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**Response to the U.S. Food and Drug Administration**

**Request for Comments on Unique Device Identification**

**November 9, 2006**

The Healthcare Information and Management Systems Society (HIMSS) is the healthcare industry's membership organization exclusively focused on providing global leadership for the optimal use of healthcare information technology (IT) and management systems for the betterment of healthcare. HIMSS represents more than 20,000 individual members and over 300 corporate members that collectively represent organizations employing millions of people. HIMSS frames and leads healthcare public policy and industry practices through its advocacy, educational and professional development initiatives designed to promote information and management systems' contributions to ensuring quality patient care.

As an organization, HIMSS is committed to achieving the benefits pervasive Automatic Identification (Auto-ID) technology brings to healthcare delivery through improvements in patient safety, clinical and administrative processes, and patient quality of life. Auto-ID is not possible without identification systems. We therefore applaud the FDA's UDI initiative. In January 2003, HIMSS established the HIMSS Auto-ID and Bar Coding Task Force as part of our Patient Safety and Quality of Care Steering Committee. In the same timeframe, HIMSS membership established a Special Interest Group (SIG) for Supply Chain Management. By bringing industry experts together through our SIG and committee structure, HIMSS hopes to offer a coordinated voice to the national discussion on these important healthcare issues. We are pleased to offer our comments

In summary, UDIs are a good idea. Specific formats should be established for the proposed UDIs based on other industry standards in use. The FDA should review the proposals from industry prior to formulating UDI standards. There is not an NDC equivalent for use as a UDI. Industry should consider use of a standard device IDs such as the Global Trade Identification Number administered by GS1 or the HIBC-LIC number administered by HIBCC. These are possible IDs that could be adapted for UDIs, and the group noted that there are some in each camp (e.g., HIBCC, GS1 US, others) and there are divided opinions about which of the standards to follow. To move the industry forward and improve the safety of patient care, HIMSS supports strong leadership action from the FDA.

The following information is provided relative to the questions raised in the FDA Call for Comments. Groups reviewing the questions noted that they fell into broad groupings and first prepared summary comments on the groups followed by specific comments on the individual questions.

45 **1<sup>st</sup> Group – Barriers & Suggestions**

46 The first group of questions discussed includes numbers 1-8. The only barriers are for those  
47 systems or devices that currently use a competing standard where the vendor / manufacturer  
48 would have to migrate from their existing standard(s) to a new standard.

49  
50 Barriers for establishing a UDI include: 1) The current lack of a common taxonomy or  
51 classification system, 2)The absence of a common repository that serves as a industry wide utility  
52 and allows synchronization for all supply chain parties 3) How to handle drug/device  
53 combination products and kits, 4) Cost of infrastructure and IT systems, 5)funding for the data  
54 repository that will ensure longevity and quality, 6) product labeling in which the information is  
55 both human and machine readable, 7) small size of many device companies and their ability to  
56 conform, 8) resistance from some manufacturers due to concerns over product commoditization,  
57 9) need for global adoption and current efforts of other countries to implement standards, 10)  
58 speed and cost of implementation for providers.

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60 Requisite to this is a complete structure for the standards. Specifically, there needs to be medical  
61 device categorization system to differentiate a bandage from an implanted item. HIMSS  
62 recommends use or adoption of an existing system such as the UNSPSC

63  
64 The group also discussed the issues of selected vendors being able to accept and use standards.  
65 Whether they are a small medical equipment manufacturer or a global company, the migration to  
66 a standard that is established in the future will need a strategy to implement.

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68 **2<sup>nd</sup> Group - Implementing UDIs**

69 The second group of questions, numbers 9-12, is related to the issues for the FDA UDI related to:

- 70 ■ “How do you do it and should it be mandated?”  
71 ■ Should the UDI be accomplished in any particular form?

