ENGELBERG CENTER for Health Care Reform at BROOKINGS

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Discussion Guide

Payer Involvement in the Sentinel Initiative

Background

The U.S. Food and Drug Administration's (FDA) Sentinel Initiative has made significant strides toward developing a national system for generating post-market safety evidence. The passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated that FDA develop a system for postmarket risk identification and analysis. In response, FDA launched the Sentinel Initiative. Mini-Sentinel is a pilot program that is proving to be a valuable tool for informing the development of an active medical product safety surveillance system and gathering important data that addresses safety concerns in near real time. With 18 data partners and access to data for over 130 million covered lives, Mini-Sentinel's success is the direct result of the strong partnerships developed between FDA and large private payer data partners and academic institutions.[1] Mini-Sentinel uses a distributed database composed of administrative claims and electronic clinical data, which is maintained behind payer firewalls. This approach allows the data partners to maintain physical and operational control over the electronic data within their existing environments and serves to protect patient privacy while permitting each partner to run queries within the unique characteristics of each data system.[2] Through collaboration with the Mini-Sentinel coordinating center, data partners have worked to develop a Common Data Model to carry out a range of surveillance activities. This design has enabled a variety of public health surveillance activities, from calculating incidence rates to conducting protocol based assessments on medical products.

While Mini-Sentinel has served as an important postmarket safety tool for FDA, there are significant opportunities to leverage the partnerships and tools as a national resource that will further support evidence generation and impact public health. Current reforms to the U.S. health care system have shifted focus toward delivering care that achieves better outcomes at lower cost and increasing emphasis on personalized medicine tailored to patients' unique characteristics. These reforms have increased the demand for more actionable evidence in postmarket settings by a range of decision-makers, including patients, providers, and payers. The methods and infrastructure established to support Sentinel present a valuable platform for developing a shared national resource

Developing Sentinel as a National Resource

FDA's vision is for the Sentinel Initiative to become a national resource for both public and private sectors that can support FDA's regulatory responsibilities and the work of a wide range of stakeholders. Multiple groups have an interest in improving our understanding of the impact of medical products and may benefit from this framework, including the National Institutes of Health (NIH), the Reagan-Udall Foundation, the Patient Centered Outcomes Research Institute (PCORI), and other stakeholders such as

[1] Mini-Sentinel Distributed Database "At A Glance." (December 2012). Retrieved February 19, 2013, from http://mini-sentinel.org/about_us/MSDD_At-a-Glance.aspx.

[2] Curtis LH, Weiner MG, Boudreau DM, Cooper WO, Daniel GW, Nair VP, Raebel MA, Beaulieu NU, Rosofsky R, Woodworth TS, and Brown JS. (2012), Design considerations, architecture, and use of the Mini-Sentinel distributed data system. Pharmacoepidemiology and Drug Safety, 21: 23–31.

academia and medical product manufacturers. This shared national resource could have the capability to support both safety and other health care research, including outcomes and quality assessments. However, such a resource will require funding support from sources outside FDA, including support from participating stakeholders. Furthermore, any expansions of the Sentinel Initiative's resources will require continued partnerships with data partners and a solid understanding of challenges that must be addressed in order to ensure success.

Workshop Discussion: Increasing the Public Health Value of the Sentinel Distributed Data Framework
Four key subject areas have been identified that relate to payers' involvement within Sentinel and a potential expansion to a national resource. Questions pertaining to those areas have been posed to help introduce the issues and guide discussion.

I. Funding and Business Model Issues

- Are there concerns with expanding the Sentinel framework into a broader national resource with funders outside of FDA?
- Are there non-FDA funders that would pose more challenges than others? (e.g., PCORI, NIH, Pharmaceutical Industry)?
    - If so, are there parameters that could be applied to their participation that would alleviate concerns?
- Are there funding mechanisms that would be more acceptable than others? (e.g., unrestricted funds verses project specific funds)?

II. Efficiency and Bandwidth Issues

- Are there concerns regarding an increase in the number of requests that could be the result of expanding the Sentinel system? How can these concerns be addressed?

III. Governance Issues

- As Mini-Sentinel is transitioned to be part of a broader national resource, are there concerns relating to governance?
- Would a trusted intermediary between data partners and users alleviate concerns?
- How might data partners respond to separate coordinating centers between FDA's use of the national resource and other users?
    - What might help to facilitate this approach?
- What are important elements for sustainable and successful governance of the expanded Sentinel system?

IV. Outcomes and Research Issues

- Are there concerns with expanding participation to include assessments beyond safety (e.g., effectiveness, quality outcomes)?
- Under what conditions or parameters would data partners allow non-FDA queries of the system? Which users? Which uses?
- What are characteristics of research that are consistent with ongoing data partner participation? What are characteristics of research that may discourage ongoing data partner participation?