May 29, 2015

Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
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*Submitted electronically via regulations.gov*

**Re: CMS-3310-P: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3; *and* RIN 0991-AB93: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications**

Thank you for the opportunity to comment on the 2015 Electronic Health Record Certification Criteria and Meaningful Use Stage 3 proposed regulations issued by the Office of the National Coordinator for Health IT (ONC) and Centers for Medicare & Medicaid Services (CMS), respectively.

These proposed rules rightly recognize the importance of documenting the unique device identifier (UDI) of implanted devices in patients' health records to improve safety and enhance care quality.

The UDI system—developed by the FDA—will provide each medical device with a code corresponding to its manufacturer, model, and other clinically relevant data, such as expiration date. Incorporating UDIs into electronic health records (EHRs) will help hospitals, clinicians and patients identify individuals implanted with recalled devices; support care coordination for patients that see multiple clinicians; provide patients and physicians with accurate information on products implanted; and improve analyses of device performance.

The EHR certification criteria and Meaningful Use Stage 3 proposed rules are critical changes to advance UDI incorporation into patients' health records. These proposed rules would help implement recommendations from the Food and Drug Administration (FDA), the National Medical Device Postmarket Surveillance Planning Board, the Health Information Technology Policy Committee and many other expert organizations that have called for the inclusion of UDI data in patients' health records.[1-4]

*Comments on EHR Certification Criteria*

We strongly support provisions in the EHR certification criteria regulations that would allow EHRs to capture and transmit the UDI.

First, we support provisions in the regulations to create a field in EHRs to list the UDIs of implanted medical devices, which would give hospitals, physicians and patients the ability to know exactly which devices are implanted to better inform clinical decisions.

Second, we support the provisions that would enable EHRs to extract information about the device from FDA's Global Unique Device Identifier Database (GUDID) into the health record. Providing this data directly in the EHR will ensure that patients and physicians have information at their fingertips on those products without requiring them to use a supplementary database, which could be time consuming and error prone.

Third, we support the provision to include the UDIs of implanted devices as a core component of patients' medical history by adding this information to summary of care documents, known as the Common Clinical Data Set. Incorporation of UDIs in summary of care documents will ensure that the list of devices implanted in patients is exchanged among providers caring for that individual. As implanted devices are a critical component of the patients' health history, this information should be exchanged along with data on the patients' medications, allergies, current problems and other information contained in summary of care documents.

We do, however, request two changes to the proposed rule to enhance the utility of these requirements. First, we are concerned that the proposed rule does not require any form of automatic identification and data capture (AIDC) capabilities to record the UDI. There is potential for UDIs to be several dozen digits in length; failure to support some form of AIDC capabilities will require providers to manually enter the information, increasing the chances of an error and discouraging clinicians from documenting the devices implanted in the patient. In harmony with FDA's requirement that medical device labels include at least one form of AIDC capability, ONC should require EHRs to also support at least one form of automated UDI capture.

Second, ONC proposes to extract only the "Device Description" field from FDA's GUDID. Unfortunately, this field is voluntary and unstandardized, potentially leading to the lack of critical human-readable information contained in the EHR. Instead, ONC should require EHRs to extract information from mandatory and standard GUDID fields, including those that describe the manufacturer, model, size and MRI-compatibility of the implant.

*Comments on Meaningful Use Stage 3*

In parallel to the proposed EHR certification criteria, the Meaningful Use program can encourage the use and exchange of UDI among health care providers. The proposed Meaningful Use Stage 3 objective would provide financial incentives to encourage physicians and hospitals to exchange the Common Clinical Data Set, which would—in accordance with the proposed EHR certification criteria—include the list of patient UDIs.

As the products implanted in patients are a key component of individuals' health history, encouraging the transmission of UDI through the summary of care documents will ensure that clinicians have relevant and up-to-date information on the devices their patients use. We strongly

support this proposed Meaningful Use Stage 3 objective so that the UDIs of implanted devices are exchanged between clinicians and facilities as a part of routine care.

While CMS indicates that summary of care documents are expected to "contain the most recent and up-to-date information on all elements," CMS should clarify that this requires the documentation of the UDIs of implanted devices at the time of the procedure.

*Conclusion*

As medical devices receive unique identifiers, it is now possible to associate each patient with the specific model of a product implanted in their body. In both the EHR certification criteria and Meaningful Use Stage 3 proposed rules, ONC and CMS both rightly recognize the importance of incorporating in patients' health records the UDIs of implanted medical devices so that they are available for clinicians and patients to improve safety and enhance care coordination.

Should you have any questions or if we can be of assistance, please contact Josh Rising, director of healthcare programs at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org. Thank you for your consideration of our comments.

Sincerely,
American Association of Orthopaedic Surgeons
American Joint Replacement Registry
National Association of ACOs
National Health Council
Pacific Business Group on Health
The Leapfrog Group
The Pew Charitable Trusts
The Society of Thoracic Surgeons
Trust for America's Health

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[1] Food and Drug Administration, Center for Devices and Radiological Health, "Strengthening our National System for Medical Device Postmarket Surveillance," (Sept. 2012), accessed April 17, 2015, http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf.

[2] Letter to Sylvia Mathews Burwell at Department of Health and Human Services, (Jan. 20, 2015), accessed April 17, 2015, http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2015/01/pew-submits-letter-to-health-and-human-services-regarding-electronic-health-record-certification.

[3] National Postmarket Surveillance Planning Board, "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," (Feb. 2015), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM435112.pdf.

[4] Health Information Technology Policy Committee. Transmittal Letter from HIT Policy Committee to the National Coordinator for Health Information Technology. (April 1, 2014), http://www.healthit.gov/sites/faca/files/HITPC_MUWG_Stage3_Recs_2014-04-01.pdf.