Strategic Marketplace Initiative

Shaping the Future of the Healthcare Supply Chain

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Division of Dockets Management (HFA– 305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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Reference: Docket No. FDA-2011-N-0090 and/or RIN No. 0910-AG3
Unique Device Identification Proposed Ruling – Comments

Dear Food and Drug Administration,

The Strategic Marketplace Initiative (SMI) is pleased to submit for your consideration our comments on the proposed ruling. We are also prepared to discuss our comments directly with the FDA if desired.

SMI is a non-profit, member-driven organization dedicated to improving the healthcare supply chain. Since our formation in 2006, SMI has delivered on our mission through direct information exchange and collaboration between senior healthcare supply chain executives from integrated provider organizations and senior supply chain executives from supplier and service provider organizations. SMI members include over 50 prestigious healthcare providers and academic medical centers; and over 50 well-recognized medical manufacturers, medical distributors, and other healthcare supply chain businesses. Created to influence, shape and advance the future of the healthcare marketplace, SMI provides an open forum for innovative idea-exchange and the development of collaborative process improvement initiatives. SMI members and staff have actively supported the industry's development of supply chain data standards to improve patient safety and to foster improvements in the supply chain. Attached with this letter is a list of SMI members. For additional information about SMI, please visit our web site at: **www.smisupplychain.com**.

The comments contained in this letter are the output of an SMI Board-appointed subcommittee convened to respond to the proposed UDI rule. These comments do not necessarily represent the opinions of individual SMI members and their organizations.

Introduction

The Strategic Marketplace Initiative is pleased that the FDA has released its proposed rule for the industry to review and comment. SMI is also pleased that the proposed rule clearly focuses on creating a UDI system to enhance patient safety, particularly given the complex supply chain environment at care provider sites.

SMI believes that the FDA should support the rapid adoption of an efficient UDI system. Supply chain technology in hospitals lags behind supply chain technology in other industries, in large part due to the enormous energies hospitals and physician's office must commit to achieve their main mission of delivering quality patient care.

Many supply chain systems in hospitals will need significant investment to adopt UDIs. Supply chain technology does not traditionally receive a high level of investment in healthcare, even though it is common for a hospital to distribute the individual contents of a package received at their loading dock to several hundred patient care locations at a single facility, e.g., a large, acute care hospital. An integrated delivery network with multiple hospitals may distribute a package's contents to several thousand locations throughout its system. Accurate item identification, enabled through technology in this environment, should improve patient safety and the ability to recall any items. However, many current supply chain systems in hospitals lack the number of digits needed for both the device identifier and necessary production information and these systems need to be replaced or upgraded. Interfaces using the UDI to carry device information from purchasing and inventory systems to point-of-use systems (at the bedside or Operating Room) also need attention. Interfaces to accounts payable systems generating payments to suppliers will also need to accommodate UDI data and most presently cannot. Scanners to move UDI data at the point-of-use into individual EMRs for incidences of patient care will also need adjustment to accommodate the UDI.

While the proposed rule and its thoroughness are reflections on the FDA's consistent interaction and engagement with the healthcare supply chain industry, SMI offers the following comments for your consideration:

Comment 1 – Multiple Systems, Multiple Issuing Agencies

SMI believes that there is inherent inefficiency and complexity in allowing multiple UDI systems to be in place with multiple issuing agencies. SMI believes that in order to create the clearest pathway to speedy adoption across the industry by both healthcare providers and labelers, the FDA and other government agencies should take steps to encourage the industry's adoption of a single, truly uniform system.

> We understand that the FDA has not mandated a specific identification system. The FDA proposed rule asks in Question 24: Will the existence of multiple UDI systems confuse device user facilities or impose unreasonable costs on device user facilities? SMI believes it is in-efficient and confusing for the industry to have multiple identification systems. There is added complexity and cost for both labelers and healthcare providers to utilize multiple identification systems, which would unnecessarily complicate the sharing of data, electronic commerce, information system configurations, and interpretation of supply data.

Dealing with two or more identification systems could cause additional costs/work for providers in several areas, including:

- Cost of modifying software systems/upgrades for multiple UDI systems
- Training hundreds of staff on determining the correct barcode to scan
- Potential lack of efficiency in master data management processes since some product data will be accessed through a data pool while other product data may come from the manufacturer

By approving a single UDI system, the FDA could reduce the costs of industry adoption of appropriate technology. SMI encourages the FDA to take steps to move the industry toward early adoption of a single system. For example, should the FDA decide to be an issuing agency, one suggested approach to achieve a single standard and a single issuing agency could be an FDA-led competitive process for issuers like GS1 or HIBBC to bid on granting a license to the FDA to utilize its system. Adoption and issuance of a particular UDI system by the FDA is likely to encourage the entire industry to move more quickly to use of that system.

