The Official Comment of

The Association for Healthcare Resource & Materials Management (AHRMM)

to the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION (FDA)

regarding

UNIQUE DEVICE IDENTIFICATION FOR MEDICAL DEVICES
DOCKET NO. FDA-2011–N–0090

The Association for Healthcare Resource & Materials Management (AHRMM) applauds the United States Food and Drug Administration (FDA) for its steadfast commitment to promoting the adequate identification of medical devices through distribution and use. The unique medical device identification (UDI) system will substantially reduce existing obstacles to the adequate identification of medical devices used in the United States. In addition, it 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, and to manage their supply chains.

AHRMM congratulates the FDA on the publication of the proposed rule, and appreciates the opportunity to provide this comment.

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

Advancing the Healthcare Supply Chain

The Association for Healthcare Resource & Materials Management (AHRMM) of the American Hospital Association 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. With approximately 4,000 members worldwide, AHRMM is the premier membership group for healthcare supply chain professionals.

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OBJECTIVES & POTENTIAL USES

Which of the objectives and potential uses identified for the UDI system are most important to you? Are there any important objectives or uses we have not identified or have not adequately discussed?

AHRMM supports all of the outlined objectives and potential uses identified for the UDI system. There are two in particular that warrant further discussion as they underscore the importance of two additional objectives that AHRMM recommends the FDA consider for the UDI system now and going forward.

Simplify the Integration of Device Use Information Into Data Systems

As discussed in the proposed rule, simplifying the integration of device use information into data systems promotes the use of UDIs in patient records and computerized physician order entry (CPOE) systems. This is especially important for AHRMM because the use of UDIs in patient records and CPOE systems extends supply chain visibility of medical devices to the bedside. This enables supply chain and materials management professionals (i.e., those responsible for procuring and managing the products used in patient care) to electronically and accurately track products from the point of purchase through use and beyond – which is the foundation of any effective recall management system.

For this reason, AHRMM recommends that *"increased automation and visibility in the healthcare supply chain"* should be regarded as an <u>important objective</u> of the UDI system, not simply a benefit.

Additional Benefits

Under the description of "Additional Benefits," the FDA noted that the UDI system would provide a basic infrastructural element to support unambiguous identification of medical devices throughout their lifecycle, which would provide the foundation for a host of benefits. AHRMM agrees, and believes that the "*definition of a foundational infrastructure that promotes compatibility and interoperability*" is so important that it also should be regarded as a core objective in the development and design of the UDI system.

The UDI system is designed to facilitate adequate identification of medical devices through distribution and use – in other words, across numerous parties (e.g., manufacturer, distributor, hospital, etc.). In addition, many of the intended benefits hinge on implementation of the UDI system across as many touch points in the device's lifecycle as possible – in other words, across numerous systems (e.g., enterprise resource planning systems, clinical systems, electronic health records, etc.). The key to both is a foundational infrastructure that ensures interoperability and compatibility across the numerous parties and systems that will touch a device during its lifecycle.

A foundational infrastructure will promote widespread implementation of the core components of a UDI system (i.e., Automatic Identification and Data Capture (AIDC) technologies and information technology (IT) systems) and maximize usage of UDIs by healthcare delivery systems. For example, several objectives reference the value of using AIDC technology to capture the UDI on product labels. However, the lack of alignment in the

choice of AIDC carriers used by suppliers to date has slowed the implementation of AIDC technology by healthcare delivery systems (e.g., the relatively low usage of medication barcodes) because it diminishes the value of investments in AIDC technology (i.e., those investments only work for some products/suppliers). This is a tremendous problem for healthcare organizations trying to make the case for investments in AIDC technology in business environments already challenged by scarce resources. A foundational infrastructure can resolve this problem by strongly encouraging (if not requiring) suppliers to use AIDC carriers that will maximize readability (and therefore investments) by healthcare delivery systems.

