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Association**

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*Submitted Electronically*

November 7, 2012

Margaret A. Hamburg, M.D.  
Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: *Unique Device Identification System Proposed Rule (FDA-2011-N-0090)***

Dear Commissioner Hamburg:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our nearly 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed rule published in the July 10 *Federal Register* regarding implementation of a unique device identification (UDI) system.

A fully implemented UDI system would enable a medical device tracking system for hospitals to use in patient care, response to safety recalls and supply chain management. The growing number of medical device recalls, coupled with the increased use of such devices, underscores the importance of such a system for patient safety.

**We urge the U.S. Food and Drug Administration (FDA) to accelerate the timing of the complete roll-out for the UDI across all medical devices from the proposed seven years to three years.** Congress passed legislation requiring development of the UDI in 2007. The country should not have to wait until 2020 (seven years after the publishing of a final rule in 2013) to realize the patient safety benefits of a fully implemented UDI system. Our specific comments on timing and other technical issues follow.

**BACKGROUND**

The proposed rule would phase in over seven years a requirement that many device labels and packages include a UDI based on international standards. Under the rule, some devices would be marked directly with the UDI, such as those that are implanted or are likely to become separated from their labeling. Each UDI would be provided in both plain-text and in a form that uses automatic identification and data capture (AIDC) technology, such as a barcode. In addition, information about each device would be submitted to a public database maintained by the FDA, referred to as the Global UDI Database (GUDID). The rule also proposes a standard format for presentation of dates on medical device labels.



### **PROVIDER SUPPORT FOR THE UDI**

The AHA has long supported the development of a UDI and we are confident that hospitals will make good use of the identifiers once they are available. A unique medical device identifier will provide an important means for hospitals to better track devices used in patient care, act in the event of safety recalls and manage their supply chains. The proposed rule cites the many benefits that will accrue to patients, ranging from ensuring that the right device is available, to ensuring that patients receiving recalled devices are notified and treated, and allowing for better post-market surveillance to support a learning health care system. Information about UDIs also can be incorporated into electronic health records (EHRs). The information maintained in the FDA's public GUDID would be an important, centralized source of basic information on medical devices.

Hospitals are committed to using the UDI and have been investing in barcoding and other technologies to track medical devices, pharmaceuticals and laboratory specimens, and to ensure that patients receive the right items and services. The AHA annually surveys hospitals on their use of health information technology, including the use of barcoding technology. In 2008, 52 percent of surveyed hospitals already had implemented barcode technology for supply chain management, or were planning to do so within a year. Given that larger facilities are more likely to implement barcoding technology, the share of hospital admissions occurring in hospitals with barcoding for supply chain management in 2008 was even greater – 68 percent. The AHA did not collect data specifically on use of AIDC for supply chain management in 2009 through 2011. However, we are currently surveying the field, and the results will provide 2012 data on use of barcoding and other AICD technologies in supply chain management. We will share that information with the FDA when it becomes available. We know that hospital investments in barcode technology continue apace. Data collected in 2011 suggest that 96 percent of hospitals were using barcode technology for at least one of the following uses: laboratory specimens, tracking pharmaceuticals, pharmaceutical administration and patient identification.

Hospitals are clearly committed to using the kinds of automated technologies that are needed to maximize the benefit of a UDI. In fact, many hospitals already are using these technologies to track devices using their own numbering systems – an inefficient approach. This does not provide the system-wide benefits of a UDI system. Hospitals also will be increasing these investments in coming years due to federal requirements under the Medicare and Medicaid EHR Incentive Programs to use these technologies as part of their electronic medication administration records.

### **NEED TO ACCELERATE TIMING**

Under the proposed rule, the FDA would phase in the labeling and marking of a device with a UDI over time, by device class. Implementation would begin with Class III devices (highest risk), which would need to be labeled with a UDI within one year of publication of a final rule, and include direct marking after three years. Class II devices would need to be labeled within three years, with direct marking within five years, while certain Class I devices (lowest risk) would need to be labeled within five years, and include direct marking within seven years. Many Class I devices would be exempt.

**The AHA urges the FDA to accelerate this timeline.** Safety advocates and patients have waited a long time for the UDI – we see no compelling reason to wait an additional seven years.

In addition, the *FDA Safety and Innovation Act of 2012* requires implementation of rules for all devices that are “implantable, life-saving and safe sustaining” within two years of the regulation being finalized – this requirement should arguably encompass all Class III and Class II devices. Given that legislative imperative, the AHA recommends the following timeline to complete the rollout of the UDI:

- one year for Class III devices, label and direct marking;
- two years for all Class II devices, label and direct marking; and
- three years for Class I devices, label and direct marking.

