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POLICY & ACTION FROM CONSUMER REPORTS

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Submitted electronically
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National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue SW, Suite 729D
Washington, D.C. 20201

RE: Consumers Union's Comments on Proposed Rulemaking – RIN 0991-AB93-2015 Edition Health Information Technology Certification Criteria

Dear Dr. DeSalvo:

Consumers Union, the policy and advocacy division of Consumer Reports, appreciates the opportunity to provide input on the 2015 Edition Health Information Technology Certification Criteria. Health information technology (health IT) has a great potential for improving patient safety on both the individual and greater community levels. Although this proposed regulation touches upon many aspects of health IT, our comments here are limited to § 170.315(a)(20)— Implantable Device List.

We strongly support the capture and exchange of an implantable device list through the Common Clinical Data Set as the first step toward using health IT to track device implantation and outcomes, enhance patient knowledge and use of implanted devices, facilitate device recalls, prevent device-related adverse events, and improve patient safety. This new criterion strengthens patients' access to information about what devices are in their bodies, makes it easier to share that information with the patients' various healthcare providers, and enables consumers and providers to be vigilant to alerts and recalls for the duration of their device. Indeed, at some point this capability might be coupled with a national implantable device registry.

ONC does not propose at this time to include automatic identification and data capture (AIDC) technology to record the unique device identifier (UDI). The fact remains that such technology would prevent human error in typing lengthy serial numbers, etc.— the very type of medical error that UDIs and implantable device lists are intended to prevent. In contrast, the FDC recently established a system that requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. Given that companies are now required to have this by one agency, it is seems logical that ONC should incorporate

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this kind of capability as well. We also urge ONC to consider how best to access and integrate other important data beyond the "Device Description." As ONC notes, access to information such as MRI-compatibility and latex content at the point of care is likewise important and can prevent adverse medical errors and events.

Thank you once again for this opportunity to provide input to ONC's proposed 2015 Edition Health Information Technology Criteria and the significant role they can play in improving patient safety and health outcomes as part of an upgraded system of healthcare delivery.

Sincerely,

Dena B. Mendelsohn, JD, MPH
Health Policy Analyst