PREMIER TRANSFORMING HEALTHCARE TOGETHER®

November 1, 2012

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
Attention: FDA-2011-N-0090
Submitted electronically at: http://www.regulations.gov

Re: Unique Device Identification System

Dear Dr. Hamburg:

On behalf of the Premier healthcare alliance serving more than 2,700 hospitals, including large multi-hospital healthcare systems, small and rural community hospitals, urban hospitals and academic medical centers, and 90,000-plus other non-acute healthcare sites, we appreciate the opportunity to submit comments regarding the proposed rule on the unique device identification system, which was published in the July 10, 2012 issue of the *Federal Register*.

Premier strongly supports the implementation of a unique device identification (UDI) system and commends the FDA for issuing the proposed rule. UDI is the missing link to protect patient safety. Enabling healthcare providers to track medical devices electronically in the supply chain will improve the speed and accuracy of product recalls, as well as adverse event reporting. In addition to these important safety benefits, automating the now manual process of tracking of medical devices is projected to save the healthcare industry approximately $16 billion each year from greatly improved efficiencies.

In brief, the proposed rule would require:

- The label and package of medical devices to bear a unique device identifier (UDI) unless alternative placement is permitted or an exception applies;
- Certain devices to be directly marked with a UDI;
- Labelers of medical devices to submit information concerning each device to the Global Unique Device Identification Database (GUDID), which FDA would establish and which would contain information about devices labeled with a UDI; and
- Dates on medical device labels (such as expiration dates) to conform to a standard format.

The proposed rule would also establish the accreditation requirements for agencies that may operate a system for the issuance of UDIs and the conditions for when FDA might act as an issuing agency.

UDI basics

The proposed rule calls for the following UDI framework:

13034 Ballantyne Corporate Place
Charlotte, NC 28277
T 704.357.0022
F 704.357.6611

444 North Capitol Street, N.W.
Suite 625, Washington, DC 20001
T 202.393.0860
F 202.393.6499

PREMIERINC.COM

- A UDI would be a unique numeric or alphanumeric code that includes a mandatory device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date, when those attributes are included on the label.
- The UDI would need to be displayed on the label and package of medical devices.
  - FDA notes that a UDI would be required to appear on an individual device package, on a box of five packages, and on a carton of 10 boxes of five device packages, because the package, box and carton would all be considered device packages.
  - The UDI would need to be directly marked on the device itself for certain categories (an issue discussed in more detail later in these comments).
- A different UDI would be required for each version or model of a device.
- If a product is discontinued, its UDI would not be reassigned or reused for another product.
- Labelers would be prohibited from using more than one device identifier from any particular accredited system to identify a particular version or model of a device, but if they use systems operated by two or more issuing agencies, they would be permitted to identify a device with one identifier from each system.
- The UDI would need to be displayed in plain text format and also in a form using automatic identification and data capture (AIDC) technology, such as bar codes, radiofrequency identifiers, or other near-field communication.

Comment: Premier supports the general UDI framework. We wish to emphasize, however, that UDI requirements should apply down to the normal unit of use for a patient so that a device can be properly identified as it is being used by or furnished to the patient. We believe this is the intent of the proposed rule as articulated with respect to UDI requirements applicable to boxes and cartons containing multiple device packages.

Definitions

The proposed UDI requirements would apply to device labelers. The proposed rule defines the term “labeler” to mean 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 this regard, FDA notes that the labeler would, in most instances, be the device manufacturer, but that the labeler may be a specification developer, single-use device reprocessor, convenience kit assembler, repackager, or relabeler.

Comment: Premier believes that the final rule must more specifically describe when a repackager, device reprocessor, or other non-manufacturer would be subject to UDI requirements (that is, when such an entity would be considered a “labeler” for UDI purposes). For example, some of our members purchase unsterilized devices in bulk and then sterilize and package them for use within their individual hospitals or healthcare systems. Others may purchase discrete products and assemble convenience kits for internal use within their hospitals or healthcare systems. Similarly, many of our members transfer products within their system (which may include hospitals and other providers in multiple states, obviously requiring product movement across state lines). In other instances, a product might be re-branded, which would raise questions about which entity incurs UDI compliance obligations, including GUDID data submission.

Comment: Premier believes that hospitals, healthcare systems, and other entities that repackage devices, assemble kits, or reprocess single-use devices for internal use only, not for purposes of interstate commerce (that is, sales outside the hospital or healthcare system), should not be subject to UDI-related requirements, even when the repackaged products, assembled kits, or reprocessed devices must cross state lines in the process (for

example, because the healthcare system includes facilities in more than one state). We believe that the final rule should clarify that this was FDA's intent all along. If this is not the case, we believe that the UDI system would end up overreaching.

