July 8, 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 are writing to urge you to finalize U.S. Food and Drug Administration (FDA) regulations establishing a device identification system. This unique device identifier (UDI) system will serve as the cornerstone to improving medical device safety and quality. Section 614 of the Food and Drug Administration Safety and Innovation Act mandated that the administration finalize the UDI regulations by June 19. Further delay will impair the FDA's ability to conduct important safety surveillance of medical devices to improve patient safety and the quality of 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.

Premier is the nation's largest performance improvement alliance of more than 2,800 hospitals and 95,000 alternate sites using the power of collaboration and technology to lead the transformation to coordinated, high-quality, cost-effective care. Owned by healthcare providers, Premier is a world leader in measurably improving patient care through the nation's largest performance improvement collaboratives, including one in partnership with the Centers for Medicare & Medicaid Services.

Recent recalls and failures of medical devices—including metal-on-metal hips and cardiac defibrillator leads—clearly demonstrate the need to more quickly identify problematic products before they are used in hundreds of thousands of U.S. patients. Additionally, the Government Accountability Office found that more than half of medical device recalls conclude without the correction or removal from the market of all defective products.

Improved device identification will help address these deficiencies and realize significant benefits to patient care. Through the UDI system, medical device packaging—and, when applicable, the device itself—will bear a code corresponding to the product make and model as well as other relevant information, such as expiration date and lot number. The UDI system will ensure more accurate adverse event reporting, enable improved evaluations of marketed devices, reduce medical errors through improved device identification, decrease healthcare supply chain costs, and facilitate more comprehensive recall resolution.

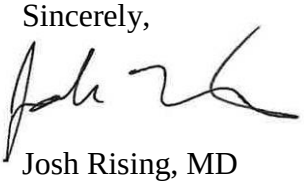
To achieve the benefits of the UDI system, the administration must first promptly finalize the UDI rule. The FDA has sought use of the UDI for well over a decade, and Congress instructed the FDA in 2007 to develop a medical device identification system to track products through their distribution and use. In 2012 Congress again mandated the development of the UDI system, this time requiring a final UDI rule within six months of closing the comments period on the proposed rule—that is, by June 19, 2013.

The FDA has identified UDI as a central component to the national medical device postmarket safety plan, which committed the agency to release the UDI regulations by the end of June. Furthermore, the final UDI rule is essential in order for the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services to consider the capture of device identifiers into the next updates to electronic health record standards and meaningful use criteria. The agencies intend to commence rulemaking next year on these topics based on input from federal advisory committees, which are already compiling recommendations and have begun discussions on UDI.

Given the importance of this new device identification system to improve patient care and the missed statutory deadline, we strongly urge you to promptly complete review of the UDI final rule. This will clear the way for the FDA to begin implementing this new device identification system and achieving its significant benefits to physicians, health systems, manufacturers and—most importantly—patients.

Should you have any questions or if we can be of assistance to help realize the important benefits of the UDI system, please contact Josh Rising, director of medical devices at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org or Blair Childs, senior vice president at the Premier healthcare alliance, at 202-879-8009 or blair_childs@premierinc.com.

Sincerely,



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