ConnectedHealthInitiative

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: **Comments of the Connected Health Initiative to the Office of the National Coordinator for Health Information Technology on *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability* (89 FR 63498)**

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the Assistant Secretary for Technology Policy's (ASTP) proposed rule seeking to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information through proposals for standards adoption; adoption of certification criteria to advance public health data exchange; expanded uses of certified application programming interfaces, such as for electronic prior authorization, patient access, care management, and care coordination; and information sharing under the information blocking regulations.[1]

I.   Introduction and Statement of Interest

CHI is the leading effort, driven by consensus that spans the healthcare ecosystem, to drive policies that enable the responsible deployment and use of digital health tools throughout the continuum of care to improve individual patient outcomes, reduce costs, augment population health, and streamline the clinician experience. For more information, see www.connectedhi.com.

The effectiveness of the technology tools needed to improve patient outcomes, advance precision medicine and population health, and save costs is dependent in large part on the availability of massive data sets. The free and secure flow of information, and interoperability, are central to improving outcomes for all patients, and CHI is committed to advancing health data interoperability throughout the continuum of care. Further, CHI is committed to advancing the responsible development and use of artificial intelligence (AI) in healthcare and appreciates ASTP's efforts to advance efficacious and

---

[1] 89 FR 63498.

accountable AI. Building on our community's consensus, we provide detailed views on a range of ASTP's proposals below.

II. CHI Views on Various ASTP Health IT Certification Program Updates

CHI generally appreciates ASTP's continued curation of health IT certification program requirements to support data exchange between patients, providers, and payers. We also recognize that its companion regulation mandating certification for any HHS contractor or grantee will advance the need for participation in the certification program. and offers the following views and specific inputs on ASTP's proposals:

- USCDI v4: CHI supports ASTP's proposal to provide USCDI v4 as a baseline. CHI supports USCDI expansion, consistent with technology and competitive neutrality principles, to include social determinants of health (SDOH) with scaled security and privacy risk management practices that recognize the sensitivity of SDOH data that may be shared or disclosed. This includes incorporating SDOH data that considers social and environmental factors of patients' lives outside of the healthcare system in the USCDI with adequate safeguards; and we support ASTP's coordination with the HHS' Office for Civil Rights, standards development organizations, and other affected stakeholders.

  We urge ASTP (and CMS) to collaborate to gather and share SDOH data, and to support the responsible leveraging of SDOH data. However, It is essential that we protect sensitive personal health information—as both a foundation for health equity but also to mitigate the risk of negative impacts to individuals resulting from the disclosure of their information. To that end, CHI urges ASTP to move forward with the granular data segmentation policies concurrently with adopting USCDI v4. In many instances, it will be inappropriate to share all USCDI v3 elements unless granular segmentation is enabled to protect privacy related to sensitive data elements, in accordance with patient preference, state and federal law and regulation.

- EHI Encryption: CHI supports the adoption of updated Federal Information Processing Standards, which will ensure that developers align with industry best practices for encryption and decryption. As CHI has raised before ASTP and across HHS in the past, supporting the use of the strongest technical protection mechanisms, namely end-to-end encryption, is vital to security and privacy at both the end-user and server-side endpoints. We welcome ASTP providing further detailed guidance on operationalizing encryption to support the responsible and safe adoption of cloud-based solutions including mobile apps. Finally, CHI supports phasing in implementation to support smaller practices that may be resource constrained as they begin to leverage encryption solutions.

