December 15, 2015

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

Submitted electronically via regulations.gov

Re: CMS-3310-FC & CMS-3311-FC: Medicare and Medicaid Programs: Electronic Health Record Incentive Program -- Stage 3 and Modifications to Meaningful Use in 2015 through 2017

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Meaningful Use Stage 3 final regulations, which will help ensure that clinicians have information on the specific medical devices implanted in their patients. These regulations will help improve safety, outcomes and care coordination for patients that rely on cardiac stents, artificial hips and other life-saving and life-changing products.

The unique device identifier (UDI) system—developed by the Food and Drug Administration (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 identify individuals implanted with recalled devices;
- Physicians coordinate care for patients that see multiple clinicians;
- Providers and patients access accurate information on products implanted; and
- Researchers conduct analyses of device performance using clinical data.

To achieve these benefits, EHRs must have a dedicated field to document UDIs and providers need to share this information with other clinicians caring for an individual and patients so they have access to their own health data.

Through the final EHR certification criteria released by the Office of the National Coordinator for Health Information Technology (ONC) that establish standards for patients' medical records, ONC advances the first objective by requiring a field in EHRs to list the UDI and key information about the product—such as its name and whether it is MRI compatible. Additionally, ONC in the final rule requires the incorporation of UDI in summary of care information—referred to as the Common Clinical Data Set (CCDS)—that provides clinicians with the individual's core health history, including medication and problem lists.

CMS further supports the exchange of UDI among providers by requiring transmission of the CCDS as part of the Meaningful Use program. Once Stage 3 of the Meaningful Use program begins, CMS will require participating hospitals and clinicians to send, receive and reconcile information in the CCDS, which includes UDI. Transmission of UDIs via these summary of care documents will ensure that providers can appropriately coordinate care and follow up with patients who have implanted devices.

Exchange of this information is especially relevant given the increased need for clinicians and hospitals to enhance care coordination and quality, such as through the merger of the Meaningful Use program into the Merit-based Incentive Payment System (MIPS) established through the Medicare Access and CHIP Reauthorization Act of 2015. Equipping providers with better, more accurate information on the medical devices they use will help improve patient outcomes and ensure that clinicians have the data they need to make informed decisions.

Additionally, by encouraging the transmission of UDI among providers, CMS helps implement recommendations from 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 this information in patients' health records.[1-4]

Thank you for considering our comments on how the UDI provisions in the final Meaningful Use regulations will enhance patient safety, quality and care coordination.

Sincerely,

American Academy of Orthopaedic Surgeons
American College of Cardiology
American Congress of Obstetricians and Gynecologists
American Joint Replacement Registry
American Medical Informatics Association
Geisinger Health System
Healthwise
Kaiser Permanente
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] Medical Device Registry Task Force, "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research," (Aug. 2015), http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm459368.pdf.