

# Practical and Legal Implications of REMS

Title IX, Subtitle A, Section 901 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (FDCA) to provide the FDA with new authorities to require sponsors of approved drugs to conduct postmarketing studies and clinical trials (section 505(o)(3) of the FDCA), **develop and comply with REMS** (section 505-1 of the FDCA), and make safety related labeling changes (section 505(o)(4) of the FDCA) based upon new safety information that becomes available after approval of the drug. These provisions took effect on March 25, 2008.

***“The law might seem burdensome but it was made to protect you and your patients”***

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## REMS and Basic Obligations when Prescribing