AHRMM Comment: Providing for More Rapid, More Efficient Resolution of Device Recalls

The FDA noted that providing for more rapid, more efficient resolution of device recalls is an important objective of the UDI system. To make the best use of the UDI in recall situations, AHRMM recommends that the FDA should include the UDI in all recall communications, and that the GUDID display and highlight the recall status of a device.

AHRMM Comment: UDI & EHRs

In conjunction with the discussion above regarding the foundational infrastructure of the UDI system, AHRMM recommends that the FDA encourage the Office of the National Coordinator for Health Information Technology to include accommodation of the UDI in its certification requirements for electronic health records (EHRs). Material Management Information Systems (MMIS) are the originating source of device information in hospitals. With MMIS' transitioning to UDIs for the identification of medical devices, it is essential that EHRs also be required to use UDIs to ensure a seamless connection between device information contained in both systems. Use of UDIs in all IT systems that touch device data from MMIS through to the EHR (e.g., OR, Cath Lab; Radiology, payable systems; etc.) is a key factor for managing recalls, conducting track and trace, and assisting in post-market surveillance. Including accommodation of the UDI as a certification requirement for EHRs promotes the goals of both the UDI system and EHRs.

AHRMM Comment: Clarifying the Definition of Labeler

In the proposed rule, device "labelers" are responsible for complying with the UDI requirements. The term "labeler" is defined as "*any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label.*" AHRMM had the opportunity to discuss this definition with FDA representatives at the UDI Conference 2012 held on September 18th and 19th, 2012 to clarify that hospitals are not considered labelers under the proposed rule. In addition, it was also clarified that labeling requirements are not triggered when hospitals reprocess single-use devices, repackage items, or assemble convenience kits for use in their own facilities without the items entering into interstate commerce. AHRMM recommends that the FDA include these clarifications in the proposed rule.

OVERALL IMPLEMENTATION TIMELINE

Do the proposed effective dates provide adequate time to prepare to meet the rule's requirements?

AHRMM believes that the proposed 7-year implementation timeline is unnecessarily long. In its *Final Report on Unique Device Identification (UDI) For Medical Device* submitted to the FDA, the Eastern Research Group found that:

"A total of 32 firms out of an estimated 5,234 firms (0.6 percent) are estimated to incur compliance costs in excess of 1 percent of revenues."*

* Eastern Research Group, Unique Device Identification (UDI) For Medical Devices. Final Report, May 2012. Section 1.3, page 1-6.

Certainly, the improvements in patient safety generated by the implementation of the UDI system far outweigh such minimal costs. It should also be emphasized that those cost estimates include costs for direct part marking (DPM). Therefore, there is no cost justification for delaying DPM beyond the labeling requirements. DPM offers a substantial opportunity to improve the efficient resolution of recalls in settings that are not yet technology enabled. There are many healthcare organizations and settings that still do not have the ability to utilize AIDC technology, especially smaller, resource-constrained organizations and non-acute settings like home care. For some time, patient care has been transitioning from acute to non-acute settings along the care continuum. Implementation of the *Affordable Care Act* will only accelerate this transition, especially in the home care segment. AHRMM is concerned that a delay in DPM during the same period when patient care delivered in non-acute settings is on the rise will increase the level of risk in those settings.

Based on the studies and trends, the benefits to patient safety are significant whereas the costs to implement UDI are minimal. Therefore, AHRMM recommends that the FDA reduce the implementation timeline, and adjust the deadlines as follows:

Class III	label and direct part marking	1 year after publication
All Class II	label and direct part marking	2 years after publication
All Class I *(with no categorical exceptions)*	label and direct part marking	3 years after publication

Will the 1-year effective date for the formatted date requirement result in less efficient planning as compared to a later date?

The standardized date format requirement in the proposed rule is a *format change*, not the introduction of a new requirement. For that reason, AHRMM does not believe that the 1-year effective date will be burdensome or result in less efficient planning as compared to a later date.

IMPACT ON KITS AND COMBINATION PRODUCTS

If a combination product's primary mode of action is that of a device, is it appropriate to require each device constituent part of the combination product to bear its own UDI? If a combination product's primary mode of action is not that of a device, is it appropriate to require each device constituent part of the combination product to bear its own UDI?

