American Health Information Management Association (AHIMA)
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October 1, 2024

Dr. Micky Tripathi
Assistant Secretary for Technology Policy
Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology
330 C Street NW
Floor 7, Mary E. Switzer Building
Washington, DC 20201

RE: ASTP HTI-2 Proposed Rule

Dear Dr. Tripathi:

On behalf of the American Health Information Management Association (AHIMA), we are writing in response to the Office of the Assistant Secretary for Technology Policy Office of the National Coordinator for Health Information Technology (ASTP) Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule published in the August 5, 2024 *Federal Register* (HHS-ONC-2024-0010).

AHIMA is a global nonprofit association of health information (HI) professionals with over 61,000 members and more than 88,500 credentials in the field. The AHIMA mission of empowering people to impact health® drives its members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Leaders within AHIMA work at the intersection of healthcare, technology, and business, occupying data integrity and information privacy job functions worldwide.

Among several recommendations detailed in our response below, **AHIMA recommends ASTP:**

- **Provide more education to healthcare organizations, clinicians, HI professionals and other end-users, including patients on the implementation needs in organizational policy and workflow resulting from these proposals;**
- **Consider the implementation timeline of regulatory requirements across all ASTP and US Department of Health and Human Services (HHS) rules and adjust compliance deadlines where appropriate to minimize burden as entities work to achieve compliance;**
- **Align proposals with requirements included in other HHS regulations, including the HHS Office for Civil Rights (OCR) HIPAA Privacy Rule to Support Reproductive Healthcare Privacy Final Rule with the information blocking requirements; and**

- **Explore additional avenues to engage health information technology (IT) end-users in the formulation of these policies to gather accurate information on the needs of the industry and how these policies can be implemented effectively, which includes real-world testing.**

The following are our more detailed comments and recommendations on selected sections of the HTI-2 proposed rule.

III. ONC Health IT Certification Program Updates

B. New and Revised Standards and Certification Criteria (USCDI v4, SMART App Launch 2.2, User-Access Brands and Endpoints, etc.)

AHIMA supports the adoption of United States Core Data for Interoperability version 4 (USCDI v4) but recommends that adoption should be delayed until the health system implements USCDI v3, which is scheduled for implementation on January 1, 2026. It is important for the health IT community to continue its work developing standards to best capture the world that patients and clinicians exist in today. This development should be undertaken at an appropriate pace to ensure clinicians and technology developers can accomplish the policy requirements that are already in place. By taking a measured implementation approach through delayed implementation, ASTP can review the USCDI v3 implementation process to determine what, if anything, should be altered to ensure success with USCDI v4. While the data elements included in USCDI v4 are important for the health system to have implemented, those elements will not be useful if we do not ensure they are implemented in an appropriate manner.

In addition to delaying the implementation timelines, AHIMA urges ASTP to consider the following to achieve the desired policy outcomes. First, ASTP should review and reconsider the proposed process under which new and updated products are real-world tested. The standards development process today does not make adequate room for end-users of those standards to participate in real-world testing activities. End-users are also often sidelined when the health IT products are designed and built until submission for certification. This leads to products that do not accomplish their intended goals when placed in healthcare organizations resulting in additional implementation costs. As ASTP continues to develop the certification program, AHIMA recommends that real-world testing is required at the beginning of product development, not the end. If a delay in the implementation date for updated products is needed to ensure adequate real-world testing is achieved, AHIMA recommends ASTP alter its policymaking timeline to ensure it is able to accommodate this needed change. Inclusion of a standard in regulation should not be considered a sign of maturity. Rather, it is only when real-world testing has been completed and comprehensive report-outs on the testing are made public should the standard be considered mature enough for inclusion in regulation.

Additionally, throughout the proposed rule, ASTP indicates that certain implementation guides (IGs) should be used unless an updated version is finalized and available for use prior to rule finalization. We recommend ASTP be specific and concrete in the standards and IGs it is proposing for the development of new health IT products. Creating ambiguity with the caveat that an updated IG can be used leads to

clinicians being unable to prepare for implementation and use of health IT products. The caveat also makes it difficult to provide comments on these proposals as supporting a standard and IG today may not be accurate if a new IG is later finalized. Without knowing what IGs may be finalized prior to rule finalization it is impossible for clinicians to comment on whether the stated policy goals may be accomplished because IGs can alter the way a health IT product is designed, implemented, or used. To provide better certainty, AHIMA urges ASTP to reconsider allowing current draft IGs to be used as part of the final rule.