The proposed rule also states that the FDA itself will be an "issuing agency" for UDI standards. The stated purpose of the proposal is to ensure that fees charged by the current issuers are kept reasonable and are not a significant burden on small business.
Question 25 of the proposed rule asks: "Would it 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?" SMI believes the answer is yes. Multiple issuing agencies could be very confusing and inefficient. One national issuing agency with a single identification system is preferable.

Comment 2 – Scope of Ruling is Limited To Labelers

The proposed rule only <u>partially</u> enables effective recalls in the healthcare supply chain since the scope of the ruling applies only to labelers and not to provider organizations.

SMI believes that since the proposed rule applies only to labelers, the impact of the proposed rule could be more limited beyond "the hospital receiving dock". Since hospitals and other healthcare providers are not required to implement unique device identification, the rule will only partially enable effective and rapid product recalls by labelers.

Implementation of the proposed rule by labelers will positively impact product identification by manufacturers and distributors through their delivery of the goods to a healthcare provider. However, only the most <u>advanced</u> healthcare provider supply chain operations that adopt the UDI will be able to track and quickly retrieve a recalled device as long as:

1. the device is not subject to one of the exceptions;
2. the location of the device can easily and quickly be identified once it leaves the healthcare providers loading dock; and
3. the device continues to retain UDI identification once distributed to the users.

All the above adjustments present considerable expense to hospitals, but they are necessary to optimize the value of UDI to improve patient safety. The existence of multiple issuing agencies, differing identifier composition, multiple location identifiers, and multiple data pools complicate adoption in hospitals. For this reason, barriers to adoption in hospitals increase exponentially due to perceived extreme implementation and operational expense.
SMI wishes to emphasize that it is not uncommon for healthcare providers to distribute a device received at their loading dock to several hundred locations at a single facility, e.g., a large, acute care hospital. An integrated delivery network with multiple hospitals may distribute that single device to several thousand locations throughout its system. In order to quickly identify and remove recalled items, these providers must have inventory tracking systems that allow them to trace recalled devices by the unique device identifier in a timely manner. Even if the provider can quickly trace the devices to a particular location, the benefit of the UDI identifier may be lost if the item is no longer marked, e.g., because it has been removed from a package. It is not clear that the FDA itself can take steps to encourage providers to develop effective tracking systems. SMI encourages the FDA to support provider adoption of UDI's with other government stakeholders.

Comment 3 – Length of Phase In Period

SMI believes that the proposed phase-in period is too long and will delay patient safety benefits.

The FDA's timeline for phasing in the requirements of the rule appears to be too long. While it is encouraging to see in the proposed rule that Class III devices must have a UDI label on the package within one year and on the device itself in three years, the proposed rule also requires that Class II device packages, with exceptions for life sustaining devices, will not have to be labeled for three years and Class I device packages do not have to be labeled for five years and will not require a marking on the device itself for seven years.

SMI recognizes the need to balance the urgency of implementation with the effectiveness of the industry's implementation. However, the protracted seven year total implementation period could contribute to confusion in the supply chain, since only a portion of the items will be labeled with a UDI during the period. The patient safety benefits with improved effectiveness for product recalls will also be delayed. SMI believes the FDA should consider accelerating the actions proposed for Class I devices in years 6 and 7 with a goal to shorten the implementation period to a five year phase-in schedule.

Comment 4 – Broad Exemptions

The proposed rule contains specific exceptions that will potentially exempt hundreds of products from the UDI requirement.

The exemptions appear to be too broad. We also believe the rationale for the exemptions is not clear and the process for obtaining an exemption is not specified. While the intent of requiring UDIs for every device is to improve patient safety, the introduction of multiple exemptions will result in a healthcare supply chain that can only identify a percentage of the items utilized on a daily basis for patient care. Thus, a number of products in the healthcare supply chain that are exempt from a UDI will not be able to be recalled effectively. The existence of exempted devices may also negatively impact the supply chain's ability to conduct business electronically. SMI believes that the rationale for exemptions and the process for obtaining an exemption should be clarified and where there is no persuasive justification for the exemption, it should be eliminated.

Comment 5 – The Retail Exemption

The rationale for the retail exception proposed by the FDA is unclear, and this exemption has the potential to exempt many devices from having a unique device identifier.

The proposed rule contains a specific exception for devices that are sold in the retail marketplace (see p. 40749.) Many of these items are purchased on a regular basis by healthcare providers. In order to adapt to the retail industry's UPC numbering system, healthcare providers and their information systems will need to make costly adjustments to work with this numbering system - in addition to other systems - to track and recall these items.

The proposed rule does not clarify the reasons for the retail exemption and is also not clear on whether ANY sales at retail would mean that the device does not require a UDI, even if the great majority of these devices are sold directly to hospitals. SMI believes that the introduction of this retail exemption will significantly reduce the percentage of devices subject to the UDI requirement and will contribute to a less-than-optimal healthcare supply chain. SMI believes that the reasoning for this retail exemption is unclear and should be clarified by the FDA.

Comment 6 – Date Format

The proposed date format is US-centric and may not be accepted internationally.

