October 4, 2024

The Honorable Micky Tripathi, Ph.D., M.P.P.
Assistant Secretary for Technology Policy
The Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C St SW
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (89 FR 63498, RIN 0955-AA06)

Assistant Secretary Tripathi:

We represent a diverse coalition of stakeholders that span the healthcare and technology sectors, all of whom support the necessary expanded use of digital and connected health technologies for patient care. We write to provide collective input on the ASTP's second Health Data, Technology, and Interoperability proposed rule ("HTI-2" or "NPRM").[1] Specifically, in the 21st Century Cures Act,(Cures Act) Congress' required that health information exchange occur "without special effort" for providers.[2] Here, as we explain below, however, HTI-2 results in the opposite for a group of providers who, if HTI-2 is finalized as proposed, will only be able to exchange health information with other providers after undertaking special efforts.. We request that ASTP **not** finalize the NPRM's provisions related to TEFCA, and instead seek public input through a new request for information (RFI) followed by a notice and comment rulemaking; alternatively, ASTP should clarify that an omission is prohibited information blocking when it is "[n]ot exchanging EHI under circumstances in which such exchange is lawful *even if the disclosing Actor is a signatory to TEFCA and the RCE's June 2024 Standard Operating Procedures for exchange for treatment might apply under TEFCA*" [emphasis added].

Who We Are: A growing evidence base continues to demonstrate that the responsible use of digital health to deliver health care produces same or better patient outcomes, reduces costs, can operate in otherwise underserved communities like rural communities, augments population health management, improves the healthcare workforce experience, and provides solutions that help keep Americans healthier in the face of a stark shortage of in-person care. The undersigned provide direct patient care using digital health, or support organizations that do so, or organizations who help their workforces and patients effectively use digital health tools and services. Some of the undersigned use certified electronic health records regulated by rules promulgated by the Assistant Secretary for Technology Policy (ASTP), while others use bespoke EHRs that are built solely for their own organization (and are not sold or licensed). All of us handle patient health information as prescribed by HIPAA or other applicable law, and many of the undersigned who provide direct care to individuals are provider covered entities under federal law. Further, many of us embrace voluntary standards (e.g., HITRUST certification and SOC-2),

[1] 89 FR 63498.

[2] Pub. L. 114-255, Dec. 13, 2016, hereafter "Cures Act")

demonstrating a further commitment to ensuring the privacy and security of health data beyond minimum legal requirements.

Summary of Argument: ASTP's HTI-2 rulemaking represents a vital step in supporting interoperable health information exchange as required by Congress in the Cures Act, in the HITECH ACT, and HIPAA itself,[3] and we share ASTP's goals. However, we have significant concerns with ASTP's HTI-2 proposals that would take several steps backwards for data interoperability. Specifically, HTI-2, through its proposed reliance on TEFCA, would privilege licensed health care providers and exclude all other providers of healthcare services in creating a two tiered system where providers who are subject to federal privacy and security laws but are not licensed health care professionals as defined in TEFCA Standard Operating Procedures will have to undertake actions above and beyond those taken by licensed health care providers to ensure that their queries for patient health information for treatment are responded to and not blocked. The creation of such a dynamic is counter to the Cures Act requirement that "special effort" not be required.[4] In addition, by artificially siloing data from digital-first health care providers, the proposed rule severely hampers the access, exchange, and use of a growing subset of electronically accessible health information by the full ecosystem of providers in the interest of patients, as we'll discuss below regarding impact.

ASTP's Proposed Rule Would Create a Two-Tiered System: ASTP's NPRM proposes that it would be information blocking to "not exchange EHI under circumstances in which exchange is lawful"[5] though exchange is lawful under HIPAA between two provider covered entities.[6] ASTP further proposes to let stand, and indeed tacitly endorses, a privately adopted operating rule[7] among TEFCA signatories that says that signatories need only respond to the queries from licensed health care professionals, but not all health care providers to whom EHI may lawfully be disclosed.[8] ASTP's proposed approach thus functionally codifies these privately adopted operating procedures which, in turn, render the proposed information blocking by omission meaningless. As discussed above, the undersigned include these further HIPAA-covered providers which are not licensed health care professionals as defined in the TEFCA Standard Operating Procedures or are organizations who support the health care businesses of such providers. We and the patients we serve will be directly disadvantaged by this two-tier system when our queries are not responded to by TEFCA signatories.