Finally, the results of the Da Vinci Project Electronic Prior Authorization (ePA) FHIR application programming interface (API) pilots[1] contained in the report created on behalf of and provided to the Centers for Medicare & Medicaid Services (CMS) must be released to the public prior to the imposition of a mandate to utilize this technology. At this time, it is unclear where in the development process the FHIR APIs are, or if they are close to deployment for use and implementation. For ASTP, and ultimately CMS, to achieve their stated policy goals related to ePA, the FHIR APIs must be ready for implementation and functional. Without knowing the results of the FHIR API pilots it is difficult for the health IT community to gauge the timeline for implementation or what may need to change with the APIs or their IGs to ensure implementation can be minimally burdensome to clinicians and developers alike. Asking the public to comment on these APIs without giving them the tools to fully understand the state of technology hinders ASTP's ability to receive meaningful comments.

IV. Information Blocking Enhancements

A. Defined Terms

ASTP proposes to update the definition of "health care provider" to include definitions of "laboratory" and "pharmacist." ASTP proposes to codify that, for purposes of the information blocking regulations, "health information technology" and "health IT" have the same meaning. ASTP proposes to codify that "business day" or "business days" means Monday through Friday except for public holidays or federal holidays.

AHIMA supports the proposed updates to the definition of health care provider and codifications of the health IT and business day definitions for industry-wide consensus and understanding. We appreciate ASTP clarifying that patient health care and health data include data held by pharmacies and laboratories.

ASTP proposes to add a new section to the information blocking regulations that would codify certain practices that constitute "interference" for purposes of the information blocking definition.

AHIMA supports the proposal to add a new section to the information blocking regulations of practices that constitute interference. We appreciate ASTP providing examples of interference that are broad enough for proper interpretation by actors yet not too descriptive to avoid running the risk of conflicting with state laws and regulations, as well as future changes that may occur in the business and operational

[1]Available at: https://confluence.hl7.org/display/DVP/Da+Vinci+Trebuchet+FHIR+Pilots.

landscapes of healthcare and health IT. If an actor is found guilty of information blocking due to a practice that falls into one of these categories of interference, AHIMA recommends ASTP indicate whether such practice falls under one of these categories of interference in publicly posted information. We believe this will promote a greater understanding of the real-world applications of interference with information sharing.

ASTP clarifies that it would likely not be considered "interference" for the Trusted Exchange Framework and Common Agreement (TEFCA) Qualified Health Information Networks (QHINs), participants, or subparticipants to comply with required provisions of the Common Agreement (CA) and the incorporated TEFCA Terms of Participation and TEFCA Standard Operating Procedures (SOPs). This does not extend to permissible or optional practices that are not required by the CA.

AHIMA supports this clarification to promote clearer insight into the intersection between TEFCA and the information blocking requirements. AHIMA continues to support the operationalization and use of TEFCA to advance nationwide interoperability and encourages its membership to engage in TEFCA. We recommend ASTP continue to monitor the development of TEFCA and make clarifications and adjustments in the information blocking program to accommodate the exchange of electronic health information (EHI) via TEFCA as necessary.

B. Exceptions

1. Privacy Exception

ASTP proposes to broaden the applicability of the sub-exception for denying individuals access on "unreviewable grounds" so that it is available to any information blocking actor (rather than limiting it to actors who are also HIPAA-covered entities and BAs) who is responding to a request for EHI.

As written, it is unclear the changes this proposal may introduce in practice, thus AHIMA cannot make a recommendation on the finalization of this proposal. If finalized, AHIMA encourages ASTP to provide additional resources and education for healthcare organizations, non-HIPAA-covered entities, and end-users, including HI professionals, on implementing this regulation. Actors need more information on potential changes in policies and workflows that may be needed to comply with this proposed requirement.