The new proposed human readable date format is not a globally accepted format. As American device manufacturers sell their goods globally, a required US-centric date format could negatively impact device labeling globally, possibly increasing packaging expenses if multiple date formats are required by other countries. Having a consistent and clear format for expiration dates will enable clinicians and healthcare providers to accurately identify medical devices that are within their established shelf life. The proposed date format is inconsistent with the existing ISO 8601 International Standards which defines the representation of dates. SMI believes the FDA should seek a globally accepted format for dating.

Comment 7 – Date Format Transition

The date format's one-year transition period is too quick and could result in costly inventory waste.

The proposed rule requires a one year phase-in period for all labels to be revised with a new non-ISO format. Given the amount of inventory currently passing through the healthcare supply chain, labelers would actually need to implement the date format's requirements sooner than one year in order to insure that all products in the chain are in compliance. This requirement is likely to result in non-compliant product being thrown away or being re-labeled in order to meet the requirement, both costly options. SMI encourages the FDA to consider transitioning to the ISO date format on the same schedule that the product class converts to the UDI format. This will prevent labels and specifications from needing to be changed twice and prevent the industry from wasting time and resources on re-labeling.

Comment 8 – Change in Specifications

The "change in product specifications" clause is unclear and possibly excessive

The proposed rule states that a change in device specifications would require the unique device identifier on the product to change. The proposed ruling does not clarify what constitutes a change in product specifications. The rapid advances in technology and materials have greatly contributed to new and improved medical devices that support quality patient care. Large and small alterations to products specifications occur on a regular basis. The requirement to change a device's unique identifier with every specification change may present an unnecessary burden on manufacturers while creating confusion in the marketplace over product identification. SMI believes the FDA should provide a clear definition on what constitutes a "change in product specifications".

Comment 9 – Class II Product Labeling

Class II product labeling required at "each" unit level may not fit on the product or label

The proposed rule states that all Class II products must have the following information at all three levels of packaging:

- Human Readable Product Identifier (GTIN)
- Human Readable Production Data (Lot, Expiry, Manufacturing Date, etc.)
- New Date Format
- Bar Code Product Identifier (GTIN)
- Bar Code Human Readable Production Data (Lot, Expiry, Manufacturing Date, etc.)

Since many devices are physically small, and hence their packaging is also small, it is very possible that this required data will not fit on many "each" level packages. SMI suggests that for some Class II products FDA allow for alternative placement of the UDI. The shelf pack (dispensing pack) that contains the Class II, single use device should exhibit full UDI markings per the proposed rule. The outer case or shipping container should also carry FDA's proposed UDI markings in an AIDC and human readable format. SMI is proposing that the "each" level package, which serves as the sterile barrier, be permitted to utilize a human readable UDI format when space on the product itself is limited. When packaging space allows, the device identifier (GTIN) should also be provided in an AIDC format. We encourage the FDA to re-examine this requirement to reflect the reality of package sizes.

Conclusion:

SMI supports unique device identification and firmly supports a clear, speedy industry implementation that will yield the patient safety impact desired by the FDA. As already stated, SMI believes that a combination of factors is likely to delay the implementation of a uniform and comprehensive UDI system for many years. Those factors include the following:

1) the absence of any requirement to adopt a specific identifier system
2) the existence of multiple issuing agencies, potentially resulting in the use of multiple UDI systems.
3) the long phase-in period for implementation
4) the inclusion of a number of potentially broad exceptions
5) the absence of any adoption requirement placed on providers.

Moreover, it is possible that the final rule will be even less comprehensive if there is significant public comment opposing the proposal. Consequently, the benefits of a comprehensive UDI system may still not be fully realized for many years.

SMI would like to suggest some general actions that the FDA and other federal agencies, including CMS, might consider in order to promote uniform, speedy adoption by both suppliers and providers, even if there is no federal requirement to do so. In past discussions and communications with government leaders, SMI has proposed a number of possible government/industry actions to promote adoption by both suppliers and providers:

- Sponsor workshops and conferences where both providers and suppliers are encouraged to discuss and share their processes of UDI implementation, promoting speedier adoption.
- Consider the adoption of a UDI system by providers as a required element of "meaningful use" of health information technology.
- Offer financial incentives to providers to support provider adoption, such as planning grants, adjustments in Medicare reimbursement related to implementation, etc.
- Consider a proposal to require UDI adoption as a requirement of Medicare participation, to go into effect in the future, e.g., in 2018. CMS might state that its decision to propose such a rule will depend in large part on the pace of voluntary adoption.

SMI is pleased to submit these comments for your consideration. We are willing and ready to work with the FDA, government agencies, and the industry to promote successful implementation of this long awaited enhancement to patient safety. Please do not hesitate to contact us if clarification is required or if further communication is desired. We look forward to the future where unique device identification contributes to an improved national healthcare system.

Sincerely,

Thomas Hughes
Executive Director
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Cc: SMI Board of Directors
Jonathon Blum, CMS

Attachment: List of SMI Members

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