

**Congress of the United States**  
**Washington, DC 20515**

September 12, 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:

As members of the New Democrat Coalition, we are writing to obtain a status update on U.S. Food and Drug Administration (FDA) final regulations establishing a unique device identifier (UDI) system. Despite the Office of Management and Budget's receipt of the UDI proposed rule more than three months ago on June 11, 2013, the administration has not yet finalized the regulations.

The New Democrat Health Care Task Force is committed to harnessing technological, scientific, and medical innovations to achieve the promise of a 21st century health care system. Once fully implemented, the UDI system will serve as the cornerstone to improved safety and patient outcomes by improving adverse event reporting, facilitating product recalls, and enabling more sophisticated postmarket surveillance.


We are disappointed that the administration has missed the statutory deadline established by the Food and Drug Administration Safety and Innovation Act to promptly finalize the regulations. We are especially concerned with this delay given that the proposed UDI regulations were under OMB review for approximately a full year.

Prompt finalization of UDI regulations is the critical first step to achieving the system's full benefits. As articulated by the FDA, incorporating UDI into electronic health information—such as patients' medical records and insurance claims forms—is an essential next step, but that cannot occur until the administration finalizes the UDI rule.

The UDI system will significantly advance the safety and quality of care for Americans who rely on medical devices. With each passing day, delays implementing and adopting the UDI system throughout health care delivery only prolong the realization of these essential benefits for patients across the country.

We look forward to an update from your office and for the prompt finalization of UDI regulations. Thank you for your attention to this matter.

Sincerely,

  
Allyson Y. Schwartz

  
Ron Kind

  
Bill Owens

  
Kurt Schrader