TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

June 3, 2019

Don Rucker, MD
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building; Mail Stop: 7033A
330 C. Street SW
Washington, DC 20201

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RE: Proposed Rules | RIN 0955-AA01; 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker:

On behalf of our nearly 53,000 physician and medical student members, the Texas Medical Association (TMA) thanks you for the opportunity to comment on the above-reference proposed rules.

TMA lauds the Office of the National Coordinator (ONC) for its forward-thinking ideas, but as with many ideas and programs, the devil is in the details. TMA cautions ONC to think about unintended consequences of each new idea proposed. For example, TMA agrees that patients should have access to their electronic health information (EHI) at no cost, but that does come at a cost to stakeholders. Even though ONC is cognizant of reducing physician burden, there will be additional burden as patients, at the point of care, will have questions about how to access the information provided via payer applications, whether the applications are secure, and whether the information is accurate. Patients trust their physician and have more interactions with their physician and the physician's office staff with than others in the health care system, thus burdening already busy practices with additional questions. It is important that ONC contemplate ways to offload questions such as ensuring that contact information within the applications is clear. In addition, patients should have access to patient-service representatives who can answer questions about the applications and the information conveyed to the patients using the applications.

III.B.1. Removal of Randomized Surveillance Requirements
Comment: TMA agrees that the removal of randomized surveillance makes sense for all stakeholders. TMA further agrees that ONC should continue offering reactive surveillance to support complaints from physicians and other certified electronic health record (EHR) technology users.

III.B.2. Removal of the 2014 Edition From the Code of Federal Regulations

Comment: TMA generally agrees that outdated editions should be removed from the Code of Federal Regulations (CFR). TMA cautions that doing so too soon could result in unintended consequences. For example, without specific instruction and guidance, ONC-authorized users could interpret the deletion from the CFR as a signal to delete data required as part of the 2014 version, that were not carried over into the 2015 version.
Recommendation: ONC should study whether the removal of the 2014 edition from the Code of Federal regulations has unintended consequences on users and patients.

IV.B.1. The United States Core Data for Interoperability Standard (USCDI)
Comment: The continued changing of standards' names, i.e., from the (1) "Common MU Data Set" to the (2) "Common Clinical Data Set" and now to the (3) "US Core Data for Interoperability" serves to confuse those who are not intimately following every step ONC takes. We can understand the reason for replacing "MU" with "Clinical," but the new title (USCDI) takes several steps backward. First, by adding "US," ONC has implicitly narrowed the applicability of the standard to the United States, and it invites dozens of other versions from other major countries, making interoperability difficult across international borders. Second, the use of the phrase "for Interoperability" implicitly restricts usage of the data standard to interoperability, when it could have significant benefits independent of interoperability, such as in research, quality improvement, patient empowerment, and the like.
Recommendation: We strongly suggest not changing the name. To achieve the goals ONC desires, "Common Clinical Data Set (CCDS)" can apply to all features of the USCDI to make it as effective as desired.

Please note that we will use the term USCDI for clarity since that is the nomenclature for the ONC document on which TMA is commenting, despite the fact that we support the term CCDS.

IV.B.1.b.ii. The United States Core Data for Interoperability Standard (USCDI): Address and Phone Number
Comment: Regardless of the name, the proposed USCDI is still amazingly primitive compared with what is needed for interoperability. For example, while the addition of address and phone number is an improvement, the lack of standard definitions makes this concept far weaker than it should be. Seven-digit dialing still exists in some areas of North America, and some people still use it when asked for their phone number. In addition, many modern cellular phones automatically append the telephone's own area code if the user enters only seven digits, sending a total of 10 digits. This is also the case with many landline providers. This small example – where the same person could have a seven digit number or a 10-digit number – illustrates the weakness of adding a standard without standard definitions.
Recommendation: Data classes and elements should not be added without strict definitions. To do so only invites future problems.

IV.B.1.b.iii. The United States Core Data for Interoperability Standard (USCDI): Pediatric Vital Signs
Comment: We strongly support the addition of the "pediatric vital signs" concept in the proposed USCDI. However, ONC provides:

> *[C]ertain health IT developers and their customers may not find these capabilities and information useful. Therefore, we request comment on the inclusion of pediatric vital signs in the USCDI v1, including the potential benefits and costs for all stakeholders stemming from its inclusion in the USCDI v1.*

Given the above language, we are deeply concerned that ONC will permit usage of systems without this capability for care of children, which would, simply put, be dangerous.
Recommendation: We strongly insist that systems choosing to not support the "pediatric vital signs" be prohibited from use in the care of children, with sanctions for breaking this regulation.

