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October 3, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker,

On behalf of the Electronic Health Record (EHR) Association, we are pleased to provide additional detail elaborating on the feedback we submitted in June 2019 on ONC's "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (the "proposed rule").[1] We appreciated the opportunity to discuss our perspectives with you and your team on September 23, 2019.

The EHR Association's 33 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these critical technologies.

The Association supports the Administration's focus on driving more competition in the healthcare industry with the goal of bringing consumer prices down. We support the concept that patients should be informed and able to make decisions about as much of their health experience as possible and that increasing their access to their own medical data is fundamental to that ability. Health information technology companies understand our important role in this effort, and we appreciate the relationship between interoperability and the desired increased transparency and accordingly, the efforts by the Department of Health and Human Services to promulgate regulations supportive of those goals.

[1] https://www.regulations.gov/document?D=HHS-ONC-2019-0002-1468

The proposed rule states a desire to promote innovation in the health IT industry: "Throughout the years, we have worked to improve the [certification] Program with a focus on ways to reduce burden, offer flexibility to both developers and providers, and support innovation." Encouraging innovation in the healthcare and health IT industry is an important goal and one that the Association supports. However, as we expressed in our submitted comments on ONC's proposed rule, we believe that, as written, ONC's proposals jeopardize ownership and protection of intellectual property (IP), which actually reduces incentives to invest and innovate in this space.

As discussed in the meeting on September 23, we believe certain provisions included in the proposed rule are inconsistent with the goal of encouraging innovation and may actually exceed Congressional intent. We believe that the changes outlined below would better achieve this goal without exceeding Congressional intent as expressed, in plain language, in the 21st Century Cures Act.

There are several long-established types of protection for intellectual property: trademarks, copyrights, patents, trade secrets, and confidential or proprietary information. Each software and technology developer relies on different combinations of these protections to ensure that when they invest research and development dollars into a project, they are able to retain ownership of the output of that investment and benefit from its success in the marketplace. Unfortunately, ONC's proposed rule does not acknowledge the breadth of protections in use and instead appears to assert that copyrights are the primary form of intellectual property protection used in the industry. As a result, several concepts in the proposed rule run in direct conflict with long-standing and successfully enforced intellectual property protection strategies, effectively undermining companies' ability to protect their hard-earned innovations.

In the attachment to this letter, we will:

1. Provide background on the variety of intellectual property protections currently in use by health information technology developers
2. Confirm our understanding of ONC's intent related to the provisions affecting intellectual property
3. Detail how the currently drafted proposals from ONC would likely threaten those intellectual property protections
4. Share alternative suggestions that would preserve intellectual property rights while still achieving Congress' and ONC's goals of expanding information exchange in healthcare

Again, the EHR Association appreciates the opportunity to provide further detail regarding the comments we submitted on the Information Blocking and Interoperability proposed rule in June 2019. We hope the additional examples provided, as well as the suggested alternative approaches, will be considered with all due seriousness, as we believe finalization and implementation of the proposals as drafted initially would have severe consequences for innovation in health IT.

Finally, because of the seriousness of the challenge here and the fact that we believe it will be necessary for stakeholders to review and discuss with ONC the next iteration of definitions and regulatory

proposals, we repeat our suggestion that ONC release the next version of this regulation as a supplemental NPRM or interim final rule. We recognize the sense of urgency from the Administration but suggest consideration of the oft-repeated words of the Chairman of the Senate HELP Committee, Mr. Lamar Alexander: "My major concern is to remind the administration of the advice that my piano teacher used to give me before a recital. 'Play it a little slower than you can play it. You're less likely to make a mistake.'"

