AJRR American Joint Replacement Registry

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Karen De Salvo, MD, MPH, MSc
National Coordinator for Health IT
U.S. Department of Health and Human Services
Hubert H. Humphrey Building Suite 729 D
200 Independence Avenue SW
Washington, D.C. 20201

Subject: 2015 Edition EHR Standards and Certification Criteria Proposed Rule
RIN 0991-AB92

Dear Dr. De Salvo:

The American Joint Replacement Registry (AJRR) appreciates the opportunity to provide comments on the Office of the National Coordinator for Health Information Technology (ONC) *Notice of Proposed Rulemaking on Voluntary 2015 Edition Electronic Health Record Certification Criteria; Interoperability Updates and Regulatory Improvements*, published in the February 26, 2014 *Federal Register.*

The AJRR, the nation's largest hip and knee arthroplasty registry, appreciates the opportunity to make comments on this proposed rule. At this time, AJRR has enrolled 272 hospitals from 48 states and has collected data representing over 100,000 orthopaedic procedures. AJRR currently collects Level 1 data from hospitals pertaining to patients, surgeons, devices and revision complications as reported under the ICD-9 procedural codes for primary hip and knee arthroplasty. AJRR is pilot testing Level 2 (co-morbidity and complication information) and Level 3 (Patient Reported Outcome Measures – PROMs) data collection in a subset of participating hospitals.

AJRR reports will be available in summary (de-identified) form annually to the public and in detail to participating hospitals and surgeons, and will compare facility/ Eligible Professionals (EPs) and other measures to national database benchmarks.

AJRR's goal is to become a " Qualified Clinical Data Registry " (QCDR) and to submit Physician Quality Reporting System (PQRS) data on behalf of the hip and knee surgeons enrolled in our registry.

report results better outcomes register

AJRR receives a majority of hospital procedural data directly from hospital Electronic Health Record (EHR) technology and wishes to thank the ONC for moving ahead to implement a more frequent approach to health information technology certification regulations and to update certification criteria editions every 12 to 18 months to provide more incremental regulatory changes and policy proposals. As a stakeholder, AJRR appreciates having more time to provide input on policy proposals under consideration for future rulemaking by ONC.

AJRR would like to provide comments on the ONC proposal to adopt a new 2015 Edition certification criterion that would require EHR technology to be able to record and display a Unique Device Identifier (UDI) and other information about a patient's implantable devices.

AJRR commends ONC for taking this first step toward enabling EHR technology to facilitate the widespread use of UDI data to prevent device-related medical errors and to improve the ability of hospitals and clinicians to respond to device recalls and device-related patient safety information to achieve improved patient safety and public health benefits consistent with the Health Information Technology for Economic and Clinical Health (HITECH) Act.

UDI capture in EHRs will benefit patient care by improving recall resolution, enhancing care coordination and providing a source of information for patients and providers on medical devices implanted in the patient. In the short-term 2015 Edition, creating a directory of UDIs will ensure this information is included in the EHR. In the 2017 Edition, the additional proposed functionality and EHR data content will greatly enhance the information available to patients and clinicians without requiring them to utilize an external resource to obtain information on the device.

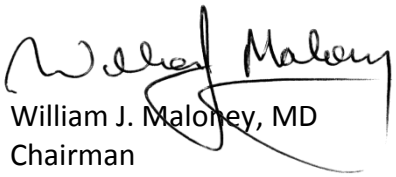
AJRR believes there is value to require at least one form of Automatic Identification and Data Capture (AIDC) in the 2015 Edition. Otherwise, clinicians would be required to manually enter the UDI into each EHR, which will result in data entry errors and workflow inefficiencies. AJRR supports the ONC proposal to create a field in EHRs to list the UDIs of implantable devices in the 2015 Edition.

AJRR is concerned about the 2017 Edition proposal that would create data fields in EHRs to list more than just the UDI. This would require data entry stating the device manufacturer, model, single use application, latex content and Magnetic Resonance Imaging (MRI) compatibility. The proposal would also have these fields automatically populated by an external database. AJRR would urge ONC to require that these additional fields be automatically populated to reduce work inefficiency and data entry errors. If a provider has the UDI, this information should be readily available.

AJRR strongly supports the ONC proposal to ensure that UDIs can be transmitted to reporting systems and registries that collect data on the devices used by registry participants. As stated in the proposed rule, this will facilitate better and more accurate reporting of adverse events and other information critical to clinical data registries. This data will enable expedient root cause analysis resulting in more effective corrective actions in response to device recalls and alerts and other device-related patient safety information.

The AJRR appreciates this opportunity to provide comments to the *2015 Edition EHR Standards and Certification Criteria Proposed Rule.* We look forward to continued collaboration with ONC and providing guidance and input on issues related to EHR and clinical data registries. If you have any questions regarding our comments, please do not hesitate to contact our Executive Director Jeffrey P. Knezovich, CAE at (847) 430-5036 or at knezovich@ajrr.net.

Sincerely;



William J. Maloney, MD
Chairman
American Joint Replacement Registry

Cc: Jeffrey P. Knezovich, CAE, Executive Director
David G. Lewallen, MD, Medical Director