AHRMM believes that it is not appropriate to require that each device constituent part of a combination product bear its own UDI in either instances (i.e., where the combination product's primary mode of action is that of a device or where the combination product's primary mode of action is not that of a device). Combination product manufacturers are subject to good manufacturing practices and are therefore required to record production numbers for each device constituent part of a combination product. As long as these records are updated to include the UDI for the combination product, manufacturers' records can be used to connect the UDI for the combination product with the production numbers for the individual components. Beyond that, AHRMM does not believe that providers would actually use UDIs for device constituent parts because it is not how they work and because provider systems would not be able to store the additional UDIs anyway. As a result, such a requirement would just add unnecessary cost for manufacturers.

Should FDA require a UDI on the label and package of every combination product that has a device constituent part, regardless of its primary mode of action, except when the primary mode of action is not that of a device, and the combination product is labeled with an NDC?

AHRMM recommends that the FDA should only require a UDI on the label and package of a combination product that has a device constituent part when the *primary mode of action is that of a device*. In such instances, AHRMM recommends that the UDI appearing on the label should be for the combination product itself, and the information appearing on the label about each product within the combination product should be descriptive. In addition, AHRMM recommends that the manufacturer should maintain the UDI for each product within the combination product.

Is it necessary to require a UDI for each device included in a convenience kit?

AHRMM believes that it is necessary to require a UDI for all devices included in convenience kits in order to support effective recalls.

Would it be appropriate to provide an additional exception from UDI labeling for any Class I device included in a convenience kit, even if intended for more than a single use?

AHRMM does not believe that it would be appropriate to provide an additional exception to UDI labeling. AHRMM believes that all Class I devices included in a convenience kit should bear a UDI.

Instead of requiring a UDI on the label of each device included in a convenience kit, would it be more appropriate to require the label of the convenience kit to identify each device included in the kit, together with the UDI of each such device?

AHRMM does not believe that it would be more appropriate to require the label of the convenience kit to identify each device included in the kit together with the UDI of each such device. Rather, AHRMM believes that the label of a kit should bear the UDI for the kit itself, and only a description and quantity of each product contained within the kit. The UDI for each item in the kit should be maintained by the kit manufacturer.

DIRECT PART MARKING

Is it appropriate to require direct marking for all implantable devices? Should the requirement be limited to certain types of implants?

AHRMM believes that it is appropriate to require DPM for all implantable devices, and that the requirement should not be limited to only certain types of implants. The importance of DPM for implantable devices cannot be overstated as the tremendous optimism for improved patient outcomes at the time of implantation is frequently overshadowed by later recognition of product flaws, failures and threats to patient safety. Devices need to be definitively identified *when implanted within the human body* to support and improve the response to such incidents. Moreover, the responsibility for maintaining medical device identification information should rest with the industry. Patients cannot be and should not be expected to maintain careful files detailing the identity of an implanted deice.

AHRMM recommends that all implantable devices be directly marked unless marking technology will interfere with the effectiveness of the device. There should be no categorical exception for the DPM, such as whether there is a UPC already assigned or if the implants are distributed in the retail supply chain. Instead, labelers seeking an exception from the DPM requirement for an implantable device should follow the case-by-case process for exceptions outlined in § 801.35 of the rule.

AHRMM Comment: Proposed Review Process for Exceptions to the DPM Requirement

AIDC technology development is in its infancy, as is the availability of life-enhancing implants. Because of this, AHRMM believes that the UDI rule should include language that provides the FDA with the flexibility it needs to respond to developments for both implant technology and AIDC direct marking technology. To achieve that, AHRMM recommends that the FDA establish a regular review of devices that have received an exception from the DPM requirement every two years so that the exception can be reconsidered in light of any advancements in AIDC technology. For example, if bone screws are granted an exception from the DPM requirement 2015 because the mark would interfere with the device, those same bone screws (if still offered by the labeler) would be reviewed in 2017 (and again in 2019, etc.) to assess whether advancements AIDC technology would enable the screws to be directly marked without interfering with the effectiveness of the device. If/when the answer is yes, the exception should be revoked and the DPM requirement reinstated.