- New Imaging Requirements: CHI supports ASTP's proposal to revise the certification criteria found at "transitions of care" in § 170.315(b)(1); "application access—all data request" in § 170.315(g)(9); and "standardized API for patient

and population services" in § 170.315(g)(10) to include certification requirements to support capturing and documenting hyperlinks to diagnostic imaging. CHI also supports ASTP's proposal to revise the certification criterion "view, download, and transmit to 3rd party" in § 170.315(e)(1) to add functional support for (a) viewing and direct download of diagnostic and lower quality images and (b) inclusion of a hyperlink to those diagnostic images in either a downloaded or transmitted Continuity of Care Document, with the view and download functionalities having to be accessible to the patient through the same internet-based technology as the other functionalities of § 170.315(e)(1). While ASTP is not proposing a specific standard associated with the support of this functionality, CHI agrees that this proposal will promote more consistent access to images for providers; CHI urges ASTP to consider additional standards that facilitate better patient and provider visibility in to data points such as pharmacy availability, cost savings attributed to drug discount programs, and other factors that patients and providers can immediately leverage to ensure adherence to a prescribed medication regimen.

- Revised Electronic Prescribing Criteria: CHI supports ASTP's proposed updated "electronic prescribing" certification criterion in § 170.315(b)(3) to incorporate the NCPDP SCRIPT standard version 2023011, which will support the responsible and safe transfer of controlled substances. CHI agrees that this proposal will reduce burdens related to resending prescriptions in the event of shortages and backorders. We further encourage ASTP to recognize and support the important role of the pharmacist here in data exchange and visibility.

- Real-Time Prescription Benefit Criteria: CHI supports the addition of electronic prescribing and real-time prescription benefit (RTPB) technology into the base electronic health record definition, as well as certification criteria requiring support of the National Council for Prescription Drug Programs (NCPDP) electronic prior authorization and RTPB standards. Increasing provider access to these high-value functionalities will address well-known transparency issues and administrative burdens related to drug prescribing and prior authorization. We again encourage ASTP to recognize and support the important role of the pharmacist here in data exchange and visibility.

- Supporting Public Health Data Exchange: CHI supports ONC's proposals aimed at improving public health data exchange, including updates to existing criteria for reporting public health data; revised standards for areas such as immunizations, electronic lab reporting, cancer registry reporting, and health care surveys; and new certification criteria to support the ability to receive, validate, parse, and filter data; and the proposal for a new, FHIR-based API for public health reporting.

- New Modular API Capabilities: CHI supports ASTP's proposed provisions for workflow triggers/CDS hooks, subscription frameworks, privacy and security, including asymmetric certificate-based authentication and the use of SMART App Launch for authentication. Such provisions will create better access to and utilization of real-time patient data for providers.

- Patient, Provider, and Payer APIs: We generally support ASTP's proposed updates to certification criteria for payer and public health software functionalities being made to align with CMS-establish API requirements. CHI supports ASTP's proposal to establish standards related to drug formulary information accessible via Patient Access APIs, which will allow for timely comparisons and specifying prices for prescribed medications (including available alternatives). ASTP, in partnership with CMS and other partners, should continue to provide more patient-specific cost data, including their deductible and out-of-pocket spend status, prior authorization and utilization management requirements, and available alternatives, which will fundamentally improve the ability for patients and providers to take actionable steps to improve their health care. This can and should also be made available through unauthenticated APIs as another patient-facing resource to surface publicly available information in an appropriate form factor.

  ASTP's proposals would require the use of the CMS-created Implementation Guides (IGs) for patient, provider, payer-to-payer, and prior authorization APIs – which CMS does not require the use of per its final rules intended to advance interoperability and improving prior authorization processes.[2] Requiring these IGs as part of certification will benefit patient care. However, we are concerned that, absent requirements that payers use matching certified technology, providers and patients will not realize the full benefits of these new APIs—particularly APIs that support electronic prior authorization. Certified technology used by providers need a corresponding and standardized technical "handshake" with payer API systems to function effectively. CHI urges ASTP to harmonize its approach with that of CMS establishing a trajectory of requiring payer use of certified API systems as relevant IGs matures.

  CHI also urges ASTP to consider policies to improve the response times of APIs such that they are near real-time (e.g., a latency period of 30 or 60 seconds for queries is far too long and often discourages engagement on time-sensitive health care decisions).

