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Technology Today For A Healthy Tomorrow

May 28, 2019

Don Rucker, M.D., National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C Street SW
Floor 7
Washington, DC 20201

Submitted via the Federal Regulations Web Portal, www.regulations.gov

RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (RIN 0955–AA01)

Dear Dr. Rucker:

I am writing on behalf of the Workgroup for Electronic Data Interchange (WEDI), the nation's leading nonprofit authority on the use of health IT to create efficiencies in health care information exchange. We want to commend you for the work the Office of the National Coordinator for Health Information Technology (ONC) has undertaken to advance the interoperability of electronic health information. The 21st Century Cures Act pushed the issues of information blocking and lack of interoperability to the forefront of the industry and this proposed rule is a step towards addressing these issues.

As ONC further develops their approach to advancing interoperability, we encourage the collaboration with the Centers for Medicare & Medicaid Services (CMS), as well as industry stakeholders such as WEDI. As an advisor to the Secretary of the Department of Health and Human Services (HHS) and a multi-stakeholder organization comprised of health plans, providers, vendors and SDOs, WEDI offers the structure for intra-industry collaboration. WEDI has proven leadership engaging the industry to address the most impactful changes of our time, including the National Provider Identifier, ICD-10, health claim attachments and prior authorization.

WEDI supports this proposed rule, which is ONC's initial phase to advance interoperability across the United States (U.S.) health care system in support of the access, exchange and use of electronic health information. This letter focuses our comments on those provisions specifically of interest to WEDI's membership.

The comments contained herein have been reviewed and approved by the Executive Committee of the WEDI Board on May 28, 2019. On behalf of the WEDI Board of Directors, I am sending them to you for review and consideration. WEDI appreciates the opportunity to collaborate with ONC and stands ready to assist in clarifying the attached as needed. Charles Stellar, President and CEO of WEDI, or I would be pleased to answer any questions pertaining to WEDI's recommendations, which are enclosed herein.

Sincerely,

/s/

Jay Eisenstock
Chair, WEDI

cc: WEDI Board of Directors

About WEDI

WEDI was formed in 1991 by then-Secretary of HHS Dr. Louis Sullivan. Named in the bipartisan Kassebaum-Kennedy HIPAA legislation as an advisor to the HHS Secretary, we have worked closely with every Administration. WEDI is a multi-stakeholder organization, whose membership includes ambulatory providers, hospitals, health systems, health plans, health information technology standards organizations, health care information technology vendors and government entities. We continue our role of working with both the public and private sectors to reduce health care administrative costs and facilitating improvements in information exchange through voluntary collaboration.

WEDI has been an instrumental force in establishing and later enhancing HIPAA standards for electronic administrative transactions, data privacy and data security; driving down the costs associated with manual, paper-based transactions and increasing the confidentiality of patient information. Our robust workgroups, white papers and other industry guidance, informative conferences, surveys and online webinars provide critical industry education and foster collaborative partnerships among diverse organizations to solve practical, real-world data exchange challenges.

We have also worked closely with both the Centers for Medicare & Medicaid Services and the Office for Civil Rights on industry outreach and education.

Workgroup for Electronic Data Interchange (WEDI)

WEDI Comments on the 21st Century Cures Act:
Interoperability, Information Blocking, and the ONC Health IT Certification Program
Notice of Proposed Rulemaking (RIN 0955–AA01)

As approved by the
Executive Committee of the WEDI Board on May 28, 2019

This document contains comments developed by WEDI in response to the recent 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Notice of Proposed Rulemaking (RIN 0955–AA01).

Section IV. Updates to the 2015 Certification Criteria: The rule proposes to update the 2015 Edition by not only proposing criteria for removal, but by proposing to revise and add new certification criteria that would establish the capabilities and related standards and implementation specifications for the certification of health IT.

> **WEDI Comment: WEDI supports** an attestation where functionality exists. Certification/accreditation by a non-biased third party should also be considered. If new functionality is required, sufficient time should be provided to allow the new standards to be met without impeding the flow of information. As proposed, the 24-month timeline would be insufficient to allow for required EHR vendor development, provider adoption and implementation.

Section IV.B.1. The United States Core Data for Interoperability Standard (USCDI): The rule proposes to remove the CCDS definition and its references from the 2015 Edition and replace it with the ''United States Core Data for Interoperability.'' It also proposes to adopt the USCDI as a standard, naming USCDI Version 1 (USCDI v1) in §170.213 and incorporating it by reference in §170.299. The USCDI standard, if adopted, would establish a set of data classes and constituent data elements that would be required to be exchanged in support of interoperability nationwide.