Sincerely,

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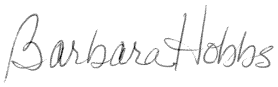

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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Background on Intellectual Property Protections Used By Health Information Technology Developers

A number of intellectual property protections are used by health information technology developers to defend their solutions and services and encourage ongoing investment in research and development to advance state-of-the-art development in the industry. By way of example, a clinical workflow embodied in health IT software may be covered by:

- A **trademark** indicating the source of the software;
- a **utility patent** to protect the new and non-obvious systems and processes embodied by the workflow;
- a **design patent** directed to the ornamental design in the graphical user interface (GUI);
- **copyrights** in the source code, documentation and original expressions in the GUIs; and
- **trade secrets** and **contractual protections** to prevent disclosure and use of confidential information regarding the workflow.

These rights work together to protect varying aspects of the developer's intellectual property, and the rights should be considered individually and collectively as ONC finalizes any future rule.

Proposed Exception for Reasonable and Non-Discriminatory Terms

ONC's proposed rule establishes that information blocking occurs if "there is a reasonably foreseeable risk that a practice will interfere with the access, exchange, or use of EHI"[2] (electronic health information). This includes a refusal to license interoperability elements. ONC states:

> "We believe that a practice would satisfy the information blocking provision's ''likelihood'' requirement if, under the circumstances, there is a reasonably foreseeable risk that the practice will interfere with access, exchange, or use of EHI. For example, where an actor refuses to share EHI or to provide access to certain interoperability elements, it is reasonably foreseeable that such actions will interfere with access, exchange, or use of EHI."[3]

The 21st Century Cures Act defines interoperability with respect to health information technology as

> "…such health information technology that—
>
> (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
>
> (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

[2] 7516. https://www.federalregister.gov/d/2019-02224/p-1181

[3] 7516. https://www.federalregister.gov/d/2019-02224/p-1181

(C) does not constitute information blocking as defined in section 3022(a).''.

It is our understanding that the intention underlying this statutory definition is to ensure that electronic health information (i.e., clinical, administrative or financial information specific to a patient) managed and maintained in one health information technology (e.g., an EHR, payer system, registry, public health repository) is available to another health information technology (e.g., a consumer-focused app, another EHR, another payer system) without special effort so that the electronic health information can be used by the recipient health information technology. Electronic health information exchange methods are intended to be standards-based to eliminate special efforts on the part of the user.

We further understand the intent to be that when such exchange standards are available, further licensing of other technology or services from the source system is not necessary. We agree that this is one of the key advantages of focusing on standards for interoperable exchange, and is a reason that the Association has for many years advocated for standards adoption across other areas of the industry affecting information exchange related to patients beyond EHRs.

ONC's intent is that standards-based exchange represents the majority of activity. We understand from our discussion on 9/23/2019 that the exception around RAND licensing is intended to address a narrow fringe case for certain electronic health information that might not be included in the initial target data set (USCDI). When exchange of electronic health information is necessary, and standards are not yet available, certain technology licenses may be required to enable the exchange of this information with another health information technology (or to enable another health information technology to access and use the relevant data).

In these cases, the goal is to provide data access and exchange from the source system to allow the use of the electronic health information by the recipient system. We understand that it is not the intent to require access to or licensure of technology beyond what is necessary to facilitate access to the data.

In our meeting, we used an illustrative example of a medication ordering module. ONC indicated that that it is not their intent to mandate licensing of the medication ordering module itself or to control how it is licensed to users who have selected that product for their own medication management. Our understanding is that ONC instead intends for the prescription data maintained in that source medication ordering module be accessible to recipient health information technology using standard methods, such as e-prescribing interfaces or FHIR medication resources. Any license of technology should be limited to include only those intellectual property rights required to access and exchange the prescription data between the two systems; for example, the license should be limited so as not to include patented technology in the solution, or trade secrets in the schema inherent to the electronic health data exchanged.

We appreciate ONC's intent. Below we have identified language in the proposed rule that exposes more IP to mandatory RAND licensing requirements than would be essential to accomplish ONC's intent. We offer alternative suggestions to reframe the proposed exception for RAND licensing to better match ONC's stated goals in a manner that does not create undue risks to health IT developers' intellectual property rights. If the clarifications proposed in this letter are not adopted, we are concerned that the

relevant provisions in the final rule may overreach Congressional intent and create an undue burden for health IT developers, healthcare providers, and other affected organizations.

