May 23, 2019

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

RE: RIN 0955-AA01

Dear Director Rucker,

On behalf of URAC, I respectfully offer our comments in response to the proposed rule implementing provisions of the 21st Century Cures Act related to interoperability, information blocking and the ONC health information technology (HIT) certification program.

URAC is a nationally recognized, non-profit accreditation organization with nearly three decades of experience accrediting managed care and its related functional areas. Our mission is to advance healthcare quality through leadership, accreditation, measurement and innovation. URAC is keenly focused on protecting patients as advocates for high-quality patient care. Our accreditation programs run the gamut of healthcare as we are the premier accreditor of pharmacy quality and the only accreditor of pharmacy benefit managers (PBMs). We also accredit telehealth, utilization management, clinically integrated networks, and health plans. Given our footprint across the different sectors of healthcare, we are acutely aware of the importance of interoperability as it promotes seamless care transitions and efficient care coordination.

As a former Chief Quality and Informatics Officer in a large health system, I am mindful of how important HIT is at relates to advancing care outcomes. I’m also sensitive to administrative burden and the impact it has on patient care. However, I believe these proposed rules strike a nice balance and can be a meaningful step forward if carefully implemented.

As detailed in our comments included with this letter, URAC is encouraged by ONC’s recognition that there should be exceptions to information blocking and the importance of HIT as it relates to improving care across the healthcare continuum. URAC supports ONC’s efforts to increase access to and the exchange of electronic health information (EHI) without increasing administrative burden. We believe enhancing patient’s access to their EHI will help them make informed decisions and thereby allow them to be active members in their care team. As ONC continues to explore ways to advance interoperability, please do not hesitate to call on URAC as a resource at any time.

Sincerely,

Shawn Griffin, M.D.
President and CEO
Proposed Definition for Interoperability

As the healthcare system continues to embrace value-based care, ensuring interoperability is vital. We support the proposal to codify the definition of interoperability as defined in the Cures Act. While interoperability is often limited to the secure exchange of HIT across different providers and their respective systems, we believe the proposed definition ensures ready access to patient information via HIT. We agree with ONC that EHI should be securely exchanged “without special effort on the part of the user [and] allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and does not constitute information blocking as also defined by the Cures Act.”

Too often our healthcare system focuses on the mere sharing of HIT without regard to the ability of a patient, their designee, or a healthcare provider to access this information with relative ease. During my career, I’ve overseen both the implementation of Cerner and Epic and the various challenges with each system. By merely focusing on the successful exchange of HIT and not the end user’s ability to interact with it, we have created a system that does not allow for timely, coordinated care. As such, we strongly support codifying the definition of interoperability as outlined in the Cures Act and encourage ONC to consider issuing guidance that is publicly accessible on their website to further explain what “without special effort on the part of the user” means by including examples. This will ensure there aren’t any discrepancies with respect to access due to differences in interpretation.

Provisions Against Purposeful Information Blocking

URAC strongly supports ONC’s provisions against purposeful information blocking as it is perhaps the greatest barrier to interoperability. We support the proposal to allow specific conditions within an exception to apply to a certain actor as providers, HIT developers, health information exchanges (HIEs) and health information networks (HINs) have different needs and uses for HIT. In doing this, each individual actor is allowed the opportunity to demonstrate the applicability of a certain exception to their practice. This should ensure that exceptions are appropriately applied within the context of the regulated actor’s needs rather than uniformly applied using the lowest common denominator.

Given our position as a managed care accreditor, URAC is aware of the impact information blocking can have on improving patient outcomes across the entire care continuum. Too often, one healthcare provider or HIT system conceals a patient’s health information which interrupts the ability of healthcare providers to readily access one’s health data in a meaningful way, such as avoiding a costly duplicative procedure. Therefore, URAC is supportive of the seven proposed exceptions to the information blocking provision. Furthermore, the outlined three related policy considerations are clear and easy to understand.

To ensure these exceptions are thorough, we encourage ONC to consider providing more detailed commentary in final rulemaking or subsequent formal guidance. For example, in the proposed exception “recovering costs reasonably incurred”, ONC provides a thorough illustration for the related condition non-discriminatory terms but does not provide a comparable example for all the other conditions. Including an example for each condition would provide greater consistency and provide greater clarity for actors seeking to use a particular condition.