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73 Given the fact that the industry has not embraced a UDI, HIMSS supports FDA mandates to  
74 establish a UDI system. However, the focus should be on capturing data in one of the existing  
75 standards leaving flexibility for current and future technologies e.g., bar codes, text or RFID.

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77 One of the issues is to have the standard format be readable by a machine as well as human  
78 readable and to determine what the key information is. Another issue to be considered is to  
79 clearly indicate which data is mandatory and which should be voluntary or recommended for  
80 enhanced UDI structure. Voluntary or recommended data should be governed by the same  
81 standard(s) that govern the mandatory information.

82

83 Examples of mandatory data elements include:

84 Manufacturer:

- 85 □ 1st layer/class – Make & Model –  
86 □ 2nd layer/class – Lot Number & Expiry – Expiration Date  
87 □ 3rd layer/class – Serial Numbers  
88 □ 4th group/class – Drawn from Table of Reference for Product  
89 Information – product type indications for use – device is an accessory  
90 for another device, etc.

91

92 Requirements for an FDA UDI should be mandatory standards for use. If the standard is  
93 voluntary, it will not force the marketplace to place UDI in both matching readable as well as  
94 human readable labeling. There is also a need to link to a repository with reasonable time line for  
95 implementation.

96 The scope should focus at the packaging level and to determine the appropriate starting point for  
97 implementation of any recommended or mandated standards, e.g., shipper case or individual unit  
98 of use. Also, some items are not amenable to marking.  
99

100 UDI standards have to have a classification system. For each class, there have to be different  
101 level of requirements as to how the package or item would be labeled, e.g., sutures at the package  
102 level but not on the item itself. For each class, how would it (the items) be marked and also what  
103 level of information would be coded.  
104

105 In the simplest form there may be two (2) classifications:

- 106 1) What is more important for patient safety, for example implantables, and what is  
107 the related or potential impact on patient safety concerns; and,
- 108 2) What is the level of practicality, for example, bone screws are important to track,  
109 but these may need to be tracked at a unit level but it may not be practical in the  
110 actual process and use. Further, the costs may be prohibitive if the small  
111 components are required to be tracked as part of a surgical implantation.  
112

### 113 **3<sup>rd</sup> Group - Costs & Benefits**

114 The third group of questions discussed includes numbers 13-20. These questions are related to  
115 the issues for the FDA UDI related to:

- 116 ■ Tracking of items that have caused problems
  - 117 □ Follow where it (the item) came from to where it is being used
- 118 ■ Tracing of items
  - 119 □ Ability to find where the items are if they are in the supply chain
  - 120 □ Also ability to trace items that have been issues/sold so that they might  
121 be tracked

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123 The key driver is for patient safety includes:

- 124 ■ Use of the right device for the right purpose
- 125 ■ Making make sure the patient caregiver uses the right device/supply  
126 configuration
- 127 ■ Tracking a device to a patient, but not to track the patients, for:
  - 128 □ Infection control
  - 129 □ Performance
  - 130 □ Safety
- 131 ■ Combating counterfeiting
- 132 ■ Capturing and managing device maintenance and calibration
- 133 ■ Out-of-stock is a patient safety event

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135 The infrastructure costs to develop use of UDIs in the user environment are not well know nor  
136 understood. Some things seem apparent however:

- 137 ■ New technology breakthroughs are not needed
- 138 ■ New major applications are not needed. UDIs would impact the tables used by  
139 applications
- 140 ■ Equipment currently in place in hospitals is cycled in general 5 year cycles. Thus  
141 regulatory typical timelines would enable new technology to be implemented  
142 with little incremental cost

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144 Therefore, to be effective, UDI has to be labeled down to the point-of-use and administration for  
145 selected items that impact patient safety.

