AdvaMed
Advanced Medical Technology Association

May 29, 2015

<u>Via Electronic Mail</u>

Karen B. DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: RIN 0991-AB93

**Re: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015
Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification
Program Modifications Proposed Rule**

Dear Dr. DeSalvo:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide
comments on the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015
Edition Base Electronic Health Record (EHR) Technology Definition, and ONC Health IT Certification
Program Modifications, Proposed Rule *(Federal Register, Vol. 80, No. 60, Monday, March 30, 2015, p.
16804).*

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.

ONC proposes to establish a new certification criterion for Health IT Modules which would require health
IT to demonstrate capability to perform all of the following functions with respect to implantable medical
devices:

- To record, change, and access a list of unique device identifiers (UDIs) that correspond to a
  patient's implantable device or devices.
- To parse certain data from a UDI.

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- To retrieve the Device Description attribute associated with a UDI in the Global Unique Device Information Database (GUDID) maintained by the Food and Drug Administration (FDA).
- To make both the parsed data and retrieved data user accessible.

ONC indicates that this proposal is a first step toward enabling health IT to facilitate the widespread availability and use of unique device identifiers to protect patient safety and improve health care quality and efficiency. Specifically, ONC believes this proposed criterion could prevent device-related adverse events, enhance clinical decision-making related to devices, improve the ability of clinicians to respond to device recalls and device-related safety information, and achieve other important benefits. ONC also notes that the proposed criterion is significantly scaled back from its proposal for the Voluntary Edition proposed rule of last year.

AdvaMed believes that providing a standard and clear way to document device use in electronic health records is important, and 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 also believe it is useful that the certification criterion for UDIs include the ability for a user to change UDIs from a patient's implantable device list in order to delete erroneous or duplicative entries from a patient's implantable device list and update the list in the event that a device was removed from the patient. Even if automated readers are capable of capturing this UDI data and transmitting them to health IT, users must be able to double check the accuracy of these entries and have the capability to update the information when necessary. However, the health IT should track the user that makes the initial data entry and any subsequent changes to those entries.

AdvaMed supports the proposal to include this certification criterion in the definition of Base EHR as a means to increase availability of this 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 devices. We recommend retaining the focus on implantable devices for the 2015 Edition certification criteria and on the three areas of baseline UDI functionality ONC proposes.

AdvaMed appreciates the hard work and complexities associated with the establishment and implementation of certification criteria for the EHR meaningful use program and for other purposes. Thank you for your consideration of these comments.

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