**REMS (Risk Evaluation Mitigation Strategy)**

**Section:** Operations

**Compliance:** URAC Specialty Pharmacy 2.1

**URAC Standards:** SDrM 5, PHARM-OP 12

**Policy ID:** 5.6

**Approved by:**

**POLICY**

This policy specifies how <insert practice name> employees and patients will participate in the provision of drug therapies that have established REMS programs. **[SDrM 5 (a, c)]**

**PROCEDURE [PHARM-OP 12 (d)]**

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage a known or potential serious risk associated with a drug or biological product. A REMS will be required if the Food and Drug Administration (FDA) determines that a REMS is necessary to ensure the benefits of the drug or biological product outweigh its risks. A REMS can include a Medication Guide, Patient Package Insert, a communication plan, elements to assure safe use, and an implementation system. <http://www.ashp.org/REMS>

It is not uncommon for some specialty drug products to have FDA-approved REMS programs. Some of these programs place specific requirements on prescribers and patients. Some add responsibilities for pharmacy providers. **[SDrM 5 (a, c)]**

1. The staff of <insert practice name> will comply with the manufacturer’s FDA-approved REMS program requirements
2. Each patient will receive a patient monograph for each newly-prescribed drug therapy
3. Each patient will require other printed materials as required by the specific REMS program requirements. These may include Medication Guides or similar printed items
4. Patients will be entered in any required REMS program registry
5. Commonly dispensed specialty drugs at <insert practice name> with a REMS program as of August 2015 include but are not limited to:
* Testosterone gel (Androgel) – Medication Guide included with product
* Varenicline (Chantix) – Medication Guide included with product
* Lenalidomide (Revlimid) – Medication Guide included with product Patient Registry required, counseling with each prescription
* Mycophenolate – Medication Guide included with product
* Thalidomide (Thalomid) – Medication Guide included with product, Patient registry required, counseling with each prescription
* Pomalidomide (Pomalyst)– Medication Guide included with product, Patient Registry required, counseling with each prescription
* Transmucosal Immediate-Release Fentanyl Products – Medication Guide

The drug(s) identified above with registry requirements are flagged in <insert practice name>’s automated dispensing cabinet as to special requirements upon dispensing (registry verification, etc.) to prompt employees to comply with REMS requirements. **[SDrM 5 (a, c)]**

|  |  |  |
| --- | --- | --- |
| **DATE:** | **REVISED BY:** | **REVISION:** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |