April 28, 2014

Comments of Members of the Patient, Consumer, and Public Health Coalition
On the Department of Health and Human Services (HHS) Proposed Rule
"Voluntary 2015 Edition Electronic Health Record Certification Criteria: Interoperability Updates and Regulatory Improvements"
[HHS-OS-2014-0002-001]

As members of the Patient, Consumer, and Public Health Coalition, we want to express our support for the Office of National Coordinator for Health IT's (ONC) proposal to create a field in Electronic Health Records (EHRs) to list the unique device identifier (UDI) for patients who have received implanted devices.

We strongly encourage ONC to include automatic identification and data capture (AIDC) such as bar codes in its 2015 Edition and not wait until the 2017 Edition. Using an AIDC system saves physicians time and is more accurate (it avoids human error such as transposing of numbers).

Adding UDI information to EHRs would improve patient care in several ways. It would:

- More accurately identify recalled devices. Many devices may have the same name, but only some of the lot numbers or models are being recalled.
- More accurately identify patients who received the recalled device so that it will be easier to contact them for follow-up care.
- Help to more accurately report adverse events to registries. The Food and Drug Administration's current adverse events database for devices, the Manufacturers and User Facilities Device Experience (MAUDE), has been widely criticized for under reporting adverse events including severe injuries and deaths.

- Help doctors make better informed patient care decisions, especially when patients switch physicians or see several physicians, all of whom may need information about the specific device implanted in the patient.
- Provide more information on the effectiveness of devices, such as which device works better for certain patient subpopulations. Finding out which devices work better than others will benefit patients by providing them with the most effective and safe medical device. It will also save insurers and government agencies such as Medicare and Medicaid millions of dollars by avoiding ineffective or less effective devices.

We also support the additional EHR technology capabilities that ONC is considering as part of its 2017 Edition. The additional data fields in EHRs would include the manufacturer's name, brand name, device model, single use indicator, whether the device contains latex or natural rubber, MRI safety status and other information. Adding this information directly to the EHRs will save patients and doctors from having to retrieve the information from external Websites. The additional data will greatly enhance the utility of the UDI for both patients and health care providers. For instance, it could be used to alert doctors of certain device risks such as MRI compatibility or latex allergies.

Conclusion

Many patients use implantable medical devices, and this will increase as baby boomers age and as more patients are eligible for Medicaid or able to afford health insurance. By maintaining accurate records on these devices, we can better assess whether or not the devices are safe and effective. For all of the above reasons, members of the Patient, Consumer, and Public Health Coalition supports the ONC's proposal to create a field in Electronic Health Records (EHRs) to list the unique device identifier (UDI) for patients' implanted devices.

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