IV.B.1.b.iv. The United States Core Data for Interoperability Standard (USCDI): Clinical Notes
Comment: While we welcome the addition of clinical notes in the USCDI, we are saddened that ONC chooses not to use the 11 types identified by the Argonaut Project. Setting up separate approaches undermines the legitimacy of private-sector approaches and solidifies the concept, particularly for burned-out physicians, that "the government is in charge of the EHR." The note types chosen by ONC are very physician- and hospital-centric.
Recommendation: We support inclusion of additional note types, particularly nonphysician notes such as those relating to social work, nursing, therapy, and the like. Following private-sector guidance (e.g., HL-7, the Argonaut Project) in terms of which note types are acceptable will help avoid "note-type explosion."

IV.B.1.b.v. The United States Core Data for Interoperability Standard (USCDI): Provenance
Comment: While we support the concept of "provenance," ONC itself "acknowledge[s] that there is currently work to help define provenance in a standard robust manner, and we anticipate adopting the industry consensus once it becomes available." To include the provenance concept in the USCDI at this time is premature. Physicians and health care organizations need clear definitions of the process for determining appropriate provenance and when it should change. The guidance ONC is providing is essentially nonexistent, which will have the effect of generating nonsense – or worse, incorrect – provenance data.
Recommendation: We strongly encourage delaying inclusion of this concept until an implementation guide for establishing and changing provenance is created.

IV.B.1.b.vi. The United States Core Data for Interoperability Standard (USCDI): Unique Device Identifier
Comment: We strongly support the addition of the Unique Device Identifier for Implantable Devices. While this will help a small subset of patients, it is incredibly important, particularly if the settings of the device can be found. This also can be a stepping stone for additional device information in the future. For example, knowing the size of a tracheostomy tube can be critical, but finding it in an EHR or Consolidated Clinical Document Architecture (C-CDA) is extremely difficult.

IV.B.1.b.vii. The United States Core Data for Interoperability Standard (USCDI): Medication Data
Comment: We support the concept of expanding "Medication Allergies" to include reactions, but we are extremely concerned that the expansion to "Substance Reactions" will generate so much data as to bury important medication reactions. For example, "sneezing" can be a reaction to exposure to cats. Assuming this is not an anaphylactic reaction, sneezing is far less important than a true penicillin allergy. Without a process for making critical reactions stand out for the clinician, we urge delay in implementation of this concept until there is an implementation guide for "Substance Reactions."
Recommendation: Delay implementation until there is an implementation guide.

USCDI Additional Comment: We are extremely disappointed that the USCDI discussion makes no mention of privacy. Interoperability will fail if patients and their representatives, including physicians,

are not able to manage at a granular level who sees what. A simple example is that a podiatrist does not need to see the diagnosis of trichomonas if the patient does not wish to disclose this. Adolescent privacy is even more important as many health systems shut off portal access during a patient's adolescence rather than deal with the privacy issue. While there are not yet adequate standards as to how to accomplish privacy, we do not feel ONC is paying adequate attention to this issue.

IV.B.3. Clinical Quality Measures – Report Criterion
Comment: Removal of HL-7 QRDA Standard requirements: The fact that the HL-7 Quality Reporting Document Architecture (QRDA) is not yet used widely does not mean the CMS QRDA implementation guide should be used instead. This is another case where ONC/Centers for Medicare & Medicaid Services (CMS) could undermine the efforts of the private sector to self-regulate, effectively making ONC the designer of EHRs. Quality reporting standards need to be standard across all recipients, i.e., government and the private sector (e.g., an insurer).
Recommendation: We strongly support that CMS adopt the HL-7 QRDA standard and do away with its own. If CMS feels certain aspects of its standard are superior, it should work with HL-7 to get these approved within the HL-7 standard.

Comment: Hospital and Physician QRDA Standards: ONC states that "we solicit comment on whether we should consider an approach that permits certification to only one of the [QRDA] standards depending on the care setting [hospital versus physician office] for which the product is designed and implemented." As long as ONC has a stringent regulation that prevents usage of products in areas where they can't support all users, this is not a problem. However, in the real world, we can foresee hospital systems selecting products unable to support physician quality reporting, then requiring use of that inferior system by affiliated physicians, who often have no real ability to choose which EHR they use.
Recommendation: Regulations should ensure usage of products only in areas where they can support all users.

IV.B.4. Electronic Health Information Export
Comment: TMA agrees that a new export criterion is needed so physicians can receive complete data exports when transitioning EHRs. This also will assist with health information exchange. TMA implores ONC to not allow vendors to use transitioning as an opportunity to create another revenue stream. Physicians already pay hefty fees to purchase or lease the software in addition to annual licensing fees.
Recommendation: ONC should hold vendors responsible for standardized export practices that do not punish the EHR purchasers and users.

