HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION
Serving Medical Products Distributors Since 1902

November 9, 2006

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

RE: Unique Device Identification; Request for Comments; Docket No. 2006N-0292

To Whom It May Concern:

I am writing to you on behalf of the Health Industry Distributors Association (HIDA) and its 200 member companies to comment on the Food and Drug Administration's (FDA) plan to implement a program mandating unique device identification (UDI). Our members account for over 80 percent of the medical products distributed through the healthcare supply chain.

HIDA supports a program that would help reduce medical errors, facilitate device recalls, improve adverse event reporting, and help ensure product integrity. However, criteria must be established to ensure that this program will be implemented in the most cost effective and practical way possible.

Uniform Standards and Compatibility

It is imperative that any UDI program harmonize with current federal and international requirements. An FDA program that lacks compatibility might result in a multitude of costly and contrary requirements for distributors and hospitals around the world.

Moreover, the FDA should adopt a standard for UDI coding that is consistent with existing standards and compatible with existing systems and technologies, as well as existing coding practices of medical device manufacturers. One such standard is American National Standard 10.8.2 (ANS 10.8.2). This existing umbrella standard is where the current medical device coding standards HBIC and GS1 reside. In addition, this standard has also been endorsed by the International Standards Organization (ISO), produced as ISO/IEX 15418, making it a globally accepted standard.

Human Readable UDI

We support a UDI program, but not all medical products need a bar code. We support the development of a UDI program that utilizes a human readable UDI coding system for all medical products. We also urge the FDA to recognize that a bar code or other type of automatic identifier may not be appropriate for all medical products. We encourage the FDA to continue to pursue a separate standard for a human readable UDI code on medical devices and refrain from identifying a specific automatic identification technology to read that code.

A clear standard of what is expected for manufacturers and distributors is critical for those in the supply chain to effectively execute a UDI program. The FDA must clarify what constitutes a "device," how the list of products that need to be tagged with a UDI will be developed and by

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whom, the type of UDI that will be required, and what information about the device should be included. We recommend that the FDA focus on high risk devices in order to recognize the distinction between disposable supplies and medical devices.

Implementation Timeline

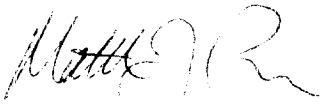
The success of the UDI program is reliant upon a practical implementation timeline. The FDA's suggested timeline of three to five years raises serious concerns regarding the costs and changes in business practices necessary to implement a comprehensive UDI system. We ask the FDA to fully consider the potential effects on the distribution industry before final rules and timelines are put in place. HIDA believes that five to six years is a suitable timeline for implementation. Such a timeline will afford the supply chain industry adequate time to upgrade their existing information technology systems, invest in new technology and equipment, hire and train new staff, coordinate with their industry customers and partners to achieve a smooth transition, and work with the FDA to troubleshoot, ask questions, and foster further dialogue. We recommend that the FDA allow systematic adoption of a UDI system over a period of five to six years.

Conclusion

HIDA strongly supports a UDI system that is relevant and cost effective for the wide range of medical products, from supplies such as cotton balls to infusion pumps to implantable devices. In the process of developing a UDI system, we ask that the FDA take into account the effect that a UDI system will have on distributors of medical devices and supplies.

On behalf of HIDA and its members, thank you in advance for your consideration of our comments and recommendations. Please contact me at (703) 838-6118 or rowan@hida.org if I can be of assistance or provide further information.

Sincerely,



Matthew J. Rowan
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