Effective dates

Table 7 of the proposed rule lists the proposed implementation timetable. In brief, the proposed rule would impose UDI labeling requirements and related GUDID information submission requirements for class III, II and I devices beginning one, three and five years, respectively, following publication of the final rule. In addition, for devices not classified into class I, II or III, the proposed rule would give labelers five years to comply with UDI requirements relating to labels, packaging and GUDID submission. Further, for devices subject to direct marking requirements (discussed below), compliance with these requirements would be required two years after the date specified for compliance with UDI label requirements for a device category. This would make for a seven-year implementation timeframe. The recently enacted FDA Safety and Innovation Act, P.L. 112-144, will, however, require implementation of final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than two years after the regulations are finalized, and thus the proposed timetable would need to be adjusted accordingly.

Comment: Premier believes that the proposed seven-year implementation timeframe is far too long. Among other things, we are concerned about the long implementation time proposed for unclassified devices, many of which play roles akin to those of class II or III devices and raise important patient safety issues. In our view, such unclassified devices should not be treated any differently than comparable class II or III devices. And we believe that the recently enacted FDA Safety and Innovation Act clearly demonstrates congressional interest in seeing relatively prompt implementation of UDI requirements. We urge FDA to complete the implementation of UDI requirements for all affected devices (with respect to labels/packaging) within two years of the effective date of the final rule.

We recognize that this could be accomplished in a variety of ways. For example, a labeler with only a single class of devices (including even class I devices) could be required to come into compliance within one year, while a labeler with multiple product classes might be given more time. We definitely agree with the proposed one-year timeframe for class III devices. As noted above, we also recognize that the FDA Safety and Innovation Act will require compliance with UDI requirements (with respect to label/packaging) no later than two years after the effective date of a final rule for all devices that are implantable, life-saving, or life sustaining (including class II devices of these types). We also wish to emphasize that under our recommended timetable, labelers should be required to submit all relevant information to the GUDID at the same time that UDI requirements relating to labels and packaging take effect. The information to be incorporated into the GUDID is of critical importance to public safety and public access to such information at the earliest opportunity will be of enormous benefit to all stakeholders.

We strongly believe that UDIs must be adopted as quickly as possible for all devices in order to achieve the intended benefits in a sufficiently timely way. We believe that the timeline described above should be sufficient for all labelers to come into compliance. According to the American Hospital Association (AHA), even without a national UDI system, hospitals have invested significantly in barcoding and other medical technologies to track medical devices, pharmaceuticals and laboratory specimens in their supply chains. According to a 2008 AHA survey, hospitals with 68 percent of the nation's admissions had already implemented or were planning to

implement within one year barcode or RFID technology for supply chain management. Moreover, AHA data from 2011 shows that 96 percent of hospitals are utilizing barcode technology for at least one of the following: tracking laboratory specimens, pharmaceuticals and pharmaceutical administration, and patient identification. Of course, as the proposed rule itself notes, the UDI-related deadlines that will ultimately be finalized by the FDA will apply to labelers and will not impose any specific obligations on hospitals or others with respect to when and how UDIs need to be incorporated into patient medical records and other provider information systems. Nonetheless, it would be a mistake to say that many or most hospitals will not be prepared in the near future to take full advantage of UDI benefits.

Combination products and convenience kits

Under the proposed rule, a combination product whose primary mode of action is that of a device would be subject to UDI labeling requirements. On the other hand, if the FDA has determined that the primary mode of action of a combination product is not that of a device, it would not require a UDI on the label or package of the combination product. In addition, each device constituent part of a combination product would need to have its own UDI regardless of whether the combination product itself is subject to UDI labeling unless such constituent part is "physically, chemically, or otherwise combined with other constituents of the combination product in such a way that it is not possible for the device constituent part to be used except as part of the use of the combination product." The FDA also proposes to require a UDI on the label and device package of each convenience kit, as well as a distinct UDI for each device in a convenience kit, unless an included device is intended for a single use (e.g., an adhesive bandage).

Comment: Premier generally supports the above policies. We wish to emphasize, however, the importance of ensuring that any device constituent parts of a combination product that may be used independently or any device within a convenience kit that may be used more than once (whether or not intended for single use) is individually labeled with a UDI. In fact, we believe that labelers should err on the side of redundant labeling to ensure patient safety.

