September 6, 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 Director Burwell:

We are writing to strongly urge you to promptly complete review of unique device identifier (UDI) regulations developed by the U.S. Food and Drug Administration (FDA). Once established and adopted into clinical practice, this UDI system will serve as the foundation to improvements in medical device safety, enhanced care quality and supply chain efficiencies. The Food and Drug Administration Safety and Innovation Act required that the administration finalize UDI regulations by June 19. Further delays finalizing the UDI rule will only postpone the significant benefits to patients and health systems afforded through UDI implementation.

In 2010, five healthcare systems—Geisinger Health System, Intermountain Healthcare, Kaiser Permanente, Mayo Clinic and Mercy—formed an action-oriented collaboration to share best practices and drive needed positive change across the healthcare supply chain. The collaboration, called the Healthcare Transformation Group (HTG), evolved as an extension of each member's involvement in healthcare's movement toward standards adoption. HTG members share this common foundation: accelerate change across the supply chain, enhance patient safety, improve supply chain efficiencies, drive the adoption of GS1 Standards with suppliers, and communicate in the marketplace through one voice.

We fully support release of the UDI regulations, and expect to promptly incorporate this new device identification system into a number of key processes. The HTG Research and Development Team will be working to establish a standard language and network of data sets within our healthcare systems. The project, which is an expansion of a UDI demonstration project currently underway with the FDA, will eventually provide a pathway to integrate UDI into each HTG healthcare system's clinical processes.

Through UDI implementation and incorporation into electronic health information, the UDI system will enable the tracking of medical devices through their distribution and use; create data sets for research and safety surveillance; support comparative effectiveness research; facilitate better management of product recalls; and help generate health system savings. The UDI rule's finalization is the first step to achieving these benefits and must promptly occur in time for the next updates to electronic health records standards and policies.

Should you have any questions or if we can be of assistance to help realize the important benefits of the UDI system, please contact me at (626) 405-6700 or via email at Laurel.L.Junk@kp.org.

Sincerely,

Healthcare Transformation Group

Laurel Junk

Chair, Healthcare Transformation Group

Vice President Supply Chain, Kaiser Permanente

Healthcare Transformation Executive Committee:

Deborah Templeton
Chief, Care Support Services
Geisinger Health System

Gene Kirstner
President, ROi
Mercy

James Francis
Chair, Supply Chain Management
Mayo Clinic

Brent Johnson
Vice President, Supply Chain and Support Services
Intermountain Healthcare

Dr. Joseph Drozda
Chair, HTG Research & Development Team
Mercy