ASTP proposes to broaden the applicability of the sub-exception for respecting individuals' request not to share EHI with others by removing its existing limitation to individual-requested restrictions on EHI sharing that are permitted by other applicable law. This would extend the sub-exception to an actor's practice of implementing restrictions that an individual has requested, even if the actor has concern that another law or instrument would compel an actor to disclose EHI that would be contrary to the individual's expressed wishes.

AHIMA appreciates the intention of ASTP to broaden this sub-exception to assist actors in honoring individual requested restrictions while maintaining compliance with information blocking requirements.

However, AHIMA has concerns about the implementation and effect of this update. There may be potential unintended legal consequences for actors who restrict the sharing of EHI under the information blocking rule that may be contrary to existing law. Additionally, patients requesting such restrictions may be under-informed on both the potential safety impacts of choosing to restrict information sharing, especially with other clinicians within the patient's care team, and the feasibility of requests to restrict data, as EHI is often more far-reaching in speed and scope than commonly understood.

If finalized, AHIMA recommends ASTP provide education to patients on the ability (or lack thereof) of actors to fulfill requests for restrictions and the risks of doing so. As the information blocking regulations affect both patients and clinicians, AHIMA urges ASTP to consider the role, capability, and feasibility of actors implementing such restrictions, particularly the more specific requests may get, and note the possibility of variations in the implementation of this policy if finalized. Health information professionals note that electronic health record (EHR) systems often do not have the dimensions or capabilities to implement specific restrictions based on patient choice. AHIMA recommends ASTP recognize the capabilities of current technology when finalizing policies that allow patients to request specific restrictions on the use and sharing of EHI, and how this impacts actors' abilities to comply with such requirements. Should ASTP pursue these types of future requirements, AHIMA recommends the agency pursue certification program initiatives to create the needed technology.

2. Infeasibility Exception

ASTP proposes to update the segmentation condition by expanding it to include circumstances where an actor cannot segment from other EHI, the EHI that they cannot share or have chosen to withhold consistent with privacy sub-exceptions applicable to denials of individual access on unreviewable grounds or health IT developer of certified health IT not covered by HIPAA; or the proposed new Protecting Care Access Exception.

If the proposed updates to the privacy sub-exceptions are finalized, AHIMA supports this proposal to promote compliance with and harmonization of the information blocking requirements.

ASTP proposes to update the third party seeking modification use condition to indicate that it would not apply when third party modification use is sought by any HIPAA-covered entity or BA from an actor that is their BA, or by any healthcare provider who is not a HIPAA-covered entity from an actor whose activities would make the actor a BA of the same healthcare provider if the healthcare provider were a HIPAA covered entity.

AHIMA recognizes and supports the intention of the update of this condition to ensure HIPAA-covered entities and their business associates, as well as non-covered entities that have relationships with actors and handle EHI (such as non-HIPAA-covered health applications used by patients), safeguard the privacy, security, and integrity of EHI. However as written, the proposed update is unclear and thus difficult for healthcare organizations to understand, implement, and operationalize.

If finalized, AHIMA urges ASTP to provide clearer definitions of "non-covered entity" and "provider" as well as related resources to support implementation. This could include sub-regulatory guidance on the technical execution of this update with examples of organizations and companies that would be classified as HIPAA-covered entities, business associates of HIPAA-covered entities, healthcare clinicians who are not HIPAA-covered entities, and healthcare clinicians who are not HIPAA-covered entities that would be considered business associates if they were HIPAA-covered. This should also include examples of relationships between these types of actors and scenarios in which they may interact, in line with the framing of this proposed update. Actors need this information to effectively communicate and provide training to clinicians and their staff on changes to workflows that may be impacted by this update. This is particularly important in the context of this condition and its proposed update, which would broaden the ability for additional entities to modify EHI within the records or systems maintained by the actor.

ASTP proposes to modify the responding to requests condition by establishing more flexible response time frames beyond the current requirement of an actor responding within ten business days of receiving a request, when the reasons for infeasibility are consistent with the manner exception exhausted condition or the infeasible under the circumstances condition.

AHIMA supports the proposal to extend the timeframe within the responding to requests condition beyond 10 business days for the manner exception exhausted and the infeasible under the circumstances conditions. In addition to those two conditions, we recommend ASTP apply a longer timeframe to the segmentation condition because it may take entities additional time to determine if a request is feasible or not to segment, as requests can be made in different ways and to different specificities. Which data to segment and to what extent can vary across requests, therefore the actor's determination of their ability to segment or not can change based on the request. This is even more true with the proposed update to the segmentation condition which, if finalized, would add more instances where an actor must determine whether segmentation is possible.

