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June 14, 2013

Sylvia Mathews Burwell
Director
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

RE: Release of the Unique Device Identifier Final Rule.

Dear Ms. Burwell:

We write to urge the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) to speedily complete review of regulations to develop a unique device identifier (UDI) system. When fully implemented, this system will help realize significant improvements to patient care.

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.

Congress first enacted legislation in 2007 to instruct the U.S. Food and Drug Administration (FDA) to promulgate regulations implementing a UDI system. Several years later in 2012, Congress passed the Food and Drug Administration Safety and Innovation Act (FDASIA), which required the agency to finalize UDI regulations within six months of closing the comments period.

The FDA closed the comments period for the proposed rule on November 7, and then closed the comments period for an amendment to the draft regulations on December 19. As we approach six months from the latest of those two dates, it is incumbent on the administration to promptly finalize the UDI rule. Given that OMB review of the UDI proposed rule lasted for approximately a full year, we have serious concerns that additional delays will postpone the benefits of a device identification system.

Once implemented by the FDA and utilized by healthcare providers, the UDI system will be the cornerstone for significant improvements in postmarket surveillance of medical devices. As laid out by the FDA in the proposed rule, the UDI system will benefit patients and public health by providing for faster identification of medical devices associated with adverse events and assisting with more rapid and efficient resolution of device recalls.

To realize those benefits, clinicians, hospitals, payers and others must adopt UDI into clinical practice. According to the FDA's recent update to the medical device postmarket surveillance strategy, "Strengthening Our National System for Medical Device Postmarket Surveillance", the inclusion of UDIs in electronic health records and claims data will enable critical device monitoring capabilities. The FDA states in that report:

> UDI will significantly enhance postmarket surveillance activities by providing a standard and unambiguous way to document device use in electronic health records, clinical information systems, claims data sources, and registries, potentially making vast amounts of previously untapped clinical information available for assessing the benefits and risks of medical devices and more meaningfully and efficiently linking data sources (like registries and claims data).

We agree with the FDA that UDI incorporation in electronic health records and claims data will generate significant improvements to postmarket surveillance and, ultimately, patient safety. To that end, we have urged advisory committees to the Office of the National Coordinator for Health Information Technology (ONC) to recommend the capture of UDIs for implanted devices as a Stage 3 core objective for the meaningful use of electronic health records. We have also urged those advisory panels to revise the certification standards for electronic health records to support UDI capture. The Centers for Medicare & Medicaid Services (CMS) and ONC intend to propose updates in these areas early next year. It will be difficult for them to include UDI in these updates unless the final rule is released in a timely fashion.

Until the administration issues a final rule, the FDA, manufacturers, doctors and patients will not have a robust device identification system to improve adverse event reports, better track patient outcomes and enable faster and more complete recalls. Therefore, we strongly urge the administration to expedite the finalization of the UDI rule.

Should you have any questions or if we can be of assistance to help realize the important benefits of UDIs, please contact Josh Rising, director of medical devices, 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