

First Supply Chain Impact Study of Risk Management Drug Mandate on Healthcare: Collaboration Critical to Ensure Success of Risk Evaluation Mitigation Strategies

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New research from the Center for Healthcare Supply Chain Research highlights that cross-industry collaboration and uniformity are essential ingredients to successfully implement the federally mandated risk evaluation and mitigation strategies (REMS) initiative.

The Center for Healthcare Supply Chain Research, the non-profit research foundation of the Healthcare Distribution Management Association (HDMA), recently conducted a study to understand the impact of REMS on the pharmaceutical supply chain. Using interviews and secondary data the study, *Assessing the Impact of Risk Evaluation and Mitigation Strategies (REMS) Requirements on the Pharmaceutical Supply Chain*, documents the impact of REMS programs on manufacturers of brand, generic, biologic and small-molecule drugs; three classes of distributors — traditional, specialty and specialty pharmacy; and providers, including physicians, nurses, patient advocates, and retail and specialty pharmacists. The research presents challenges, opportunities, and recommendations for process improvement and, for the first time, offers insights into the economic impact of REMS, as required by the 2007 *Food and Drug Administration Amendments Act*.

Background on REMS Requirements

The 2007 law authorized the Food and Drug Administration (FDA) to require risk evaluation and mitigation strategies (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. These strategies reflect FDA-approved manufacturer mitigation objectives and are broken down into four REMS components: medication guides for patients; communications plans to educate healthcare professionals; elements to assure safe use (ETASU) such as training, certification and registries documenting compliance; systems to implement the ETASU; as well as, for all strategies, timetables to submit assessments of their effectiveness (see Figure. REMS Elements That the FDA May Require). More than 175 drugs currently have REMS.

Evolving Initiative Raises Potential Inadvertent Challenges That Need to Be Addressed

The research found that two-thirds of REMS require only a medication guide, along with assessments mandated for all programs. Even these relatively simple strategies presented issues that may affect patient care. Interviews with retail pharmacists documented an observation noting REMS overemphasis on risk may dissuade patients from taking a needed drug. This concern was articulated independently by providers (physicians and patient advocates) who stated that communication regarding the benefits of medications requiring a REMS should not be unduly overshadowed by discussions of risk. Further, one participant, (a physician) noted concern that very few methods were in place to evaluate how patients viewed these risk-mitigation plans and how they influenced their behavior.

Pharmacists indicated that more complex REMS — those often requiring training, certification and registries to obtain access to the drug — can pose a challenge to the supply chain flow, with the potential for unforeseen results on patients. The Center's report presents case studies to highlight the complexity of three programs, revealing supply chain interdependencies and the intricacies that each unique program requires. Aside from building systems to address REMS introduced complexities, pharmacists echoed the concerns of their upstream supply chain partners over potential lag time in product availability as a by-product of untested strategies. Distributors, dispensers and providers all articulated a request to be involved in the design and implementation of REMS programs. This appeal underscored their desire to provide input to the program, obtain

sufficient time to develop internal training to ensure smooth program execution and time to test the system prior to product launch. Interviews with manufacturers revealed a growing willingness to work with downstream partners while advancing with the design of REMS programs.

Impact on Pharmaceutical Manufacturers, Distributors, Providers and Patients

All study participants expressed concerns about delays that ultimately can hinder patient access to drugs. The report detailed the challenges faced and processes manufacturers employed to develop their REMS, noting apprehension over delays in FDA approval of REMS programs (particularly complex ones).

Pharmacists and physicians reported their concern in facing the daunting challenge of dispensing and administering a multitude of medicines with different REMS. The need for uniformity was identified as one of their most important needs, particularly the desire to have uniform templates for reporting the data required for registries and assessments. Uncompensated time spent addressing one-off requirements were a noted challenge. Physicians repeated this sentiment adding that filling out and filing REMS paperwork reduced their time spent with patients.

Costs Significant, Require More Research

The study's economic analysis indicated that REMS requirements are costly to the supply chain. Manufacturers reported investing millions of dollars in developing the most complex REMS.

Study interviews revealed a lack of documented information about the time and expense for pharmacists, physicians and nurses to perform diverse activities, such as counseling patients, undergoing specialized certification and training and meeting the paperwork requirements.

Finally, the research provides recommendations on how to improve REMS in the future, as well as insights that are helpful to anyone seeking to understand the potential impact of REMS on the pharmaceutical supply chain.

The report *Assessing the Impact of Risk Evaluation and Mitigation Strategies (REMS) Requirements on the Pharmaceutical Supply Chain* is available for purchase. For more information, contact Tonya Martin of the Center for Healthcare Supply Chain Research at tmartin@hdmanet.org.

About the Center for Healthcare Supply Chain Research

The Center for Healthcare Supply Chain Research is a 501(c)(3) non-profit charitable organization that serves as the knowledge partner of the Healthcare Distribution Management Association (HDMA). The Center serves the healthcare industry by providing research and education focused on healthcare supply chain issues. The Center's mission is twofold: to conduct research and disseminate information that will enhance the knowledge base, efficiency and effectiveness of the total healthcare supply chain; and to provide thought leadership to further enhance the safety and security of the healthcare supply chain through future-focused study and programming.