In addition to the imprecise scope of the RAND exception, the overly broad definitions of "EHI"[4] and "interoperability element"[5] make the scope of the proposed rule broader than what we understand ONC intended and what is contemplated in the 21st Century Cures Act. These two definitions cause the proposed rule to effectively require the licensure of all health IT, including the medication ordering module described above. We have recommendations on how ONC could modify these definitions to reduce the risk of exceeding statutory intent and avoid unintended consequences.

The proposed rule includes seven exceptions permitting certain actions that would otherwise constitute information blocking. One of those exceptions is the licensing of interoperability elements on a reasonable and non-discriminatory basis (RAND).[6] As ONC notes, RAND frameworks are not uncommon in standards development organizations (SDOs).[7] However, as ONC also notes, SDOs typically create RAND obligations on a *voluntary* basis.[8] In these contexts, a patent holder may choose to—or choose not to—propose that its patented technology be included within a standard. ONC's proposed model of compulsory licensing deprives IP owners from that critical choice and proposes that IP owners be limited to licensing on RAND terms to all parties, including competitors. Similar involuntary licensing frameworks—characterized as "guerilla standardization"[9]—have been "few and far between" and academics have expressed doubts that the involuntary licensing approach is "doable."

Under ONC's proposed rule, a competitor may claim a RAND license is required on the basis that it seeks to access an interoperability element which is covered by a patent (and/or other intellectual property rights) in order to access electronic health information. ONC's only attempt to address any wrongdoing by a competitor looking for discounted access to proprietary technology is to create one exception to the exception:

> *"There may be firms that simply want to license the actor's technology for use in developing their own interoperability elements. Their interest would be for access to the technology itself—not for the use of the technology to interoperate with either the actor or its customers. This may be the case, for example, if the relevant intellectual property included patents that were applicable to other information technology applications outside of health IT. In such cases, the actor's licensing of its patents in such a context would not implicate the information blocking provision."*[10]

[4] https://www.federalregister.gov/d/2019-02224/p-1127
[5] https://www.federalregister.gov/d/2019-02224/p-2478
[6] https://www.federalregister.gov/d/2019-02224/p-1481
[7] 7545-6. https://www.federalregister.gov/d/2019-02224/p-1494
[8] 7545-6. https://www.federalregister.gov/d/2019-02224/p-1494
[9] Lerner & Tirole, *Standard Essential Patents*, *Journal of Political Economy*, June 2015 at 566-67.
[10] 7544. https://www.federalregister.gov/d/2019-02224/p-1482

This "exception to the exception" gives short shrift to valid concerns about the appropriate protection of proprietary technology.

For instance, a licensee might want the technology in order to develop further technology for the creation of interoperability elements (in the form of, for instance, interoperability software that might compete with the licensor's patented software). A competitor might want a license to the patented technology to integrate it into its larger healthcare IT solution as well. The competitor, in either case, can make a plausible argument that its interest is merely in the "use" of the technology to interoperate. This risk is particularly acute in light of the fact that ONC proposes the open access of APIs—even to competitive technology. Thus, ONC appears to endorse RAND licensing of technology (as opposed to "use of technology" for interoperability purposes) where it is accessed via API but not where patents are implicated. These are, of course, not mutually exclusive scenarios, and ONC does not explain how parties are to navigate those opposing approaches.

Further, the exception appears to turn on the "interest" or intent of the potential licensee. How, or when, ONC proposes that the Office of Civil Rights will litigate a party's "interest" is not discussed, nor does ONC discuss how "access to the technology itself" is somehow exclusive of "use of the technology to interoperate with either the actor or its customers."

