

January 14, 2013

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Office of the National Coordinator for Health Information Technology

Patriots Plaza III

355 E Street, SW

Washington, DC 20201

RE: Health Information Technology Policy Committee's request for comments on its draft recommendations for meaningful use Stage 3.

The Medical Device Initiative of The Pew Charitable Trusts and the American College of Cardiology welcome the opportunity to submit comments regarding the preliminary recommendations of the Health Information Technology Policy Committee regarding Stage 3 of the meaningful use of health information technology.

The Pew Charitable Trusts is an independent, non-profit organization that applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. The Medical Device Initiative seeks to improve the safety of medical devices and to foster innovation that benefits patients through streamlined device approvals.

The American College of Cardiology is a 40,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards, and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care.

We strongly encourage the incorporation of medical device identifiers developed under the FDA's unique device identification (UDI) system into both electronic health record (EHR) certification criteria and Stage 3 meaningful use (MU) objectives.

UDI Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and section 614 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) both require the FDA to develop a UDI system for medical devices. The FDA issued a proposed rule to implement such a UDI system on July 10, 2012 (FDA-2011-N-0090). A UDI is a unique numeric or alphanumeric code that identifies the specific version or model of a device and relevant production information, such as the lot or batch number. The UDI proposed rule would require the label of most medical devices and device packages to bear a UDI that can be used to identify the device throughout its distribution and use; some devices would also need to be directly marked with the UDI. Medical devices are one of the only products used by consumers that do not have such an identification system already in place.

Once implemented, the UDI system will be the cornerstone for significant improvements in postmarketing surveillance of medical devices. As articulated by the FDA in the UDI proposed rule, the UDI system will benefit patients and public health by:

- providing for more rapid identification of medical devices associated with adverse events;
- assisting with more rapid and efficient resolution of device recalls; and
- delivering an easily accessible source of definitive device identification.

UDI also has the potential to improve many types of postmarketing surveillance, such as medical device registries, by facilitating the use of electronic records to provide data to these important surveillance systems.

Manufacturers must comply with the FDA's final rule on UDI once it is issued. However, in order for the public health gains discussed above to be realized, the healthcare community must incorporate the UDI into clinical practice. This will not be possible unless EHRs support these efforts. Accordingly,

certification standards and MU objectives must be updated to reflect this new source of data that has significant potential to improve patient care.

EHR Certification Criteria

We strongly recommend that the ability to capture UDIs is included as a criterion in the next update to EHR standards and certification regulations. This is a crucial step to ensure widespread incorporation of device information into EHRs and support a number of proposed MU Stage 3 objectives, including SGRP405 and SGRP408. Given that Congress required the FDA to publish the UDI final rule by May 2013, **the EHR certification criteria need to be updated as early as possible, but certainly in the next stage of MU.**

There are a number of specific elements that are important to include as part of this new standard.

1. **Identify a technical specification for UDI data;**
2. **Require that certified EHR technology be able to electronically import, manage, and export the UDI explicitly as data per the technical specification chosen above; and**
3. **Require that certified EHR technology handle the UDI and any associated data (especially the verbose description of the device) in a specific, dedicated section of the EHR.**

Meaningful Use: Improving Quality, Safety, and Reducing Health Disparities

We have two recommendations for modifications to the proposed MU objectives.

1. **Develop a new MU Stage 3 Eligible Hospital and Eligible Provider core objective under the “Improving quality, safety, and reducing health disparities” section. The core objective, to be satisfied through attestation, that we propose is: “the incorporation of the UDI into EHRs for patients whose care involves an implanted medical device.”** The benefits of a fully implemented UDI system align closely with the quality and safety goals of MU objectives. For example, a fully operational UDI system will allow the integration of device data into various postmarketing surveillance systems and identification of recalled products at the supplier and

provider level more quickly. Each of these will allow for earlier identification and resolution of safety problems.

2. **MU proposed objective SGRP408:** *“Capability to electronically send adverse event reports (e.g., vaccines, devices, EHR, drugs or biologics) to the Federal Drug Administration (FDA) and/or Centers for Disease Control and Prevention (CDC) from the Certified EHR, except where prohibited, and in accordance with applicable law and practice.”*

We support this new MU objective and the associated EHR certification criteria. **However, we support this effort as a Stage 3 objective, rather than a Future Stage objective. We also recommend clarification that the adverse event report include the UDI of the associated medical device.** The draft UDI regulation requires health care facilities to include the UDI when reporting medical device adverse events. Additionally, we suggest that the FDA’s two main documents for mandatory and voluntary reporting, the 3500 and 3500A, be named as the standardized adverse event report messages.

Thank you for your consideration of our comments. Should you have any questions, please contact Josh Rising at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,



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