REMS OVERVIEW

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A Risk Evaluation and Mitigation Strategy (REMS) is an FDA-mandated approach to ensuring the safety of medications.

The baseline for ensuring the safe use of prescribed medication is professional labeling. REMS applies to situations where professional labeling is considered inadequate to ensure the safe use of a drug or class of drugs. REMS are FDA-required risk management plans that use strategies beyond professional labeling to ensure that the benefits of a drug's use outweigh its risks. The risk must be serious enough that it is documented on the drug's label. The FDA can require a REMS for either an IND or after a drug has received regulatory approval.

A drug's sponsor develops the REMS and the FDA reviews and approves it. A REMS is uniquely tailored to the risks associated with a specific drug or class of drugs (i.e.no two REMS will be identical). REMS are also mandated to be patient-centric.

A given REMS may or may not include an ETASU (Elements to Assure Safe Use). ETASU are required medical interventions or other actions healthcare professionals must execute prior to prescribing or dispensing a drug to a patient. In some cases, ETASU actions may also be required for the patient to continue on treatment with the medication.

Med-ic® and e-CAP™ AS ETASU

The Med-ic and e-CAP ECMs can serve as the ETASU component of a REMS to:

- identify risky patterns of non adherence including:
  - deliberate over use as in addiction
  - erratic, over or underuse that reduces the drug's efficacy
- engage the patient and clinician in a program of education and cooperative guidance
- allow for early intervention in risky use patterns using targeted education
- establish monitoring criteria for a patient to continue to have access to a medication
- assure the authenticity of drugs by unique package IDs (Med-ic® Smart Blister Pack and Syringe Pack)
- identify tampering with the drug package (Med-ic®)
- detect and prevent drug fraud (Med-ic®)
- detect multiple doctoring (Med-ic®)

Med-ic® has applicability to controlled substances and drugs for which non-adherent use can be dangerous. Both Med-ic and eCAP are relevant for populations known to have poor adherence(e.g. substance users, the elderly, and psychiatric populations).