146 HIMSS offers its support and appreciation to FDA leadership to facilitate faster adoption of Auto-  
147 ID in the provider setting. We appreciate that there is little if any authority the Agency can  
148 exercise over the provider community and is thus heavily influenced by manufacturers and  
149 distributors. At times what is best for that constituency is not best for providers and their delivery  
150 of patient care. HIMSS stands ready to assist in any way to assure that FDA initiatives create  
151 effective delivery of safe devices in the patient care setting.  
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<p>1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?</p> <p><u>HIMSS Response:</u> First, a clear classification system for devices must be adopted. UNSPSC would be an excellent starting point for such a classification system. Second, based on such classifications, identification approaches and standards from other industries should be adopted for medical devices.</p>
<p>2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?</p> <p><u>HIMSS Response:</u> FDA must make UDIs mandatory or it will not happen in the foreseeable future. Without a mandate, the industry has too many conflicting interests and absence of incentives for the establishment of UDIs.</p>
<p>3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?</p> <p><u>HIMSS Response:</u> Enhanced patient safety, operational efficiency, infection control improvements, enhanced inventory and supply processes, and other operational benefits.</p>
<p>4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?</p> <p><u>HIMSS Response:</u> The breadth of medical devices makes this a daunting task. UDI must be defined based on a classification system of medical devices. HIMSS recommends starting with UNSPSC. But to be useful it must encompass 100% of items. Nomenclature, scope, physical labeling and to what level of pack must all be articulated within the context of classification in an unambiguous manor</p>
<p>5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided.</p> <p><u>HIMSS Response:</u> Current recommendations from the Association for the Advancement of Medical Instrumentation are that items should be uniquely identified for each sterile processing cycle and tracked as to use on each specific patient. This is a software requirement for item identification and tracking that hospitals are expected to implement in the future and some software vendors are developing software to do this.</p>
<p>6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?</p> <p><u>HIMSS Response:</u> In developing a UDI all devices should be considered. However, actual requirements should focus on high impact, patient care, high risk and manageable categories, Selected classifications of medical devices will have basic identification requirements while others will have additional requirements for expiry, lot numbers and serialization tracking.</p>

7. At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?

HIMSS Response: With emerging technology, identification could be to an individual item level (serial #). This may not be practical for all categories of medical devices. E.g., there isn't value in serializing 4x4 bandages. In many categories, identification to a lot (with expiry date) would be useful.

8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)? Implementing Unique Device Identifiers.

HIMSS Response: HIMSS has not developed solutions in this area. We have encouraged our members to respond to this question.

GHX has at least the start of device repository in the AllSource® product content repository, which is open to any supplier to publish product data. While there is still a long way to go before healthcare has a comprehensive repository, this effort has the beginnings with data on well over 2.3 million products, and the capability for suppliers to publish data in more than 150 fields, from item number to whether or not the product contains latex. It is a proof of concept for the feasibility and value of UDI

As noted above, trends in software for surgical pack/set tracking are to incorporate unique IDs to track a specific instance of assembly and sterilization of an instrument or set and then track the use of the “serial” number of the item to the individual patient for optimum life cycle tracking.

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

HIMSS Response: UID as a license plate that could be linked to a repository for detail may be the best approach. Safety impact varies by category and classification. Areas of safety improvement include recalls, hospital management (cleaning, calibration, etc.) of devices.

10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

HIMSS Response: Private with government mandated parameters. Assignment of URL may serve as a model. FDA assignment of a labeler ID in NDC is another model that should be considered in developing future standards.

11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

HIMSS Response: Both

12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be “compatible” with those used for the drug bar code rule? If yes, why? If not, why not? UDI Benefits and Costs

HIMSS Response: Should be open. Linear or two-dimensional bar codes (any AIM recognized symbology with sufficient capacity) or RFID. The GS1 EPC, designed by the packaged good industry, may not be flexible enough for UDI. HIMSS has in the past recommended changes/clarifications to the FDA Bar Code Rule. Leaving additional information (lot and expiry) optional without specifying the format standard and symbologies has left providers frustrated in their efforts to embrace this patient safety technology

13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

HIMSS Response: Identifying devices that pose a safety problem and managing the recall or correction of the problem. UDIs will facilitate Improved infection control through tracking and enhanced proper maintenance of devices, especially medical equipment.

