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June 3, 2019

Don Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health & Human Services
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

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

Dear Mr. Rucker,

On behalf of our over 135 member hospitals and integrated health systems located in Wisconsin, the Wisconsin Hospital Association ("WHA") appreciates the opportunity to comment on RIN 0955-AA01, a proposed rule regarding healthcare interoperability issued by the U.S. Department of Health and Human Services ("HHS"), Office of the National Coordinator for Health Information Technology ("ONC").

Our Wisconsin member organizations—both large and small and urban and rural—provide services well beyond the four walls of a hospital, and those services are provided by physicians, advanced care providers, and other non-physician practitioners. WHA's member organizations operate a full continuum of care, including hospitals, clinics, outpatient surgery, rehab, long-term care, home health, and other healthcare services.

Our members' embrace of coordinated care delivery models and provision of care across a continuum of services inside and outside of the hospital has been a key driver in Wisconsin regularly being recognized for high-quality healthcare. With that comprehensive approach to care delivery, our members bring a perspective that often is unique compared to other parts of the country.

WHA supports healthcare interoperability—*i.e.*, the capacity to send and receive a patient's health information from multiple sources between different systems and locations—as a way to improve healthcare coordination, safety, and quality, to empower patients, and to increase efficiency.[1] As ONC works to advance our mutual goals of interoperability, WHA urges ONC to do so in a way that reduces the burden on providers of using EHRs and that aligns mandated EHR use with provider workflow and patient need.

Because regulatory burden creates additional healthcare costs and limits provider productivity, reducing EHR-related burden on physicians and hospitals is a priority for WHA. We believe that ONC should minimize EHR-related regulatory burdens and ensure that any additional EHR investments, additional time spent using EHR technology, or adjustments to workflow that are necessary to comply with regulatory requirements are outweighed by healthcare cost-savings and improvements in patient outcomes. For example, in our comments

[1] Am. Hosp. Ass'n, Sharing Data, Saving Lives: The Hosp. Agenda for Interoperability (2019) 3-4, available at: https://www.aha.org/system/files/2019-01/Report01_18_19-Sharing-Data-Saving-Lives_FINAL.pdf.

on the ONC's recent draft "Strategy on Reducing Regulatory & Administrative Burden Relating to the Use of Health IT & EHRs" ("Strategy"), WHA encouraged HHS to identify additional regulatory reforms to reduce EHR-related provider regulatory burden when such regulations do not meaningfully improve healthcare quality, safety, and efficiency.

We understand that HHS likewise has committed publicly to reducing EHR-related provider burden. On March 5, 2018, in remarks to the Federation of American Hospitals, Secretary Azar identified the following as a "key engine for transformation" of healthcare: "addressing any government burdens that may be getting in the way of integrated, collaborative, and holistic care for the patient, and of structures that may create new value more generally."[2] Further, in ONC's draft Strategy, ONC acknowledges that while EHRs have the potential to support high-quality healthcare delivery, regulatory and administrative burdens associated with the use of EHRs can decrease productivity, increase healthcare costs, and detract from patient-centered care.[3] ONC identifies as significant source of EHR-related burden the misalignment between EHR and clinical workflows and says that "[a]s EHRs continue to evolve, it is imperative that they support the workflows that have been established in clinical practice so as not to add to clinician burden."[4]

As is explained in more detail below, WHA offers the following recommendations with respect to this proposed rule:

- **While WHA opposes a burdensome mandate for hospitals and other healthcare providers to disclose price information, we urge ONC to work together with insurers and providers to figure out the best way to bring price information to consumers in a way that preserves and even improves access to healthcare in a free market. As ONC proceeds with this work, we urge ONC to be careful not to disrupt current efforts that providers and insurers are already undertaking to innovate in price transparency.**
- **WHA supports a robust set of exceptions to the 21st Century Cures Act prohibition of electronic health information blocking, but we urge ONC to finalize a definition of "electronic health information" that includes a narrower set of data elements. We also urge ONC to provide additional clarity on (1) what documentation is necessary for a hospital to overcome its burden of proof that it is not engaging in information blocking and (2) the relationship between the proposed information-blocking exceptions and HIPAA.**
- **WHA generally supports ONC's proposed Conditions of Certification and Maintenance of Certification requirements for health IT developers, but at the same time we urge ONC to be cautious about creating additional regulatory burdens for developers that ultimately will make EHR products more expensive for healthcare organizations.**
- **WHA supports ONC's proposal to establish a new export criterion that enables the export of electronic health information for a single patient at the patient's request and for all patients when a provider migrates to another EHR system.**

[2] Azar, Alex, Remarks on Value-Based Transformation to the Fed'n of Am. Hosps. (March 5, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-value-based-transformation-to-the-federation-of-american-hospitals.html.
[3] Office of the Nat'l Coordinator for Health Info. Tech., Strategy on Reducing Regulatory & Admin. Burden Relating to the Use of Health IT & EHRs (2018) 9-10, available at: https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf.
[4] *Id.* at 31.