- Confronting Compliance Gamesmanship: CHI reiterates is call for ASTP to ensure that it collaborates with CMS to ensure that gamed compliance and related excessive fees are avoided. As a prime example, innovative developers seeking to compete in the digital health ecosystem currently experience a range of practices that undermine Congress' and ASTP's goals, including inflated annual program fees with reduced support, a failure to provide reliable responses to treatment-based queries paired with requests to pay fees for use of "more reliable" proprietary APIs (a dynamic that will likely be exacerbated by ASTP not defining standard APIs, for example), and redundant costly re-certification requests. Such practices materially interfere with health data exchange, and can

---

[2] https://www.cms.gov/files/document/cms-0057-f.pdf.

and should be addressed by both ASTP as well as ONC-Authorized Certification Bodies.

- <u>Minimizing Administrative Burdens:</u> CHI generally encourages ASTP to reduce provider administrative/reporting burdens. We encourage ASTP to work with CMS to advance the joint agency goals of gaining insight into interoperability and reducing provider reporting burdens by allowing provider reporting to be accomplished through a yes/no attestation to meeting Performing Interoperability Objectives, instead of requiring the reporting of a numerator/denominator, which would be complemented or supplemented by EHR developer-reported Insights Conditions data.

III.   Supporting Innovation in Healthcare Artificial Intelligence

CHI appreciates ASTP's support for AI's growing role in improving healthcare. AI is an evolving constellation of technologies that enable computers to simulate elements of human thinking, such as learning and reasoning. An encompassing term, AI entails a range of approaches and technologies, such as machine learning (ML), where algorithms use data, learn from it, and apply their newly-learned lessons to make informed decisions, and deep learning, where an algorithm based on the way neurons and synapses in the brain change as they are exposed to new inputs allows for independent or assisted decision-making. AI-driven tools are having, and will continue to have, substantial direct and indirect effects on Americans in how they manage their health. Some forms of AI are already being used to improve American consumers' lives today; for example, AI is used to accomplish backend administrative functions for healthcare providers. Moving forward, AI has incredible potential to advance the Quadruple Aim; for example, healthcare treatments and patient outcomes stand poised to improve disease prevention and conditions, as well as efficiently and effectively treat diseases through automated analysis of x-rays and other medical imaging. Nonetheless, AI's growing use raises a variety of challenges, and some new and unique considerations, for policymakers as well as those making AI operational in healthcare. CHI appreciates ASTP's efforts to provide reliable guidance to stakeholders to reassure end-users that AI systems are legal, effective, ethical, safe, and otherwise trustworthy.

As part of its commitment to responsibly advance AI in healthcare, CHI has developed a number of resources for policymakers, linked below. We encourage ASTP to align its next steps with each of these resources:

- CHI's *Health AI Policy Principles*, a set of recommendations on the wide range of areas that should be addressed by policymakers examining AI's use in healthcare (available at https://bit.ly/3m9ZBLv);

- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://bit.ly/3n36WO5); and

5

- CHI's *Health AI Roles & Interdependency Framework*, which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; and suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept (https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf).

Consistent with CHI's shared goal of ensuring that health AI recommendations are fair, appropriate, valid, effective, and safe (FAVES), health AI developers, whether subject to this ASTP rule or not, to (1) proactively take steps to address and mitigate disparities; (2) protect patient privacy, and the security and integrity of patients' data; and (3) leverage robust and constant feedback loops throughout a health AI offering's lifecycle to track and mitigate real-world issues that may arise. A comprehensive approach to responsible health AI development, deployment, and curation will include consideration of intended and reasonably expected use(s), evidence of safety, efficacy, level of automation, and conditions of deployment. Health AI's adoption will be best facilitated by as much information about clinical limitations, risks, and liability being available and understood throughout the value chain. CHI agrees that trustworthy AI requires transparency. ASTP can advance these shared goals by supporting the appropriate distribution and mitigation of risk and liability by providing that those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so, and by enhancing communications about DSI intended uses, risks, and benefits to patients as well as providers.