AHRMM Comment: UDI for Direct Marking

In section § 801.50(b), the proposed rule states that the UDI provided through a direct marking on a device may be identical to the UDI that appears on the label of the device, or a different UDI used to distinguish the unpackaged device from any package containing the device. This will result in two numbers for the same device (i.e., in its packaged state and its unpackaged state). However, most provider systems do not have the ability to store multiple IDs. As a result, multiple UDIs for the same device would create a significant barrier to implementation across many provider systems.

Moreover, permitting the UDI for direct marking to be different from the UDI that is on the label will introduce unnecessary confusion into hospital electronic health records and automated supply chain tracking systems. Therefore, AHRMM recommends that the FDA require that UDI for direct marking on the device be the same as the UDI that appears on the packaging.

Is it appropriate to require direct marking for all devices intended for more than one use that require sterilization before each use?

AHRMM believes that it is appropriate to require direct marking for all devices intended for more than one use that require sterilization before each use. As the FDA thoughtfully addressed in the proposed rule, these types of devices pose unique risks to patients. In a clinical setting, there is a risk that a sterile version or model of a

device could be confused with a version or model that is not sterile and which requires sterilization prior to use. Moreover, the fact that these types of devices may be used over several years poses additional risks. During that time, the device package (with its label and any package insert) might be lost, leaving uncertainty about whether the device needs to be sterilized and what type of sterilization process should be employed. For these reasons, AHRMM agrees with the FDA that it is particularly important to ensure the adequate identification of such devices throughout the entire product life cycle. AHRMM believes that DPM is the best way to achieve that.

Are there good reasons to require direct marking for all devices intended for more than one use, regardless of whether the device must be sterilized before each use?

One good reason for requiring DPM for such devices is that it supports providers in responding to a faulty device used on multiple patients. Sterilization requirements do not impact the need for information when a device fails. In such instances, DPM on the device enables the provider to identify all patients on whom the device was used, and to locate the device itself within health care settings to assure removal. For this reason, AHRMM believes that it is important to require direct marking for all devices intended for more than one use, regardless of whether the device must be sterilized before each use.

Does the "component" distinction provide enough clarity for you to understand when software is stand-alone software that requires direct marking?

AHRMM believes that the "component" distinction provides enough clarity at this point regarding what software constitutes "stand-alone software" for which DPM is required. Considering the ever-changing, fast-paced technological environment, AHRMM recommends that the FDA revisit this definition on a regular basis (i.e., every two years) and update it as needed to ensure that exceptions are only made for *appropriate* stand-alone software and their related devices.

EXCEPTIONS

AHRMM Comment

AHRMM believes that all categorical exceptions are inappropriate, and that exceptions should only be considered on a case-by-case basis after a careful evaluation of the device's function and how a contaminated or faulty instance of that device would impact patient safety. The procedure defined in § 801.35 provides a reasonable process for accommodating requests for exception from, or alternative to, the general rule for UDI labeling. AHRMM believes that there should be no exceptions other than those granted under this section.

Categorical exceptions diminish the ability of hospital systems to use one standard identifier for all medical devices. Providers need to rely on a single standard for device identification in order to leverage materials management systems for track and trace, recall, and other application vital to patient safety. Consider the example of Class 1 devices: Although Class 1 devices are usually not expensive, most stock-keeping units (SKUs) and lines ordered in hospital supply chains are Class 1 devices. In order to ensure internal consistency, hospitals have been assigning their own numbers to these devices. However, this approach has been a failure because hospital-assigned numbers mean nothing to the larger supply chain, including distributors and suppliers. Providers are looking to the UDI to correct this structural failure in the medical device supply chain so that they can leverage their materials management systems to conduct effective recalls, and to support other application vital to patient safety, like track and trace.