14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

HIMSS Response: Actual cost to convert from internal identification schemes to a UDI would be significant. However, the technology and tools are generally in place to encourage using a mix of local and vendor identification structures. While many applications would have to be reviewed and modified, there should not be a requirement for major new applications. While we do not want to downplay the cost implications to the manufacturers, distributors and providers, they are more than offset by operational and safety benefits.

15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

HIMSS Response: We have encouraged our members to respond to this question

16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

HIMSS Response: In the absence of a mandate or major pandemic, very, very slow.

17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?

HIMSS Response: (See response to #4) Lack of market incentives to create a UDI system and vested economic incentives for device manufactures and distributors to no allow comparisons UDI will enable

18. For hospitals and other device user facilities considering technology investments, what would be the relative data sharing capabilities across hospitals and other device user facilities, and other possible advances?

HIMSS Response: As informatics solutions continue to evolve, the FDA should consider the implications for establishing standards that are complementary to other existing and emerging standards such as those previously noted. These standards should consider the ability of systems to be developed in the future to transfer patient related data in a HIPAA secure

environment with processing to facilitate analysis of risks to patient safety and track patient care modalities and item use/abuse. The development of RHIOs are specific areas where transfer of data related to patients and their specific treatment with medical devices identified by UDIs will require further study to qualify and quantify the benefits of UDIs.

19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?

HIMSS Response: Sufficient technology exists today with bar coding. RFID technology is not sufficiently mature, but it is not essential to implementation. Many facilities and organizations have not yet made the investments in software and hardware necessary to realize the benefits of these automated technologies.

20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?

HIMSS Response: HIMSS is not a hospital and cannot comment. We have encouraged our members to respond to this question

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#### **Additional Comments**

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Considering the direction of the American Health Information Community (AHIC) with the focus on Consumer Empowerment and telemedicine, and where that fits into sharing information in an interoperable way, we would be remiss in not mentioning what is not apparent in the above 20 questions which are focused on a health care delivery arena that is not in the home setting.

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However, what happens when those “home setting” devices appear in the provider setting and documentation needs to occur about that device. A second phase for consideration might be for the home setting device to have a UID that at least is logged into a personal health record, so that device can be identified.

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Certainly there are many, many medical devices in the home setting such as Home Ventilators, CPAP machine, nebulizers, insulin pumps, glucometers, telemedicine equipment, automated blood pressure cuffs, tele-monitoring devices, SIDS monitors, O2 saturation devices, portable cardiac monitors, RFID devices for Alzheimer patients, and neuromuscular monitoring devices to name a few. These devices all certainly qualify as medical devices, and many of them are used for delivery of medications.

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There is also the issue of currently implanted medical devices, pacemakers, automatic defibrillators, that were implanted with a device serial number identified rather than perhaps a UID. Devices certainly get implanted with an identification card and a serial number for the consumer to have, but that serial number is not necessarily a UID.

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We would advise considering how home monitoring devices fit into the big picture of UID, and also how all medical devices and UID fit into the picture of what should be captured in an electronic medical record or personal health record. The Certification Commission for Healthcare Information Technology (CCHIT) Inpatient Interoperability Criteria II-6.2 under Chronic Disease Management and Patient Communication has a defined placeholder for importing physiologic monitoring data from patients with standards being evaluated by the Inpatient Workgroup for CCHIT.

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185 The inclusion of this type of information from the home setting could have huge benefit in a large  
186 scale evacuation in a public health emergency to identify those individuals in the community who  
187 could be physically harmed by a long period of without electricity, or those individuals with  
188 fragile respiratory status, or those people who are maintained in a very fragile chronically ill state  
189 in the home setting.