

Eli's Hospice Insider

INDUSTRY NOTES

The FDA has approved Onsolis to treat severe breakthrough pain for cancer patients ages 18 and up. The drug delivers fentanyl through an absorbable film that sticks to the buccal membrane in the mouth, according to an FDA release. Onsolis is indicated to treat breakthrough pain for patients who are already receiving opioid pain medications around the clock and can safely take high doses of an additional opioid.

To reduce the risk of abuse and misuse of Onsolis, the FDA required the drug to have a Risk Evaluation and Mitigation Strategy, or REMS. As part of the REMS, Onsolis will only be available through a restricted distribution program that will provide clinicians and pharmacy personnel with training materials before they prescribe or dispensing the medication.

Patients will receive an educational counseling call before the pharmacy dispenses Onsolis to ensure they understand how to use the drug appropriately. "Prescription orders will be filled only by participating pharmacies that send the product directly to the patients' homes," states the FDA in the release. "The REMS for Onsolis was specifically tailored to that drug and should not be viewed as a model REMS for long-acting and extended-release opioid products," said **Douglas Throckmorton, MD**, deputy director of the Center for Drug Evaluation & Research.

For more information go to www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders.

Beware: There's a new sheriff in town for HIPAA enforcement.

The Department of Health and Human Services (HHS) is handing over the administration and enforcement of the Security Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to the HHS Office for Civil Rights.

CMS formerly oversaw enforcement of the rule. The Security Rule specifies a series of administrative, technical, and physical security procedures for covered entities to use to assure the confidentiality of electronic-protected health information.