



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

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HEALTH AFFAIRS

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

To Whom it May Concern:

On behalf of the Department of Defense, I am pleased to respond to the request for comments on the use of a UDI system [Docket No. 2006N-0292].

The Department of Defense strongly supports the Food and Drug Administration's (FDA) efforts to establish the UDI program and offers the following recommendations for implementation:

- The FDA should mandate UDIs for all medical devices
- UDIs should be based on industry and/or global standards
- Each UDI should be associated with industry agreed to mandatory standard product data attributes
- The source of the UDI and the associated product data attributes should be the manufacturer of the product
- An industry Product Data Utility (PDU) should be a mandatory source for UDI related data

Enclosed is detailed response, prepared by the Joint Federal Data Synchronization Work Group (JFDSWG), to the elements of the request for comment. The JFDSWG serves as a forum for collaboration on efforts conducted within the Federal healthcare sector to establish standard data, prove the value of data synchronization, investigate uses of Automatic Identification Technologies (AIT), and present a unified face to the healthcare industry.

Please contact LTC Scott Svabek, 703-845-8348 or [Scott.Svabek@ha.osd.mil](mailto:Scott.Svabek@ha.osd.mil), for clarification or questions.

A handwritten signature in black ink that reads "Ellen P. Embrey".

Ellen P. Embrey  
Deputy Assistant Secretary of Defense  
Force Health Protection and Readiness

Enclosures: as stated

Cc: Chair, Medical Logistics Proponent Committee

## **Position Paper**

### Joint Federal Data Synchronization Work Group Comments On the Use of a Unique Device Identification (UDI) System

**Reference:** [Federal Register: August 11, 2006 (Volume 71, Number 155)] [Page 46233-46236], DEPARTMENT OF HEALTH AND HUMAN SERVICES, Food and Drug Administration, [Docket No. 2006N-0292], Unique Device Identification, Request for Comments

### **Executive Summary**

**The Federal Data Synchronization Group strongly supports the FDA's efforts to establish the UDI program for all medical devices to:**

- **Improve patient safety**
- **Improve DoD/VA's ability to support wartime contingencies and disaster relief efforts**
- **Eliminate unnecessary costs from the medical supply chain**

**We look forward to continued collaboration with the FDA, as discussed with and agreed upon by Dr. Kessler in 2005. DoD Medical Logistics urges the FDA to work with the Healthcare Industry, DoD, and VA, in conjunction with US and/or international standards groups, and adopt standards for uniquely identifying medical surgical devices and their product data attributes. This is best accomplished through a program of synchronized product data housed in an industry Product Data Utility (PDU). This process is already in place for other industries; many healthcare manufacturers are required to provide standard item identifiers and their associated product data attributes to be able to sell their healthcare products to drug store chains, grocery chains, and retail chains (e.g. Wal-Mart.)**

#### **Recommendations for UDI Implementation:**

- **The FDA should mandate UDIs for all medical devices.**
- **UDIs should be based on industry and/or global standards**
- **Each UDI should be associated with industry agreed-upon, mandatory, standard product data attributes**
- **The source of the UDI and the associated product data attributes should be the manufacturer of the product**

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- **An industry Product Data Utility (PDU) should be a mandatory source for UDI related data**

## **Background:**

### **Joint Federal Data Synchronization Work Group**

This work group was convened by the Medical Logistics Proponent Committee (MLPC) to serve as a forum for collaboration on efforts conducted within the Federal healthcare sector to establish standard data, prove the value of data synchronization, investigate uses of Automatic Identification Technologies (AIT), and present a unified face to the healthcare industry. Participants include the Department of Defense (DoD) Defense Logistics Agency (DLA), the TRICARE Management Activity, the Military Services, and the Veteran's Administration (VA). The MLPC is chartered by the DoD Force Health Protection Council for functional proponentcy of Medical Logistics operational policy and Business Process Improvements (BPI) under the direction of the Deputy Assistant Secretary of Defense (Force Health Protection & Readiness).

