

RISK EVALUATION & MITIGATION STRATEGY (REMS)

Did You Know?

REMS programs are safety strategies proposed by the FDA that are premised on the management of known and/or potentially significant risks associated with certain medications.

Safely Providing Products

CuraScript SD Follows REMS Standards and Policies

01 | Understanding REMS

In 2007 the Food and Drug Administration Amendments Act (FDAAA) gave the FDA the authority to require REMS from manufacturers to ensure that the benefits of the drug outweigh the risks. These requirements are necessary for approval of a new product or any product receiving updated safety information. REMS focus on preventing, monitoring and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to reduce the frequency and/or severity of an event. Examples of REMS components are:

- Medication Guide
- Patient Package Inserts
- Communication Plan
- Implementation System
- Elements to Assure Safe Use

02 | Why REMS is Important

REMS ensures that patients and physicians are properly informed on the medications they are receiving/ administering. It also provides transparency and clarity so all parties may better decide on the best products and options. Most importantly REMS supports safety initiatives for better administration and patient care.

03 | How Does This Effect Physicians?

Some manufacturers require additional data from practices and physicians to ensure the medication is being used properly. This means that CuraScript SD must collect this information from the purchasers to ensure adherence to the policy. Examples of information that may be collected or verified are:

- Administering Physician
- Enrollment
- Patient Information
- Certifications
- Office Procedures

04 | Long-term Benefits

REMS can help medications gain approval, offer new indications, support market longevity, and streamline requirements. The data collection and analyzation provide necessary information that can progress a medication allowing for easier access. This information can also prove a medication to have too many adverse events outweighing the benefits. All the REMS data and analyzation leads to safety and trust amongst manufacturers, distributors, patients, and physicians.

For More Information

For more information about our products, practice solutions or to request a quote, click [here](#).

References

<https://curascriptsd.com/Provider-Solutions/specialty-distribution>

<https://www.fda.gov/aboutfda/transparency/basics/ucm325201.htm>