ONC, without explanation, concluded in the proposed rule that the "exception to the exception" is more likely to apply where the patent at issue can apply to an application outside of health IT. There is no basis to conclude that the technology breadth of a particular patent has bearing on whether the intended use is for purposes other than the exchange of EHI.

Suggested Alternative

As an alternative, the EHR Association believes that if the definition of electronic health information focused on an evolving U.S. Core Data for Interoperability (USCDI) definition, there would be minimal need for RAND licensing exceptions, as USCDI would be accessible using standard APIs and capable of export using a standard format for the purposes proposed. ONC seemed to agree with this expectation in our 9/23/2019 meeting, saying that this exception would only be necessary to "mop up edge cases." This approach of more narrowly focusing the definition of electronic health information would reduce the complexities of other information blocking exceptions, and the boundary of information blocking would be clear. This approach is consistent with the intent of the 21st Century Cures Act, where USCDI would grow to encompass the larger electronic health information data set (including the Designated Record Set) that we all strive to support.

However, if a USCDI-focused approach is not adopted and the broad definition of electronic health information implicating information blocking is preserved, then the EHR Association proposes a more tailored approach than the ONC's proposed RAND licensing model as described below.

The Administration's proposed definition of "interoperability element" includes several provisions (in bold) subject to an interpretation inconsistent with the intent and policy goals.

(1) ***Any functional element*** *of a health information technology, whether hardware or software, that* ***could be used*** *to* ***access, exchange, or use*** *electronic health information* ***for any purpose****, including information transmitted by or maintained in disparate media, information systems, health information exchanges, or health information networks."*

Access, exchange OR use: "Access" and "use" independent of the clause "Access, exchange, and use" contribute to the misunderstanding that the direct user of a health IT system is using an interoperability element. In our medication management system example above, a clinician who had purchased that module for her clinic would presumably "access" and "use" that system, making that system definitionally an interoperability element. We believe this is not what ONC intended.

Any functional element: "Any functional element" could be interpreted to encompass technology in the source system itself because the source system uses electronic health information. In the example above, the medication management software (source system) uses the prescription data (EHI), but rights to the technology in the medication management system itself are not required to provide access and exchange of prescription data to a recipient system, nor to allow the recipient system to use the prescription data.

Could be used; for any purpose: This language creates a number of issues. The universe of technology that "could be used" to "use" electronic health information is immense and untethered to advancing access and exchange of EHI and use of that EHI by a recipient system. In the example above, this could encompass the source medication management system itself, even though the technology for the source system is not required for the recipient system to successfully access and use the EHI.

The optionality ("could be") and unbounded nature ("for any purpose") of the proposed definition are overly broad. In the standards context, a RAND license is strictly limited to the minimum rights "required" or "essential" to offer solutions and services that conform to a detailed specification setting forth the standard. The licensor does not receive rights in the intellectual property beyond practicing the standard. In this context, the RAND license should similarly be limited to those *essential, necessary or required*. In the absence of a standards specification, the license should be narrowly tailored to allow for access and exchange for unfettered use of the data (not the technology itself) by the recipient system.

We suggest that an alternate definition of Interoperability Element would address these concerns:

Any functional element of a health information technology (whether hardware or software) that is essential to enable the exchange of data from a source data system to a recipient data system that is not the same as the source. The recipient data system could include apps, EHRs, or other health information systems.

Interoperability element is inclusive of technical information that describes such functional elements (e.g., a standard, specification, protocol, data model, or schema) that are essential for the supplier of the recipient's health information technology to use the functional elements for the permitted purpose.

With this revised definition, the term interoperability element hones in on the access and exchange of the relevant data, while the use of such data, e.g., in context of usability and safety considerations, can be addressed separately. Otherwise, the conflation of these verbs (access, exchange, or use) will result in the unintended consequence of exposing more software and hardware to RAND licensing requirements than is essential to the access and exchange of the relevant electronic health information.