### **DoD Data Synchronization and Pilot Product Data Utility**

The data in the Medical Surgical Industry is disorganized, redundant, and highly inaccurate. Inaccurate data is costing the Healthcare industry and ultimately, the consumer, billions of dollars. DoD Medical Logistics has been working with the Healthcare Supply Chain to establish and promote standardized and synchronized data with a centralized data utility for medical surgical items. We have developed a Pilot Product Data Utility (PDU) as a proof of principle for the industry. This program has been supported by annual Congressional funding as well as Joint Incentive Funding by DoD and VA.

DoD, including the Military Health System (MHS) and the Defense Supply Center Philadelphia (DSCP), part of the Defense Logistics Agency (DLA), has formed an extensive partnership with the healthcare industry including manufacturers, group purchasers, international standards organizations, associations, and other Government agencies to test the PDU concept and address data shortfalls in the medical/surgical product industry.

When FDA held a series of meetings in 2005 to discuss the need for Unique Identification for Devices, DoD met with Dr. Larry Kessler to brief him on our data synchronization program and how standard, clean, uniform, and synchronized data is the key to any program or technology involving data for devices. DoD requested that FDA partner with DoD and VA in this initiative; Dr. Kessler agreed. We encourage the FDA

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to collaborate with the DoD, VA, and the healthcare industry in utilizing, to the maximum extent possible, the data standards which will be selected for inclusion in an industry PDU.

DoD has made a significant investment in this program, primarily to improve the efficiency and timely support for contingency operations and disaster responses. We found, through experience in deploying troops for the war in Iraq as well as responding to the Tsunami and Hurricane Katrina, that a uniform and standardized system of product identification, synchronized through the Medical Surgical Supply Chain via a PDU, will provide the tools to improve response time and promote efficiencies for deployments.

In addition to readiness concerns, we recognized that Data Synchronization and a PDU will improve supply chain efficiencies in our peacetime hospitals, reduce the cost of healthcare delivery in DoD, and allow the creation of a single “Universal Medical/Surgical Product Catalog”

Most importantly, data standardization and synchronization were found to have a significant potential to improve patient safety. A standard format for product ID and labeling requirements that are understood and accessible by the IT system, the supply delivery system, and the end user will increase the probability that the right product gets to the right place, at the right time, and is used on the right patient. Other patient safety benefits include:

- Tracking of devices to determine medical/surgical products with best outcomes
- Identification of items that may contribute to infections or other adverse events
- Easier identification of recall items and location of unsafe items
- Improved tracking of key devices in patients (implants, invasive items)
- Improved timely tracking of critical equipment in hospitals
  
- Complete product information to include latex vs. non-latex, one time vs. reusable items, sterile vs. non sterile, etc.

### **DoD Item Unique Identification (IUID) Program**

The DoD has implemented a program to uniquely identify all equipment with a purchase cost of \$5000 or more. This program spans all commodities and items purchased by the DoD, and is not Healthcare specific. The DoD IUID Program Office will respond directly to this request for information.

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## **Joint Federal Data Synchronization Work Group Response to FDA Questions:**

### *Developing a System of Unique Device Identifiers*

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

**The unique device identification system should be part of a comprehensive solution that results in consistent and standard data, to the maximum extent possible, across the various projects that the Federal Government imposes on the healthcare industry (e.g., UID, RFID, UDI, etc). The DoD MHS urges the FDA to adopt for medical devices a numbering convention that is in consonance with the data standards agreed upon by the med/surg supply chain, and not to impose unique data requirements for elements already identified as represented by a specific standard.**

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 this system be voluntary or mandatory?

**The FDA played a crucial role in developing a numbering scheme for pharmaceuticals (i.e., National Drug Code or NDC) that has resulted in improved patient safety and significant cost savings in both human and financial capital. We see the FDA playing the same role to bring order to the medical/surgical commodity. The system should be mandatory for all manufacturers and any organization that repackages these items for resale or distribution.**

3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?

