THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700
Philadelphia, PA 19103-7077
215.575.9050 Phone
215.575.4939 Fax

901 E Street NW, 10th Floor
Washington, DC 20004
202.552.2000 Phone
202.552.2299 Fax
www.pewtrusts.org

April 3, 2013

MacKenzie Robertson
FACA Program Lead, Office of Policy and Planning
Office of the National Coordinator for Health Information Technology
Patriots Plaza III
355 E Street, SW
Washington, DC 20201

RE: Pew comments on draft recommendations for meaningful use, Stage 3.

Dear Ms. Robertson:

Thank you for the opportunity to submit comments on preliminary recommendations regarding Stage 3 meaningful use objectives and standards for electronic health records (EHRs). These comments follow our remarks at recent meetings of the Health Information Technology (HIT) Policy Committee and HIT Standards Committee.

The Pew Charitable Trusts is an independent, non-profit organization that applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. The Medical Device Initiative seeks to enhance medical device safety and foster innovation that benefits patients through streamlined device approvals.

Both the HIT Policy and Standards Committees can play critical roles advancing medical device safety by improving postmarket surveillance systems and product recalls through recommendations to enable the capture of unique device identifiers and encourage their adoption for implanted products as a Stage 3 core meaningful use objective.

The Importance of the Unique Device Identification System

Without a tracking system for medical devices, the Food and Drug Administration (FDA), patients, clinicians and manufacturers lack a robust postmarket safety system to quickly identify problems with medical devices and recall harmful technology from the marketplace. In fact, the Government Accountability Office found that 53 percent of medical device recalls conclude without all products either corrected or withdrawn from the market.[1]

To remedy this problem Congress required the FDA to develop a UDI system to track medical devices. The UDI system will be the cornerstone for significant improvements in medical device safety, but only once it is in widespread use by healthcare providers.

The UDI system will benefit patients, clinicians, and public health officials by:

- providing for more rapid identification of medical devices associated with adverse events;
- assisting with prompt and efficient resolution of device recalls;
- delivering an easily accessible source of definitive device identification; and
- increasing health savings through a more accurate accounting of the devices used.

Including UDIs in the EHR will also allow the FDA's postmarket surveillance Sentinel Initiative to evaluate the safety of medical devices once they are approved. By proactively monitoring data from EHRs and other sources rather than relying on spontaneous reporting from manufacturers and health care providers, Sentinel can more systematically identify safety issues. However, without device identifiers to track the products used, Sentinel cannot evaluate patient outcomes following the utilization of specific devices. A UDI system will allow information about specific medical devices to be integrated into patient health records and health insurance claims, two of Sentinel's main data sources.

To realize these important public health goals, healthcare providers and hospitals must incorporate UDI into clinical practice.

Recommendation to HIT Standards Committee

We urge the HIT Standards Committee to recommend that EHRs have a standard method of capturing UDIs in the next standards and certification regulations update. Enabling the capture of UDI will facilitate meaningful use objectives SGRP405 and SGRP408, which encourage the reporting of information from EHRs to registries and the FDA. This new standard should identify a technical specification for UDI data; require that certified EHR technology be able to electronically import, manage, and export the UDI; and mandate that certified EHRs display the UDI and any associated data in a dedicated section of the EHR.

Recommendations to HIT Policy Committee

We encourage the HIT Policy Committee to recommend the capture of UDI in EHRs for implanted devices as a Stage 3 core meaningful use objective. While the UDIs of other devices may also be appropriate for capture in EHRs, implanted products are a clearly identifiable set of technology already associated with significant adverse events and, therefore, capture of their UDIs should be essential.

The Committee should recommend the development of this new Stage 3 core meaningful use objective for eligible hospitals and providers under the "Improving quality, safety, and reducing health disparities" section to be satisfied by "the incorporation of the UDI into EHRs for patients whose care involves an implanted medical device."

Aside from developing meaningful use criteria to incentivize UDI capture, we also urge the HIT Policy Committee to recommend that any proposed objective to electronically transmit adverse event reports to the FDA be included in Stage 3 and not in a future stage. This objective should also clarify that adverse event reports include the UDI of the associated medical device.

Conclusion

These committees can begin signaling to CMS, ONC, providers, and patients the importance of UDI adoption by recommending the appropriate EHR standards revisions and Stage 3 core meaningful use criteria to incentivize UDI capture for implanted devices—two critical steps to facilitate device postmarket surveillance, improve recalls, and increase health savings. Through those recommendations, these committees can help advance patient safety through effective and valuable use of the medical device HIT infrastructure.

Thank you for considering our comments. Should you have any questions, please refer to our comments submitted to the public docket or contact Josh Rising, director of the Medical Device Initiative at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

Josh Rising, MD
Director, Medical Device Initiative
The Pew Charitable Trusts

[1] U.S. Government Accountability Office (June 2011). Medical Devices: FDA Should Enhance Its Oversight of Recalls (Publication No. GAO-11-468).