Providers need all medical devices to use one standard identifier that will be used in all hospital-based, procure-to-pay systems that track purchases, manage inventory and pay supplier invoices. Because categorical exceptions result in the incomplete assignment of UDIs within the universe of medical devices, categorical exceptions could be a major impediment to hospital adoption of the UDI in both procure-to-pay systems, as well as in interfaces to clinical and billing systems. Low adoption in hospitals would undermine the ability to track and trace medical devices, and recalls would likely continue at their current rate of inadequate effectiveness.

For these reasons, AHRMM recommends that there be no categorical exceptions, and that exceptions only be granted on a case-by-case basis pursuant to the process defined in § 801.35

Should devices sold over-the-counter at retail be excepted as provided by proposed §801.30(a)(1), or should they instead be subject to the proposed rule in the same manner and to the same extent as other devices?

As a preliminary matter, AHRMM believes that there should be no over-the-counter / retail exceptions for Class 3 or Class 2 devices. Beyond that, AHRMM notes the following statements made by the FDA in the proposed rule:

"Some devices sold over-the-counter at retail have been the subject of recalls and adverse events, and we would likely see significant benefits from participation in the UDI system. It is also possible that many other devices sold over-the-counter at retail would benefit from participating in the UDI system, and that those benefits would outweigh the costs of participation."

AHRMM agrees with those statements and believes that devices sold over-the-counter at retail should be subject to the proposed rule in the same manner and to the same extent as other devices. In order to conduct effective recalls, all medical devices should have a UDI.

Moreover, providers need to rely on a single standard for device identification regardless of whether devices are sold at retail. If there is a "retail" exception, UDI would only be available on a small segment of Class 1 devices and on Class 2 and Class 3 devices. Because of that, hospitals would not be able to use the UDI in their systems as the standard, and hospital information systems would need to respond to at least two sets of numbering systems to cover the product lines that are purchased.

Are any of the categorical exceptions provided by the proposed rule inappropriate?

As discussed above, AHRMM believes that all categorical exceptions are inappropriate (see the *General Comment* at the beginning of this section), and that devices sold over-the-counter at retail should be subject to the proposed rule in the same manner and to the same extent as other devices (see the comment to the previous question). In addition, AHRMM also believes that the exception #9 (for the Strategic National Stockpile) is also inappropriate. Expiration dates are of particular importance in stockpiled devices because they are necessary to support the management of the stockpile over time, and to ensure that the required amount of viable (i.e., not expired) devices are available in an emergency. Moreover, without proper identification of devices maintained in the stockpile, there would be no way to remove unsafe or unreliable products from the stockpile in the event of a recall. Products in the Strategic National Stockpile are maintained for national emergency. It is of the utmost importance that such products are reliable and safe for use. Therefore, AHRMM believes that devices in the Strategic National Stockpile should be subject to the proposed rule in the same manner and to the same extent as other devices.

Should all Class 1 devices be exempt from production identifiers?

Although some Class 1 devices may not need production identifiers, *many do*. Therefore, AHRMM does not believe that all Class 1 devices should be exempt from production identifiers.

Production information is helpful for recalls of devices in any class. However, it is absolutely vital for recalls of Class 1 devices -- and these products are everywhere in hospitals. Without production data, hospital staff needs to wade through bedside storage areas to look for recalled products, and this time commitment is next to impossible for large hospitals. Recall effectiveness will not be improved unless production data is available on the majority of Class 1 devices. Fortunately, once hospitals have adapted their systems to include the UDI for Class 2 and Class 3 devices, they will be positioned to receive complete information for every device *(including production information for Class 1 devices).*

In the proposed rule, the FDA stated that production identifiers for Class 1 devices could be omitted because medical records are unlikely to include Class 1 device information. Although this is certainly true in the short term, full product information in the medical record will likely evolve when data collection at the bedside becomes technically effortless and data storage less burdensome over the next ten years. However, there is no need to wait because, in the meantime, systems will be adapted to accommodate complete information for every device, and Class 1 production data can be used to enhance recall effectiveness for the myriad of Class 1 devices in hospitals.

