AHRMM
Association for Healthcare Resource & Materials Management of the American Hospital Association

American Hospital Association

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Mailstop HFZ-541
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Re: Adoption of Unique Device Identification

In addition to comments submitted last fall to the FDA from the Association for Healthcare Resource & Materials Management of the American Hospital Association (AHRMM) and the American Hospital Association (AHA) on Unique Device Identifiers, please consider this addendum regarding the use of attributes when implementing this classification.

The adoption of a Unique Device Identification (UDI) system is critical to patient safety. With the adoption of a device identification system, there must be a foundation of data that will support the information necessary to make the system work. A Product Data Utility (PDU) is a synchronized, industry-wide data pool that contains the supporting information necessary for a device to move through the entire supply chain and clinical record processes.

The *minimum* attributes needed for an effective data pool would be:

- Name of manufacturer
- Organizational identification (e.g. GLN)
- Manufacturer product number
- Packaging information
- UNSPSC or GMDN
- GTIN or unique item number for the product
- Lot number
- Serial number
- Date of manufacturer
- Indication of whether the product sterile

The minimum attributes are those recommended by industry groups piloting the PDU in healthcare, and are consistent with those used in successful models in other industries.

AHRMM advocates the use of other clinical attributes based on environmental and occupational needs. In addition to the URL location of the MSDS sheet, these attributes would indicate whether the product:

- Contains latex
- Contains PCB
- Contains PVC
- Contains mercury
- Is considered a biological hazard
- Is considered a chemical hazard
- Is considered a nuclear hazard

- Is considered a radioactive hazard
- Is flammable
- URL location of the MSDS information

These attributes represent dangers that can threaten the health of our patients, employees, and communities, and create extra costs to manage the product lifecycle from procurement to disposal. By making this information available to a hospital through the data pool, healthcare professionals will be able to easily identify products that need special consideration in their handling and care and ensure they are managed correctly. Hearings should be held to discuss the larger safety issues posed by medical products.

Creating a UDI protocol is the first step of a much larger standardization effort underway in healthcare. The healthcare industry is working to implement a PDU for all medical products. When implemented, the United States will be joining with several other countries that have already adopted standards to create a global product information network.

Please consider that the FDA might pioneer the UDI internationally as part of a Global Data Synchronization Network (GDSN) of data for medical products. The FDA and the GDSN share the same objectives and, with a little flexibility on both sides, the two can share the same bank of data. Having the leadership of the FDA will be a valuable asset in forming a healthcare Product Data Repository that can interact internationally to aid the health and safety of us all.

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