

FDA-2009-N-0143

Risk Evaluation and Mitigation Strategies (REMS) for Opioids

Comments by the American Academy of Pain Medicine (AAPM)

The Food and Drug Administration (FDA), in response to Congressional mandate, has begun development of Risk Evaluation and Mitigation Strategies (REMS) for Opioids. The stated goal of these REMS is to “ensure that the benefits of these drugs continue to outweigh certain risks.”

The American Academy of Pain Medicine is fully supportive of this goal and has framed its recommendations in the context of two key questions:

1. **What public policy decisions will further the desired goal?**
2. **What public policy decisions will confound the desired goal?**

AAPM recognizes that it has a responsibility to offer actionable solutions that can be rapidly and widely implemented and operationally and budgetarily sound. With these principles in mind, AAPM offers the following recommendations, believing that a thoughtful and reasoned application of REMS will positively impact two major health crises in America today—the crisis of undertreated pain and the crisis of prescription drug abuse.

1. **What public policy decisions will further the desired goal?**

- **Implement a national (or coordinated state) Prescription Monitoring Program (PMP) with real-time data available to physicians and pharmacists.** The value of PMPs is clearly outlined in the National All Schedules Prescription Electronic Reporting (NASPER) Act, which was signed by President Bush on August 12, 2005. Yet, funding for the implementation of PMPs has been lacking. Additionally, prescribers must be able to access PMP data from a confidential site, so that this information can be used as a prophylactic, rather than reactive, tool.

NOTE: Auditing for use of this system can be readily automated, providing a ready means of attributing REMS effectiveness.

- **The REMS should cover the entire class of opioid medications.** Any attempt to regulate only a portion of the opioid class of medications will drive prescribers, users, and misusers of these medications to the other, less stringently regulated, but often abused members of the class of medications. This will not diminish abuse or misuse and will very likely result in decreased access to appropriate therapy for some legitimate patients.

- **Develop REMS education programs with extensive expert input.** The REMS should provide a comprehensive core curriculum that builds on proven approaches to training and spans the continuum of medical education from medical school through CME. The curriculum should be offered through a variety of means and media—including electronic, print, and in-person offerings—to ensure the broadest reach and accessibility. Individuals completing this curriculum should be entitled to Continuing Education credits from respective sources (medical, nursing, pharmacy). Content should include core principles of prescribing and practice, with key elements from the Controlled Substances Act (and respective State statues/code for state-based tailoring of curriculum), the Federation of State Medical Board Model Policy, the American Academy of Pain Medicine / American Pain Society Guideline for Chronic Opioid Therapy and other authoritative sources. An active link could be maintained on the FDA website, with reminder notices sent to all pharmacists and potential prescribers (physicians, nurse practitioners) in advance of state license renewal and DEA registration renewal.

NOTE: Auditing for use of this system can be readily automated, providing a ready means of attributing REMS effectiveness.

2. What public policy decisions will confound the desired goal?

- **REMS must protect and not interfere with patient access to these important medicines.** The stated goal of REMS is similar to the well known policy principle of balance which is to curb abuse, misuse, and diversion while maintaining appropriate access for legitimate patients to opioid medications that are essential to ease suffering from pain. Frequent and meaningful evaluation of the REMS and its impact on these goals will be essential to ensure this balance is maintained.
- **Do not include Patient Registries in the REMS.** No evidence exists to suggest that a patient registry will diminish abuse or misuse of these medications. Evidence does exist, however, that such an approach stigmatizes patients and imposes significant burdens on all parties, resulting in a chilling effect on prescribing and inadequate pain management. Enhancements to the existing and growing state Prescription Monitoring Programs infrastructure would be a better option to consider for achieving the REMS goals.

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