**Incentives are similar to those that accrue from data standardization:**

- **Facilitate patient safety**
  - **Improve ability to recall dangerous items**
  - **Improve item identification to ensure the right item is ordered**
  - **Reduce clinical frustration with receiving wrong item and delaying surgery**
  - **Improve speed of item delivery to avoid treatment delay**
- **Reduce costs**
  - **Eliminate manual order rework from purchasing the wrong item**
  - **Improve analysis of alternative items**
  - **Reduce operational expense by reducing item research time**

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- **Improve business intelligence to enable item standardization and improve contracting actions through volume purchasing**
- **Improve back office productivity by improving management of ordering, receiving, and catalog data**

4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

**We see three major barriers to implementing UDI. 1) The range of medical/surgical products to include equipment and consumable items is a challenge in terms of the level of unique identification and how items are managed. Different rules may be necessary for consumable vs. non-consumable to both identify (e.g., box, each, serial number, lot number, date of manufacture, etc.) and manage them (e.g., new vs. refurbished or modified). 2) The benefit of UDI will be limited if associated data is not cleansed, standardized, synchronized, and centralized in a PDU. We strongly recommend collaboration among government agencies on data requirements to minimize multiple formats from various Government entities and programs. Government agencies should follow an industry sponsored PDU concept with a single set of standard, consistent data to be shared by all members of the supply chain.**

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.

**DoD Item Unique Identification (IUID) Program— The DoD has implemented a program to uniquely identify any item of equipment, which meets specific criteria, in order to more effectively manage operations. This program covers all items purchased by DoD and is not healthcare specific. The equipment requires Unique Identification if it fulfills one of the following requirements:**

- 1. Item is serially managed**
- 2. Item is in controlled inventory**
- 3. Item is mission essential**
- 4. Item costs more than \$5,000**

**The DoD IUID Program Office will respond directly to this request for information on the specifics of the DoD IUID Program.**

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?

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**UDI should be considered for all devices including equipment and consumables.**

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?

**For consumable items, we recommend UDI be assigned to at least 3 basic units of packaging (e.g., case, box, each). For equipment implants a single level of packaging (each) may be all that is required. If the UDI will be the basic identification for recall actions, the UDI marking also should include a human readable component to allow easy identification of the recalled item. In the future, we expect the UDI will be entered into a patient's electronic health record, and would allow for retrospective studies for efficacy or patient notification.**

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)?

**DoD has started implementation of a two-dimensional barcode for legacy equipment items to comply with the DoD IUID with human readable marking (where possible). The MHS will be in a position to begin automatically reading these tags and the information into the DMLSS application in 2009. DoD is also exploring the use of RFID at the case and pallet level and unit of issue to track medical/surgical items and pharmaceuticals.**

#### *Implementing Unique Device Identifiers*

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?

**Ideally, the data set for UDI should be consistent with the healthcare industry selected standards to be used in the PDU. However, a minimum data set that would support locating items in case of a recall would include:**

- **UDI**
- **UPN**
- **Item Description**
- **Special Characteristics (latex vs. non-latex; sterile vs. non-sterile; reusable)**

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- **MSDS**
- **Manufacturer**
- **Serial Number**
- **Unit of Measure and Quantity**
- **Lot or Batch Number**
- **Part Number**

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?

**The UDI and associated attribute data should be provided by the manufacturer and the manufacturer should be held accountable for data accuracy. The manufacturer data should be entered into an industry sponsored Product Data Utility.**

**The DoD MHS and DSCP with its healthcare industry partners are conducting a pilot PDU on consumable items as a proof of principle. This pilot is being further extended on a small scale to test using GS1 and its Global Data Synchronization Network (GDSN) to host a medical/surgical PDU. An open and neutral PDU ensures that all parties have access to standardized and synchronized data.**

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?

**If there is sufficient room on the tag or the area to be marked, then having a human readable UDI makes sense for easy identification in the absence of automated scanner/reader capability. Applying the UDI directly on the item versus using a label is preferable for durability, but is more costly than labeling. Marking methods should be commensurate with environmental conditions in which the device will be used, the size of the item, how it is issued and stored, and to ensure that product structural integrity is maintained.**

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?