Before adopting a longer timeframe for any condition, AHIMA urges ASTP to review comments from relevant stakeholders on the appropriate maximum timeframe for responding to requests. Any longer timeframe should include enough time to accommodate circumstances in which the determination is difficult yet not be too long that sharing of EHI is impeded.

3. Protecting Care Access Exception

ASTP proposes a new Protecting Care Access Exception that would cover actors' limiting EHI sharing in order to reduce a risk of potentially exposing patients, providers, or others who facilitate care to legal action based on the mere fact that a person sought, obtained, provided, or facilitated lawful reproductive health care. This proposed exception would require actors to meet the threshold condition and at least the patient protection condition or care access condition.

AHIMA appreciates the effort from ASTP to align the information blocking program with the HHS Office for Civil Rights (OCR) HIPAA Privacy Rule to Support Reproductive Healthcare Privacy Final Rule and offer

actors flexibility in balancing the protection of patients' privacy without information blocking. However, operationalizing this proposed new exception would be difficult as it creates ambiguity in comparison with the OCR rule. Specifically, the OCR rule provides a clear process for either disclosing or not disclosing EHI potentially related to reproductive healthcare based on an organization's policy and definition of "reproductive healthcare data" and whether the information will be used in criminal proceedings concerning a patient, clinician, or other individual involved in seeking, providing, or facilitating reproductive healthcare. In contrast, the proposed Protecting Care Access Exception indicates that clinicians may be able to block the flow of information potentially related to reproductive healthcare due to concern that the information may be used against a patient, clinician or individual, but with a different basis of rationale. Rather than being based on adopted organizational policy, this new exception relies in part on a "good faith estimate" to determine risk, which is not included in the OCR final rule and introduces a subjective basis to make that determination.

It will be difficult to educate clinicians and healthcare organization staff on implementing policies that accommodate both this proposed exception and the OCR rule. The subjective nature of the "good faith estimate" is not based on the facts and circumstances patterns that the information blocking regulation has followed in the past. This will make it difficult for organizations to interpret this policy and implement it across staff who may have different interpretations of what risk is present. In turn, this places organizations at risk of complying with one regulatory requirement while violating another. Additionally, AHIMA has concerns with the implications of setting such a precedent to protect actors who do not disclose information based on what is a subjective analysis of present or potential risk. If finalized, AHIMA recommends ASTP harmonize this approach with that of the OCR rule by providing a clear fact pattern that organizations should follow in determining the risk associated with disclosing information.

We also note that adding more exceptions to the information blocking program increases the complexity of the requirements clinicians are to comply with and risks undermining the intent of the program, to reduce unnecessary and unlawful inhibitions of access, exchange, and use of EHI. AHIMA encourages ASTP to continue to work to streamline the program as the health IT landscape evolves.

4. Requestor Preferences Exception

ASTP proposes a new Requestor Preferences Exception that would apply when an actor honors a requestor's preference for limitations on the amount of EHI made available to the requestor; the conditions under which EHI is made available to the requestor; and when EHI is made available to the requestor for access, exchange, or use. This proposed exception would require actors to meet four conditions: the request condition, the implementation condition, the transparency condition, and the reduction or removal condition.

AHIMA supports the proposal to introduce enhanced choice for patients, healthcare clinicians, and other requestors when managing the influx of data by allowing them to determine which data, when, and how data is made available for access, exchange, or use. This can be helpful in scenarios where an individual may wish to receive EHI only during certain times of day or not immediately, an individual may wish to have their ordering clinician review EHI including diagnostic and imaging test results before it is shared

with them, patients or healthcare organizations who may wish to receive information via one method over another, or healthcare organizations that may only need one subset of a patient's EHI or the most recent test results, for example.