Exceptions and alternatives

The proposed rule (§801.30) provides a large number of exceptions to the UDI and related GUDID information submission requirements, including one for devices, other than prescription devices, that are sold at retail establishments, such as drug stores, and this proposed exception would apply even when such devices are sold directly to a hospital or other healthcare facility. The FDA gives as examples automatic external defibrillators, insulin syringes, glucometers, tampons, thermometers, toothbrushes and bandages, and notes further that for those labelers that choose to submit data to the GUDID on a voluntary basis for such excepted devices, a UPC may serve as a UDI. FDA requested comments on the extent to which devices sold in retail establishments should be subject to the requirements of the proposed rule.

Comment: Premier believes that the proposed exception for retail products is ill-advised as currently stated. Instead, we believe that these products should be subject to UDI requirements, but that their UPC should be deemed to be the UDI for this purpose. In particular, we believe it is essential that labelers of the affected retail products be required to submit UPC data to the GUDID. Instead of the proposed exemption, we believe that non-prescription devices sold at retail establishments should be required to comply with all UDI-related requirements save for the need to obtain a UDI other than their UPC.

Direct marking of devices

The FDA proposes that the following devices would need to be directly marked with a UDI:

- An implantable device (but only if it is intended to remain implanted continuously for a period of 30 days or more, unless the FDA Commissioner determines otherwise in order to protect human health);
- A device that is intended to be used more than once and that is intended to be sterilized before each use; and
- Stand-alone software that is a "device" under §201(h) of the FD&C Act (FDA notes that this category excludes software that is an integrated component of a device, such as software embedded in a chip that is part of a circuit in a device).

Direct marking would have to be provided through easily-readable plain text and/or AIDC technology (or any alternative technology that will allow for identification of the device). If the device is stand-alone software, the direct marking would have to be provided through an easily-readable plain-text statement displayed whenever the software is started and/or an easily-readable plain-text statement displayed in response to a menu command.

Under the proposed rule, the UDI conveyed by direct marking could be either the UDI that appears on the label of the device, or a different UDI used to distinguish the unpackaged device from the device while it remains in packaged form. The FDA further proposes that the requirement for direct marking of a device would go into effect two years after the date specified for compliance with UDI label requirements for that device (that is, three years after publication of the final rule in the case of class III devices, for which the UDI label requirements would take effect one year after publication of such final rule, and seven years after publication of the final rule in the case of class I devices).

Comment: Premier strongly recommends that labelers not be allowed to use different UDIs for packaged and unpackaged implantable devices or in other instances when direct marking is required. We believe this would introduce too much confusion. Hospitals and others need a simple way to determine a device's UDI so it can be efficiently recorded into patient and other appropriate records. We see no value in allowing unpackaged devices to be directly marked with a UDI that differs from the UDI assigned to the same device when packaged.

Premier also recommends that all devices that will be implanted for 24 hours or more be subject to direct marking requirements, not just those slated to remain implanted for 30 days or more. For example, this would mean applying direct marking requirements to temporary or retrievable inferior vena cava filters even when they are not intended to be implanted for more than 30 days. We believe this would be a safer approach, as frequently such filters (and many other kinds of implantables) end up remaining in the body longer than was originally foreseen. We also believe that the proposed option for the FDA Commissioner to determine, on a case-by-case basis, whether devices implanted for periods of less than 30 days must be directly marked would introduce unnecessary and unhelpful complexity and uncertainty.

Premier also believes that the proposed timeline for direct marking of devices is too long. We believe that all devices for which direct marking is required should be so marked within three years of the effective date of the final rule. We believe this timeframe will be adequate for labelers, most of whom will be device manufacturers, while also assuring that important public health goals are achieved at the earliest possible opportunity.

Finally, Premier is concerned about how direct marking will work in the case of stand-alone software. We fear disagreements or uncertainty regarding whether software is – or is not – stand-alone, or an integrated component of a device. We believe that, at the very least, the final rule would have to provide far more guidance about this matter. We also are unsure about the implications of direct marking when there are multiple versions of the "same" software. As you probably know, it is not uncommon for software to have relatively frequent, automatic updates to address security or other issues. We are concerned that the volume of software versions could overwhelm the UDI assignment and tracking process. At the very least, FDA would need to give more guidance regarding the magnitude of change that would occasion the need for a new and different UDI. In fact, it might be prudent not to apply direct marking requirements to stand-alone software initially while more experience with the UDI is gained. This would also provide more time to consult with stakeholders regarding all relevant issues and possible options.

Formatting of dates on medical device labels

FDA proposes a standard formatting for dates provided on medical device labels: Month, Day, Year, with the month shown as a three-letter abbreviation of the month, the day shown in modern Arabic numerals (with no leading zeros) and the year shown in modern Arabic numerals, using the civil calendar in use in the United States, in four digits (e.g., JAN 3, 2012 and SEP 30, 2012).