What if any Class 1 device should require a production identifier?

AHRMM recommends that production identifiers be required for all Class 1 devices, and that exceptions should only be made on a case-by-case basis using criteria established to protect patient safety (e.g., the procedure defined in § 801.35). AHRMM believes that the FDA should avoid categorical exceptions based on supply chain definitions (e.g., retail) because they do not promote the goal of the UDI system to protect patient safety.

Does the procedure outlined in the rule (Section 801.35(a)) provide a reasonable basis for accommodating requests for exceptions from, or alternative to, the general rule for UDI labeling?

AHRMM believes that the procedure defined in § 801.35 is clearly outlined, and provides a reasonable process for accommodating requests for exception from, or alternative to, the general rule for UDI labeling. Moreover, AHRMM believes that this section should be the basis for all exceptions, and that there should be *no exceptions* other than those granted under this section.

AIDC

Should FDA require the use of specific AIDC technologies or have a role in approving the use of new AIDC technologies that are used to provide a UDI, or should we leave this decision to the healthcare community and issuing agencies?

AHRMM believes that the FDA should require the use of specific AIDC technologies and have a governance role in approving the use of new AIDC technologies for UDI.

There are a variety of AIDC technologies in the market today, and each continues to evolve. Mature AIDC technologies like barcoding may be more robust, whereas newer AIDC technologies like quick response (QR) coding and voice may be in their infancy and/or less widely used in the healthcare supply chain. Because of this, the application of AIDC technology to UDI should be carefully measured and monitored by a central governing body.

Moreover, unified governance is necessary in order to promote a harmonized approach to AIDC technologies for UDI. Leaving these decisions to multiple issuing agencies and disparate healthcare organizations within the healthcare community would not provide for a cohesive, singular authority for establishing standards or standard criteria for selecting specific AIDC technologies. This would promote competing processes to support a single approach to AIDC for UDI. Different AIDC technologies could be adopted by different suppliers or specialties, creating a complicated and costly maze for providers trying to implement AIDC for UDI in their facilities.

Should we restrict this provision to allow use of the generic symbol only where there is no symbol endorsed in an international standard, and no symbol generally recognized by the persons who typically use the device?

If the AIDC technology that carries the UDI is not evident upon visual examination of the label or device package, AHRMM recommends that the FDA require the use of the AIDC symbol proposed in § 801.45(c) of the rule.

As the FDA noted in the proposed rule, rapid and accurate identification of a device may be impeded if a device user is not aware of the AIDC technology that carries the device's UDI. Because this would diminish the effectiveness of the rule, it is essential that UDI labeling be clear. Other AIDC symbols, like radio-frequency identification (RFID) or near field communication (NFC), only provide notice of *AIDC technology*. They do not provide notice of *AIDC technology for UDI*. The use of a unique symbol from the UDI rule itself provides a clear signal to the healthcare community that AIDC technology for UDI is on-board.

ISSUING AGENCY

Do the accreditation requirements outlined in proposed Sec. 830.100 provide sufficient opportunity for interested and qualified organizations to be accredited as an issuing agency?

AHRMM believes that the accreditation requirements outlined in proposed Sec. 830.100 do provide sufficient opportunity for interested and qualified organizations to be accredited. However, AHRMM recommends that the FDA add a provision to limit the number of issuing agencies to *no more than two within a specialty* (e.g., blood; organs; skin grafts; etc.) in order to avoid the creation of several new agencies looking to make a profit, not to fulfill a need.

Will the existence of multiple UDI systems confuse device user facilities or impose unreasonable costs on device user facilities?

