The American Medical Association (AMA) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology (ONC) proposed draft of the U.S. Core Data for Interoperability (USCDI) and proposed expansion process. The AMA supports ONC's efforts to improve the exchange and use of patient data. Physicians and patients have an expectation that all of a patient's health information stored electronically should be able to be exchanged in a trusted and safe manner. Expanding data classes, at the appropriate pace, is a necessary step in bolstering the availability of information to provide better, more effective patient care.

USCDI Principles

As outlined in separate comments, the AMA supports the advancement of the Trusted Exchange Framework and Common Agreement (TEFCA) to build more efficient and effective infrastructure for health information exchange built 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 USCDI would redefine the health data required to be electronically exchanged 12 months after the new data classes have been officially added, 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.

However, systems today are unable to reliably and completely exchange clinically meaningful and essential information. Despite the large amounts of health data being gathered, data are not always meaningful, organized, or structured in a way that can easily be used, accessed, or shared by people and systems. ONC proposes to revise the common clinical data set (CCDS) managed by 2015 Edition certified electronic health records (EHR) and primarily used to participate in the Centers for Medicare and Medicaid Services' (CMS) Merit-based Incentive Payment System (MIPS) and Meaningful Use (MU) programs.

As a set of guiding principles, the AMA 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; consider the physician burden for capturing new data elements; and eliminate the automatic link between annual data class updates and requirements for data classes to be included in the TEFCA.

Review of industry readiness

The primary model for health information technology (health IT) today is regulatory-centric, deployed around narrow federal reporting program requirements, rather than the promotion and maintenance of patient health and wellness. This is a result of a confluence of well-intended actions based on assumption, rather than evidence. MU program design decisions, for instance, were driven by aspirations and haste without first establishing need. The AMA recognizes that

ONC has, however, created a USCDI Task Force as part of the newly-formed Health Information Technology Advisory Committee (HITAC). We strongly agree with this decision. Ensuring a successful phased-in approach for new health data classes will require a concerted effort by a wide-range of stakeholders. It will also be crucial that ONC collect real-world evidence on the issues, gaps, and utility of current CCDS implementation to inform a robust USCDI process.

The AMA recommends that ONC appoint to its USCDI Task Force individuals that have data system implementation, clinical, quality measure development, and informatics experience. The initial charge of the Task Force should be to survey the use of CCDS data elements and generate a status report addressing the collection, exchange, and use of these data elements, as well as to explore whether there is industry consensus on the representation of these data.

Health IT testing

The ability of physicians to exchange data classes easily and efficiently must be assessed before the exchange is required by the USCDI—a step that is missing in the current proposal. The ONC certification program incorporates a set of standards in EHRs. Since the launch of the certification criteria in 2011, new standards and draft standards for trial use have been included in EHRs that physicians have been required to use in order to meet regulatory requirements. Experience with the current program indicates that the lack of adherence to constrained interpretations of standards has resulted in variation among EHR vendors and difficulties for physicians 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 EHR technology (CEHRT) commensurate with the increased data that is expected to be exchanged. Greater testing under real-world conditions will be needed to provide confidence that certified EHRs adhere to the agreed-upon interpretation of the standards and support the increased information exchange required by the USCDI. This concern is also mirrored in our TEFCA comments. Furthermore, testing should ensure that physician practices are capable of adopting the USCDI standards and that administrative burden is minimal for the day-to-day operations of a physician practice.

The AMA recommends that ONC closely monitor 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 CEHRT to include testing that explicitly validates their readiness to support the exchange of the USCDI.

Reevaluate expansion process

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 rolling 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. Furthermore, the draft TEFCA proposes that Qualified Health Information Networks (QHIN) must update their data format and/or Application Programing Interfaces (API) to include new USCDI data classes not less than 12 months after being officially added to the USCID. Together, these timelines suggests an eventual lifecycle where physicians must add technology functionality to meet annually updated requirements. Yet, in reality, as standards are developed, tested, evaluated, and then implemented, the technology that supports the standards also has a life cycle. Experience to date indicates that it takes 18-24 months for vendors to develop new technology and for physicians to safely update, switch, and implement products. 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 value(s)/result(s) and care team members.

The AMA recommends that ONC revise the proposed timeline to permit organizations to undertake the work needed to develop standards and technology—with a focus on testing—to support accurate and useful information exchange, while also allowing for implementation considerations that are unique to physician practices.

Most health systems and physicians are exchanging the 2014 Edition standard to support health information exchange pending the widespread availability of 2015 Edition EHRs. While the 2015 Edition EHRs are being implemented by physicians, the AMA recommends that ONC reconsider the data classes in the context of their clinical priority and expected difficulty. ONC should develop a maturity scorecard for data classes that includes a metric for physician burden on capturing new data elements. The AMA also recommends that any **requirement that physicians exchange the USCDI be suspended until the overwhelming majority of physicians have adopted 2015 Edition EHRs and the results of the pilot tests are shared broadly, and in no event earlier than 2019.**

Furthermore, 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, data 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 (PDMP)

The AMA 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 health data located in disparate technology systems. Currently, standards-enabled integration among these systems varies. 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.

Additionally, the AMA is aware of issues related to the bidirectional flow of information back from PDMPs into EHRs. For example, physicians querying prescription drug information from multiple PDMPs cannot easily reconcile prescription information back into their EHRs. PDMP data is often provided in an unstructured format—limiting physicians' use of their EHR's clinical decision support (CDS) functionality, drug-drug / drug-allergy checking capabilities, or incorporating codified medication information in Continuity of Care Documents (CCD).

The AMA recommends that ONC work with the state PDMPs and HIEs to utilize agreed upon standards to facilitate effective and efficient bidirectional information exchange. The AMA also recommends that ONC work with pharmacy networks, state HIEs, EHR vendors and the Drug Enforcement Administration (DEA) to continue efforts to overcome barriers to information exchange.