> **WEDI Comment: WEDI acknowledges** the adoption of the USCDI as a critical step in establishing interoperability across the U.S. health care system. The free and easy exchange of all patient information is an important goal, however for the information flow to generate real value, all stakeholders, particularly providers and health plans, need to build automated, machine-enabled workflows. A primary contributor to the successful roll out of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements for administrative simplification was the regulatory provisions that prevent modification of transaction data content. In addition, requirements to adhere to adopted standards resulted in a defined data set for which the industry has implemented business and care practice rules and guidelines. WEDI believes the success of this model can provide a blueprint for how USCDI can be implemented.

By naming the USCDI v.1.0 as a baseline standard that defines the minimum data set that must be captured, tracked and exchanged through specified methodologies, ONC has established a defined and achievable goal for the industry.

WEDI supports developing a mechanism to regularly review and update the rules governing the use of the USDCI and any subsequent versions. This is similar to the maintenance and modifications processes of transactions and code sets under HIPAA.

While it is always important to plan for implementation, including appropriate timeframes, it is especially important when preparing to implement new standards and process, to ensure all stakeholders have adequate time to prepare.

WEDI has extensive experience providing outreach and education of the HIPAA transactions and code sets requirements and is willing to assist in the implementation of the USCDI.

Section IV.B.2. Electronic Prescribing Criterion: The rule proposes to update the electronic prescribing (e-Rx) SCRIPT standard in 45 CFR 170.205(b) to NCPDP SCRIPT 2017071, resulting in a new e-Rx standard eventually becoming the baseline for certification.

WEDI Comment: WEDI supports updating the electronic prescribing standard as outlined in the NPRM. This aligns with the standards that the pharmacy sector has identified are most appropriate for use in electronic prescribing.

Section IV.B.4. Electronic Health Information Export Criterion: The rule proposes a new 2015 Edition certification criterion for ''electronic health information (EHI) export'' in §170.315(b)(10), which would replace the 2015 Edition ''data export'' certification criterion (§170.315(b)(6)) and become part of the 2015 Edition Base EHR definition. The proposed criterion supports situations in which we believe that all EHI produced and electronically managed by a developer's health IT should be made readily available for export as a standard capability of certified health IT. Specifically, this criterion would: (1) Enable the export of EHI for a single patient upon a valid request from that patient or a user on the patient's behalf, and (2) support the export of EHI when a health care provider chooses to transition or migrate information to another health IT system.

WEDI Comment: WEDI supports initiatives providing patients easier access to their health information. There is complexity, however, in developing interfaces offering patients the ability to download and share their health information with individuals or entities they designate. As the technology evolves and access becomes more interoperable, patients will benefit from the improvement in quality, efficiency and accessibility to health care. Given this complexity, WEDI suggests that the industry utilize the experience with patient record exporting as best practices for considering an appropriate timeframe for the migration of electronic health records (EHRs). ONC may also want to consider offering providers multiple timeframes to ease the burden of transition. WEDI also encourages ONC to consider the requirements, including data set limitations, already in place for data handled by HIPAA Covered Entities and Business Associates.

Section IV.B.6. Privacy and Security Transparency Attestations Criteria: The rule proposes to adopt two new privacy and security transparency attestation certification criteria, which would identify whether certified health IT supports encrypting authentication credentials and/or multi-factor authentication.

> **WEDI Comment: WEDI supports** an attestation for privacy and security transparency. Additionally, certification/accreditation by a non-biased third party could be considered as a means to validate that ongoing transparency occurs. Enhanced authentication is supported, but as base security and cybersecurity continues to change, a certification/accreditation body with subject matter experts could be used to review the Health IT Developer criteria as opposed to making technology recommendations through regulation. This is consistent with suggesting that the Health IT Developers/Suppliers must become part of the health information network (HIN) to facilitate sharing information in a trusted environment.

Section IV.B.7. Data Segmentation for Privacy and Consent Management Criteria: The rule proposes to remove the current 2015 Edition Data Segmentation for Privacy (DS4P) and Consent Management criteria and replace it with three new 2015 Edition ''DS4P'' certification criteria (two for C–CDA and one for a FHIR-based API) that would support a more granular approach to privacy tagging data consent management for health information exchange supported by either the C–CDA or FHIR-based exchange standards.

> **WEDI Comment: WEDI has not determined** whether to support the concept of "privacy tagging" as it is unclear how using a variety of tagging functions will benefit interoperability and make patient information available at the point of service/care. For example, tagging information could be suppressed or removed within an EHR, thereby resulting in incomplete information. WEDI encourages further exploration of use test cases and operational implementation issues related to this important topic, as well as coordination with other industry initiatives, such as Substance Abuse and Mental Health Services Administration's (SAMHSA) Consent2Share project.
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> We offer our assistance in convening industry stakeholders to further explore best practices for privacy tagging.

