CuraScript SD®
CARING FOR THOSE WHO CARE

Risk Evaluation & Mitigation Strategy (REMS)

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 drug's benefits outweigh the risks. These requirements are meant to help reduce the frequency and/or severity of particular safety concerns regarding specific medications. They are also essential for the approval of a new product or any product receiving updated safety information. REMS focuses on preventing, monitoring and/or managing a specific serious risk by informing, educating, and/or reinforcing actions. Examples of REMS components are:

- Developing materials for patients
- Communication to healthcare providers, healthcare settings, and pharmacists
- Completing certifications
- Documenting a "safe use condition"
- "Elements to Assure Safe Use"

Why REMS is Important

REMS provides patients safe access to specific drugs available on the market. It also ensures more transparency and better communication about the risks involved with using these particular drugs between pharmaceutical manufacturers and healthcare professionals as well as patients.

This leads to REMS supporting physicians in offering safer and better patient care.

How Does This Effect Physicians?

Requirements vary for practices and physicians, which may include:

- REMS/Patient Enrollment
- Training
- Patient counseling documentation
- Monitoring
- Compliance documentation with safe use conditions

With our relationship between manufacturers and physicians, CuraScript SD must collect this information from the purchasers to ensure adherence to the policy.

Long-term Benefits

REMS can help medications gain approval where they otherwise may not have been allowed in the market, offer new indications, support market longevity, and streamline requirements. In turn, data collected and analyzed on the medications provide essential information that allows for easier access for patients. One of the strongest benefits is the REMS data and analysis leads to safety and trust among manufacturers, distributors, patients, and physicians.

Did you know?

While all medications require informational labels about risks, only a few are required by the FDA to have REMS.

Learn More

For more information about our products, practice solutions and to request a quote, click here.

References:

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

https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems

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