For Nearly 25 Years, HHS has Treated All Providers Equally in Terms of Health Information Exchange: The federal government has long recognized that providers in the health care system encompass more than just licensed healthcare professionals. In its 1998 proposed rule on National

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[3] Douville, et al Advanced Health Technology, Routledge 2023.

[4] 21sr Century Cures section 4002, adding 42 USC 300jj-11(D)(iv)

[5] 89 FR 63803

[6] 45 CFR 164.506(c)

[7] These operating procedures were adopted without opportunity for public transparent notice and comment, far from meeting the procedural requirements for rulemaking in the Administrative Procedures Act. They are also private governance terms and are subsidiary to federal law.

[8] Sequoia Project's *Standard Operating Procedure: Exchange Purpose Implementation: Treatment;* https://rce.sequoiaproject.org/wp-content/uploads/2024/07/SOP-Treatment-XP-Implementation_508.pdf.

Provider Identifiers (NPI), the CMS predecessor proposed an additional category of provider besides licensed professionals.[9] By 2000, that NPI concept was also adopted for the privacy provisions of the HIPAA regulations, which included language that remains in 45 CFR 160.103 defining a provider for purposes of privacy and the permissible and prohibited disclosures of PHI described in the HIPAA Privacy Rule.[10] Today, the HIPAA rules are the federal baseline for when can PHI be exchanged, and expressly permit two providers to exchange health information about an individual they are both providing services to, without resultant disclosures being a breach of HIPAA.[11],[12]

Much later, in implementing the Cures Act, HHS defined "interoperability" in 2016 as "health information technology" that:[13]

> (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*; [emphasis added]
> (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
> (C) does not constitute information blocking as defined in section 3022(a).

Further, we note that in Section 3022 of the Cures Act, Congress defined established prohibitions against information blocking and, importantly for this context, did not make any distinctions among providers.

Even more recently, ASTP delegated to the Sequoia Project (in a sole source contract paid for by U. S. taxpayers) the ability to make detailed rules about how Congressionally-prescribed "Trusted Exchange Framework" would operate. Following this development, in 2024 the Sequoia Project adopted an exchange protocol which, as discussed above, creates the two-tiered system among providers for exchange, even though under federal law <u>all</u> providers as described in federal regulation have the same rights and privileges as to relevant patient information. The Sequoia Project adopted this Standard Operating Procedure with input from advisory groups where it approves the membership, but not the public at large, as would have occurred with notice and comment rulemaking.

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[9] The 1998 proposed rule states "[w]e believe that an individual or organization that bills and is paid for health care services is also a provider for purposes of the [HIPAA] statute." 63 FR 25320, 25355 (May 7, 1998). See also The Secretary elaborated on this same concept in the 1999 NPRM on the Administrative Simplification (Privacy) Rule, referring to "on-line" health care providers. 64 FR 59927, 59930 (November 3, 1999)

[10] 65 FR 83456, 82477-78, December 28, 2000. In the August 2002 revisions to the Privacy Rule, this definition remained unchanged.

[11] 45 CFR 164.506.

[12] The Office of Civil Rights (OCR) has reinforced the breadth of the definition of provider in Q&As on its website, which it uses to articulate official interpretations of HIPAA. For example, in 2004, OCR reiterated that a medical device company could be a health care provider for the purposes of disclosing PHI. See "When may a covered health care provider disclose protected health information, without an authorization or business associate agreement, to a medical device company representative?" Available at https://www.hhs.gov/hipaa/for-professionals/faq/490/when-may-a-covered-health-care-provider-disclose-protected-health-information-without-authorization/index.html. Accessed on September 24, 2024.

