

November 21, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Attention: FDA-2013-D-0636-0001
Submitted electronically at: <http://www.regulations.gov>

Re: Global Unique Device Identification Database

On behalf of the Association for Healthcare Resource & Materials Management (AHRMM) of the American Hospital Association, we appreciate the opportunity to submit comments regarding the *Draft Guidance for Industry* on the global unique device identification database (GUDID), which was issued September 24, 2013.

With approximately 4,200 members worldwide, AHRMM is the premier organization for healthcare supply chain and materials management professionals. AHRMM strives to advance healthcare through supply chain excellence, providing leadership, education, networking, and industry-specific resources. AHRMM strengthens the nation's healthcare supply chain by advancing the field and enhancing the professional development of its individual members.

AHRMM commends the FDA on the release of the UDI Final Rule on September 24, 2013. The unique medical device identification system will substantially reduce existing obstacles to the adequate identification of medical devices used in the United States and will provide an important means for hospitals to better track medical devices used in patient care, to act in the event of a safety recall, to gather data necessary to understand the role products play in improving the quality and cost of healthcare, and to manage their supply chain.

This letter is in follow-up to AHRMM's comments submitted November 6, 2012 regarding the proposed rule on the Unique Device Identification (UDI) system in which AHRMM applauded the United States Food and Drug Administration (FDA) for its steadfast commitment to promoting the adequate identification of medical devices through distribution and use.

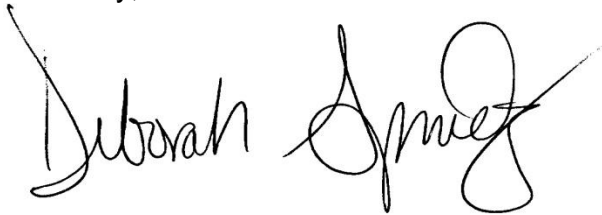
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AHRMM supports all of the outlined attributes identified for the GUDID system; however, AHRMM's comments pertain to three specific GUDID attributes that we strongly recommended be included in the GUDID database requirements in our November 6, 2012 response to the UDI proposed rule. These three attributes no longer appear in the DI Information table included as Appendix B in the Draft Guidance Document. AHRMM reiterates that the following attributes should be added to the database requirements. These attributes provide critical information that can be the difference between whether a device contributes to or detracts from quality patient care.

- **Labeled as hazardous:** End-users should always be aware of devices that may pose hazards in order to ensure safe handling as well as product integrity.
- **Contains radioactive isotopes** (*e.g., radioactive element and atomic number*) This information is important for environmentally-safe disposal and end-user handling.
- **Has Safety Data Sheet (SDS)** This information provides end-users with a reliable and readily-available source of information should an urgent need arise.

We appreciate the opportunity to comment on the proposed rule. Please direct any questions to Kathy Ryan at kryan@aha.org or 312-422-3840.

Sincerely,



Deborah Sprindzunas
Executive Director
AHRMM