May 29, 2015

Via Electronic Mail

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3310-P

Re: CMS-3310-P: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3

Dear Mr. Slavitt:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments on the regulation proposed by the Centers for Medicare & Medicaid Services (CMS) for Stage 3 of the electronic health record (EHR) meaningful use program.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies.

AdvaMed’s comments focus on the implications of the CMS proposed rule for collection of the unique device identifier (UDI) for implantable medical devices. This issue arises in the context of Objective 7, Health Information Exchange, especially with respect to associated Measure 1, which focuses on the creation of a summary of care record for patients transitioning or referred to another setting of care or provider of care.

UDI and Meaningful Use

The CMS proposed rule notes that the 2015 Edition proposed rule issued by the Office of the National Coordinator for HIT (ONC) includes a criterion and standard for capturing the UDI for implantable medical devices. CMS adds that hundreds of thousands of Medicare beneficiaries receive some type of implantable medical device each year. CMS also discusses the value of having UDI information in the EHR and concludes that “the documentation of UDIs in a patient medical record and the inclusion of
that data field within the Common Clinical Data Set (CCDS) requirements for the summary of care documents is a key step toward improving the quality of care and ensuring patient safety.”

AdvaMed believes that providing a standard and clear way to document device use in EHRs would facilitate more accurate reporting, review and analysis of postmarket data for medical devices. We support ONC’s initial focus on the fundamental capabilities for this criterion subject to available and tested technological standards for recording, changing and accessing this data. We further support the ONC proposal to include a UDI-related certification criterion in the definition of Base EHR as a means to increase the availability of UDI information to health care providers involved in the treatment of a patient as well as to strengthen the reliability of the information for the patient’s implantable device(s).

Notwithstanding our support for the ONC proposal, we also recognize that creating a mechanism to capture UDI for implantable medical devices also raises questions about the entity responsible for doing so, and under what circumstances. For example, for purposes of meeting CMS meaningful use requirements, would the physician implanting a device and/or the hospital where the device is implanted have any obligation to include UDI information in the patient’s EHR and/or in any summary of care documents created for purposes of subsequent transitions of care or referrals? Also, for purposes of meeting EHR meaningful use requirements, if a primary care physician subsequently refers a patient with an implanted device to a dermatologist, would the required summary of care record created by the primary care physician need to include UDI information for the implanted device? Under the preceding scenario, if the primary care physician had not previously received UDI information from the physician who implanted the device and/or from the hospital or other facility where the implantation took place (or from any other source), would such primary care physician have any obligation to include UDI information in the summary of care record prior to referring his or her patient to the dermatologist?

In sum, we believe there are many possible scenarios in which a summary of care record might be created that would raise questions regarding the UDI-related responsibilities of the eligible professional and/or hospital creating the document. None of this was explicitly addressed in the proposed rule.

Thus, while we support efforts to incorporate UDI information in EHRs, we recommend that CMS provide an opportunity for public comment if and when the agency decides to impose specific UDI-related obligations on eligible professionals and/or hospitals, especially given the associated administrative burdens and provider workflow implications.

AdvaMed hopes the above comments are helpful. If you have any questions regarding these comments or need more information, please contact me at (202) 434-7203 / DMay@advamed.org or Steven Brotman at (202) 434-7207 / SBrotman@advamed.org.

Sincerely,

/S/

Don May
Executive Vice President,
Payment and Health Care Delivery Policy