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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 submit comments to CMS-3310-P and RIN 0991-AB93.
I strongly support the proposed EHR certification criterion that would establish a new field in EHRs for Unique Device Identifiers (UDI) of implanted medical devices. I believe that the inclusion of this critical information as part of the Common Clinical Data Set (CCDS) will help to ensure that UDIs and associated data attributes will be part of the core dataset to be transmitted across the continuum of care as specified in the Meaningful Use objectives. In addition to the basic proposal, I believe that the criterion should be strengthened to require the use of automatic identification and data capture (AIDC) to auto-populate the UDI and key linked data attributes into structured data fields used to populate OR records and improve the quality of data available in the implantable device list and in operating room implant logs. If AIDC is not used, the implantable device list could be populated via manual data entry of the UDI alphanumeric string and be prone to human error, but still meet the EHR certification criteria. If appropriate data attributes linked to the UDI and stored in the Global Unique Device Identification Database are not included in the CCDS, then the benefits from the UDI system to facilitate discrete capture of key device information will not be fully realized. Healthcare providers will continue to manually populate implant logs with hospital-specific data that could be auto-populated with standard GUDID data attributes. Using AIDC and standard data from the GUDID would result in an implantable device list with improved data accuracy and completeness and a significant reduction in the existing error-prone manual data entry burden currently experienced by those who document and charge for medical devices during implantable device procedures.

In July 2012, FDA published the Unique Device Identification (UDI) rule that provides the foundation for a consistent and standard way for patients, healthcare providers, medical device industry, researchers, and payers to identify medical devices throughout their distribution and use. Most devices will be required to have a UDI in both human and machine-readable (AIDC) form on their label and packaging, and for certain devices, on the product itself. In addition to the labeling requirement, manufacturers are also required to submit standard data attributes associated

with the UDI to a publicly accessible FDA database – AccessGUDID[1]. UDIs will be phased in over several years, but the UDI will be required on all implantable devices by September 24, 2015. The FDA's foresight in developing a requirement for a machine-readable UDI on the label of the device gives the opportunity to create an equally important requirement to input that information in a machine-readable format at the points where the device is distributed and used. In addition, the extensive set of standard device attributes (brand, model, MRI compatibility), that are being populated in and made publicly available at AccessGUDID provide the foundation to establish a minimum standard device identification data set for adoption as part of the development of the requirement for this newly required implantable device list.

EHR Certification Criteria Comments

I strongly support the provisions in the EHR certification proposed rule that would: 1) create a field to list the UDIs of devices implanted in patients; 2) require the EHR extract human-readable information into the EHR from the a government-recognized master data source (e.g. GUDID or NLM); and 3) incorporate UDI and linked data attributes into the CCDS for transmission among providers.

Creating a device list in EHRs that contains meaningful information will give hospitals, providers and patients definitive information on implanted devices on a per patient level. The UDI itself can be divided into standard data elements—such as lot number, expiration date and manufacture date. This information should be stored in discrete fields populating an implantable device list to enable doctors and hospitals to more effectively identify patients who have received recalled implantable devices. In addition to the information that can be gleaned from the UDI itself, several other standard GUDID attributes are required fields and should appear on the implantable device list. ONC should identify those data fields that are currently captured manually in surgical implant logs and require certified EHRs to auto-populate those fields with standard data from the GUDID. A direct link to GUDID is not necessary to retain it as the recognized authoritative source for use by downstream systems. AccessGUDID provides nightly downloads from GUDID that could be used to populate appropriate systems and ensure data quality. Examples of data attributes that could be auto-populated by fields from the GUDID include manufacturer, brand name, model number, catalog number, Global Medical Device Nomenclature (GMDN) name (aka device category/type), size and MRI safety status. These data elements are described in GUDID as "Company Name", "Brand Name", "Version or Model", "Code^", "Size Type", "Size Value", and "What MRI safety information does the labeling contain?".

Current implementations of manually entered implant logs are prone to data entry and typographical errors, as well as outright omissions of key data. This limits the usefulness of such data to provide accurate device safety and evaluation information at the patient and population health level. Auto-populating this set of data will reduce staffing time spent manually entering this information and will reduce errors and improve consistency and completeness of the core device identification information currently collected in implant logs for implant tracking purposes. The inclusion of UDI and associated data attributes linked to the patient will allow

[1] AccessGUDID – public database populated by the Global Unique Device Identification Database and housed at National Library of Medicine. Located at: http://www.accessgudid.nlm.nih.gov

clinicians to create reports to improve individual patient care decisions such as whether an implanted device could be contributing to a symptom or whether the patient can undergo an MRI scan. It would also allow a care provider to create reports by patient group or by device type to improve population health decision making. Automatically populating fields in the EHR with this information is essential to making sure that the UDI produces value for clinicians and the patients they serve.

Meaningful Use Objective: Comments on Transmission of UDI across the Continuum of Care

Incorporating UDI in the CCDS will ensure that the UDIs of implanted devices are able to be transmitted from the hospital originally implanting the product to the patient's other care providers—such as the primary care physician or long term care staff-- to improve patient care. Including UDI across the entire continuum of care will also enable better information to support adverse event reporting, recalls, and device evaluation and decision making.

I strongly support this objective to facilitate the exchange of critical patient information—particularly the UDIs of implanted devices—through the transmission and receipt of the CCDS. I also encourage ONC to work with HL7 and other standard exchange groups (X12, NCPDP) to ensure that the mechanism for storing UDI in the HL7 CCDA and other exchange messages is clearly specified to support consistent capture of UDI across EHR systems.

Automated Capture of UDI is Essential

While I am very supportive of a requirement to record UDI, I am concerned that the proposed rule does not require EHRs to support some form of automatic identification and data capture (AIDC) capabilities, such as barcode. Given that the UDI could be several dozen characters long, there is high probability that the lack of AIDC capabilities would result in incomplete or inaccurate UDI data entry. In addition, a required AIDC function and a link of the device identifier to a recognized data source would allow fields that are currently manually entered in implant logs to be auto-populated with potential to improve procedure workflows.

While, as you note in the proposed rule, FDA does not mandate the use of specific AIDC capabilities, the Agency does require that UDI be displayed via some form of automated, electronic capture. FDA also recognized that, given the potential length of UDI, automated capture is essential to prevent errors associated with manual entry. While the criteria—like the FDA's UDI rule—should not favor one form of AIDC over another, ONC should require EHRs to support AIDC standards for capture of device label information.

Conclusion

Both ONC and CMS have underscored the importance of patient and physician access to accurate information on the implanted devices. Those implanted devices are a critical component

of a patients' health history and should be documented and exchanged between patients, primary care physicians and specialists.

Many organizations representing providers, public health groups, patients and large businesses all support efforts to incorporate UDI information into EHRs to provide clear information to patients and their doctors. As the National Postmarket Surveillance Planning Board stated: "Capture of UDI in EHRs is a critical step for comprehensive availability of medical device data for clinical care and for postmarket surveillance purposes."

By allowing physicians and patients to know which devices are implanted and used in care, the UDI system has the potential to empower patients in their healthcare decision-making, facilitate recalls, improve the quality of implant procedure data, improve clinical decision support and enhance medical device performance decision-making—but only once incorporated into electronic health information that includes patients' medical records.The development of EHR certification criteria and a Meaningful Use objective to support UDI capture and transmission are critical next steps to achieve those benefits.

Thank you for your consideration of my comments on the UDI provisions in these rules. Please contact me with questions at tzreed@mac.com