February 4, 2013

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National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, DC 20201

RE: Health Information Technology Patient Safety Action & Surveillance Plan for Public Comment

We write on behalf of the American College of Cardiology, Consumers Union, the National Women's Health Network, the National Research Center for Women and Families, the Trust for America's Health, and The Pew Charitable Trusts.

We appreciate the importance of the two patient safety objectives laid out in the document: 1) Use Health IT to make care safer, and 2) Continuously improve the safety of Health IT. Unfortunately, the plan does not outline specific strategies and actions that the government intends to take for the first of these objectives. **We urge the Office of the National Coordinator for Health Information Technology (ONC) to expand the next version of the plan to include strategies and actions to use Health IT to make care safer**.

In particular, we believe that the ONC should address the potential for the unique device identification (UDI) system for medical devices to improve the safety of medical care. The FDA has issued a proposed rule that would require manufacturers of medical devices, with certain exceptions, to place a unique identifier on the label of medical devices. Some medical devices would also need to be directly marked with the unique identifier.

When the UDI system is implemented by manufacturers and fully taken up by the healthcare system, it has the potential to improve safety in a number of ways:

1) *Facilitation of recalls of medical devices*. Currently, it can be difficult for manufacturers and healthcare facilities to identify patients with an implanted medical device that has been recalled or to locate unused recalled devices. Incorporation of the UDI into the electronic health record and electronic inventory management systems will result in more rapid and precise identification of recalled products, resulting in safety improvements. In addition, the UDI would allow the FDA to include more specificity in public safety alerts about the particular device that is the subject to the recall.

2) *Improved adverse event reporting.* Adverse event reports are an important way to bring devices with potential safety problems to the FDA's attention. Unfortunately, it can be difficult for the FDA to utilize these reports because they often lack specificity about which device was associated with the adverse event. The presence of the UDI on medical devices and their labels will go far in addressing this problem.

3) *Identification of medical devices with safety problems through active surveillance*. The presence of a UDI in electronic health records and other forms of electronic data, such as medical claims, will facilitate robust postmarketing surveillance efforts, such as registries and FDA's Sentinel system. The FDA, clinicians, patients and manufacturers can use the information generated in postmarketing surveillance initiatives to identify devices with safety problems and take appropriate action.

We encourage the Department to facilitate adoption of the UDI throughout the healthcare system by: 1) including a UDI field as a certification standard for electronic health records, and 2) establishing a new Stage 3 meaningful use core

objective to incorporate the UDI into electronic health records for patients whose care involves an implanted medical device.

Thank you for your consideration of our comments. Should you have any questions, please contact Josh Rising at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

The Pew Charitable Trusts

American College of Cardiology

Consumers Union

National Research Center for Women and Families

National Women's Health Network

Trust for America's Health