

**America's Health
Insurance Plans**

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November 8, 2006

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

Re: Unique Device Identification; Request for Comments
[Docket No. 2006N-0292]

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing in response to a Request for Comments on Unique Device Identification (UDI) published by the Food and Drug Administration (FDA) in the *Federal Register* on August 11, 2006 (71 Fed. Reg. 46233)

AHIP is the national trade association representing the private sector in health care. AHIP's nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans.

AHIP strongly supports efforts to more accurately identify and track medical devices and believes that such initiatives will improve health care quality and effectiveness and patient safety. As noted in a recent report to the FDA, the creation of a unique device identifier has the potential to reduce medical errors, facilitate recalls, improve reimbursement and inventory control, and reduce product counterfeiting.¹

Adopt a Unique Medical Device Identifier

The FDA should use its rulemaking authority to adopt a unique device identification system in a manner similar to the regulations for the bar coding of certain types of human drugs and biologics (21 C.F.R. Parts 201, 606, and 610). Each medical device should be assigned a universal product number (UPN) created by either by the Health Industry Business Communications Council or the GSI organization.

As part of the UDI final rule, the FDA should "harmonize" the process for the assignment of UPNs by these two organizations. A process should be created to require medical device manufacturers to assign a single, unique number to identify each medical device. In order to ensure patient safety and to enable tracking of a device to a specific patient, all singular device items should be tagged and not aggregated by lots (e.g., surgical sponges, tubing, etc.).

¹ *ERG Final Report: Unique Identification for Medical Devices*, March 22, 2006.

Phase-In Adoption of Device Identifiers

While the use of an UPN should be required for all medical devices, the FDA may wish to consider appropriate and timely phase-in of the adoption of device identifiers. Initial efforts should focus on use of UPNs on Class III medical devices (which by definition pose a safety risk) with subsequent adoption on Class II and Class I devices. The highest priority for UPN use should be assigned to implantable medical devices which have the most inherent risk to a patient.

Use Device Identifiers in Reporting and Investigational Studies

The FDA should develop standards requiring the linking of medical device identifiers to adverse event reporting. The use of identifiers should also be required in all investigational and research studies involving medical devices. In addition, the FDA should take steps to incorporate the UPN into any databases that collect and maintain information about medical devices.

The FDA should also reach out to stakeholder groups involved in the collection and use of health information to encourage the use of device identifiers. This initiative should include the standards development organizations responsible for creating electronic health care transactions (ANSI X12, Health Level 7, National Uniform Claims Committee, and the National Uniform Billing Committee) as well as public and private bodies involved in the creation of standards for health information technology (Certification Commission for Health Information Technology and Health Information Technology Standards Panel).

We also strongly believe that health insurance plans should be included in the development and implementation of a UDI system. Health insurance plans serve as a nexus between patients, health care providers, and device manufacturers, and could assist the FDA in implementing an effective program to use UDNs in post-marketing reporting and investigational studies.

Promote Interoperability

The UDI system (including hardware and software) should be interoperable. For example, software should have standardized parameters and an open source code, allowing full access for software and hardware developers, thereby enhancing competition and constraining health care costs.

Creating a New Regulatory Approach

In addition, we would ask the FDA to consider its overall approach to the regulation of drugs, biologics, and medical devices. In particular, AHIP urges the FDA to adopt the recommendations included in our March 14, 2006 letter regarding the Medical Device User Fee

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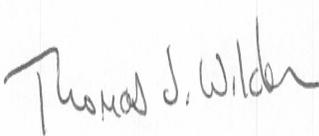
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Modernization Act of 2002. The comment letter, which is attached, outlined five recommendations to facilitate the transition to a more evidence-based, safe, and effective health care system:

- Require and adequately fund post-market studies of prescription drugs, biological products, and medical devices.
- Develop public-private partnerships to conduct post-marketing studies of drugs and devices.
- Provide early warning monitoring through linkages to the National Health Information Infrastructure.
- Establish procedures to track implanted medical devices.
- Encourage accountability for device failures.

AHIP believes the FDA has an important role in protecting patient safety and encouraging quality and cost-effective health care. We support the development and adoption of unique identifiers for medical devices and look forward to working with the FDA on this important initiative.

Sincerely,

A handwritten signature in cursive script that reads "Thomas J. Wilder". The signature is written in dark ink on a light-colored background.

Thomas J. Wilder
Vice President, Private Market Regulation

Attachment