Comment: Premier does not support the proposed standard format for dates. Instead, we urge FDA to mandate adoption of the International Standards Organization (ISO) date standard as articulated in ISO Standard 8601, under which the all numeric date format is yyyy-mm-dd, with leading zeros used as required. We believe this alternative is preferable given the global nature of device distribution and because dates in this format can easily be sorted by computers. We further recommend that use of "00" for the date be interpreted as the last day of the month (for example, for purposes of communicating the expiration date).

UDI issuing agencies

FDA proposes to define "issuing agency" as an organization accredited by FDA to operate a system for the issuance of UDIs. The proposed rule would permit multiple issuing agencies and, under certain circumstances, FDA could act as an issuing agency. FDA further proposes to accredit as issuing agencies only private nonprofit organizations or state agencies "in order to minimize potential conflicts of interest and to help ensure that the fees assessed are reasonable to small businesses." FDA further proposes to act as an issuing agency during any period where there is no accredited issuing agency, or if it determines that a significant number of small businesses would be substantially and adversely affected by the fees required by all accredited issuing agencies. If FDA acts as an issuing agency, it would not, under current law, assess a fee for its services, and any labeler (large or small) would be permitted to use FDA as its issuing agency. In the proposed rule, FDA asks whether the existence of multiple UDI systems would confuse device user facilities or impose unreasonable costs on device user facilities, and also whether it would be preferable for FDA to accredit only one national issuing agency, through careful evaluation of the strengths and weaknesses of alternative systems, through a competitive contract or some other means.

Comment: Premier believes that with regards to the ability of multiple issuing agencies to be accredited as proposed, FDA should consider the operational difficulties that having multiple UDI standards could pose for hospitals.

Premier also strongly believes that having FDA function as a "no cost" issuing agency should only be considered as an absolute last resort (for example, if no private entity could be found to exercise the issuing agency role). A "no cost" issuing agency would obviously place all other "non-free" issuing agencies at a distinct disadvantage, especially since FDA intends that both large and small labelers could avail themselves of the FDA's UDI-issuing services. If FDA remains concerned that small labelers could be disadvantaged, we believe that it would be preferable to incorporate necessary safeguards into the agency's agreement with an issuing agency in order to address these concerns, rather than the alternative of having FDA take on the role of UDI issuing agency.

Global unique device identification database (GUDID)

Under the proposed rule, FDA would establish the GUDID, which would contain critical information submitted by device labelers on the attributes of medical devices and which would be publicly accessible without charge. Labelers would be responsible for submitting data concerning a device to the GUDID, and for keeping the information up to date. UDI data would need to be submitted to the GUDID no later than the date the label of the device must bear a UDI. In addition, labelers who wish to submit information prior to a device's effective date would need to submit a request to FDA to do so, and FDA says such requests would be accommodated when consistent with the agency's ability to process the additional information in an orderly manner. Further, FDA would require electronic submission of required data except where such electronic submission is not technologically feasible for a labeler, which FDA expects will be extraordinarily rare.

Comment: Premier believes that more specificity is needed regarding the GUDID data-submission and updating process. For example, it is not completely clear how the updating of previously submitted data would be accomplished or how easy this process would be for responsible labelers. We also presume that data submission and updating could occur on a 24/7 basis, but this is also not clear. We also have questions about how entities required to submit data to the GUDID would interact with FDA, and what safeguards would be in place to ensure a secure data submission process. Further, with respect to labelers ready to make early submissions to the GUDID, we urge FDA to do everything it can to accommodate submissions ahead of any regulatory deadline. As we have noted above, we consider it extremely important to reap the benefits of the UDI as quickly as possible. We also believe that at least some labelers will choose to adopt UDIs for all their devices at the same time, for the sake of efficiency and consistency, rather than waiting to do so on some staggered basis; it would be most unfortunate if the GUDID was not prepared to incorporate information regarding all these devices earlier than their mandated timeframe.

Premier also urges FDA to provide more information about how device recalls will be handled in the context of the GUDID, and what the responsibilities of FDA, manufacturers and others will be in this process. We believe that recall information should be readily accessible through the GUDID and not require those accessing the GUDID to conduct complex searches or access multiple links in order to find this vital information. When a hospital accesses the listing or entry for a device in the GUDID, it should be readily and immediately apparent if a recall applies to that given device. In addition, FDA should ensure that all device recall notices sent to hospitals and others include the UDI(s) of the product(s) being recalled. In this regard, it would also be extremely important for recall information to be available in a standard format. We note that FDA has developed a model recall letter and routinely provides guidance to manufacturers with respect to the content of their recall communications. In our

view, anything that helps further standardize the information presented to hospitals at the time of a device recall and when they access the GUDID looking for potential recall information would be most helpful.

