The Society of Thoracic Surgeons

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April 24, 2014

The Honorable Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW.,
Washington, DC 20201

Re: 2015 Edition EHR Standards and Certification Criteria Proposed Rule

Dear Dr. DeSalvo:

On behalf of The Society of Thoracic Surgeons, I write in support of efforts to capture Unique Device Identifiers (UDI) in Electronic Health Records (EHR). We thank you for the opportunity to comment on the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements Proposed Rule.

Founded in 1964, The Society of Thoracic Surgeons (STS) is an international, not-for-profit organization representing more than 6,700 surgeons, researchers, and allied health care professionals in 85 countries who are dedicated to providing patient-centered high quality care to patients with chest and cardiovascular diseases, including heart, lung, esophagus, transplantation, and critical care. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The STS National Database was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The STS National Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. The fundamental principle underlying the STS database initiative has been that engagement in the process of collecting information on every case, robust risk-adjustment based on pooled national data, and feedback of this risk-adjusted data to the individual practice and institution will provide the most powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients and the public. As we work to integrate registries with all aspects of the new health care system, we are keenly aware of the benefits of UDI.

UDI capture in EHRs will result in several benefits to patient care—including improved recall resolution, enhanced care coordination and a definitive source of information for patients and providers to know which product is implanted in the patient. In the short-term (the 2015 Edition), creating a list of UDIs will ensure that this information is present in the EHR. With the 2017 Edition, the additional proposed functionality would greatly enhance the information available to patients and clinicians, without requiring them to utilize an external resource to obtain information on the device.

2015 Edition proposal

- We support the proposal to create a field in EHRs to list the UDIs of implanted devices.
- We think there is value to require at least one form of automatic identification and data capture (AIDC) in 2015. Otherwise, clinicians would have to manually enter the UDI into each EHR; this would result in data entry errors and workflow inefficiencies. Currently, ONC proposes to only require ADIC capabilities in 2017.

2017 Edition proposal

- The proposal would create data fields in EHRs to list more than just the UDI. These fields would state the device manufacturer, model, single use indication, whether it contains latex, and MRI safety status. The proposal would also have these fields automatically populated by an external database.
    - Putting this data directly in the EHR would give patients and doctors critical information without requiring them to go to an external website and manually enter the UDI.
    - This data would also allow hospitals to search through their EHR systems for patients that are using a type of device—such as drug-eluting stent.
- Additionally, we support the proposed capabilities to ensure that UDIs can be transmitted to reporting systems and registries that collect data on the devices used in care.
- While not listed in the proposed rule, ONC may also want to consider two additional capabilities:
    - First, EHRs should have the capability to automatically alert clinicians in the event of known device risks with MRI compatibility and latex allergies. Upon ordering an MRI scan or use of a latex-containing product, the provider should receive an automated alert if the patient has an MRI-incompatible device or latex allergy.
    - Second, ONC should consider how best to provide patients with UDI data, label information and instructions for a device. This information could occur through the incorporation of UDI into patient portals, for example.

FDA has listed UDI capture in EHRs as an essential step to achieving the full benefits of this device identification system. The UDI final rule states,

> FDA anticipates that providers will include the UDIs of a wide variety of devices in patients' Electronic Health Records (EHRs) and Personal Health Records (PHRs). This information will strengthen the health care community's ability to identify the specific devices implanted into patients and will improve response to postmarket surveillance activities, including adverse event reporting and recalls.

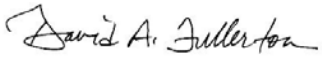
We believe that creating a new field in electronic health records (EHRs) to list the UDIs of devices implanted in patients' will dramatically improve care:

- *Better clinical decision support and care coordination:* The inclusion of UDIs in EHRs will allow providers to make more informed decisions on patient care. This information is critical when patients switch providers or see multiple physicians, all of whom may require information on the specific device used in care.
- *Patient engagement:* UDI documentation in EHRs will create an accessible data source for patients to take a more active role in their healthcare by providing a clear source of data on the device implanted in their body.
- *Improved adverse event reports:* Inclusion of UDIs in EHRs will enable patients and providers to submit more precise adverse event reports that identify the make and model—and in some cases lot number—of a potentially malfunctioning device.

- *Supply chain efficiencies*: A new field for documenting implants used in care will complement efficiencies and savings associated with integrating UDI throughout the supply chain, enabling automated charge capture, re-ordering and inventory control.
- *Enhanced interoperability*: As electronic systems used in hospitals can use a variety of nomenclatures to identify medical devices used in care, UDI provides uniform identifiers that will support standardization and interoperability among the many databases used throughout the supply chain, billing and patient care departments.

Thank you for the opportunity to provide these comments. Should you have any questions, please contact Courtney Yohe, Director of Government Relations, at 202-787-1222 or cyohe@sts.org.

Sincerely,



David A Fullerton, MD
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