RISK EVALUATION AND MITIGATION STRATEGY (REMS): WHAT PSYCHIATRISTS NEED TO KNOW

The Food and Drug Administration Amendments Act of 2007 (FDAAA), signed into law on September 27, 2007, gave the FDA authority to require drug manufacturers to submit a Risk Evaluation and Mitigation Strategy (REMS) whenever the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks.

WHAT IS A REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug. A REMS may include any of four components:

1. A medication guide or patient package insert;
2. A communication plan for healthcare providers;
3. An implementation system; and/or
4. Elements to assure safe use (ETASU).

The ETASU component might include the following requirements:

- That healthcare providers prescribing the drug have specialized training or certification;
- Those who dispense the drug (such as pharmacists) have specialized training;
- The drug be dispensed only in hospitals;
- The drug be dispensed to patients based on evidence of safe use conditions (such as laboratory test results);
- That each patient using the drug be subjected to certain monitoring; and/or
- That each patient using the drug might be enrolled in a registry.

The number of components a REMS contains is scalable to the risks associated with the drug, so a REMS might contain fewer than all four components.

A REMS may be required by the FDA during a drug's approval process. For drugs already approved, the FDA will base its decision to require a REMS on information from clinical trials, adverse event reports, and other scientific data.
REMS are enforceable against drug manufacturers through monetary penalties for violations of the REMS regulations. If a manufacturer fails to submit a REMS, the subject drug could be deemed misbranded and the FDA could seek injunctive relief.

HOW DO I KNOW WHETHER A DRUG I PRESCRIBE HAS A REMS?

The FDA has begun to require REMS for certain drugs. To date, the FDA has approved 175 REMS, which are available on the FDA's website (www.fda.gov). Some medications with approved REMS that are of particular interest to psychiatrists include

Suboxone (sublingual film and sublingual tablets) and Zyprexa Relprevv (extended release injection). The REMS for Suboxone consists of a medication guide, ETASU (specifically, safe use conditions and monitoring), plus an implementation system wherein the manufacturer assures that prescribing physicians receive an instruction letter and monitors documentation compliance and evaluates implementation of the ETASU. The REMS for Zyprexa (Relprevv) consists of a medication guide, communication plan, ETASU (specifically, a certification plan, dispensing only by pharmacies and health care settings, and certain monitoring initiatives), plus an implementation system. It is possible for medications that once had a REMS requirement to be released from that requirement. Visit the FDA website for a list of medications that have been released from the REMS requirement.

WHAT WILL BE THE LIKELY IMPACT OF REMS?

Compliance: In the case of drugs with REMS that include a communication plan or ETASU, a psychiatrist's ability to prescribe those drugs may depend on the psychiatrist's compliance with the REMS for those drugs.

Standard of care: REMS likely will help shape the standard of care in psychiatric malpractice litigation. There are many factors that a psychiatrist expert witness could use as evidence of the applicable standard of care for a particular patient care issue. Federal regulations – such as regulations from the FDA – are one factor. Should a patient experience an injury that likely would have been prevented by compliance with an applicable REMS, it may be difficult to defend a psychiatrist who fails to do so.

Informed consent: REMS also may establish a floor for what information is conveyed to patients during the informed consent process.

WHAT DO I NEED TO DO?

Visit the FDA website at www.fda.gov to see whether a REMS exists for a drug(s) that you are prescribing. If so, review the component(s) of the REMS. If a medication guide is a component of the REMS, review it. Medication guides are available on the FDA website. If necessary, you may need to revise your informed consent process in light of your review of the medication guide. Psychiatrists should monitor the FDA website at regular intervals for revisions to and publication of additional REMS.

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