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Submitted via regulations.gov

Re: Docket ID: HHS-OS-2014-0002 – Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements.

Thank you for the opportunity to submit comments regarding the proposed voluntary 2015 Edition Electronic Health Record (EHR) certification criteria and topics under consideration for the 2017 Edition. We strongly support the Office of the National Coordinator for Health Information Technology's (ONC's) proposed criterion that would establish a new field in EHRs for the unique device identifier (UDI) of implanted medical devices, such as artificial hips and cardiac stents. Having this information in EHRs would allow hospitals to locate individuals affected by recalled devices, support care coordination among physicians and provide patients with accurate information on the products implanted in their bodies.[1, 2]

The Pew Charitable Trusts is an independent, non-profit research and public policy organization. Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

The Food and Drug Administration (FDA) last September finalized regulations establishing the UDI system, which will provide each device with a code corresponding to its make, model and other clinically relevant information, such as expiration date. Manufacturers are preparing to implement this system, and the highest risk devices will have UDIs starting this fall.

Achieving this system's full benefits requires UDI integration throughout health care delivery, including EHRs.[3] The proposed EHR certification criteria will help accomplish this goal in the following ways:

- *Enhanced recall resolution*: A list in EHRs of implanted devices will help providers identify patients implanted with recalled products and deliver appropriate follow-up care.
- *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 the lot number—of a potentially malfunctioning device.
- *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 need information on the specific device.
- *Patient engagement:* UDIs will provide a clear, accessible source of data on the devices implanted in patients' bodies, enabling individuals to take more active roles in their care.
- *Analyses on device performance*: Increased data on device utilization can support hospital analyses on product performance in their patients. Hospitals could examine outcomes associated with different devices, identify patient subpopulations that respond differently to certain technologies, and better understand data on how physicians use certain products. As efforts progress to extract and aggregate data from multiple EHRs, these analyses will become more sophisticated and will deliver increasingly relevant results.

Mercy, a large multi-state health system, conducted a pilot project integrating cardiac stent device identifiers into electronic data systems. Mercy experienced several benefits, including improved supply chain management and an ability to assess patient outcomes associated with different types of stents (drug-eluting compared to bare-metal).

Specific comments on the proposed 2015 Edition EHR certification criteria

We support the proposed 2015 Edition EHR certification criterion to enable the recording and viewing of the UDIs for patients' implanted devices. We have three suggestions that would improve public health and minimize the burden on EHR vendors and health systems.

- ONC proposes to postpone adding UDI capture via automatic identification and data capture (AIDC) technologies until the 2017 Edition. However, delaying AIDC capabilities until 2017 means that providers would need to enter the UDI into the EHRs manually. Given that the UDI could be several dozen characters long, there is high probability that either: a) providers will choose not to enter the UDI into the EHR, or b) there will be a high error rate associated with recording the UDI (in addition to workflow inefficiencies). Neither of these two possibilities is desirable.

Therefore, ONC should consider requiring that certified EHR technologies have the capability to electronically record the UDI via at least one AIDC technology in the 2015 Edition. While FDA's final UDI rule is technology-neutral, we suspect that standard bar coding capabilities will be among the most prevalent AIDC technologies used. Each EHR vendor should be able to choose which AIDC technology to implement, but ensuring some automatic recording capability is critical to effectively using UDI.

- Generating a list of patients with a particular device is essential to many of the purposes of recording the UDI, including aiding hospitals with recalls and letting facilities perform analyses of device outcomes. The proposed rule, though, does not include this capability in the 2015 Edition and delays it until the 2017 Edition. Given the importance of this feature, ONC should consider requiring this capability in the 2015 Edition. ONC should also clarify that certified EHR technologies should be capable of generating these lists using either the device identifier or the device identifier and production identifier in tandem.

- Finally, the proposed rule does not specify whether the certification criteria would apply to all EHRs or only products used in certain care settings. Given that this proposed certification criteria focuses on implanted devices, ONC should consider whether this proposal should apply to all certified EHRs or only technologies used in hospital and ambulatory care environments. For certified EHR technologies intended for health care settings that do not perform implant procedures, the ability to capture the UDI may be unnecessary at this time.

Specific comments on the topics for consideration for the 2017 Edition EHR certification criteria

While the proposed 2015 Edition certification criteria will establish baseline functionality, we fully expect and support additional capabilities for the 2017 Edition.

- First, we support the proposal to develop dedicated data fields for device attributes and to automatically populate them via an external database. The attributes associated with each UDI—including the manufacturer, brand name, model number, Global Medical Device Nomenclature (GMDN) name, single use indication and MRI safety status—provide critical information on the product for use by both clinicians and patients. Automatic population of these fields from an external database, such as the FDA's Global Unique Device Identifier Database (GUDID), will ensure that this information is accurately incorporated and available to clinicians and patients without requiring them to manually retrieve and enter data. There are several reasons why this functionality is important.

- A clinician treating a complex patient should be able to tell from a quick glance at the EHR the devices that are implanted in a patient. However, if EHRs do not link to any external data sources, the clinician would just be presented with a list of UDIs with no contextual information. The provider would then need to cross reference the GUDID or another database and enter each UDI in order to figure out all of a patient's medical devices.