**A linear barcode, same as the drug barcode, would be acceptable for consumable devices. The DoD IUID equipment asset tracking program requires a 2-D matrix**

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**barcode. This type of bar code is less susceptible to loss of data where the barcode is damaged than one-dimensional bar codes used to comply with the drug barcode rule. Data carrier durability is more important for equipment devices than for medical/surgical consumables and pharmaceuticals; however, consistency is also important. Many barcode readers are able to read both types of barcodes. In addition, barcode technologies are more prevalent in the healthcare industry at this time than other Automated Information Technologies (AIT) such as Radio Frequency Identification (RFID). However, progress in RFID technologies may not rule out that technology as a potential solution in the future. Different categories of devices may require differing technologies to maximize the benefit.**

*UDI Benefits and Costs*

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.

**Key to any recall system is the ability to quickly identify, locate, and remove the recalled item from use. The UDI will allow those responsible to quickly and unquestionably identify the recalled item(s). However, automation is required in order to reap the full benefit of the UDI in this process. An automated system should tell one where the item is located or to whom it was issued without having to physically scour the hospital for it. Ultimately, if the UDI is ever recorded in a patient's electronic health record, an automated system will be able to reveal instantly who the item was used on or implanted in. Key is to have accurate and timely data to be used; otherwise the UDI is only as good as the data source. The data source should be an industry sponsored PDU.**

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.

**See # 15 below.**

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?

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**DoD has uniquely identified medical equipment devices in its hospitals for the past 4 years. It is difficult to break out the costs associated with uniquely identifying equipment since this was part of a 10-year roll out of a \$40 million hospital automated logistics system. The automated system generates a unique (to that hospital) Equipment Control Number (ECN) and populates an equipment maintenance record and separate property record within the Equipment & Technology Management module. The ECN is used to facilitate inventory processes and accountability, maintenance management, and consolidation of excess equipment for reutilization. The ECN makes equipment life cycle management and administration of any associated maintenance contract services efficient and effective. The contributions to patient safety include rapid location of item in the event of a recall, provision of preventive maintenance and servicing, and end of useful life tracking to plan for replacement.**

**The MHS currently is implementing the DoD IUID program within the hospitals for existing medical equipment. Manufacturers are not yet participating. Costs include \$930K for modifying our existing medical logistics system and approximately \$5M to purchase barcode printers, scanners, and verifiers for 168 DoD medical facilities. Training is expected to be an insignificant cost factor.**

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

**Depending upon the construct of the UDI, cross referencing should be a minimal effort. We would encourage the use of industry standard data via a PDU to facilitate implementation both in DoD and VA, as well as industry participants.**

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

**See response to # 16 above. No major obstacles are anticipated.**

18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside bar coding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?

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**The other initiatives are not competing with UDI in DoD because their focus is on the clinical side of prioritization vs. Medical Logistics.**

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?

**DoD could begin using UDI for equipment management along with DoD IUID implementation. The basic infrastructure and technology will be there; the potential differences should be able to be handled by minor software modifications. It would take some minor modification of our logistics systems to use UDI for inventory management and recall of consumable medical devices.**

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?

**DoD has a single office that consolidates recall notifications and notifies the MHS of a recall and, in some cases, provides disposal instructions. A recall by UDI would be of benefit for all recalls. This information loaded into our logistics systems would make it simpler to narrow in on and accurately identify the recalled product held in inventory and quickly segregate it for disposal. Again, this assumes that the base data is accurate and up to date; a case for collaborating with the industry PDU effort.**

#### **DoD Recommendations for UDI Implementation:**

- The UDI program should be mandatory for all medical devices.
- The UDI program should be a collaborative effort with industry and other government entities to include industry initiatives and approved standards. The Federal government should collaborate to the maximum extent possible on data requirements for the various item identification programs (UID, RFID, and UDI).
- The UDI should be associated with industry standard data attributes stored in an accessible database.
- The source of the UDI and associated product data attributes should be the manufacturer. A process must be put in place to ensure the accuracy and completeness of all data (PDU).

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- The FDA should look to established standards organizations for the make up of the UDI.
- The UDI should be marked on all medical devices where practical.
- As part of the UDI program, the FDA should partner with DoD, VA, and the med-surg industry supply chain in pursuit of data standardization and synchronization centralized in an industry Product Data Utility (PDU).

The UDI program will improve the quality of DoD patient care and add significant value to efforts to improve end-to-end supply chain management. This position paper was approved by the Medical Logistics Proponent Committee on 2 November 2006.