Section V. Modifications to the ONC Health IT Certification Program: The rule proposes modifications to the ONC Health IT Certification Program (Certification Program).

> **WEDI Comment: WEDI supports** the adoption of new and emerging technologies to promote the exchange of EHI among all stakeholders, providers, patients, health plans, public sector, etc., and it follows that the Certification Program requirements need to be updated. Any and all efforts to align the Certification Program with the goals of a Final Rule, are critical to the success of ONC's initiatives.

Section VII. Conditions and Maintenance of Certification: The rule proposes to establish certain Conditions and Maintenance of Certification requirements for health IT developers based on the conditions and maintenance of certification requirements outlined in section 4002 of the 21st Century Cures Act. It proposes an approach whereby the Conditions and Maintenance of Certification express both initial requirements for health IT developers and their certified Health IT Module(s) as well as ongoing requirements that must be met by both health IT developers and their certified Health IT Module(s) under the Program.

> **WEDI Comment: WEDI supports** the validation of ongoing conditions and maintenance for Health IT Developers/Suppliers on an annual/bi-annual certification/accreditation basis that is conducted by a non-biased third party. Subject matter experts could be used to review ongoing compliance if the Health IT Developers/Suppliers are also required to become part of the HIN to facilitate sharing information in a trusted environment. All of the requirements listed in addition to enhanced scrutiny of the Systems Development Life Cycle and related applicable testing and release should be included in curriculum as part of ongoing certification/accreditation.

Section VII.B.4. Application Programming Interfaces: The rule proposes to adopt a new API criterion in §170.315(g)(10), which would replace the ''application access— data category request'' certification criterion (§170.315(g)(8)) and become part of the 2015 Edition Base EHR definition. This new ''standardized API for patient and population services'' certification criterion would require the use of Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standards 2 and several implementation specifications. The new criterion would focus on supporting two types of API-enabled services: (1) services for which a single patient's data is the focus and (2) services for which multiple patients' data are the focus.

> **WEDI Comment: WEDI supports** the use of standards and standard methods to exchange patient information between providers, health plans, employers and public sector agencies. We support ONC leveraging current technology to promote interoperability and directing the industry to fully engage patients as consumers in the free exchange of EHI. We encourage ONC to work with the standards development organization to ensure the version of the standards adopted are the most stable and mature. WEDI also encourages ensuring the standard has been tested through pilots and demonstrations of business use case implementations, e.g., HL7's Da Vinci project.
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> **WEDI encourages** ONC to provide the industry sufficient time to make the systems and process changes needed to support these new technologies. Implementing the mandated HIPAA EDI technology infrastructure has been a significant investment for the industry, both in time and expense. Based on this experience, ONC should consult the industry when addressing implementation issues related to FHIR. Pursuing a strategy that defines quickly achievable meaningful wins with FHIR and API's, along with a glide path for transition away from legacy technologies and methods can be a very effective approach. The concept of standards harmonization pursued by ONC in the early days of health IT reformation proved in many cases to be problematic and ultimately unresolvable. This experience offers important lessons in helping to ensure a coordinated effort to achieve the goals proposed by ONC through this NPRM.

Section VIII. Information Blocking: The rule identifies several reasonable and necessary activities as exceptions to the information blocking definition, each of which as proposed would not constitute information blocking for purposes of section 3022(a)(1) of the Public Health Service Act (PHSA). The seven proposed exceptions are based on three related policy considerations. First, each exception is limited to certain activities that clearly advance the aims of the information blocking provision. These reasonable and necessary activities include providing appropriate protections to prevent harm to patients and others; promoting the privacy and security of EHI; promoting competition and innovation in health IT and its use to provide health care services to consumers, and to develop more efficient means of health care delivery; and allowing system downtime in order to implement upgrades, repairs, and other changes to health IT. Second, each exception addresses a significant risk that regulated actors will not engage in these beneficial activities because of uncertainty concerning the breadth or applicability of the information blocking provision. Finally, each exception is subject to strict conditions to ensure that it is limited to activities that are reasonable and necessary.

> **WEDI Comment: WEDI supports** using HIPAA requirements as a basis to promote interoperability. The HIPAA Privacy and Security provisions have been effective for protecting the privacy of health data and have served as the privacy foundation for health information for individuals, covered entities and business associates. The health care industry relies on these effective provisions to protect information while allowing the appropriate handling of data to support patient treatment and care.

> **WEDI cautions that** the definition of EHI is vague and downstream consequences may occur as a result of being too broad. A logical, objective approach to promoting interoperability is necessary to reduce confusion. As such, ONC should limit EHI for the purposes of information blocking to the data content of the USCDI at this time.

