## Risk Evaluation and Mitigation Strategies (REMS) Medications and Requirements Chart

**The FDA uses Risk Evaluation and Mitigation Strategies (REMS) to ensure high-risk medications are used safely. Because each program is uniquely tailored to a drug's specific risks, the requirements for prescribing, verifying, and dispensing vary between medications. These charts are designed to help navigate the individual protocols and ensure compliance at every step during the inpatient dispensing process. Use this information in combination with LH 900.3002 REMS Drugs. Contact your site authorized representative (director, clinical or operations manager) with additional questions regarding dispensing at your site. The FDA list of REMS drugs is always under review – our list of REMS drugs is updated frequently with additions, deletions and program changes. See also REMS Public Dashboard, designed to accompany the REMS@FDA site.**

**Chart Legend:**

- Columns with an "✔" under the designated roles indicate requirements for that role related to the REMS programs
- For medications that are on LH Formulary (including with restrictions), the medication name is linked further in the document to more detailed REMS requirements pertaining to healthcare facilities/pharmacies, prescribers, and/or patients

**NOTE:** In some instances, a patient may be on a REMS medication and go to a hospital that is not REMS certified. Specific requirements to continue patients on their REMS medications can be seen in the prescribing information and additional information is found at the link below. A pertinent excerpt from that link is also copied below: Roles of Different Participants in REMS | FDA

**EXCERPT**: "Even if your hospital/health care setting isn't certified to dispense a REMS drug, a patient who is on a REMS medication may be admitted to your hospital or to your emergency department. For example, if you work in an emergency department, you may be treating a patient who experienced a serious adverse event related to a drug he or she is already taking that has REMS requirements. Patients on a REMS drug may also be admitted to your hospital for an unrelated reason and may need to continue treatment on their REMS drug. If you work in an inpatient setting, it may be important for you to understand that your hospital may not stock certain REMS medications. The approved prescribing information is a good resource for medication information as well as information about specific requirements to continue that patient on a REMS medication. Approved prescribing information can be found at Drugs@FDA: FDA-Approved Drugs or DailyMed. Information about REMS requirements can be found at Approved Risk Evaluation and Mitigation Strategies (REMS), in product labeling, or on REMS-specific websites.

**Chart 1. REMS Medications with Legacy Health Build/Pharmacist Workflow in Place**

| Medication<br>Generic (Brand) | Sites Enrolled | RDA/ Portal Access* | POM OK | Certification/Enrollment Requirements (ETASU)* | | | Pharmacist information/ education | Legacy required SLM/E+ |
|---|---|---|---|---|---|---|---|---|
| | | | | Pharmacy | Prescriber | Patient | | |
| Alvimopan<br>(Entereg®) | RMH, RMH1 | | | ✔ | | | Information brochure | Pharm.Alvimopan REMs Training - SLM, updated 2/21 |
| Bosentan | RMH, RMH1 | | yes | ✔ | ✔ | ✔ | Pharmacy guide | Pharmacy.In-Patient Bosentan Risk Evaluation and Mitagation Strategy (REMS) - SLM, updated 2/25 |
| Buprenorphine ER<br>(Brixadi®) | RMH, RMH1 | | | ✔ | | | REMS document | |
| Buprenorphine ER inj (Sublocade®) | | ✔ | | ✔ | | | REMS document | |