**AHRMM Learning UDI Community**

**Comments to the FDA’s Draft Guidance for Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices, FDA-2017-D-6841**

**INTRODUCTION:**

The following comments to the Food and Drug Administration’s Draft Guidance for Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices FDA-2017-D-6841, are being made by the Association for Health Care Resource & Materials Management (AHRMM), Learning UDI Community (LUC).

The AHRMM LUC is a collaboration of key stakeholders from across the health care field including providers, manufacturers, distributors, standards organizations and the FDA. Its purpose is to expand adoption and utilization of the Unique Device Identifier (UDI) and accomplishes this through the creation of multi-disciplinary workgroups that identify barriers and develop consensus-based leading practices to overcome those barriers.

Based on the input from health care providers, manufacturers, distributors, solution providers and other stakeholders, the following comments are offered.

**COMMENTS:**

We recommend that information related to all Class I Medical Devices be included in the GUDID without exception. The intent of the GUDID is to provide a single repository of data for all regulated medical devices. This source in turn would allow patients, consumers, retailers, health care providers and any interested stakeholder the ability to verify legitimacy and confirm a specific product is an FDA regulated medical device. Categorizing Class I Medical Devices that are sold direct-to-consumer through brick and mortar and on-line stores as “consumer health products” and exempting them from inclusion in the GUDID will cause confusion and potentially increase consumer risk. The rationale for this recommendation is outlined below.

* The UDI is intended to support a host of patient/user-centric activities (e.g., recalls, adverse event reporting, eIFUs). Likewise, the GUDID is intended to serve as a comprehensive database of all regulated medical devices. If a product is to be regulated, by the FDA, it should be trackable in a public database. There is no reason to exclude consumer health products from the broader ecosystem.
* Advocacy efforts are underway to improve the medical device recall process to make it more transparent and timelier for all stakeholders. One way to improve the process is ensuring the UDI-DI is included in all recall information. Excluding information from GUDID could negatively impact consumers purchasing those Class 1 Medical Devices classified as consumer health products.
* Experience during the COVID pandemic has highlighted the risks associated with counterfeit and sub-standard PPE. Many of these products such as masks, gloves, and gowns, are considered Class I medical devices and are distributed through multiple channels, including as healthcare consumer products. Due to shortages, health care providers have been forced to purchase these products from brick and mortar and on-line retail stores.
* The guidance indicates that the policy does not apply to Class I Medical Devices sold to “Professional Healthcare facilities.” Information related to these devices must be included in GUDID. The clarification that devices sold to both brick and mortar and on-line retail stores as well as professional healthcare facilities must be included in GUDID is included in a footnote. There is concern that manufacturers of Class I products will interpret this guidance to mean that if any of their products are sold in brick and mortar or on-line stores that category of product is exempt from inclusion in the GUDID. A policy that requires inclusion of data from all Class I products in GUDID eliminates confusion.
* Care continues to move from formal health care settings into patient’s homes. Brick and mortar and on-line retail stores exist to serve this growing home health patient population. It is unclear if Class I medical devices sold in this setting would be included in the GUDID.
* The category of Class I devices includes a large, diverse group of products produced by a wide range of manufacturers with varying levels of expertise and internal controls. Because these devices are largely 510k-exempt, the FDA does not have a means to monitor performance and safety. The implementation of UDI was specifically intended to help bring clarity to this segment of class I devices.
* We are unaware of any studies or data backing up the contention that UPNs for Class I medical devices (as opposed to general retail products) change significantly more often than the UDI-DI for other categories of medical devices.