AHRMM
Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain
A personal membership group of the American Hospital Association

CQO: The Future of Healthcare Supply Chain

April 25, 2014

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building
Suite 729D
2000 Independence Ave., SW
Washington, DC 20201

Attention: 2015 Edition EHR Standards and Certification Criteria, Proposed Rule; 79 Federal Register Notice 10880 (Feb. 26, 2014)

Dear Coordinator:

The Association for Healthcare Resource & Materials Management (AHRMM) is pleased to submit for your consideration our comments on 2015 Edition proposed rulemaking by the Office of the National Coordinator for Health Information Technology ("ONC Proposed Rule").

I. Background on AHRMM

The Association for Healthcare Resource & Materials Management (AHRMM) is the leading national association for executives in the healthcare supply chain profession. A personal membership group of the American Hospital Association, AHRMM serves more than 4,300 active members by preparing them to contribute to the field and advance the profession through networking, education, recognition, and advocacy. In 2013 AHRMM launched the Cost, Quality, and Outcomes (CQO) Movement promoting a more holistic view of the correlation between **C**ost (expenditures as they relate to supplies, services, and other areas in supply chain control [Total Cost of Ownership – TCO] as well as the total cost of care), **Q**uality (patient-centered care aimed at achieving the best possible clinical outcomes), and **O**utcomes (financial reimbursement driven by outstanding clinical care at the appropriate costs) as opposed to viewing each independently. AHRMM has developed a first-of-its-kind training and educational framework to support the CQO Movement and equip health care supply chain professionals with the skills and expertise they will need to master the intersection of cost, quality, and outcomes. For additional information about AHRMM, please visit our web site at http://www.ahrmm.org/

The comments below do not address the introduction of a voluntary certification process of EHRs or the several questions presented for public response, but are narrowly tailored to comment on one issue raised within the NPRM, specifically the role of certified EHRs in the capture of the information from the unique device identifier (UDI). The comments below were prepared by an AHRMM appointed committee convened to respond to the ONC Proposed Rule. These comments have been approved by the Board but do not necessarily represent the opinions of individual AHRMM members.

II. The FDA's UDI Rule

A. The Benefits of UDI

We commend the ONC for their wise approach to ensure that technology platforms, e.g., electronic health records, can capture the UDI documentation. . We certainly appreciate and value the potential for UDI data to reduce medical errors, promote patient safety and facilitate effective recalls. .Because implantable devices are among the highest risk and expense and will be among the first to carry the UDIs, we believe the most immediate and potentially greatest benefit from UDIs will occur in the OR and Cath Lab settings in the hospital. To promote safe and efficient use of a UDI, we recommend that the EHR have the capacity to support the capture of the UDI information based upon the auto identification and data capture (AIDC) technology used by the labeler. An EHR user should not be able to manually record the UDI. Given the lengthy alphanumeric symbol that will comprise the UDI, user entered UDI information will increase the risk of harm due to inaccurate capture of the UDI.

The FDA's UDI rule (78 FR 58786; Sept. 24, 2013) represents a major development in the use of standardized data to identify and track medical devices. AHRMM has strongly supported the FDA's rule because it has the potential to result in several benefits for the health care industry: faster and more effective adverse event reporting and recall management, better demand and consumption data for inventory management, more reliable and useful data for comparative effectiveness research, and increased efficiency in transactions in the health care supply chain.

B. The Pace of UDI Adoption by Providers

Much of the ONC and FDA's vision to realize the value of unique device identification will depend upon the ability of hospitals and healthcare systems to capture the UDI with auto identification and data capture (AIDC) technology for documentation in electronic health records. However financial constraints will make it difficult for these organizations to invest in more sophisticated scanning technology that will read the variety of AIDC carriers allowed in the FDA UDI rule. Just as the federal government has provided incentives for hospitals to adopt certified EHR technology, we recommend the consideration of policy changes that could help create incentives for faster adoption of more sophisticated AIDC technologies.

C. UDI Requirements for the 2017 Edition – Record a minimum set of data elements

In regard to your question about including additional data elements in the EHR (see 79 FR at 10895), many of the data elements you are considering will already be contained in the publicly available GUDID, established as part of the FDA's UDI rule. Thus, we encourage you to facilitate data exchange that enables providers to link to the GUDID database to obtain these data elements in order to achieve the same purpose. Unnecessary or duplicative data capture by providers and clinical staff increases workload and the opportunity for data inconsistencies.

The Association for Healthcare Resource & Materials Management (AHRMM) wishes to thank you for the consideration of these views. If we can provide any further clarifications or answer any questions, please do not hesitate to contact us.

Sincerely,

Deborah Sprindzunas
Executive Director
Association for Healthcare Resource & Materials Management (AHRMM)

cc: AHA
AHRMM Board of Directors