



Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

November 2, 2012

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Mostashari,

The HIT Standards Committee's (HITSC) Clinical Operations Workgroup and the Vocabulary Task Force prepared comments in response to the Federal Drug Administration's Unique Device Identification System Notice of Proposed Rulemaking Making. The comments were presented to the HITSC on October 17, 2012 and accepted for transmittal to the National Coordinator.

Comments:

- The HITSC commends and supports Federal Drug Administration (FDA) efforts to provide for unique device identification (UDI) standards and processes that are expected to have many benefits for health and health care. The proposed UDI database is particularly notable as a positive step in the right direction for health care and supporting processes.
- Proposed exemptions from UDI requirements for retail devices are troublesome and problematic. Many devices that are proposed to be excluded are integral to health care and can be paid for by CMS programs.
 - HITSC proposes that many retail devices excluded from UDI requirements in the proposed rule should instead be included.
 - All measurement devices that provide information used to inform care should be required to be labeled by UDIs, whether retail or not.
 - For treatment devices new criteria should be developed by FDA to define which require UDI and which may not.
 - For prescribed devices generally all should be subject to UDI requirements, that is, any device routinely specified in a professional prescription order even if it also may be available over the counter.
 - All OTC devices frequently ordered by clinicians should be required to be labeled with UDIs.

- HITSC supports the intent of FDA to allow for primary and alternate UDIs for a device. We suggest that whenever for any reason a UDI is changed by the labeler but the device is the same, then the UDI database should include all alternate UDIs in the same record as the primary UDI so that a user does not have to perform separate operations to link records across the database to find all instances and all UDIs that identify the same device. This has been described by some as a UDI history of the device.
- HITSC recommends that the following additional data elements be included in the UDI database and be indexed and searchable in the UDI database:
 - Any NDC or NHRIC that was previously used to identify a device that is now required to have a UDI.
 - The SNOMED CT identifier that corresponds to the GMDN code and term assigned to the device.
 - LOINC codes for any and all tests performed by a device or testkit
- UDI database maintenance must be timely, and FDA should publish guidance defining timely maintenance. A particular concern for timely maintenance occurs when devices are withdrawn from the market, or when the marketing status of a device is changed for any reason.
- UDIs are especially important for implantable devices.
 - Requirements for coded entries for UDI should be included in interoperable electronic document specifications including those for discharge summaries, transition of care documents, and other applicable health summaries.
 - Patients should be able to know the UDI of devices implanted in them through both inpatient and outpatient procedures.
 - A device that has a UDI and that transmits data should be required to transmit all of the typing information associated with the UDI.

Sincerely yours,

/s/

Jonathan Perlin
Chair, Health IT Standards Committee

/s/

John Halamka
Vice Chair, Health IT Standards Committee