Request for Information on Disclosure of Price Information

In this proposed rule, ONC requests information on the parameters and implications of including price information within the scope of "electronic health information" ("EHI") for purposes of the 21st Century Cures Act prohibition on providers and others from engaging in the blocking of EHI.

While WHA opposes a burdensome mandate for hospitals and other healthcare providers to disclose price information, we urge ONC to work together with insurers and providers to figure out the best way to bring price information to consumers in a way that preserves and even improves access to healthcare in a free market. As ONC proceeds with this work, we urge ONC to be careful not to disrupt current efforts that providers and insurers are already undertaking to innovate in price transparency.

WHA and our members are strong proponents of public transparency. We have been voluntarily reporting hospital price information through a website called PricePoint since 2004. PricePoint provides complete, accurate, and timely inpatient and outpatient data about charges and services provided by Wisconsin hospitals and ambulatory surgery centers. Every hospital in Wisconsin voluntarily participates in PricePoint, and it is licensed for use in ten additional states.

One of the strengths of PricePoint is how simple it is for members of the public to use. After going to www.wipricepoint.org, one simply selects the area of the body and condition and can then directly compare service prices for up to three hospitals at a time. The site also includes an insurance checklist that directs patients to contact their health insurer to help determine their out-of-pocket cost. The checklist even includes reminders to ask about particular practitioners, such as radiologists and anesthesiologists, so as to avoid potential surprise billing issues in the event those practitioners are not covered by their particular insurance plan.

As valuable of a tool like PricePoint is, we understand it requires a little more involvement on the patient's part in a world where consumers are often accustomed to having price information at their fingertips. This is one reason why WHA is reconvening a Transparency Taskforce: to bring forward best practices and new advancements that many of our members are undertaking to make it easier for consumers to know how much they will pay for healthcare services. It is important for ONC to understand that the information consumers find most valuable is knowing how much of their bill they will be responsible for paying after their insurance has been taken into account. This is information that only insurers have.

Information-Blocking Exceptions

ONC proposes seven categories of actions in which a healthcare provider (including a hospital), developer, health information exchange, or health information network can engage that would constitute an exception to the 21st Century Cures Act prohibition on the blocking of EHI: preventing harm, promoting the privacy of EHI, promoting the security of EHI, recovering costs reasonably incurred, responding to infeasible requests, licensing of interoperability elements, and maintaining and improving health IT performance.

For purposes of these information-blocking exceptions, ONC proposes defining "EHI" as "electronic protected health information" (as defined under HIPAA regulations) and "[a]ny other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media . . . that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."

WHA supports a robust set of exceptions to the 21st Century Cures Act prohibition of information blocking, but ONC should finalize a definition of "EHI" that includes a narrower set of data elements and should provide

additional clarity on (1) how a hospital can meet its burden of proof that it is not engaging in information blocking and (2) the relationship between the proposed information-blocking exceptions and HIPAA.

The definition of "EHI" that ONC is proposing is very broadly written and essentially would include not only electronic PHI covered under HIPAA but also any other individually identifiable element of data that relates to an individual's health or healthcare. The definition as written even may include propriety material derived from EHI, such as predictive analytics, risk scores, and clinical decision support mechanisms. WHA is concerned that the definition would require providers to share information beyond current capabilities and lead to significant administrative burden and costs. In order to avoid potentially unintended consequences of ONC's overly broad definition of "EHI," we encourage ONC to limit the definition of "EHI" to a narrower set of data elements that would capture better the intent of the 21st Century Cures Act by protecting electronic information that is maintained within EHRs and needed by healthcare providers to make appropriate treatment decisions.

Further, ONC proposes that, in the event of an investigation of an information-blocking complaint, a hospital or other regulated actor "must demonstrate that an exception is applicable and that the actor met all relevant conditions of the exception at all relevant times and for each practice for which the exception is sought."[5] Because ONC proposes that the hospital assume the burden of proving that the hospital did not engage in information blocking, WHA recommends that ONC provide additional clarity as to what documentation or other proof ONC will require for the hospital to meet such burden of proof.

