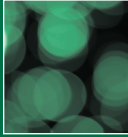


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## Post-Market Surveillance: FDA's "Sentinel Initiative" and Related CMS Rulemaking

On May 22, 2008, the Food and Drug Administration ("FDA") announced plans for what it is calling the "Sentinel System"—a new, national electronic health information surveillance system to track the performance and safety of medical products once they are on the market. See FDA, *"The Sentinel Initiative: National Strategy for Monitoring Medical Product Safety"* (May 2008), available at <http://www.fda.gov/oc/initiatives/advance/reports/report0508.pdf>. In addition to a whitepaper on the Sentinel Initiative, FDA has published a "Questions and Answers" document, a fact sheet, and information for the consumer that are all available at <http://www.fda.gov/oc/initiatives/advance/sentinel/>.

The same day, the Centers for Medicare & Medicaid Services ("CMS") announced a final rule allowing it to share prescription drug claims data for the 25 million Medicare Part D enrollees with other government agencies, as well as with "researchers." Under the rule, shared data will be available for any purpose "deemed necessary and appropriate by the Secretary," such as analysis, reporting, and public-health purposes, among other things. See 73 Fed. Reg. 30664 (May 28, 2008); CMS Fact Sheet "Medicare Part D Data Regulation" (CMS-4119-F) (May 22, 2008). The rule becomes effective June 27, 2008.

These coinciding initiatives by the two major federal health regulatory agencies are intended to improve health care quality by using information technology and data mining in new ways. However, numerous policy and strategy questions are still up for debate.

The current system for monitoring drug and device adverse events relies on health professionals and patients to: (1) recognize a potential link between an adverse event and a product; and (2) voluntarily report it, either to the manufacturer or to FDA. In recent years, controversies surrounding certain drug safety issues have contributed to criticisms by members of the public and Congress that the current system is often inadequate. To ensure that FDA would improve its current safety monitoring system, Congress passed legislation in September 2007, the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85 § 905, that required FDA to obtain access to data sources, develop a system to link and analyze product safety data available through these sources, and, using these tools, establish an "active adverse event surveillance" program. The Sentinel System, as its name suggests, is intended to accomplish these goals.

As proposed, the Sentinel System would provide FDA with access to a broad range of publicly and privately maintained health data sources so that FDA could search these sources and gather intelligence on potential safety risks associated with drugs or medical devices as trends emerge. See U.S. Department of Health & Human Services, News Release, *New Efforts to Help Improve Medical Products for Patient Safety and Quality of Medical Care* (May 22, 2008), available at <http://www.hhs.gov/news/press/2008pres/05/20080522a.html>. Through targeted queries of health information databases (such as the Medicare Part D and other claims databases), FDA claims it would be able to obtain de-identified patient data, perform analyses, and draw conclusions regarding product safety in order to improve the overall quality of medical care. FDA also states that the system would be designed to comply with appropriate security and privacy standards.

The notion that health information technology initiatives (such as electronic health records, e-prescribing, etc.) are the key to improving the quality and reducing the costs of our health care system is a major reason Congress mandated FDA's expansion of post-approval drug

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and device surveillance. Although FDA has recognized various efforts (in both the public and private sectors) to collect and make use of electronic safety, performance, and other health/patient data, as listed in the Attachment to FDA's whitepaper on the Sentinel Initiative entitled "Related Federal/Private Sector Activities," to date, such efforts have not been coordinated or standardized. The Sentinel Initiative ultimately intends to incorporate these efforts on a national level.

### **Proposed Mechanics of the Sentinel System**

Although FDA is still in the early stages of developing the Sentinel System and specific details are scarce, FDA proposes, at least initially, to capitalize on existing data systems, such as medical claims databases and electronic health record systems, through a "public-private partnership" rather than by creating a new, centralized database. Data sources would continue to be owned and maintained by their current owners. Data owners would either be members of the partnership, or contract with FDA and/or the partnership to provide data. The partnership would be subject to a "defined governance process" and structured according to an "established organizational framework," both still to be determined. Aside from the Medicare Part D claims database, potential public data sources include Medicare Parts A and B, the Veterans Health Administration, the Department of Defense, and CDC's National Electronic Injury Surveillance System ("NEISS").

The multiple data sources would somehow be linked with one another so that they would be interoperable and part of an overall, to-be-developed "information technology architecture." FDA would thus be able to send queries to a variety of data sources and obtain results quickly, which would be stripped of identifiers to comply with any applicable privacy and security laws and/or standards that protect personal and proprietary information. FDA would then be able to review and analyze the data, observe trends, draw conclusions regarding product safety and performance, and take appropriate measures to address concerns. Accordingly, the system is intended to provide FDA with a stronger, more proactive product safety surveillance capability. The system may also serve as a tool for many other types of research performed by other public health agencies and health researchers; for example, evaluating specific treatment outcomes, or assessing utilization trends.

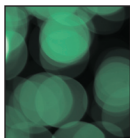
### **Open Issues and Next Steps**

Based on input from the public during a two-day public workshop FDA held in March 2007 and comment period in early 2007 (see 72 Fed. Reg. 2284 (Jan. 18, 2007)), FDA has identified the following as key issues that must be resolved prior to implementing the Sentinel System:

- How will private and/or proprietary information be protected?
- Who will have access to the system?
- How will the initiative be funded?
- What about the quality of the data, standards, and system interoperability? How will these be improved?
- How will risks and adverse events be identified through data analysis?
- How will a pilot for the system be developed and validated?

Although FDA has touched upon some of these issues in its whitepaper and related publications, and has raised numerous others (for example, the scientific credibility of the data analysis and the integrity and independence of the system's management/governance structure), they remain largely unanswered. The next phase of the Sentinel Initiative will incorporate a series of discussions on the "scientific and policy issues that must be addressed."

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Further, FDA plans to begin meeting with potential partners to formalize specific action items necessary to establish the Sentinel System.

According to the CMS fact sheet on the final Part D claims data rule, CMS will hold an open door forum in June 2008 to review the new rule and discuss the claims data release process, as well as to answer questions from the public. Once this open door forum is scheduled, information will be posted at <http://www.cms.hhs.gov/opendoorforums/>. If you would like information on how to participate in this open door forum, please contact Katie Durkin at [cdurkin@reedsmith.com](mailto:cdurkin@reedsmith.com).

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