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Micky Tripathi, Ph.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
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Washington, DC 20201

Dear Dr. Tripathi:

On behalf of the over 162,000 members of the American Dental Association (ADA), we write to you today for clarity about how the Office of the National Coordinator for Health Information Technology's (ONC) Cures Act Final Rule will be implemented. The nation's dentists are committed to innovation that empowers patients and gives patients more insight into, and control over, their dental care. As the ADA works to support dentists and to advance the oral health of the public, we appreciate the opportunity to work with ONC toward the important goal of a transparent health record and patient-centered care.

While we commend ONC for the responsiveness to provider concerns about the schedule of compliance with the rule, for the important content and manner exception to the definition of information blocking, and for the considerable efforts that have been made to explain the implications for providers, many dentists have contacted us with questions about the rule's applicability to their practice. We have also heard from our members that some clarity is needed about when and if the content and manner exception will no longer apply.

Because the large majority of dental practices are small businesses that do not use electronic health record (EHR) systems, and those EHRs are unlikely to be ONC certified, we would like explicit assurance that they will not be required to buy ONC-certified EHRs. We would also like guidance that more specifically addresses and compares what actors who use certified software need to do, and on the other hand, what actors who do not use certified software need to do.

Additionally, the final rule says that information blocking provisions will begin to apply on April 5, 2021, but the definition of electronic health information (EHI) for purposes of the rule will be limited to the EHI identified by the data elements represented in the U.S. Core Date for Interoperability (USCDI) until Oct 5, 2022. "Manner" exceptions will also apply when an actor is technically unable to respond in the manner requested or agreeable terms cannot be reached with the requestor. The actor must then respond in an alternative manner. After October 6, 2022, the EHI definition will no longer be limited to the elements represented in the USCDI, and all electronic protected health information (EPHI) as defined in 45 CFR 171.102 will be defined as EHI for purposes of the rule.

We understand that the rule does not automatically require actors to fulfill a request using the specific content and vocabulary standards identified in the USCDI, and that actors are

not required to use certified technology or any specific functionality. We also understand that health information technology (IT) providers will be required to make EHI export capability available by December 31, 2023, or 36 months from the publication date of the rule, and that new HL7® FHIR® capability and other Cures Act update criteria must be made available by December 31, 2022. However, we are seeking clarity from ONC about the status of the content and manner exception after October 5, 2022. At various places in the otherwise very helpful "Information Blocking FAQs" available on ONC's website, it is unclear whether just the content portion of the content and manner exception will end on October 5, 2022, or whether both the content and manner exceptions will end. For instance:

Q: For the period of time when EHI is "limited to the United States Core Data for Interoperability (USCDI)," does that mean the information blocking regulations apply only to EHI that is recorded or requested according to the applicable standards within the USCDI?

No… This limitation of EHI for purposes of the information blocking definition is not contingent on whether those data elements are recorded or represented using the specific content and vocabulary standards in the USCDI standard at 45 CFR 171.213. **On and after October 6, 2022, the information blocking regulations in 45 CFR part 171 pertain to all EHI as defined in 45 CFR 171.102.**

Q: For the period of time when information blocking is "limited to the United States Core Data for Interoperability (USCDI)," how is an actor expected to fulfill a request for the USCDI if they do not yet have certified health IT in place that includes an API with the USCDI standard?

An actor is not automatically required to fulfill a request using the specific content and vocabulary standards identified in the United States Core Data for Interoperability (USCDI) standard for the representation of data classes and data elements, nor are they required to use certified technology or any specific functionality… **On and after October 6, 2022, the information blocking regulation in 45 CFR part 171 pertain to all EHI as defined in 45 CFR 171.102.**

Again, the information blocking regulations do not require the use of any specific standard or functionality. Instead, the "Content and Manner" exception (45 CFR 171.301) outlines a process by which an actor may prioritize the use of standards in fulfilling a request for EHI in a manner that supports and prioritizes the interoperability of the data. This means that, for the purposes of information blocking, before October 6, 2022, an actor may fulfill a request with the EHI identified by the data elements represented in the USCDI standard, first in the manner requested and, if not, in an alternate manner agreed upon with the requestor, following the order of priority specified in the exception.[1]

[1] Information Blocking FAQs. https://www.healthit.gov/curesrule/resources/information-blocking-faqs. Accessed April 20, 2021.

In the intervening period between the end of the limitation of the definition of EHI to the EHI identified by the data elements represented in the USCDI and the compliance dates for health IT developers to meet certification requirements, if the content and manner exception is not maintained for actors whose health IT systems are not certified to applicable standards, provider-actors may still face the some of the same difficulties that led ONC to adopt the content and manner exception. We are therefore looking for clear guidance for our members on whether and how the manner exception will apply after October 5, 2022.

We are supportive of the movement towards interoperability, specifically the use of the FHIR as the API Standard and the ability for systems to exchange the core USCDI data elements. In addition to our questions regarding the Cures Act Final Rule, we would like to discuss opportunities to move the dental practice management technology in this direction.

We thank you for your attention to this matter, and appreciate your general efforts towards educating providers about the ONC Cures Act Final Rule. We respectfully request answers to our above questions in writing. We also request a meeting with ONC staff to discuss dentists' concerns about health IT, and how ADA can work with ONC to improve oral health.

We and the other members of the ADA stand ready to work with ONC as it seeks to make care more patient centered. Should you have any questions, please contact Corey McGee at mcgeec@ada.org.

Sincerely,

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President

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