FDA Award Lays Groundwork for Safety System

BY ALICIA AULT

The Food and Drug Administration has chosen Harvard Pilgrim Health Care Inc. to design a pilot of a new safety monitoring system.

The agency announced that the program, called the Sentinel System, will help it keep closer tabs on safety problems because it will analyze information collected during routine health care. The Sentinel System will allow the agency to collect data on drugs and devices at the source—from medical records. For instance, if the agency knew that a device or drug had been linked to cardiac side effects, FDA safety officers could query the Sentinel System for such problems.

Congress required the FDA to develop such a safety system as part of the Food and Drug Administration Amendments Act of 2007. It was also recommended by the Institute of Medicine in a 2006 report on drug safety.

"The FDA has been doing the groundwork for a nationwide Sentinel System," said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, in a statement. "Once operational, [it[will help us find answers to important drug safety questions, leading to stronger safeguards for public health, while still protecting the privacy and security of individual health information," she said.

The system has been under development for almost 2 years; the agency held yet another workshop with potential participants on Jan. 11.

Harvard Pilgrim, a Wellesley, Mass.–based health plan, was given a 1-year contract to establish a coordinating center. This scaled-down version of the planned Sentinal System will "identify appropriate databases, develop a scientific framework for obtaining real-time data, and ensure data quality," according to an FDA press release. ■

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