The provider community will be looking for a standard identifier that will be familiar in order to encourage scanning of the UDI. AHRMM believes that multiple UDI systems will create confusion and/or uncertainty at provider facilities and undermine the comfort level they are seeking to encourage scanning. In addition, AHRMM believes that multiple UDI systems will impose unreasonable costs on providers. Many providers are struggling to justify and encourage the initial investment in AIDC in their facilities. Although AIDC software systems may be adjusted to include a variety of carriers, these enhancements add cost and the existence of multiple UDI systems could likely result in the need for constant enhancements to provider AIDC systems to

allow for the scanning of additional types of carriers approved by the various issuing agencies. With cost always a factor for providers, the risk that AIDC investments will require constant upgrading/updating may well discourage investment and slow implementation.

To avoid confusion and provide a reliable basis for AIDC investment, AHRMM proposes that the FDA limit the number of issuing agencies to minimize confusion within the market place.

Would it be preferable for FDA to accredit only one national issuing agency? If you believe a single national issuing agency would be preferable, please explain your views and explain how FDA should make such a designation.

AHRMM believes it would be preferable to use one standard that is widely used in other public markets. Unified governance is necessary in order to promote a harmonized approach to UDI. Multiple issuing agencies would not provide for a cohesive, singular authority for establishing standards or standard criteria. This would promote competing processes to support a single approach to UDI. Therefore, AHRMM believes a single national issuing agency would be preferable. However, we are not in a position to comment on how this should occur.

Are there compelling reasons to permit a for-profit organization to be accredited as an issuing agency?

AHRMM does not believe there are any compelling reasons to permit a for-profit organization to be accredited as an issuing agency, and agrees with the FDA that the issuing agencies should be non-profit or state agencies. In the proposed rule, the FDA stated the following:

"We are proposing to require an issuing agency to be either a private nonprofit organization or a State agency. The reason for this is to minimize potential conflicts of interest and to help assure that the fees assessed by an issuing agency are reasonable to small businesses."

AHRMM supports both the proposal and the rationale expressed by the FDA in this statement.

DATA SUBMISSION & GLOBAL UNIQUE DEVICE IDENTIFICATION DATABASE (GUDID)

If you believe any of the information that would be required by proposed Sec. 830.330 is not necessary to assure the adequate identification of a medical device, please identify the information you believe is unnecessary and provide an explanation of your views.

AHRMM believes that all of the information proposed by § 830.330 is necessary to assure the adequate identification of a medical device.

If you believe that additional information should be required to assure the adequate identification of a medical device, please identify the information you believe is necessary and provide an explanation of your views.

AHRMM believes the following attributes should be added to the database requirements. All of these attributes provide critical information that can be the difference between whether a device contributes to or detracts from quality patient care.

- **Storage and handling conditions** *(e.g., maximum storage temperature, needs to be refrigerated, keep out of light, etc.)* This information enables end-users to store devices properly in order to ensure their integrity and effectiveness. This is particularly important for most tissue products and equipment.
- **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 Material Safety Data Sheet (MSDS)** *(e.g., MSDS Hyperlink)* This information provides end-users with a reliable and readily-available source of information should an urgent need arise.

Additional Comment

AHRMM encourages the FDA to make access and use of the GUDID as easy as possible for healthcare delivery organizations and other interested parties. Applications on mobile devices would be particularly helpful. AHRMM supports the use of simple and advanced search terms, and the ability to print and export portions of the database. Additional web services, such as those that allow providers to search on recalled products, is also recommended.

HUMAN READABLE FORMATS

Will a specified format for dates on medical device labels reduce confusion concerning expiration dates? Which format would patients and health care professionals better understand, the ‘‘U.S.’’ format (e.g., SEP 30, 2011), or the ‘‘international’’ format (e.g., 30 SEP 2011)? Is there a strong reason to favor one format over the other?

AHRMM believes that specifying a human readable format for dates on medical device labels will help reduce confusion concerning expiration dates. With regard to choosing between the ‘‘U.S.’’ format (e.g., SEP 30, 2011) and the ‘‘international’’ format (e.g., 30 SEP 2011), AHRMM recommends the “international” format (i.e., 2011 SEP 30) in order to be consistent with leading industry standards organizations.