Although an accelerated timeline would bring forward the burden on labelers to comply, it will ensure that important patient safety goals are achieved at the earliest possible opportunity.

#### **DEFINITION OF A LABELER**

The FDA proposes to make device “labelers” responsible for complying with the UDI requirements. The agency defines a labeler 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. In most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler (FR 40747).

**We interpret this definition to mean that hospitals are not considered to be labelers and should not have to comply with the labeling requirements when they reprocess single-use devices, repack items or assemble convenience kits for use in their own facilities without the items entering into interstate commerce. The AHA agrees with this approach.**

#### **LIMITATIONS ON PROPOSED EXCEPTIONS FOR THE UDI**

The AHA has significant concerns about a number of these proposed exceptions to the labeling requirement contained in the proposed rule.

**The FDA proposes an exception to the UDI and direct marking requirements for devices, other than prescription devices that are sold at retail establishments, such as pharmacies. The AHA believes that many of these devices pose significant safety risks and urges the FDA to omit the exception for devices sold at retail establishments from the final rule.**

This proposed exception would apply even when such devices are sold directly to a hospital or other health care facility. The proposed rule provides as examples automatic external defibrillators, insulin syringes, glucometers, thermometers and bandages, and notes that “some devices sold over-the-counter at retail have been the subject of recalls and adverse events.”

In order to conduct effective recalls, all medical devices should have a UDI. The retail exception would remove many devices from the UDI system. As a result, many of the items purchased and managed by hospitals would not have a UDI, and hospital information systems would need to accommodate at least two sets of numbering systems to cover the product lines purchased. This duplication would be inefficient and could limit the safety benefits of the UDI.

**The AHA also urges FDA not to finalize its proposed exception for a device that is packaged in a convenience kit, if the device is intended for a single use.** Devices packaged in convenience kits, such as scalpels and surgical clips, can become separated from the kit, and should therefore be independently identified. In addition, devices intended for single use can sometimes be reprocessed for sterility and reused. Items in convenience kits also should bear direct marking if that marking would be required on the device if it were sold as a stand-alone item. A UDI should be required for all devices included in convenience kits, including Class I devices, in order to support effective recalls.

**The AHA also urges the FDA to remove the proposed exception for devices that are part of the Strategic National Stockpile.** 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 sufficient devices are available in an emergency. Further, proper management of stockpiles would include removal of recalled devices, which the UDI greatly facilitates.

#### **LIMITATIONS ON PROPOSED EXCEPTIONS FOR DIRECT MARKING**

If finalized, the proposed rule would require that certain devices be directly marked with the UDI, in addition to requirements to place the UDI on labels and packaging. Direct marking would apply to implantable devices, a device intended to be used more than once, and intended to be sterilized before each use; and to stand-alone software that is defined as a medical device. FDA's rationale for requiring individual marking of these devices is that they are in use for long periods of time and are likely to be separated from their labels and packaging. The proposed rule would require direct marking only of implantable devices that are intended to remain implanted for 30 days or more.

**The AHA recommends that the FDA remove the 30-day qualification and require that all implantable devices be subject to direct marking.** Direct marking is important for patient safety. Faulty devices, whether implanted for three days or 30 days, pose significant safety risks that must be addressed as quickly as possible. It also would be easier to administer a requirement that applies to all implantable devices, rather than using an arbitrary time frame such as 30 days.

**The AHA believes that direct marking requirements should apply to all devices intended for more than one use, not just those that must be sterilized before re-use.** Including direct marking on all reusable devices would facilitate identification of faulty devices used on multiple patients, such as intravenous drug pumps.

Outside of these concerns, the AHA agrees that the proposed exceptions to the direct marking requirements outlined in the proposed rule – such as cases where direct marking would interfere with the safety or effectiveness of the device, or if direct marking is not technologically feasible – are appropriate. We also agree that the FDA should establish an explicit exceptions process to manage requests for exceptions. **However, we recommend that the FDA modify the exceptions process to add a regular, biannual review of all devices that have received an exception to the direct marking requirement to assess whether technology has changed sufficiently to enable direct marking.**

#### **ADDITIONAL DATA TO BE INCLUDED IN THE GUDID**

**The AHA strongly supports the development and widespread availability of the GUDID via the Internet**, as described in the proposed rule. It is important to maintain historical data while updating the GUDID with the newest and most accurate information. We agree with all of the data elements proposed in the rule, and strongly recommend the following additions:

- Indication that the device has been subject to a recall, with easy sorting on this data element to facilitate recall management.
- Storage and handling conditions for the device, such as requirements for storage temperature or exposure to light, to ensure proper handling that ensure device integrity and effectiveness.
- Whether the device is labeled as hazardous, to ensure safe handling and device integrity.
- Whether the device contains radioactive isotopes, including the radioactive element and atomic number to ensure safe handling and disposal.
- Notification that the device has a Material Safety Data Sheet (MSDS), and inclusion of a link to the detailed information needed for safe use and handling.

Further, to make the best use of the UDI in recall situations, the FDA should include the UDI in all recall communications, regardless of which part of the agency issues or manages a given recall.

#### **USE OF AIDC TECHNOLOGIES AND SYMBOLS**

The proposed rule points to a tension between identifying a limited set of automatic identification and data capture (AIDC) technologies for use with the UDI and technical innovation over time. There are practical challenges to using multiple AIDCs, such as both barcoding systems and radio frequency identification, within a single institution. Therefore, the AHA recommends that the FDA err on the side of promoting a harmonized approach that limits the options available at any given time. If more than a few AIDC technologies are in use simultaneously, the benefits of having the UDI will be diminished, as individual health care organizations will not be able to support the multiple technologies required. This approach will require active and ongoing collaboration between the FDA, technology companies, device manufacturers and end-users. The FDA should facilitate that collaboration, perhaps through an advisory council representative of all stakeholders, especially the end-users responsible for incorporating the technology into patient care.

Some AIDC technologies are sufficiently advanced or miniaturized that they may not be visible to the end-user. In those instances, the AHA recommends that the FDA require the use of the AIDC symbol proposed in the rule (Sec. 801.45(c)) to alert those handling the device to the presence of the UDI in an automated format. Having an AIDC technology that is not apparent to the end-user could limit the effectiveness of the rule. For example, clinical staff may not automatically record the UDI of an implanted device in the medical record if they are not aware that the AICD technology is enabled on the device. Manual recording would be possible from the human readable format on the label, but is less efficient and more prone to error than using the AIDC technology.

Margaret A. Hamburg, M.D.

November 7, 2012

Page 6 of 6

#### **USE OF INTERNATIONAL UNIFORM DATE STANDARD**

The AHA agrees with the FDA's proposal for a uniform date for use on medical device labels to decrease confusion over expiration dates and its proposal to make the requirement effective within one year after publication of a final rule. **However, we recommend that the FDA adopt an international format for the date, rather than a U.S. format; specifically, the human readable format would be Year Month Day (2013 DEC 31).**

#### **COORDINATION WITH OTHER AGENCIES**

**The AHA encourages the FDA to work with the Office of the National Coordinator (ONC) for Health Information Technology to ensure that the certification of EHRs for meaningful use includes incorporation and accommodation of the UDI and associated AIDC technologies.** In that context, we note that the UDI will originate in the materials management information system (MMIS) of the hospital or other health care provider. It will not originate in the EHR. Therefore, the key consideration for certification is that capability of the EHR to easily and accurately share data with the MMIS without undue burden on hospitals and other providers for maintaining interfaces. The EHR also should support information delivered from all of the alternative AIDC technologies used to communicate the UDI, and not just the one(s) chosen by the EHR vendor. This is a key factor for managing recalls, conducting track and trace, and assisting in post-market surveillance. Any miscommunication between the MMIS, the AIDC technology and the EHR risks limiting the benefits of the UDI and possibly causing errors or confusion that could result in harm, rather than safety benefits. The AHA will work directly with ONC to ensure that patients benefit fully from the safety enhancements provided by incorporation of the UDI into EHRs.

The AHA applauds the FDA for moving forward with the proposed rule on a unique device identifier. The safety of our health care system will be greatly enhanced by a timely final rule that accelerates the roll-out of the UDI, limits the exceptions to the UDI requirements, and provides enhanced information in the GUDID. America's hospitals already are making the investments needed to incorporate the UDI into patient care, recall management and supply chain management.

If you have any questions about our comments, or need additional information, please do not hesitate to contact me or the following members of our policy team: Chantal Worzala at [cworzala@aha.org](mailto:cworzala@aha.org) or Roslyne Schulman at [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Rick Pollack  
Executive Vice President

cc: Farzad Mostashari, ONC