From: (b)(6)
To: Williams, Letise
Subject: [EXTERNAL] Patient Engagement Advisory Committee Meeting to Discuss Medical Device Recalls - Comment
Date: Thursday, September 16, 2021 9:07:37 PM
Attachments: image001.png
image002.png
image003.png
Importance: High

Hi Leslie.

I could not find where to send in comments for the deadline today.

I'd like to make the comment below please:

I am passionate about eliminating the risk of recalled medical devices being used and if a recalled medical device has been used, notifying the patients. Notifying patients does not always occur. Many hospital systems "monitor" patients chart to see if they have had a return that may indicate a problem with the recalled device. How do they know that the patient didn't seek care at another facility? Management of Medical Device Recalls is broken.

Medical Device notifications from manufacturers do not follow a standard in reporting as shown in this Recall Communication: Medical Device Model Recall Notification Letter. In fact most manufacturers do not know this model exists. When a recall is received by healthcare facilities each is formatted differently and can contain incomplete information to remove devices or can contain hundreds of thousands of line items making it a challenge to identify in stock. Additionally, recalls can be for only a portion (example: lot number) of the medical devices model/version number making this challenge even greater and which leads to Recalled medical devices used post recall. To trace a recalled medical device there are many FDA databases (Recall Database) and APIs (OpenFDA, Enforcement) to review. If we look at the FDAs definition of a recall, recalls are voluntary. In 2021 for Class I recalls it takes an average of 48 days from the time the recall was initiated by the manufacturer to the FDA posting. Days in which Recalled devices are used. Days in which Recalled devices remain on shelves.

The Unique Device Identifier (UDI) was created to assist in the tracking of recalls. Without the UDI in the recall notice it's hard to identify the correct medical devices to remove. The incomplete and sometimes inaccurate reporting by the manufacturers to the FDA leads to patient safety concerns. Let's take the Silk Road recall this year. The FDA databases only report 5 lot number when there were 104 recalled. Where are the other 99? The Recall is still ongoing. In the evaluation of this recall for a hospital system many of the recalled items were of lot numbers dropped off as "trunk stock" so if I hadn't had knowledge of all of the recalled devices, the medical devices the manufacturer had reported as selling to this hospital did not match the lot numbers on the shelf. As a healthcare advocate, I has shown many manufacturers the "why" in how the UDI identifiers are

integral part of patient safety in the recall processes.

Patient safety must be at the forefront.

Take care,

Joan

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