
 - b. Proper enrollment of prescribers and patients will be verified to ensure medication specific REMS requirements are met.
 - c. Staff and patients will be educated on the safe use of ordered/prescribed REMS medications, and this education will be documented for audit purposes.

IMPLEMENTATION PROCESS:

1. Legacy Health Pharmacy Services maintains a list of REMS medications. This list is routinely reviewed, at least annually.
 - a. The LH Formulary contains a list of REMS medications. See LH 900.3271 Legacy Health Drug Formulary for assessment of adding a REMS drug to the formulary and see [FormWeb](#) for REMS drugs list.
 - b. REMS medications are identified in the EHR with notes to prescriber or notes to pharmacy, administration instructions and/or order specific questions, based on the individual drug and REMS specific requirements.
 - i. REMS drugs in the LH Compendium should include generic Order Instructions in the EHR to notify ordering provider of REMS status, when there is an intervention necessary for medication dispensing to admitted patients: REMS drug – a Risk Evaluation and Mitigation Strategy (REMS) program is required by the FDA to ensure benefits outweigh risk.
 - ii. REMS drug records in the EHR may also include Notes to Pharmacy and/or Order Questions and Administration Instructions depending on the specific drug REMS program requirements.
 - c. REMS medications stored in the inpatient pharmacy are labeled as REMS Drugs.
 - i. Product bins will have a standard REMS label across all sites to identify product and ensure awareness of potential dispensing and/or purchasing requirements.
2. Pharmacists will verify that the prescribing provider is enrolled in the REMS program, if required.
 - a. Verification is through the REMS program's online portal or other company approved communication method.
3. Pharmacists will verify that the patient is properly enrolled in the REMS program, if required.
 - a. Program enrollment may include verification through the REMS program's online portal or other company approved communication method.
 - b. Provide the patient with necessary counseling on the risks and safe use of the medication, the required monitoring schedule and any contraindications. This may also include providing written educational materials.
4. Pharmacists will ensure all necessary REMS-related information is included in the medication order prior to dispensing the medication.
 - a. This may include order specific questions in the EHR or other prompts for the provider to complete during the ordering process.
 - b. Provider and pharmacist are responsible for confirming that the patient meets all REMS requirements before the medication is dispensed. See also LH 900.3233 Medication Orders.
 - c. For patients admitted to the hospital receiving a REMS medication prior to admission and the patient's home supply is available, patient enrollment will be confirmed and the drug will be ordered/labeled as patient's own medication per policy. See also LH 900.3104 Patient's Own Medications: Inpatient Administration and Use.
5. All staff (providers, pharmacists and nurses) involved in the ordering, dispensing and administering of a REMS drug will maintain accurate and thorough documentation of all REMS-related activities, including patient education, enrollment status and follow-up monitoring.
 - a. Report issues or concerns related to REMS medication use, including non-compliance or adverse events, to the REMS AR.
 - b. All adverse drug events must also be reported through the iCare system and directly to FDA MedWatch, [MedWatch: The FDA Safety Information and Adverse Event Reporting Program | FDA](#), or 1-800-FDA-1088. See also LH 900.3342 Adverse Drug Event.

6. All staff (providers, pharmacists and nurses, as appropriate) involved in the management of REMS drug patients must receive training on the specific REMS programs applicable to their practice area. Training is conducted prior to the first patient receiving the drug and whenever there are updates to the REMS guidelines. Pharmacy staff training will be annually or as outlined by the individual REMS program and must include at least the following elements:
- a. Purpose of the REMS
 - b. Specific requirements of the REMS program
 - c. How to access the REMS portal
 - d. How to educate patients and healthcare providers
 - e. Reporting procedures for non-compliance or adverse events

Key Words: REMS, Risk Evaluation and Mitigation Strategy, compliance, safety

References: FDA REMS, [Approved Risk Evaluation and Mitigation Strategies \(REMS\)](#)
LH 900.3271 Legacy Health Drug Formulary
LH 900.3233 Medication Orders
LH 900.3104 Patient's Own Medications: Inpatient Administration and Use
LH 900.3342 Adverse Drug Event

Replaces: N/A

Approval: Database Administrator to fill in the approval pathway

Originator: Pharmacy Services

Owner: PharmOps (Pharmacy Operations Committee)