CHI strongly urges for a coordinated effort across both executive and independent agencies. Already, aside from ASTP, numerous regulatory agencies—some cross-sectoral and others sector-specific—are considering or advancing regulatory proposals that would take starkly different approaches to AI accountability. Some of these proposals are poised to put significant hurdles in place for the development and use of AI through one-size-fits-all approaches that have nominal public benefit at best, such as the Department of Health and Human Services Office of Civil Rights' proposed approach to preventing discriminatory outcomes in healthcare,[3] on which CHI has detailed its views publicly (and we encourage ASTP's consideration of these viewpoints as a leading example of sector-specific misalignment with other leading Administration efforts, such as that of the National Institute of Standards and Technology [NIST][4]). In some cases, such proposals are being developed based on speculative and undemonstrated harms.[5] ASTP, along with other cross-sectoral subject matter expert

---

[3] Nondiscrimination in Health Programs and Activities, 87 FR 47824 (Aug. 4, 2022); CHI's Connected Health Initiative detailed views on this HHS OCR proposal are included in this comment as **Appendix A**.

[4] https://www.nist.gov/itl/ai-risk-management-framework.

[5] Trade Regulation Rule on Commercial Surveillance and Data Security, 87 FR 51273 (Aug. 22, 2022); CHI views provided to the Federal Trade Commission in response to its Advanced Notice of Proposed Rulemaking are included in this comment as **Appendix B**.

agencies in the federal government such as NIST, should take immediate steps to ensure a harmonized and informed approach to AI governance. Further, as part of effort to advance a coordinated federal approach to health AI, ASTP should also leverage CPT Appendix S (*AI taxonomy for medical services & procedures*)[6] to advance common terminology.

ASTP has already introduced new requirements for developers of certified health IT with Health IT Modules aimed at providing transparency for predictive DSIs, in addition to establishing decision support configuration requirements and intervention risk management practices. Because so many approaches to leveraging different kinds of data are in development, CHI urges ASTP's full consideration of the impact that new regulations will have on specific health AI datasets or models. With so much AI in development and the range of technologies within the field far from mature, we urge ASTP to take steps to ensure that its DSI mandates do not have unintended consequences (e.g., locking in certain DSI capabilities and creating an artificial ceiling for innovation in the space, or contributing to information overload in reporting requirements mandating reporting that may not be effective or useful to accomplishing).

In addition, CHI recognizes the considerable steps that will be needed for DSI developer and developers of certified health IT to comply with ASTP's new DSI requirements. Collecting information from third party developers of DSIs, displaying that information to their users, and implementing a DSI risk management framework may carry significant compliance costs for developers and DSI users. CHI urges ASTP to minimize these costs and consider other unintended burdens. As one example, it appears that EHR companies may need to request that third party developers provide them with access to proprietary information about products used in their EHR, placing them in the role of enforcing DSI requirements on other companies, and effectively incenting them to decline to enable or interface with third party DSIs or limit patients from doing so to avoid liability. Transparency is very important in DSI use; however, CHI would be concerned if DSI development stagnates due to unclear or unworkable regulation.

With respect to DSI requirements, we resurface our requests that:

- ASTP utilize a scaled risk management approach to DSI, which would subject low-risk applications to less stringent requirements compared to high-risk applications.

- ASTP clearly provide that public disclosures per the DSI requirements do not include intellectual property or trade secrets.

- ASTP mitigate the burdens related to overlapping regulation of health AI by the FDA.

- DSI requirements be limited in scope to apply only to features and attributes that have been shown to successfully function in real-world deployments, e.g., ASTPs

---

[6] https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

real-world DSI testing requirements; similarly, we urge ASTP to extend DSI data review user experience (UX) requirements to those that have been demonstrated to work in practice. Taking these steps will avoid negatively impacting new and innovative health AI technologies in design or cASTPept phases.

