February 15, 2018

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20001

RE: Draft U.S. Core Data for Interoperability

Dear Dr. Rucker:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to respond to the draft U.S. Core Data for Interoperability (USCDI) released Jan. 5 by the Office of the National Coordinator for Health Information Technology (ONC). This letter also includes our comments on the exchange of data from prescription drug monitoring programs (PDMPs).

As outlined in our separate letter, the AHA supports the advancement of the Trusted Exchange Framework and Common Agreement (TEFCA) to build more efficient and effective infrastructure for health information exchange by hospitals and health systems that builds on existing efforts. Equally important to reducing the burden associated with health information exchange is the development of a process to identify the data that, when available, are required to be exchanged. The qualified health information exchange networks (QHINs) that facilitate health information exchange under the TEFCA and their participants must be capable of exchanging the USCDI when the data are available.

The USCDI proposes data elements or data classes that would be exchanged and proposes a process to identify and prioritize the data exchanged beginning in 2018. Specifically, ONC proposes to revise the common clinical data set (CCDS) that was established in the 2015 Edition certified electronic health records (EHRs) program and is to be electronically exchanged in programs such as the Merit-based Incentive Payment System program and Medicare EHR Incentive Program once 2015 Edition certified EHRs are widely available in the market and

deployed by hospitals, health systems and other providers. The USCDI would redefine the health data required to be electronically exchanged in 2018, establish a process by which data are considered ready for exchange in future years and generally set a yearly timeframe for increasing data exchange requirements.

AHA recommends that ONC include additional criteria to assess whether a data class is ready for USCDI inclusion; provide flexibility in determining the prioritization and advancement of data classes; and eliminate the automatic link between annual data class updates and requirements for data classes to be included in health information.

CRITERIA FOR READINESS

The ability of hospitals and eligible professionals to exchange data classes easily and efficiently must be assessed before exchange is required in the USCDI – a step that is missing in the current proposal. The ONC certification program for EHRs incorporates a set of standards in EHRs through certification criteria. Since the launch of the certification criteria in 2011, new standards and draft standards for trial use have been included in EHRs that hospitals and eligible providers have been required to use in order to meet regulatory requirements. Based on experience in the current program, the lack of adherence to constrained interpretations of standards has resulted in variation among EHR vendors and difficulties for hospitals and eligible clinicians attempting to exchange health information. To address this challenge, the USCDI proposal states that multi-stakeholder agreement on technical specifications is necessary to make possible the exchange of a data class. It also states that data classes that are next in line for inclusion in the USCDI must be clearly defined and have proven real-world applicability across a broad and diverse array of use cases. However, the USCDI process outlined by ONC does not reference any change in the testing of certified EHRs commensurate with the increased data that is expected to be exchanged. Greater testing under real-world conditions will be needed to provide confidence that the certified EHRs adhere to the agreed-upon interpretation of the standards and support the increased information exchange required by the USCDI.

AHA recommends that ONC provide funding for the development of the standards underlying the proposed data classes. Additionally, we recommend ONC test the exchange of the data classes in widespread pilots. ONC also should revise the test criteria for certified EHRs to include testing that explicitly validates their readiness to support the exchange of the USCDI.

TIMELINE FOR ADDING NEW DATA CLASSES

ONC proposes that the USCDI expand on an annual basis through an open and transparent process for consideration of new data classes. ONC generally expects a two- to three-year period for multi-stakeholder development of technical specifications will be sufficient to move a data class from being under consideration to being ready for inclusion in the USCDI. This timeline suggests a standards life cycle where hospitals and health systems are exclusively adding technology functionality to meet annually updated requirements. In reality, as standards are developed, tested, evaluated and then implemented in technology, the technology that supports the standards also has a life cycle. Experience to date indicates that it takes 19-24 months for

hospitals and health systems to implement safely new certified EHR technology. At the same time, hospitals and health systems evaluate, maintain and remove other technologies in their environment. As a result, the concept of an annual technology process that includes only additions and does not consider testing, evaluation and removal of technology is unrealistic. In addition, not all data classes will require equal time for development. It is possible that two years will be sufficient time for some data classes but too little for others. For example, the newly designated clinical notes data class may require agreement on factors other than the simple identification of data types in order to support the ability of the sender and receiver to have the same understanding of the information shared (semantic interoperability). The same challenge of ensuring that the meaning is conveyed also may apply to data classes currently included in the CCDS but not supported by standards, such as laboratory values/results, unique device identifiers or care team members.

AHA recommends that ONC revise the proposed timeline to permit providers and vendors to undertake the work needed to develop and mature standards that support accurate and useful information exchange.

LINKAGE TO REQUIRED USE IN EXCHANGE

ONC proposes to include the data classes identified for inclusion of the launch of the USCDI in exchange beginning in 2018. Currently, the majority of hospitals and eligible clinicians are not exchanging the CCDS that the proposed USCDI would replace. Rather, hospitals and eligible clinicians are exchanging the meaningful use data set to support health information exchange pending the widespread availability of 2015 edition EHRs necessary to exchange the CCDS. While the edition of certified EHRs that supports CCDS exchange is implemented by hospitals and health systems, **AHA recommends that ONC reconsider the data classes in the context of their clinical priority and expected difficulty. AHA also recommends that any requirement that hospitals and eligible clinicians exchange the USCDI in 2018 be suspended until the overwhelming majority of hospitals and eligible clinicians have adopted 2015 edition EHRs and the results of the pilot testing of the initial USCDI are evaluated and shared broadly**.

Finally, accurate patient identification is a high priority to ensure that the health information exchanged also supports safe patient care. While the proposed USCDI references the connection between data classes and standards and the TEFCA, the proposed USCDI does not reference a solution, framework and principles for accurate patient identification that must accompany the proposed increase in health information exchange.

PRESCRIPTION DRUG MONITORING PROGRAMS

AHA applauds ONC for raising the issue of information exchange readiness to provide insights and assistance in the opioid crisis. State PDMPs, EHRs and pharmacy systems contain important heath data located in disparate technology systems. Currently, standards-enabled integration among these systems vary. In some instances, state health information exchanges (HIEs) provide the connection between the state PDMPs and the EHR within the clinical workflow, but this functionality is not widely available. Where this is not available, clinicians may be able to access

the state PDMP from their EHR or they may be required to log into a PDMP portal for query or reporting of opioid prescriptions in a screen separate from the clinical workflow in their EHR. The AHA supports the work by state PDMPs to agree upon a common standard for retrieval and reporting of data to PDMPs. Through the National Association of Boards of Pharmacy, an interstate data-sharing infrastructure has been developed. This existing interstate data-sharing hub currently serves 37 states to securely share PDMP data.

AHA recommends that ONC work with the state PDMPs on standards that enable the PDMPs and HIEs to utilize agreed upon standards to facilitate effective and efficient information exchange. AHA also recommends that ONC work with pharmacy networks, state HIEs, EHR vendors and the Drug Enforcement Administration (DEA)-recognized bodies that verify and certify compliance with DEA electronic prescribing requirements to continue efforts to overcome barriers to information exchange.

Thank you for the opportunity to comment on the USCDI. If you have any questions, please do not hesitate to contact me or have a member of your team contact Diane Jones, senior associate director of policy, at djones@aha.org or 202-626-2305.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy