



Risk Evaluation and Mitigation Strategy (REMS)

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“REMS” is a term you have undoubtedly heard about and will continue to hear often in the months ahead. Here is a breakdown to help with understanding the concept and terminology!

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. The proposed REMS included many medications, not just opioids. The list of drugs included in REMS range from Advair to Androgel to Botox to Chantix to Zyprexa. Sandwiched in between are opioids, such as Darvon, Embeda, Exalgo, Morphine, Onsolis, and Oxycotin (1). Because opioids are included in REMS and since opioids can be prescribed by health care providers other than physicians, ASPMN along with other disciplines have intentional views and statements to offer:

ASPMN believes that REMS:

- Must protect and not interfere with patient access to pain medication
- Patient registries should not be part of REMS
- REMS should include all classes of opioids
- Education needs to include prescriber and dispenser and should be developed with expert input (2).

The ASPMN REMS taskforce, in collaboration with members from Nurse Practitioners, Physician Assistants, Nurse Anesthetists, Hospice and Palliative Nurses, the International Nurses Society on Addictions, and Oncology Nurses, submitted a comment docket to the FDA in October of 2010. The docket ensures that the voices of nurses and PA's will be represented along with physicians who will be affected by REMS. These member groups believe that:

- An opioid class wide REMS should be developed to curb misuse, abuse, diversion, and intentional or unintentional overdose of opioid medications w/o interfering with access to or timeliness in receiving these medications for people who need them
- REMS should include education for prescribers on factors for history taking, assessment and safe treatment of pain using opioids

The Recommendations for REMS from ASPMN and Affiliates are:

- Short acting opioids should be included in REMS along with long acting agents because health risks between short and long acting are comparable
- Pain management requires individual treatment and both long and short acting are often indicated
- Omitting short acting opioids from a patient's regime could result in prescribing medications that are too strong resulting in unintentional overdose and/or death, or additional abuse, diversion and a rise in use of immediate – release opioids
- If we fail to include short acting opioids in the REMS program we will be sending a signal that these medications are somewhat safer than long acting medications and would overlook the number one medication prescribed in the world that is contributing to the problems of abuse and diversion
- Prescriber education should be consistent from prescribers and dispensers, readily available, and include all classes of opioids
- REMS should not interfere with the ability of HCP to develop an appropriate pain care management regime for patients
- FDA should encourage Public Education regarding the safe use of opioids
- FDA should collaborate to devise a plan to reduce misuse and abuse of medications
- There should be an assessment tool developed and given prior to the implantation of the class wide REMS program to determine successful outcomes for patient care as well as abuse, misuse and diversion

ASPMN Goals: ASPMN, along with the above mentioned Associations, believe that an opioid class-wide REMS should be developed to curb misuse, abuse, diversion, and intentional or unintentional overdose of opioid medications without interfering with access to or timeliness in receiving these medications for people who need

them. REMS should include education for prescribers on factors for history taking, assessment and safe treatment of pain using opioids.

In summary, REMS should be required for all drugs with significant risk profiles, including short acting and long acting opioids. We will all need to be informed and educated, educate our providers and our patient's, and become aware of the FDA activities (3).

Information Sited for this article:

1. FDA Website and REMS Lecturer, Michael Barnes, Esq. at National Conference, Minneapolis 2010
2. ASPMN Governmental Affairs Report by Wade Delk 2010 Minneapolis
3. ASPMN FDA Docket Comments from Taskforce October 2010