We urge ASTP to continue its dialogue with our community to understand capabilities and the effects ASTP's proposals will have on the development and use of health AI. Further, we urge ASTP, along with other federal agencies addressing health AI, to continue education and outreach to help providers, patients, and developers (and others affected by health AI policies) understand the capabilities of health AI today and contribute to their responsible development and deployment.

IV.   CHI Views on ASTP's Proposed Updates to its Information Blocking Rules

A truly interoperable healthcare ecosystem must be inclusive and welcoming of data from a range of sources through open application programming interfaces (APIs) that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats, with interoperability facilitated by APIs, supports real-time analytics and alerting capabilities and the use of platforms for data streams from multiple and diverse sources will improve the healthcare sector, helping to eliminate information silos, data blocking, and deficient patient engagement. ASTP has made commendable progress in finalizing information blocking rules and through its HTI-1 rule (among other efforts), and HHS' Office of the Inspector General (OIG) has now advanced its awaited companion civil monetary penalty (CMP) enforcement rules for ASTP's information blocking rules.

CHI reiterates its support for ASTP's efforts to prevent illegal information blocking and to facilitate greater data access throughout the care continuum. We generally support ASTP efforts to resolve ambiguities in its requirements, and to align its information blocking requirements with the certified capabilities of health IT vendors (i.e., the U.S. Core Data for Interoperability [USCDI] and APIs), and the adoption of FHIR Release 4 and compliance with HL7 U.S. Core FHIR Implementation Guides. With respect to proposed additions/modifications to its information blocking exceptions:

- Protecting Care Access Exception: CHI supports ASTP's proposal to create a new Protecting Care Access Exception, which would support the actor's good faith belief that sharing EHI indicating that any person(s) sought, received, provided, or facilitated the provision or receipt of reproductive health care that was lawful under the circumstances in which it was provided could result in a risk of potential exposure to legal action for those persons and that the risk could be reduced by practices likely to interfere with particular access, exchange, or use of specific EHI. CHI remains concerned that the *Dobbs v. Jackson Women's Health Organization* decision is already, and may continue to, fracture health data flows based on various states' approaches to reproductive healthcare, which we have

discussed in detail in a public issues brief.[7] CHI welcomes this new information blocking exception as a needed step to addressing uncertainties facing providers supporting patient care and avoiding legal risks.

- Privacy Sub-exception — Individual's Request Not to Share EHI: CHI supports ASTP's proposal to revise the sub-exception to remove the existing limitation that applies the exception only to individual requested restrictions on EHI sharing that are permitted by other applicable law. This exception would provide needed certainty that disclosure can be delayed in the event a court order is being challenged.

- Infeasibility Exception — Segmentation condition: CHI supports ASTP's proposal to revise this exception to address situations where the actor is unable to unambiguously segment EHI that could be made available from specific EHI that the actor may choose to honor the individual's request not to share the EHI and to ensure the Privacy Exception Sub-exception — Precondition not Satisfied can be utilized by all actors without fear of being an information blocker. This change would ensure that actors have clarity that use of exceptions to prevent the disclosure of specific EHI will not be considered information blocking, specifying that actors will not be considered information blockers if they are unable to segment specific EHI from medical records that an individual has requested not to share; and that the segmentation condition includes situations where an actor is subject to other laws.

  CHI notes that innovative developers have made, and continue to make, strides in providing the segmentation of data and sharing of information consistent with patient preferences and applicable laws. Data segmentation is critical to providing patient data privacy and security, meeting patient expectations and attaining informed consent, and in managing data flows in light of legal and contractual requirements. CHI welcomes ASTP's partnership in advancing effective segmentation practices that will avoid improper sharing or withholding of a medical record due to misunderstandings about requirements on EHRs, including in the context of illegal information blocking.