> **WEDI support**s the proposed rule including topic areas and definitions from HIPAA while also including new definitions and participants, e.g. actors and participants of the HIN, who are not currently subject to HIPAA. WEDI encourages ONC to work with the Office of Civil Rights (OCR), as the primary agency that issues and interprets privacy regulations, on provisions related to privacy. This should avoid issues of conflicting or duplicate requirements that may occur when multiple agencies are involved.

Section VIII.C.3. Electronic Health Information – Price Information: The proposed rule seeks comment related to pricing information, as it continues to grow in importance as a result of various industry factors, including the increase of high deductible health plans and surprise billing, which has contributed to increases in out-of-pocket health care spending. Transparency in the price and cost of health care would help address such concerns by empowering patients to make informed health care decisions. The availability of price information could help increase competition that is based on the quality and value of the services patients receive. ONC is considering subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors and health care providers under their statutory authority.

> **WEDI Comment: WEDI supports** generally the transparency of health care price information, as it can impact a patient's ability to access necessary care in a timely manner. The mandated HIPAA transactions, including health care claims and the health care remittance advice/payment transactions, currently include functionality to report the various dollar amounts necessary for the payer to adjudicate and pay the claim submitted by the provider. The primary senders and receivers of the HIPAA adopted transactions are providers and payers. The transactions, and the data contained within them, were not intended for uses beyond this electronic interchange. It is unlikely that including additional pricing information in these transactions will benefit patients. WEDI believes the most effective method for providing price transparency to patients is through consumer tools health plans make available to their members or through third-party applications that obtain their data directly from health plans.

The following comments are in response to the Requests for Information (RFIs) within the proposed rule.

Section VII.B.2.d. Trusted Exchange Framework and the Common Agreement: The 21st Century Cures Act added section 3001(c)(9) to the PHSA, which requires the National Coordinator to work with stakeholders with the goal of developing or supporting a Trusted Exchange Framework and a Common Agreement (collectively, ''TEFCA'') for the purpose of ensuring full network-to-network exchange of health information.

Comment is requested as to whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI.

> **WEDI Comment: WEDI supports** the concept of full network-to-network exchange of health information across HINs. With the release of Draft 2 of the TEFCA for comment, WEDI will respond to questions posed by ONC on the 2019 TEFCA draft in comments specific to those documents.

Section VIII.E. Additional Exceptions:
1. Exception for Complying with Common Agreement for Trusted Exchange: ONC is considering whether they should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices that are necessary to comply with the requirements of the Common Agreement. They ask commenters to provide feedback on this potential exception to the information blocking provision to be considered for inclusion in future rulemaking. They ask commenters to consider the appropriate scope of this exception, which could include which actors could benefit from the exception and the conditions that should apply in order to qualify for the exception.
2. New Exceptions: They welcome comment on any potential new exceptions they should consider for future rulemaking.

WEDI Comment: WEDI supports ONC exploring additional exceptions and public comment to ensure that industry stakeholders are not put in a position of conflict between the TEFCA provisions and other regulations. This proposed rule specifically addresses any potential conflict between the Common Agreement under TEFCA and the information blocking requirements. We support the additional exception that is proposed to be limited to contract terms, policies or other practices necessary to comply with the Common Agreement. This exception would be applicable to any health care stakeholder entity that enters into a Common Agreement under TEFCA.

Section X.: Patient Matching: This Request for Information (RFI) seeks comment on additional opportunities that may exist in the patient matching space and ways that ONC can lead and contribute to coordination efforts with respect to patient matching. ONC and CMS collaborated to jointly issue complementary requests for information regarding patient matching. ONC is particularly interested in ways that patient matching can facilitate improved patient safety, better care coordination and improved interoperability.

WEDI Comment: WEDI supports pursuing an industry-wide solution or solutions to the issue of patient matching as a critical component of interoperability. Accurately identifying patients and their data to designated record sets is a critical challenge the industry continues to face. Finding solutions that allow identifying patients correctly is essential for health care providers, health plans and others exchanging data for both clinical and administrative purposes. Most importantly, patient care is improved and patient safety enhanced when health information is accurately transmitted between health care entities, especially in emergency situations. While numerous patient matching and identity management initiatives have been undertaken (e.g., ONC, National Institute of Standards and Technology, College of Healthcare Information Management Executives, etc.), there currently is no common patient matching strategy that has been adopted by the health care industry. Governmental and commercial market collaboration can foster the adoption of such technology solutions and allow them to improve and adapt as technology advances and new techniques are identified. If these solutions are to be effective, they must be easily implementable and broadly adopted by the industry.

WEDI offers our assistance in convening industry stakeholders to explore patient matching methodologies.