Related to the proposed definition just above, ONC should clarify that information blocking is only implicated with failure to license interoperability elements, not declining to license other health information technology. For example, if a developer declined to license their medication management system to a particular clinician, that would not implicate information blocking because there would be other ways for that actor to access the sought after EHI. In contrast, if the developer refused to license a standards-based interoperability element, such as an e-prescribing interface necessary for another health IT system to access and use the electronic health information contained within it, information blocking would be implicated.

ONC should clarify that an actor's practices with respect to its license terms and pricing methodologies will not be considered to implicate information blocking if the actor makes available standard APIs under §170.404 and/or an electronic health information export in compliance with §170.315(b)(10) and that reliance on any delineated exception is unnecessary; and for non-standard EHI outside of USCDI, ONC should allow the actor to either (1) provide access, exchange, and use of the underlying electronic health information in another structured and sufficiently-documented commercially-reasonable format, or (2) offer access to essential IP rights in Interoperability Elements on a RAND basis to enable access to such non-USCDI data.

We recognize that with this focus on access and exchange of the underlying data, the interoperability definition in the 21st Century Cures Act also includes use of such data in the receiving system. We agree that systems are not "fully" interoperable, or "end-to-end" interoperable if the data received is not used or not used properly in the receiving system. This is the responsibility of the receiving system, not the source system of the data. It should be separated from the definition of interoperability element to avoid any confusion on what functional elements of the source data system are potentially subject to RAND licensing. ONC should clarify that the receiving system is responsible for appropriate use of the data received, addressing all applicable usability and patient safety considerations without having any rights or claims beyond the ability to access the relevant data.

Proposed Condition of Certification: Restricted Communications

While the 21st Century Cures Act requires, as a condition of certification, that health IT developers do not restrict "communications regarding" the certified health IT in specific subject areas, the Proposed Rule expands that protection to include disclosures of certified health IT itself, including screenshots, even where developers have maintained that information as trade secrets. The Communications section of the proposed rule prevents health IT developers from limiting disclosures that contain certain developers' trade secrets, including proprietary screen designs and the information contained in such designs. While disclosure of screenshots may sound innocuous on some level, the information that can be gleaned from screenshots--including algorithms and configuration insights--as well as the screen

designs themselves hold significant value in the industry. If made publicly available, these screen designs could provide malicious actors with shortcuts to allow them to end-run around years of research and development.

In its proposed rule, ONC recognizes copyright protections, but the health IT industry has long accepted that copyright protection is not a great fit to provide guards sufficient to justify the immense expense of developing and maintaining health IT. Copyright is not enough to protect a health IT developer's tremendous effort researching workflows and designing layouts if the products of that work are revealed when screenshots or documentation are disclosed. Copyright can rarely be used to protect the underlying effort behind revealed screens. Trade secret protections are a more effective form of intellectual property protection for screenshots because they protect compilations of facts or any information that is confidential and creates a business advantage by virtue of not being generally known.

The proposed rule should be revised to balance the protection of users' communications about health IT with health IT developers' concerns about the loss of their intellectual property. We support ONC's aim of protecting communications including screens from any limitations in certain circumstances, such as if the recipient of the communication is a federally registered patient safety organization or if the recipient is a health IT user's colleague collaborating with the user.

We encourage ONC to provide additional guidance on appropriate uses of communications that include screen designs to ensure that these communications are made to fulfill the protected purposes of use outlined in the 21st Century Cures Act. This guidance should clarify that ONC is retaining protection for health IT developers' trade secrets while creating a framework for disclosures of a reasonable number of screenshots to help provide context for certain protected communications. The framework for disclosures of screen designs could take into account several factors, including the number of screens, the purpose of the disclosure, and whether or not algorithmic data or proprietary workflows are depicted.

The proposed rule should not be finalized in a manner that would effectively mandate forced distribution of intellectual property. If the investments of health IT developers are not protected from inappropriate use, the public will suffer as companies are stripped of the incentive to innovate on the core technology underlying the infrastructure of our healthcare system.