



November 6, 2012

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Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, room 1061
Rockville, MD 20852

Attention: FDA-2011-N-0090

Re: Unique Device Identification System

Dear Dr. Hamburg:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of a national unique device identification (UDI) system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we welcome the opportunity to submit comments regarding the proposed rule on the UDI system, which was published in the July 10, 2012 issue of the *Federal Register*.

The proposed rule would, among other things, require:

- The label and package of medical devices to bear a UDI unless alternative placement is permitted or an exception applies;
- Certain devices to be directly marked with a UDI; and
- Labelers of medical devices to submit information concerning each device to the Global Unique Device Identification Database (GUDID).

UDI basics

The proposed rule calls for the following UDI framework:

- 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.
 - The 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 ten boxes of five device packages, because both the box and the carton would 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.

We support the general UDI framework. **On patient safety grounds, we urge the FDA to ensure that UDI requirements 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.**

Effective dates

The implementation timetable in the proposed rule would mean that UDI labeling and related GUDID information submission requirements for class III, II and I devices would apply beginning one, three, and five years, respectively, following publication of the final rule. Further, for devices subject to direct marking requirements, 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 FDA Safety and Innovation Act, P.L. 112-144, enacted following publication of the proposed rule, will, however, require implementation of final regulations with respect to the packaging and labels of 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 revised accordingly.

In addition, we believe that the proposed seven-year implementation timeframe is simply too long and that patient safety would not be well served by such a leisurely implementation schedule. **We, therefore urge the FDA to finalize a shortened timetable, under which implementation of the UDI requirements relating to device labels and packaging would**

be completed within two years of the effective date of the final rule, and under which implementation of the UDI requirements related to direct marking of devices would be completed within three years of such effective date. And we strongly support the proposed one-year implementation timeframe for class III devices. 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.

Exceptions and alternatives

The proposed rule would provide a large number of exceptions to the UDI and related GUDID information submission requirements. For example, section 801.30(a)(1) proposes an exception for devices, other than prescription devices, that are sold at retail establishments, such as drug stores. This proposed exception would apply even when such devices are sold directly to a hospital or other healthcare facilities. The FDA gives as examples automatic external defibrillators, insulin syringes, glucometers, tampons, thermometers, toothbrushes, and bandages. The FDA further notes that labelers of such devices could choose to submit data to the GUDID on a voluntary basis. If they did, a device's UPC could serve as its UDI.

We are concerned about the proposed exception for devices sold at retail establishments and urge the FDA to reconsider. **For reasons of patient safety, we believe that these devices should be subject to UDI requirements, including GUDID information submission obligations, and that their UPC should be deemed to be the UDI for this purpose.** At minimum, devices, such as automatic external defibrillators and glucometers, for which a malfunction would pose a serious health threat to patients and consumers, should be subject to the UDI requirements.

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).

We generally support the above policies. For reasons of patient safety, we believe it would be important to ensure 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.

Direct marking of devices

Under the proposed rule, certain devices would need to be directly marked with a UDI, including implantable devices (but only if they are 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). Further, 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. As noted earlier, the FDA also 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 (for example, seven years after publication of the final rule in the case of class I devices).

On patient safety grounds, we are inclined to believe that allowing different UDIs for packaged and unpackaged devices for which direct marking is required could lead to some confusion. We are also inclined to believe that having the same UDI for both packaged and unpackaged products would be preferable in that it would appear to allow hospitals and others to more efficiently determine a device's UDI, record this information into medical and other appropriate records, and track devices in recall situations. **We, therefore, urge the FDA to assess these issues as it develops the final rule.**

We also recommend that all implantable devices be subject to direct marking requirements, not just those intended to remain implanted for 30 days or more. We believe this would be preferable from a patient safety perspective and simpler and easier to implement than the proposed approach of allowing 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.

As noted earlier, **we also believe that the proposed timeline for requiring direct marking of certain devices should be considerably shortened to no more than three years after the effective date of the final rule. This would help ensure that important patient safety goals are achieved at the earliest possible opportunity.**

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Global Unique Device Identification Database (GUDID)

Under the proposed rule, the 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.

We urge the FDA to provide more information about how device recalls will be handled in the context of the GUDID, including the respective responsibilities of the FDA, device manufacturers and other stakeholders. On patient safety grounds, we believe that it would be extremely important for recall information to be easily accessible to those logging into the GUDID. For example, if a hospital accesses the GUDID, it should be readily and immediately apparent if a recall applies to a given device. We, therefore, urge the FDA to take the necessary steps to ensure this outcome.

We hope the preceding comments are helpful. We are anxious to see the UDI system up and running and contributing to patient safety efforts.

Sincerely,

AARP

Alliance for Advancing Nonprofit Health Care

Alpha-1 Foundation

American Congress of Obstetricians and Gynecologists

American Nurses Association

American Urological Association

Association for Professionals in Infection Control and Epidemiology

Association of American Medical Colleges

Catholic Health Association of the United States

COPD Foundation

Failed Implant Device Alliance

Federation of American Hospitals

MedicAlert Foundation

National Association for Continence

National Association of Public Hospitals and Health Systems

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Premier healthcare alliance

The Society for Cardiovascular Angiography and Interventions

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