[13] Cures Act sec. 4003.

ASTP's Proposed Two-Tiered System Harms Patients, Providers, and Undermines the Goal of Nationwide Health Information Exchange Without Special Effort: The impact of ASTP's proposed two-tiered provider system would be wide and significant. To illustrate the reach of ASTP's proposal, we provide two examples exploring the impact of only the queries of a licensed health care provider being responded to:

> ***Example 1:*** A patient is discharged from a hospital with Chronic Obstructive Pulmonary Disease and given a prescription for home oxygen. The patient moves to another community far from this hospital to be near her daughter, and seeks to get oxygen from a nearby durable medical equipment (DME) supplier. The DME supplier, which has signed TEFCA or otherwise participates in nationwide exchange, seeks more details on the patient's diagnosis and discharge to set up oxygen and relevant monitoring, but the hospital doesn't recognize the DME supplier because the latter is not a licensed health care professional. As a result, the hospital does not respond to the DME supplier's exchange query, and the patient is delayed in receiving the care she needs to manage her condition.
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> ***Example 2:*** A YMCA in a state in the Diabetes Belt establishes a Diabetes Prevention Program, and takes advantage of the YMCA's certified EHR to keep records on its participants. But it wants to acquire blood glucose tests for its over 65 Y members so that it can clinically establish that they meet CMS' requirements for Medicare Diabetes Prevention. It tries to query the local hospital, but its query is rejected because a YMCA is an "other" health care provider, per CMS own guidance.[14]

These examples illustrate how harmful ASTP's proposed approach is for the patients who receive health care services from these "other" providers. Furthermore, ASTP's proposal would undermine digital health companies' ability to deliver care where the patient is (through smart phone or internet based technologies). Patients in underserved communities who could most benefit from using these "other" providers would be relegated to receiving lower quality, less informed care, because they cannot count on their digital health provider to have the same access to the patient's longitudinal health information history as do the licensed health care providers found in large health systems in cities. Even further, it will be detrimental for the licensed health care professional community who may find themselves unable to access and use the existing – but siloed – electronic records from digital care providers, leaving their decisions less informed.

Finally, as mentioned above, Congress sought nationwide exchange for providers "without special effort." Here, if a licensed professional can refuse to respond to a query of an "other" health care provider, those other health care providers will clearly have to engage in special efforts to participate in exchange, because they won't effectively be able to participate in the exchange paths that use TEFCA. Meanwhile, with the adoption of TEFCA by incumbent electronic health record providers, there are, practically speaking, no such other paths.

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[14] 81 Fed. Reg. 80472 (Nov. 15, 2016).

Therefore, ONC should not finalize the HTI-2 NPRM as written. We see two options instead:

ONC should immediately engage in public fact finding via an RFI. Such an RFI would provide a way for all stakeholders to weigh in on whether all federally defined health care providers should be treated under TEFCA. ASTP should use this information swiftly, in turn, to direct its contractor in the short term to broaden the set of providers with required response treatment use cases and ensure its Standard Operating Procedures for TEFCA are not contrary to federal law on information sharing among providers. In the longer term ASTP should use the information collected to develop for notice and comment rulemaking updates to ASTP's definition of "information blocking" that are supported by the evidence collected publicly, ensuring that patients and clinicians see the full benefit of digital care innovation.

Alternatively, ASTP could finalize its proposed rule on information blocking by Omissions by clarifying that an omission is prohibited information blocking when it is "Not exchanging EHI under circumstances in which such exchange is lawful *even if the disclosing Actor is a signatory to TEFCA and the RCE's June 2024 Standard Operating Procedures for exchange for treatment might apply under TEFCA*" [emphasis added].

Sincerely,

American Diabetes Association

Cardiff Ocean Group

Connected Health Initiative

Curai, Inc.

Omada Health, Inc.