The proposed rule states that submissions to the GUDID would need to include 13 types of information regarding each version or model of a device labeled with a UDI, including the Global Medical Device Nomenclature (GMDN) code. However, the proposed rule further notes that the GMDN data are not currently available to the public unless a fee is paid to the GMDN agency, but that FDA anticipates that such data will be available to the public at no cost by the time the final rule is published; if this is not the case, FDA would not include the GMDN code requirement in the final rule. Premier agrees that stakeholders, including hospitals, should not be subject to GMDN-related fees when accessing the new GUDID, and thus agrees with FDA's plan not to require submission of GMDN codes to the GUDID if public access to this information is not gratis.

Analysis of impacts

The proposed rule includes estimates of the costs to domestic labelers, issuing agencies and the FDA itself of implementing the UDI system. It also notes that requiring adequate identification of medical devices through distribution and use would serve the following public health objectives:

1. Reduce medical errors by providing rapid and continuous Internet access to a single, authoritative source of information, the GUDID, to facilitate the unambiguous identification of medical devices used in the United States.
2. Simplify the integration of device use information into data systems, including patient records, particularly electronic patient records.
3. Provide for more rapid identification of medical devices with adverse events.
4. Provide for more rapid development of solutions to reported problems.
5. Provide for more rapid, more efficient resolution of device recalls.
6. Allow for better focused and more effective FDA safety communication.
7. Provide an easily accessible source of definitive device identification information.
8. Provide additional benefits, such as use by other federal agencies for a wide variety of purposes, allowing providers to electronically capture and record important information concerning the use of a device on a patient, facilitating detection of counterfeit products, improving device traceability, improving postmarket surveillance, and supporting global public health initiatives, including more efficient and effective cross-border identification of devices, adverse event reporting and postmarket surveillance.

However, none of the above benefits are quantified.

Comment: Premier recommends that the final rule use GS1's experience with the Global Trade Identification Number (GTIN) and the Global Location Number (GLN) as a model for cost estimates relating to UDI system implementation. We also believe that, in assessing UDI implementation costs, the FDA should take into account the current market-based move to adopt GS1's GTIN for healthcare product identification, for which 2012 is considered the sunrise date. In other words, we believe that UDI implementation costs should be adjusted downward to reflect the work already done as a result of this ongoing market-based initiative.
In addition, Premier believes that the analysis of impacts could do a much better job of considering expected benefits. We believe that benefits such as reduced medical errors, increased patient safety, and more efficient product recalls will easily outweigh the costs of implementing the UDI system. Healthcare providers will also benefit because UDI will permit more accurate and efficient inventory management as well as improved invoice accuracy and reduced ordering mistakes.

Maximizing UDI benefits

FDA acknowledges that the full benefits of UDI depend on the adoption of information technology systems by hospitals and other healthcare facilities (including the use of scanners) and on statistical methodologies to interpret the data aggregated using the UDI. FDA further notes that UDI users must be able to store UDI information in various administrative, clinical and payment information systems, including electronic health records (EHRs). However, FDA emphasizes that the proposed rule does not require hospitals and other healthcare facilities to adopt specific IT technology or take actions to capture UDI information in various information systems.

Comment: Premier acknowledges that hospitals and healthcare systems will play a major role in maximizing the benefits of UDI and our members stand ready to do their part. In saying this, we recognize that UDI will end up imposing costs and burdens on hospitals and healthcare systems as they purchase necessary equipment (such as bar code readers, software conversions and updates, etc.) and adjust work flows to incorporate UDIs into patient and other appropriate records. Nonetheless, we believe that the resulting benefits to patients and to the entire healthcare system will outweigh UDI-related costs.

We urge FDA to consider conducting pilots involving early adopters to examine how UDIs are incorporated into patient medical records and other information systems by hospitals and others, and how UDIs facilitate hospital and other responses to device recalls. We understand that FDA is already considering pilots that would track devices throughout the distribution system to check for UDI data quality and other UDI-related issues, but we believe that separate pilots focusing on provider use of UDIs in recall and other situations would also be advisable.

We appreciate the opportunity to comment on the proposed rule. Please direct any questions to Blair Childs, senior vice president, public affairs, 202.879.8009, blair_childs@premierinc.com.

Sincerely,

Blair Childs
Senior vice president, public affairs
Premier healthcare alliance