- Requestor Preference Exception: ASTP's Requestor Preference Exception would give actors certainty that, under the conditions specified in this exception, it would not be considered information blocking to honor a requestor's preferences for: (1) limitations on the scope of EHI made available to the requestor; (2) the conditions under which EHI is made available to the requestor; and (3) the timing of when EHI is made available to the requestor for access, exchange, or use. CHI agrees that this Exception would support patient requests to learn about important medical information in the manner and timeframe they prefer. Yet, the technical capabilities for meeting such patient requests are not uniformly available or adopted. However, to provide needed flexibility for both providers

---

[7] [CHI dobbs issue brief]

and patients, we urge ASTP to permit verbal, as well as written, communications from patients in making these preferences known.

- TEFCA Exception: ASTP proposes to give actors assurance that complying with TEFCA requirements as a Qualified Health Information Network (QHIN), Participant, or Subparticipant would not be considered an interference. CHI generally appreciates ASTP's continued efforts to develop and support the Trusted Exchange Framework and Common Agreement (TEFCA), which must play a central role in facilitating information exchange and creating a unified framework for nationwide health information exchange through Qualified Health Information Networks (QHINs); and we generally support ASTP's proposed qualifications and requirements for entities designated as QHINs under TEFCA.

  However, we reiterate our concern that the proposed TEFCA exception could be used to elect out of participating in Individual Access Services (IAS) in a national network capacity. We urge ASTP to ensure that its TEFCA Exception is not exploited to justify systematic ignoring or rejection of legitimate data queries (and ASTP should take steps specified below, e.g., in Section V of this comment, to update its definitions under TEFCA to ensure the same).

V. **Trusted Exchange Framework and Common Agreement Proposals That Undermine Interoperability**

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,[8] and we share ASTP's goals. CHI urges push forward on the pro-patient, pro-provider components of the rule that promote choice, convenience, and accessibility while simultaneously addressing the needs of non-digital-forward entities that may not be subject to TEFCA.

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.[9] In addition, by artificially siloing

---

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

[9] 21sr Century Cures section 4002, adding 42 USC 300jj-11(D)(iv)

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 NPRM proposes that it would be information blocking to "not exchange EHI under circumstances in which exchange is lawful"[10] though exchange is lawful under HIPAA between two provider covered entities.[11] ASTP further proposes to let stand, and indeed tacitly endorses, a privately adopted operating rule[12] 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.[13] 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.

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 Provider Identifiers (NPI), the CMS predecessor proposed an additional category of provider besides licensed professionals.[14] 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.[15] Today, the HIPAA rules are the federal baseline for when can PHI be exchanged, and expressly permit two providers to exchange health information about

---

[10] 89 FR 63803

[11] 45 CFR 164.506(c)

[12] 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.

[13] 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.

[14] 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)

[15] 65 FR 83456, 82477-78, December 28, 2000. In the August 2002 revisions to the Privacy Rule, this definition remained unchanged.

an individual they are both providing services to, without resultant disclosures being a breach of HIPAA.[16],[17]

Much later, in implementing the Cures Act, HHS defined "interoperability" in 2016 as "health information technology" that:[18]

>   (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 all 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.

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:

---

[16] 45 CFR 164.506.

[17] 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.

[18] Cures Act sec. 4003.

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.

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.[19]

Example 3: A licensed psychiatrist who does not take insurance treats countless patients with a range of mental health conditions. When it makes queries under TEFCA, its query is ignored or rejected.

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.

---

[19] 81 Fed. Reg. 80472 (Nov. 15, 2016).

As a result, we urge ONC to either:

- 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].

VI.   Conclusion

CHI appreciates the opportunity to submit its comments, highlighted in this letter, and attached in full, to ASTP. We look forward to assisting ASTP in realizing a technology-enabled care continuum that provides maximum value to patients at the lowest costs.

Sincerely,

Brian Scarpelli
Executive Director

Chapin Gregor
Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005