  As one example of how this functionality is important, consider a physician who would like to order an MRI on a patient with seven implanted devices. The clinician would have to go to GUDID and enter the UDI seven different times to check each one for MRI compatibility if this information was not pulled into the EHR.

  As another example, a patient with multiple medical issues might show up at the emergency room of a medical center where he or she regularly seeks care. If this patient had multiple implanted medical devices, the treating clinician would have to spend precious time figuring out what each UDI represents. Does a particular UDI indicate that the patient has an implanted stent, a cardiac defibrillator or a metal-on-metal hip? The clinician would have to enter each UDI into GUDID to be sure he or she had a complete understanding of the patient's medical history. This function should be automated to ensure that errors are not made and to maximize the clinical benefits of the UDI.

- Similarly, patients should be presented with basic information on their care, including what device was implanted. If EHRs did not link to an external data source, patients could be given the UDI at the time of discharge but it would be difficult to provide more information easily. It is unlikely that most patients would take the extra step of going to GUDID to enter the UDI. In contrast, equipping patients with the name and model of the device as part of a discharge summary—which could be done if the EHR were linked to an external database—would equip them to engage more actively in their care, such as when they experience adverse events or hear about product recalls.

- Additionally, automatically populating these fields from an external data set will help ensure the accuracy of the UDI that is entered into an EHR, especially if the UDI field is populated manually. For example, if the physician implants a hip—but the UDI keyed into the patients' EHR displays information on a cardiac stent—the provider will know that the UDI was incorrectly entered into the patients' record and ensure that the correct information is entered.

- There are hospital-level benefits as well. Downloading these fields into the EHR will allow hospitals to search for all patients with devices in a specific class in order to notify patients affected by class-wide issues. For example, if a hospital wanted to contact all patients who had received a metal-on-metal hip at that facility, it would potentially need to perform searches for many UDIs in order to find all affected patients. However, if the GMDN code—which classifies devices—were available in the EHR, the hospital could search for all patients who had received a device with that GMDN code. Utilizing the GMDN would prevent omissions from failing to search for all the relevant UDIs or incorrectly classifying certain devices within a particular category, such as mis-categorizing a ceramic-on-ceramic hip as a metal-on-metal hip.

This functionality is not a new one; EHRs currently pull data from other third party databases for other purposes. For example, EHRs contain information on pharmaceuticals—typically loaded from third-party databases—on dosing, indications and drug-drug interactions.[4] Parity for devices for automatic population of some data elements—such as the make and model—would prevent errors, increase time for direct patient care and ensure doctors are adequately informed on the devices used by their patients.

- Second, as mentioned previously, integrating automatic UDI capture—such as through bar coding technologies—is essential to ensure the accurate recoding of UDIs, facilitate workflow optimization and support interoperability among the electronic systems within a hospital. We support enabling at least one method of AIDC in the 2015 Edition and additional AIDC capabilities in the 2017 Edition.

- Third, we strongly support the proposed capabilities to ensure that UDIs can be transmitted to reporting systems and registries. These capabilities will enable more accurate adverse event reports, facilitate efficient population of registries, and support other systems that associate patients with specific devices.

- ONC should consider adding two more capabilities for certified EHR technologies.

    - The 2017 Edition should require the capability to automatically alert clinicians in the event of known device risks with MRI compatibility. Upon ordering an MRI, the provider should receive an automated alert if the patient has an MRI-incompatible device. This is another reason why automatic integration of the EHR with the GUDID or another external database to populate device attributes is essential.

- Additionally, ONC should also consider an additional capability to proactively provide patients with information on their device beyond the UDI, make and model. Patients would benefit from accessing educational information, operating instructions and product labels. This could occur by ensuring that EHRs automatically transmit UDI data into patient portals, which could then provide this additional information. This approach is consistent with previous EHR certification criteria that required capabilities for identifying other patient-specific education resources.

Additional federal policies needed

The proposed 2015 and 2017 Edition EHR certification criteria to capture UDIs will greatly support efficient health information exchange to improve patient safety and enhance the quality of care. To ensure that these proposed capabilities are fully utilized, the Meaningful Use program should also include a new objective to encourage hospitals and providers to document UDIs when they implant a medical device in a patient. Therefore, we support the recommendation by the Health Information Technology Policy Committee to create a new Meaningful Use objective to provide incentives for hospitals to capture the UDIs of implanted devices.

Furthermore, UDI capture in EHRs alone is essential, but insufficient to achieve the full benefits of this new UDI system. UDI incorporation in materials management, charge capture, billing and claims systems will support additional benefits, including supply chain efficiencies and the availability of more data on devices to assess quality and reduce costs. Given that UDI integration throughout health care delivery is still in its infancy, ONC should—working with FDA, providers, device manufacturers, distributors, insurance companies and other health care stakeholders—develop a plan to promote the adoption and nationwide exchange of UDI data to improve patient care. In particular, the Centers for Medicare & Medicaid Services, which has access to large amounts of data, should participate in the development of this plan, especially regarding UDI integration into claims. These proposed EHR certification criteria are a positive, critical next step in that plan, but insufficient on their own.

Thank you for your consideration of our comments. Should you have any questions or if we can be of assistance, please contact Josh Rising, director of medical devices at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

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