Strategic Marketplace Initiative

Shaping the Future of the Healthcare Supply Chain

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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 Strategic Marketplace Initiative (SMI) 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 SMI

SMI is a non-profit, member-driven organization dedicated to improving the healthcare supply chain. Since our formation in 2006, SMI has delivered on our mission through direct information exchange and collaboration between senior healthcare supply chain executives from integrated provider organizations and senior supply chain executives from supplier and service provider organizations. SMI members include healthcare providers, academic medical centers, medical manufacturers, medical distributors, and other healthcare supply chain businesses. Created to influence, shape and advance the future of the healthcare marketplace, SMI provides an open forum for innovative idea-exchange and the development of collaborative process improvement initiatives. SMI members and staff have actively supported the industry's development of supply chain data standards to improve patient safety and to foster improvements in the supply chain. The attachment to this letter includes a list of SMI's members. For additional information about SMI, please visit our web site at **www.smisupplychain.com**

The comments below were prepared by an SMI Board-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 SMI members.

II. The FDA's UDI Rule

A. The Benefits of 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. SMI 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. The benefits to the healthcare system discussed in the ONC Proposed Rule do not expressly refer to lowering supply chain costs. (See 79 FR at 10894-5.) However, the reference to "public health benefits" is broad enough to encompass this goal. In any event, we urge the ONC to consider increased efficiency and lower health care costs in its analysis.

We certainly appreciate and value the potential for UDI data to reduce medical errors, promote patient safety and facilitate effective recalls. As an association of supply chain executives, we have an expanded focus on increased efficiency and reduction of health care costs and we confine our comments below to these considerations.

B. The Pace of UDI Adoption by Providers

Like many others involved in the supply chain, we are concerned that the implementation of UDI technology will be slow and limited. This concern is based on a number of factors. First, the FDA's Rule provides for a very lengthy timeframe in requiring the use of UDIs. The Rule is phased in over several years, with the final requirement applicable only in 2020. Second, because the FDA's rule only applies to labelers, e.g., manufacturers, there is no requirement for health care providers to implement technology to use UDI data. Third, the FDA did not mandate labelers use a particular auto identification and data capture system, e.g., linear barcode, 2D/data matrix barcode, RFID, etc. Thus, even for those providers who are contemplating adoption, there is uncertainty about what system their suppliers will use or what kind of technology they would need to electronically capture the UDI data. Finally, many providers may not be aware of the long-term usefulness of UDI data in managing population health. SMI believes that, over time, the benefits of UDI information will become more evident, but in the meantime, this lack of awareness about the value of the information will likely further delay their investment in UDI technology. Consequently, we are very pleased with the ONC's continued efforts to improve technological capabilities to meet meaningful use requirements, which in turn will create incentives for providers to adopt technology that supports UDI. SMI believes that these efforts by ONC will accomplish a number of objectives, including expediting UDI adoption by providers.

III. Support for ONC Proposal for 2015 Edition

We understand that the criteria included in the ONC Proposed Rule are voluntary. Nevertheless, we believe that the criteria will, at the very least, generate serious consideration by vendors of EHR technology and encourage their use and adoption by these vendors as well as the health care providers who purchase their technology. Consequently, we strongly support the Proposed Rule. Our comments address some of the specific points raised by the ONC and suggest some modifications in the proposal.

IV. Limiting 2015 Edition Proposal to Implants

The ONC Proposed Rule for the 2015 Edition is limited to implants. See Id. at 10894. This provision should be considered in the context of the FDA's UDI rule, which provides that labelers are required to include UDI data in the label for all Class III devices by September 14, 2014, and all other "implantable, life-supporting, or life-sustaining devices" by September 24, 2015. This broader category of devices includes devices implanted in the body and a broad range of other devices that are used in hospitals and clinics. The practical effect of this provision will be that thousands of products beyond implants will include UDI data on their labels by 2015.

In our view, expanding the capacity of vendor software to include life-supporting and life-sustaining devices will not require a significant modification or additional investment for vendors that meet the ONC's proposed 2015 criteria. By extending the 2015 criteria to include these devices, providers will have access to software that substantially expands their capacity to track thousands of devices. In turn, they will have the incentive to move toward more rapid and comprehensive adoption of UDI technology in their internal inventory identification and tracking systems. If the ONC decides not to extend this provision in the 2015 edition, we encourage you to incorporate it in the 2017 edition.

V. Scope of 2017 Edition

We support much of the additional UDI-related functionality you are considering for the 2017 edition, which is described at 79 FR 10895. In particular, we believe it is important for the industry to move toward more comprehensive use of automatic identification and data capture (AIDC) technology, including technology that can read both linear and 2D/data matrix bar codes.

Consequently, SMI supports including this requirement in the 2017 Edition. Using barcodes and barcode readers has become commonplace in many industries. One of the great ironies of our healthcare system is that, while it utilizes the world's most advanced technology for treating patients, the technology used to identify and track devices in a modern hospital is usually less advanced than that of the local convenience store across the street.

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 promote technology 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 increases workload and the opportunity for data inconsistencies.

VI. Issues for Subsequent Rulemaking

ONC asked for comments on other standards, capabilities and certification criteria that it did not specifically identify. Id. at 10895-6. In our view, it would be desirable for the ONC to set out a general framework for rulemaking that aligns with the timetable for full implementation of the FDA's UDI Rule. (See the timetable for compliance with the FDA's Rule at 78 FR 58816.) We are not suggesting that the ONC not necessarily include each of the scheduled compliance dates, which extend to 2020, in a single proposed rule. However, by indicating that the ONC is considering a framework for future rulemaking that aligns with the FDA rule's schedule, ONC would encourage providers to begin to plan for more comprehensive adoption of UDI technology.

VII. 2D Barcoding

The ONC asked for comment on whether the 2017 Edition should include criteria requiring EHR systems to "consume 2D barcodes and for what functions." 79 FR at 10928. Based on our discussions with manufacturers, we believe that there can be significant challenges to including all required UDI data in a linear barcode due to space limitations, at least in the case of some labels and devices. Moreover, we believe that experience with UDI technology may convince policymakers and industry participants that additional data should be included in a standard UDI label or linked databases. 2D barcoding has the advantage that it enables capture of more data in a smaller space on a device or label. Consequently, we support including criteria in the 2017 Edition that requires software vendors to handle both formats.

The Strategic Marketplace Initiative (SMI) 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,

Thomas W. Hughes
Executive Director
Strategic Marketplace Initiative (SMI)

cc: SMI Board of Directors
SMI Advocacy Committee

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