January 20, 2015

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Burwell,

We are writing to urge you to improve patient safety and care quality for the millions of patients with implanted medical devices—including artificial hips and cardiac stents—by supporting the incorporation of a new medical device tracking system into patients' health records. We are asking that the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS) include provisions to enable and encourage providers to document the specific medical devices implanted in patients as part of forthcoming rules on the electronic health record (EHR) certification and Meaningful Use programs.

Under the Food and Drug Administration's (FDA's) unique device identifier (UDI) system, each medical device will receive a code corresponding to its make and model to unambiguously identify devices used in patient care. FDA issued final regulations establishing the UDI system in 2013. Pursuant to those regulations, manufacturers began labeling all high-risk implantable devices with UDIs in 2014. The system will be phased in gradually and by 2018 all devices will bear a UDI. Once incorporated into patients' health records, the UDI system would:

- *Facilitate recall resolution:* Putting UDIs for implanted devices into EHRs will help providers identify patients implanted with recalled products and deliver appropriate follow-up care, regardless of whether that physician inserted the product.
- *Improve 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.
- *Enhance clinical decision support and care coordination:* The inclusion of UDIs in EHRs will allow providers to make more informed decisions on patient care, especially when patients switch providers or see multiple physicians.
- *Support patient engagement:* UDIs will provide a clear, accessible source of data on the devices implanted in patients, enabling individuals to take more active roles in their care.
- *Enrich analyses on device performance:* Increased data on device utilization can support hospital analyses on product performance in their patients.

EHR Certification Criteria Should Support UDI Capture

Forthcoming rulemaking from the ONC on the next EHR certification criteria—which govern the fields and capabilities of EHRs used across the country—should include a mandatory field to list the UDIs of implanted medical devices.

In addition to creating a mandatory field for UDI, the EHR certification criteria should support other capabilities. First, the criteria should require some form of automatic identification and data capture (AIDC) capabilities, particularly barcoding. Given that the UDI could be several dozen characters long, there is high probability that the lack of AIDC capabilities would result in either: a) providers choosing not to enter the UDI into the EHR, or b) a high error rate associated with the recording the UDI (in addition to workflow inefficiencies).

Second, the certification criteria should allow providers to generate a list of patients with a particular device, thus aiding hospitals with recalls and letting facilities perform analyses of device outcomes.

Third, the certification criteria should ensure that EHRs can use the UDI to automatically obtain additional information on the device from external databases. 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. This information will allow a clinician to tell from a quick glance at the EHR what devices are implanted in a patient to inform clinical decisions, such as whether an implanted device could be contributing to a symptom or whether the patient can undergo an MRI scan. Automatically populating fields in the EHR with this information is essential to making sure that the UDI produces value for clinicians.

Fourth, the certification criteria should enable EHRs to automatically alert clinicians in the event of known device risks. For example, upon ordering an MRI, the provider should receive an automated alert if the patient has an MRI-incompatible device.

ONC already collected public comments as part of its previous rulemaking on some of these capabilities, which will improve safety and the quality of care for patients with implanted devices.

Meaningful Use Should Encourage Providers to Document UDI

In addition to the creation of a field for UDI through the EHR certification criteria program, ONC and CMS must ensure that providers use this field by documenting the identifiers of implanted devices. The creation of a new Meaningful Use objective for UDI capture would provide the needed financial incentives.

Given the recognized value of UDI capture in EHRs, the Health Information Technology Policy Committee—a federal advisory panel to ONC—approved recommendations last year to create a Stage 3 Meaningful Use objective to capture the UDI of implanted devices at the time of implantation. We encourage ONC and CMS to follow this recommendation.

This objective would support several priorities for Meaningful Use Stage 3, including:

- *Better clinical decision support:* The inclusion of UDIs in EHRs will allow both primary care physicians and specialists to make more informed decisions on patient care, such as whether the patient has a recalled technology.

- *Care coordination:* UDI capture in EHRs will enable primary care physicians and specialists to know which devices are implanted in patients, essential to improve care for patients who switch providers or see multiple clinicians.
- *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.

The Meaningful Use program is an appropriate and essential avenue to support the frequent, consistent and accurate documentation of devices used in care, enhancing recall resolution, ensuring more precise adverse event reports and providing primary care providers, specialists and patients with detailed information on implanted products.

Conclusion

The new UDI system will allow physicians and patients to know which devices are implanted and used in care. This new system has the potential to facilitate recalls, improve clinical decision support and enhance the data available on medical device performance. The development of certification criteria and a Meaningful Use objective to support UDI capture are critical next steps to achieve those benefits.

Should you have any questions or if any of our organizations can be of assistance, please contact Josh Rising, Director, Healthcare Programs at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

American Association of Orthopaedic Surgeons
American Joint Replacement Registry
Geisinger Health System
Intermountain Healthcare
Mercy
Pacific Business Group on Health
The Leapfrog Group
The Pew Charitable Trusts
The Society of Thoracic Surgeons
Trust for America's Health

CC:
Margaret Hamburg, Commissioner, Food and Drug Administration
Karen B. DeSalvo, National Coordinator for Health Information Technology and Acting Assistant Secretary for Health, Department of Health and Human Services
Lisa Lewis, Acting National Coordinator for Health Information Technology and ONC Chief Operating Officer
Marilyn Tavenner, Administrator, Centers for Medicare & Medicaid Services