However, AHIMA is concerned that the proposed exception poses potential risks to patient safety if their medical record is limited in scope before sharing and potential legal risks to actors who restrict this information. There are also operational complexities associated with this exception. Like the current landscape of data segmentation, it may not be technically possible for actors to implement certain restrictions on the scope of EHI made available to a requestor. Additionally, it may be onerous for actors to explain to requestors the feasibility of technical capabilities in fulfilling different requests that vary in scope, conditions, and timing. It will also be challenging for actors to explain their varying capabilities without actors being seen as steering or inducing requestors towards one particular preference, which is prohibited in this proposed exception. While actors may be encouraged to create documented organizational policy in this area, it is inconceivable for actors to consider and plan for every request for restrictions that they may encounter from all types of requestors.

Further, the proposed rule states "an actor would be required to explain to the requestor what they can and will do to tailor EHI availability to the requestor." AHIMA recommends ASTP clarify the responsibility of actors in handling such requests, particularly, if actors are required to both assess their ability to fulfill requests and act to fulfill requests or if they can deny requests.

AHIMA reiterates that adding more exceptions to the information blocking program increases the complexity of the requirements clinicians are to comply with and risks undermining the intent of the program. AHIMA encourages ASTP to consider whether the proposed new Requestor Preferences Exception can be incorporated into the existing Manner Exception. ASTP could consider adding a second condition under the Manner Exception that relates to requestor preferences, separate from the current key condition that deals with the actual manner in which the information is transmitted. Such a "Requestor Preferences Condition" could include the four conditions included as proposed.

5. Exceptions That Involve Practices Related to Actors' Participation in the Trusted Exchange Framework and Common Agreement (TEFCA)

In the HTI-1 proposed rule, ASTP assumed all actors participating in TEFCA already reached agreements on fees and licensing. In response, many commenters expressed concern because the CA prohibits fees between QHINs but is silent on fees between participants and subparticipants, which could inadvertently allow actors to charge fees or disincentivize participation in TEFCA and encourage actors to use other methods of electronic exchange where the fees and licensing exceptions would apply. As a result, in the HTI-1 final rule, ASTP finalized policy to apply the fees and licensing exceptions to the TEFCA Manner Exception. ASTP requests comments on this approach.

AHIMA supports the finalized policy in the HTI-1 final rule to apply the fees and licensing exceptions to the TEFCA Manner Exception and applauds ASTP for acknowledging stakeholder concerns. AHIMA noted this concern in our comments in response to the HTI-1 proposed rule, noting the lack of rules for participant

fees in the Common Agreement which could create a possibility that a participant could charge a large fee for another organization to exchange data.[2] Without the application of the fees and licensing exceptions, a participant could be exempt from information blocking because they offered TEFCA exchange as a solution, even though the fees could create a potential barrier to information exchange. The finalized policy in HTI-1 to close this loophole and apply the fees and licensing exceptions to the TEFCA Manner Exception provides further reassurance and protection to actors that any fees and licensing agreements will be reasonable and appropriate, which in turn can help promote participation in TEFCA.

V. Trusted Exchange Framework and Common Agreement

AHIMA continues to be a steadfast supporter of TEFCA. We believe TEFCA can be a solution to longstanding nationwide data exchange issues. For the nation to fully embrace TEFCA, AHIMA also understands that trust is paramount. In order for trust to be maintained, a strongly recognized coordinating entity (RCE) operating independently of ASTP must be preserved. As ASTP continues to evaluate how best to manage and regulate TEFCA the agency must ensure that any further additions of text from the Common Agreement (CA) to the Code of Federal Regulations (CFR) do not erode the RCE's ability to independently manage TEFCA, its Qualified Health Information Networks (QHINS), and participants. If trust in the RCE and the independence of TEFCA is lost, then it is unclear if clinicians and patients would continue to believe TEFCA is a safe and effective way to transmit health information.

Thank you for the opportunity to comment on the ASTP HTI-2 proposed rule. AHIMA remains a committed partner to ASTP in improving the sharing of EHI across patients, clinicians, payers, and public health authorities. If AHIMA may provide any further information, or if there are any questions regarding this letter and its recommendations, please contact Andrew Tomlinson, senior director of regulatory and international affairs at Andrew.Tomlinson@ahima.org or Tara O'Donnell, regulatory health policy associate, at Tara.ODonnell@ahima.org.

Sincerely,

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[2]Available at: https://www.ahima.org/media/rrije1di/ahima-onc-hti-1-comments-final.pdf.