Table 1. EHR build evaluation tool for REMS medications using ambrisentan as an example.

REMS Name:	Ambrisentan (**LETAIRIS**)
Indication:	Pulmonary arterial hypertension
Why does it have a REMS requirement?	Risk of embryo-fetal toxicity
EHR Build needed? (Y/N)	Yes
What should be included in the order instructions?	Ambrisentan is an FDA REMS Medication for the risk of embryo-fetal toxicity with the following requirements for female patients: ☐ Provider enrollment (not required if continuation of home med) ☐ Patient enrollment ☐ Negative pregnancy test for reproductive, female patients ☐ Insert pregnancy lab result (date/time), If no result, embed pregnancy test order
Prescriber Alert? (Y/N)	Yes
Prescriber Alert Message:	Ambrisentan is an FDA REMS Medication with the following requirements: Provider enrollment (not required if continuation of home med), Patient enrollment, Negative pregnancy test (Insert pregnancy lab result [date/time]; If no result, embed pregnancy test order)
Pharmacist Intervention Task List? (Y/N)	Yes
Pharmacist Documentation needed? (Y/N)	Yes
Pharmacist Documentation template:	Ambrisentan (**LETAIRIS**) is a Risk Evaluation and Mitigation Strategy (REMS) medication. As part of the ordering process, it is required to meet certain requirements. 1) Is this a new start medication? Yes / No (continuation from home) 2) Patient enrollment in REMS program: Yes / No (contact the prescriber to get patient enrolled) / No (male patient -enrollment not required) 3) Enrollment number: ___ 4) Provider enrollment in REMS program: a) Yes (called REMS to verify) b) No (contact prescriber) c) N/A (continuation of home medication) d) N/A (male patient) 5) Is this patient a female of non-reproductive potential (FNRP)? a) Yes (pre-pubertal) b) Yes (post-menopausal) c) Yes (medical reasons for permanent irreversible infertility) d) Yes (consent form on file with REMS Program) e) No (patient is of reproductive potential) f) N/A (male patient) 6) Laboratory results in the last 30 days for a pregnancy test: (Insert pregnancy lab result [date/time]) 7) Is the patient pregnant? Must confirm a negative pregnancy test BEFORE verification of the medication. a) Yes; pregnancy test resulted positive. Do not verify the order and contact the prescriber (for new start orders) b) Yes; pregnancy test resulted positive. Do not verify the order and contact the prescriber and REMS program (for continuing orders) c) No; pregnancy test result negative (for new start orders) d) No; pregnancy test results negative or negative pregnancy test in last 30 days (for continuing orders) e) N/A (male patient or FNRP) 8) Are All REMS Requirements met? a) Yes; New start, dispense authorized b) Yes; Continuation from home; dispense authorized c) No; Requirements NOT met; dispense NOT authorized; Do NOT verify order and contact the prescriber
Nurse Education Task? (Y/N)	Yes
Medication Guide link for education task:	https://www.accessdata.fda.gov/drugsatfda_docs/rems/Ambrisentan_Shared_System_2021_06_08_Guide_for_Female_Patients.pdf
Laboratory order needed? (Y/N)	Yes
Laboratory order:	Pregnancy, urine last 30 days
Removal from REMS? (Y/N & Date)	No
EHR elements removed? (Y/N & date)	No