Moreover, under the “maintaining and improving HIT performance” exception, more clarity is needed regarding what constitutes a “period of time no longer than necessary to achieve the maintenance or improvement purpose for which the HIT is made unavailable”. While the intent of this exception is clear, there is not an established criteria by which ONC can assess if an actor indeed took HIT offline for a longer period than necessary. We encourage ONC to develop clear criteria by which an actor can justify meeting this exception so there is transparency in how ONC will determine if an actor has satisfied the
requirements. In addition, we urge ONC to clarify that an actor may take HIT offline at any time without prior notice to the supplier if there is an immediate security threat such as a malware attack. While it is reasonable to expect the HIT developer to communicate to the impacted parties the need to temporarily take a HIT system offline for an urgent situation, there may be circumstances in which contact cannot be made in a timely fashion. In these instances, the HIT developer should still qualify for this exception if there is documentation that supports they made a reasonable effort to notify the HIT recipient(s) in a timely manner upon discovery of the threat. Not allowing for this would directly conflict with the third proposed exception “promoting the security of EHI”.

**HIT and Opioid Use Disorder (OUD) Prevention and Treatment – Request for Information**

URAC supports the outlined 2015 Edition criteria which could “support care coordination and the prevention and detection of opioid misuse, abuse and diversion”. The “transitions of care” criterion would ensure that upon discharge, EHI would follow individuals with OUD to another care setting. Having warm handoffs between providers would also provide the patient with a reasonable level of comfort and support proper care coordination. For individuals with OUD, ineffective care coordination during care transitions could be the difference between life and death. For example, without a care transition plan, a person being discharged from a hospital to an outpatient setting after a near-fatal overdose could experience an adverse event like untreated withdrawal symptoms which could result in readmission or a fatal overdose.

In addition, individuals with OUD are disproportionately more likely to be homeless which only increases the need for effective care transitions. This transition process should not only be focused on having a comprehensive electronic health record (EHR) follow the patient, but also identifying a patient’s support network and community-based resources prior to being discharged from an inpatient setting. Engaging with the patient and their caregiver(s) or identifying resources in the community that could lend support prior to a change in care setting should empower the patient and their caregivers to feel like they have a voice as a valued part of the care team. This will ultimately help the patient feel more prepared to manage their own care as they move to less restrictive settings.

The “clinical information reconciliation and incorporation” criterion is invaluable when it comes to individuals with OUD. Having a patient’s entire care record is crucial to ensuring quality care. People with OUD might be receiving services from a variety of providers and if this information is not captured in one central system, avoidable errors may occur. Additionally, consistent medication management ensures the clinical appropriateness of future therapies. Timely medication management coupled with electronic prescribing will further advance care for individuals with OUD by “capturing and transmitting medication histories that are shared with PDMPs”. Electronic prescribing is a very common practice and eliminates the need for someone with OUD to have to keep track of a paper prescription while managing a serious illness.

URAC strongly supports the “social, psychological, and behavioral data” criterion as there is clear evidence of the impact social determinants of health has on one’s overall health status. This will help providers develop a more holistic approach to care which as ONC identified, is part of medicated-assisted treatment (MAT). We also encourage ONC to consider the “patient-specific education resources” criterion as a priority for supporting individuals with OUD. In addition to varying literacy levels and cognitive ability, individuals with OUD may not have proper social supports, thereby increasing the importance of being self-sufficient. Having comprehensive education tailored to the individual patient’s needs will greatly improve the likelihood of recovery. URAC also believes that developing a “non-binding informational guide” for OUD providers would be invaluable. We would be happy to provide our input as to what kind of information this guide should include.
General Comments Regarding Implementation Timeline

While understanding the desire to quickly advance interoperability, we share the concerns of other stakeholders and Congress alike regarding the relatively quick implementation timeline. For example, requiring HIT developers to be able to electronically export all EHI to patients and providers within the later date between 24 months after the effective date of the forthcoming final rule or 12 months of certification for those that did not previously certify to the 2015 Edition does not appear feasible. Similarly, we also encourage ONC to delay the date by which application programming interface (API) technology suppliers must implement the proposed specifications. While in support of the aforementioned proposals, rushed implementation can lead to a number of privacy, security and data integrity concerns. We urge ONC to work with these impacted parties to identify a reasonable implementation plan that strikes an appropriate balance between provider and vendor burden, data privacy concerns and the need for enhanced access to EHI to promote care coordination and advance patient outcomes.