VII.B.4.d.iv. Permitted Fees Conditions; Permitted Fees for Developing, Deploying, and Upgrading API Technology
Comment: ONC makes the following statement: "We propose that any fees that an API Technology Supplier charges for developing, deploying, or upgrading API technology must be charged solely to the API Data Provider(s) for whom the capabilities are deployed. We propose this limitation because we believe that these costs should be negotiated between the API Technology Supplier that supplies the capabilities and the API Data Provider (**i.e., health care provider**) [emphasis added] that implements them in its production environment." TMA is opposed to physicians bearing the cost of application programming interface (API) technology. Physician burnout is caused by many factors, and one of them is unfunded mandates. The financial stress put on a practice when physicians are constantly asked to do "just one more thing" is not sustainable. ONC needs to find a funding model for APIs that does not

allow placing this financial burden on physicians. Physicians already have to bear the cost of the patient portal via the EHR vendor. While a few vendors do not charge extra for this access, most of them do.
Recommendation: Seek a funding model for APIs that does not add financial strain to physicians.

VIII.C.1.b. Health IT Developers of Certified Health IT
Comment: ONC seeks comment regarding the role of health IT developers that no longer maintain a certified product or have had their certification suspended. Developers should follow the same record retention rules that physicians are required to follow as set by state medical boards. The developer should maintain the electronic health information and release it per the rules and regulations in place, or inform its current and former users of how the data should be accessed.
Recommendation: Health IT developers should follow the same retention schedules set for physicians by state medical boards and comply with EHI access and release requirements.

VIII.C.3. Electronic Health Information; Price Information
Comment: TMA agrees with the ONC's Health Information Technology Advisory Committee's recommendation that price transparency requirements be removed from this proposed rule. TMA further agrees that tying price transparency to this proposal would have unintended consequences as price transparency is a separate issue and should have its own proposal.
Recommendation: Remove the price transparency requirements from the information blocking regulations.

VIII.C.4.a. Access, Exchange, and Use of EHI
Comment: Until standards are in place and used by all health IT developers, the use of electronic faxing should be permitted. The e-fax is an efficient means of sharing information between physicians and providers for continuity of care for the patient. Physicians spend an inordinate amount of time and money trying to share information across disparate systems. Physicians must not be held up by inefficient technology that places them in an untenable position between health IT developers and federal regulations. Physicians need an efficient workflow, and the current requirements do not support efficiency.
Recommendation: Allow electronic faxing until standards for interoperability work well across disparate systems.

VIII.C.5.c.i. Restrictions on Access, Exchange, or Use
Comment: The following example is one of ONC's illustrations that would implicate information blocking: "A provider notifies its EHR developer of its intent to switch to another EHR system and requests a complete export of its EHI. The developer will provide only the EHI in a PDF format, even though it already and does produce the data in a commercially reasonable format." TMA strongly denounces such activity as information blocking. TMA has heard from numerous physicians who struggle to receive data from former EHR vendors when transitioning to a new product. This is a poor business practice that impedes patient care. Physicians should not have to pay for data transition. This should be a standard and complimentary service.
Recommendation: EHR vendors that do not allow for free, standardized, seamless, and complete export of patient data should be held accountable and penalized. Further, information about noncompliant vendors should be publicly posted on the CMS, ONC, and Certified Health IT Product List websites.

VIII.D.1. Proposed Exceptions to the Information Blocking Provision; Preventing Harm

Comment: Regarding this statement:

> "*This exception would not recognize an actor's conduct in not providing access, exchange, or use of a patient's electronic health record on the basis that the patient's failure to consent to the disclosure of substance abuse treatment information made the patient's record incomplete and thus inaccurate."*

We strongly object to the concept that requires a physician to release a patient's incomplete record to another physician when the releasing physician believes that harm would occur because the record is incomplete. We can easily see that a patient request to a physician to withhold information, such as by paying cash for a test, should be respected. If the withholding of such information makes the patient's record so distorted that it is misleading and could cause harm, physicians and health care organizations need to have an exception to the information blocking rule.

Recommendation: Expand the exception so that physicians are not required to release distorted or misleading information to other physicians.

The *Annals of Family Medicine* published its 2017 study citing that physicians spend more than half of their workday interacting with the EHR and performing administrative work. This is time taken away from direct patient care. CMS and ONC should use policy levers to reduce this burden on physicians by considering the burden impact of each new proposal. Greater physician time with the patient will result in higher quality care and better outcomes.

If you have questions about TMA's recommendations, please do not hesitate to contact TMA staff by calling (512) 370-1411.

Sincerely,

David C. Fleeger, MD
President
Texas Medical Association