Additional clarification from ONC also is needed with respect to the relationship between the proposed information-blocking exceptions and HIPAA. For the proposed "promoting the privacy of EHI" exception, ONC provides a HIPAA "safe harbor": if HIPAA allows a provider to refrain from the sharing of EHI in a given instance, then the refusal to share such EHI would not constitute information blocking. For the proposed "promoting the security of EHI" exception, however, ONC says only that a provider can refrain from information sharing if the action is "directly related to safeguarding the confidentiality, integrity, and availability of EHI, implemented consistently and in a nondiscriminatory manner, and tailored to identified security risks."[6] ONC should clarify further that security practices implemented in conformity with the HIPAA Security Rule would not constitute information blocking.

Conditions & Maintenance of Certification

ONC proposes a variety of Conditions of Certification and Maintenance of Certification requirements for health IT developers or vendors, including the following:

- *Prohibition of "Gag Clauses."* ONC proposes to prohibit developers from restricting communications about certified EHR technology usability, interoperability, security, user experience, business practices (*e.g.*, costs), and use (*e.g.*, work-arounds and customizations). In addition, ONC proposes that if a developer has existing agreements with prohibited "gag clauses," the developer must amend its agreements to remove such "gag clauses."
- *Open Application-Programming Interfaces ("APIs")*
    - ONC proposes to require developers to publish APIs—*i.e.*, code that allows two software programs to communicate with each other—and allow health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs. Through the APIs, a developer would have to provide access to all data elements of a patient's EHR to the extent permissible under applicable privacy laws. ONC also proposes to require that developers

[5] 84 Fed. Reg. 7,424, 7,522.
[6] *Id.* at 7,535.

make the business and technical documentation necessary to interact with their APIs freely and publicly accessible.

- ONC also proposes to limit the ability of developers to charge API-related fees to healthcare organizations that deploy the developers' API technologies. Specifically, developers may charge API-related fees to healthcare organizations only to recover the costs reasonably incurred to develop, deploy, and upgrade API technology and to support the use of the API technology.
- Finally, under the proposal, developers would have to grant to healthcare organizations the sole authority and autonomy to permit third-party application developers to connect to the API technology that the healthcare organizations have acquired and deployed.

WHA generally supports ONC's proposed Conditions of Certification and Maintenance of Certification requirements for health IT developers, but at the same time we urge ONC to be cautious about creating additional regulatory burdens for developers that ultimately will make EHR products more expensive for hospitals and providers.

With respect to ONC's proposed Condition of Certification related to prohibiting "gag clauses," we agree with ONC's assessment that developer "practices of prohibiting or restricting communication do not promote health IT safety or good security hygiene and that health IT contracts should support and facilitate the transparent exchange of information relating to patient care."[7] ONC's proposal should "help ensure that the health IT ultimately selected and used by health care providers and others functions as expected, is less likely to have safety issues or implementation difficulties, enables greater interoperability of health information, and more fully allows users to reap the benefits of health IT utilization, including improvements in care and quality, and reductions in costs."[8] Moreover, because ONC carves out several reasonable exceptions to the proposed prohibition, developers would continue to be able to protect any intellectual property rights that exist in their health IT products.

WHA also particularly supports giving healthcare organizations the sole authority and autonomy to permit third-party software developers to connect to the API technology that the healthcare organizations have acquired and deployed. We agree with ONC that such proposal will "promote the efficient access, exchange, and use of EHI to support a competitive marketplace that enhances consumer value and choice."[9]

As ONC proceeds to finalize its Conditions of Certification and Maintenance of Certification requirements for developers, we urge ONC to exercise caution about creating additional regulatory burdens for developers that ultimately will make EHR products more expensive for healthcare organizations. In conversations that WHA has had with one large health IT developer, the developer reports that an enormous amount of staff hours would be required to comply with ONC's proposals, and this staff time will have opportunity costs for healthcare organizations by diverting developer time towards compliance and away from customer requests for software features. Further, excessive regulatory burden may create additional costs for developers, which ultimately will be passed on to the developers' healthcare organization customers.

EHI Export Criterion

ONC proposes establishing a new export criterion that enables the export of EHI for a single patient at the patient's request and for all patients when a provider migrates to another EHR system. **WHA supports this proposal because it will help hospitals to migrate easily to another EHR system.**

[7] *Id.* at 7,578.
[8] *Id.* at 7,468.
[9] *Id.* at 7,477.

Thank you again for the opportunity to comment. If you have any questions, please contact Andrew Brenton at (608) 274-1820 or abrenton@wha.org.

Sincerely,

Eric Borgerding

President