



REMS in Pain Management

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The REMS landscape has continuously evolved over the last three and a half years. One of the fastest changing categories for REMS is within the pain management market, specifically the transmucosal immediate release fentanyl (TIRF) class and the long-acting/extended release opioid (L-aOA) classes. Brand and generic manufacturers within these 2 classes of products are deep in FDA negotiation on the final structure, implementation, measurement, and design of a shared system REMS for each class. In the meantime, individual pharmaceutical and generic companies have been requested by the FDA to develop and implement individual REMS to support their products.

FDA has been working with the pharmaceutical and biotech industry for more than 2 years on a class-wide REMS for L-aOAs. On January 7, 2011, the FDA announced that it would require all TIRF companies to work together to create a shared system for implementation of a class REMS.

Shared implementation systems for REMS are intended to reduce the burden on the health care system for implementation, making it easier for physicians and pharmacists, as well as any other stakeholders, to participate and comply. This has been a major obstacle for REMS in the L-aOA space, since the scale of use is so vast. The FDA's Office of New Drugs director, John Jenkins, MD, called the shared implementation system for TIRF "A significant step toward reducing the burden on the health care system of implementing REMS programs."

To move to a shared system means there will be shifts in some products' REMS to less restrictive for some and more stringent for others. Finding a compromise position that makes it easier for prescribers and pharmacies to operate in compliance is essential to ensuring access to these critical medications. Under the Abstral REMS, retail pharmacies are eligible to dispense if they complete program education, enroll in the REMS, and pass a system verification test demonstrating their pharmacy management system is configured to "interrogate" each Abstral prescription. This process uses the pharmacy switching technology to route the prescription data to the REMS program administrator's database of enrolled pharmacies, prescribers, and patients.

If the prescription meets all the rules for safe use, then the prescription can be dispensed. If not, messaging will appear to the pharmacist regarding the actions to take instead of dispensing. The "interrogation" of the Abstral prescription occurs in sub-seconds and is completely within the existing work flow of the pharmacy. Onsolis has similar controls and enrollment requirements, but it is only distributed by a single specialty pharmacy that must then connect to the Onsolis REMS program administrator to determine prescription eligibility in order to dispense.

The current L-aOA REMS design calls for voluntary education of providers, which will be funded by industry but administered through accredited medical education providers. The L-aOA REMS program design does not have controlled or restricted distri-



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bution requirements associated with it.

Pain management will continue to be a major public health focus for years to come. The Institutes of Medicine recently released a prepublication version of its study entitled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research."¹ In this important new study, the committee makes specific recommendations that will lead to a "cultural transformation in the way pain is understood, assessed, and treated." While implementation of many of these transformative recommendations may be in the distant future, REMS programs in acute and chronic pain management continue to evolve to reduce the risks associated and improve the safe use of these vital medications. **SPT**

Reference

1. IOM report accessed at www.nap.edu/catalog.php?record_id=13172.



For a table, go to www.SpecialtyPharmacyTimes.com.

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