SENTINEL ENGAGEMENT PARTNERS WORKGROUP

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SENTINEL ENGAGEMENT PARTNERS
WORKGROUP

Issue: Critical Stakeholders are largely unaware of the Sentinel System, its commitment to health, safety, and protection of patient privacy.

- Public
- Health Advocacy Groups
- Providers
- Health Plan Members
“Create a Plan of Action to Increase Awareness and Tell the Sentinel System’s Story, Successes, and Value”

“Develop Messages and Tools to Increase Awareness of the Sentinel System’s Public Health Value and Commitment to Privacy”
THE ENGAGEMENT PARTNERS WORKGROUP
WORKGROUP OBJECTIVES

Foundational Principles

• Transparency
• Relevance
• Effective Communication
STRATEGIES FOR ENGAGEMENT

• **Coordinated Communication Strategy**—Key Elements of the Sentinel System.

• **Targeted Messages**—Tailored to Each Engagement Partner’s Critical Role.
WHAT IS SENTINEL SYSTEM’S STORY?

- FDA’s Safety Mission/Another Tool
- Critical Components
- Operation
- Sentinel System in Action
- Privacy
• Background
• Coordinating Center
• Privacy and Security
• The Sentinel System Story
• Reagan-Udall Foundation and IMEDS
HOW DOES IT WORK?

Health Advocacy Groups Story

How the Sentinel System Works

The core function of the Sentinel System is to evaluate treatments and outcomes of large groups of patients treated with a particular drug, medical device, or specific vaccine. The main concern of the Sentinel System is evaluating whether patients are having an unexpected adverse event from a medical product.

For example, some of the basic questions are: How many patients on “Drug A” are having negative side-effects? How many of them are males or females? How many are young, old, pregnant, or taking other medical products? Are the side-effects the result of taking “Drug A” or for another reason?

Public Story

How does the Sentinel System work?

The Sentinel System answers questions like these: How many people are taking the same drug or getting the same vaccine? How many are having bad side-effects? How many are men and women? How many are young, old, pregnant, or take other drugs?
HOW DOES FDA USE IT?

Health Advocacy Groups Story

What does the FDA do with all of this information?

The Sentinel System asks questions of many participating organizations, aggregates their responses, and presents the findings to the FDA for its subsequent evaluation and ultimate decision(s) regarding a particular medical product’s safety or continued use. The FDA can pursue the following channels after receiving this information:

1. Non-medical product related
2. Labeling
3. Restricted Use
4. Media Alerts/MedWatch
5. Removal of the Drug or Vaccine

Public Story

What does the FDA do with all of the information?

The FDA gets important answers from the Sentinel System about bad side effects in certain drugs or vaccines. The FDA studies this new information along with other information it gets from doctors and drug companies. The FDA decides the best way to make doctors and patients aware of side effects. The FDA can send out a warning to doctors and patients. Or the FDA can issue a safety communication to warn the public about taking a medicine or getting a vaccine.
Health Advocacy Groups Story

Examples of the Sentinel System

In 2013, FDA used the Sentinel System to evaluate a vaccine to prevent diarrhea in infants. In response to reports FDA received that some infants experienced side effects from the vaccine, the Sentinel System gathered information from approximately 500,000 infants who had been vaccinated. From the Sentinel System’s analysis, FDA concluded that the side effect did occur, but was extremely rare and occurred in less than 2 out of every 100,000 babies. FDA concluded that the benefit of the vaccine outweighed this risk, but the agency alerted clinicians and parents about the possibility of this adverse effect.

Public Story

Sentinel in Action

In 2013, the FDA used the Sentinel System to look at the safety of a vaccine that was given to about 500,000 babies. The FDA found out that some of the babies who got the vaccine had side effects, but these side effects were very rare. The vaccine caused the side effect in less than 2 out of every 100,000 babies! With this new information, FDA let doctors and parents know that it was better to get the vaccine. But doctors should be aware of this very rare side effect, so that they can treat it, if it happens.
Health Advocacy Groups Story

Respecting and Protecting Patient Privacy

The Sentinel System studies summary information from large groups of patients treated with the same drug, medical device, or vaccine, whenever possible. When individual level data are needed, all individual patient identifiers are removed.

Public Story

Protecting your Privacy

No one at the FDA looks at your personal information. They do not look at your Name, Address, Phone Number, etc. The Sentinel System learns about big groups of patients taking the same medicine or getting the same vaccine.
What is the Sentinel System?

One of the FDA's biggest jobs is to make sure drugs, vaccines, and medical devices are safe. FDA wants to know if patients get bad side effects from these products. To make it faster and easier to learn about problems, FDA created a special program called the Sentinel System.

How the Sentinel System Works

Sentinel System's 3 important parts
- Information: The system looks at billing claims and patient records.
- Expert Team: Sentinel works with scientists, doctors and computer experts.
- Computer Programs: They study large groups of patients who take the same medicine, or use the same device.

Personal privacy
- No one at FDA or the Sentinel Operations Center has access to your name, address, or any other information that identifies you.
- For more information, visit sentinelininitiative.org.

Sentinel asks questions like:
- How many patients take the same drug?
- How many patients are getting bad side effects (rashes, diarrhea, fast heartbeat, etc.)?
- Are side effects more common after taking one drug than after another drug that treats the same problem?

How does FDA use the information?
- FDA can choose to collect more information.
- FDA can provide updated safety information for patients and providers.
- If you have concerns about your own medical products, please contact your doctor.
FREQUENTLY ASKED QUESTIONS

What is the Sentinel System’s Engagement Partners Workgroup?
It is a workgroup launched in January 2016 by the FDA to raise awareness about the Sentinel System as a valuable health and safety tool involving the following stakeholders: 1) The Public; 2) Health Plan Members; 3) Patient Advocacy Groups; and 4) Providers.

What did this Sentinel System Workgroup actually do?
The Workgroup developed customized narratives for each stakeholder. Each narrative describes, the “How?”, “What?”, and “Why?” of the Sentinel System. For more information, please refer to Tool #1 in your toolkit “Patient Advocacy Groups Template”, or check out this link. www.sentinelinitiative.org

What about Privacy and Confidentiality?
Each Sentinel System narrative emphasizes that the Sentinel System studies aggregate data and that all identifiers are removed, such as name, address, telephone number, Social Security Number, etc.

What can I do to share this message with our members?
You can feature the Sentinel System Story and your critical role in its success, through a variety of media channels to your members.
FREQUENTLY ASKED QUESTIONS

What media channels are you referring to?
For example, you can describe the Sentinel System in your member newsletter, organization’s website, brochures, pamphlets, Facebook, Twitter, etc.

Am I required to use all of these channels to tell the Sentinel System story to our members?
No. We would encourage you to reach out to as many members as possible, using the most effective media channels in which you typically communicate to your members.

Is there a budget for these strategies?
Unfortunately, no. We appreciate everything you have done and continue to do to increase the value of this critically important safety tool.

Is there someone I can talk to or will give me feedback? Who can I call, if I need assistance?
For help, please contact the Stakeholder Engagement Workgroup Lead, Steve Mikita, at smikita@agutah.gov and Susan Forrow, Senior Project Manager, Sentinel Operations Center, susan_forrow@harvardpilgrim.org
TOOLKIT

1. The Infographic

2. Copies of the Public Story and Patient Advocacy Group Story

3. FAQs for Patient Advocacy Groups
THANK YOU!

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