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President and CEO

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Micky Tripathi, PhD
Assistant Secretary for Technology Policy
and National Coordinator for Health IT
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

**RE: RIN 0955-AA06, Health Data, Technology, and Interoperability (HTI-2):
Patient Engagement, Information Sharing, and Public Health Interoperability
Proposed Rule**

Dear Assistant Secretary Tripathi:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying public and privately held hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's and cancer services.

The FAH appreciates the opportunity to provide the Assistant Secretary for Technology Policy (ASTP) and Office of the National Coordinator (ONC) for Health Information Technology with feedback regarding the *Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability* Proposed Rule (RIN 0955-AA03). The FAH continues to believe in the potential of health information technology (health IT) to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates ASTP's commitment to improving interoperability and patient access to information through use of standards and believes many of the policies contained in the

proposed rule would advance those goals. The FAH offers the below comments and recommendations to help guide these efforts.

New and Revised Standards and Certification Criteria

ASTP proposes to update a range of functions and standards that must be accommodated by certified health IT. The FAH shares ASTP's goal to make continued progress toward interoperable health IT systems that can improve healthcare by supporting the efficient access, exchange, and use of relevant data. We are pleased to see the focus on data systems to support public health agencies (PHAs) in receiving data from hospitals and health systems needed to ensure the public health.

However, we are concerned about the broad scope and fast pace of regulatory change being proposed in HTI-2. In particular, this proposed rule must be considered in the context of the HTI-1 final rule, which was only released in January 2024 – barely six months before the release of the HTI-2 proposed rule. In addition, eligible hospitals and clinicians must use certified electronic health record (EHR) technology (CEHRT) to meet the requirements of the Medicare Promoting Interoperability Program (PIP) or face significant payment penalties. Given recent rulemaking by CMS, any change to the ONC definition of the Base EHR is an automatic change to the definition of CEHRT, and hospitals and health systems must upgrade their technology on the timeline specified by ASTP to be in compliance with the CMS requirements.

Adding a multitude of new functionalities and requirements to certified health IT at a time when the HTI-1 provisions have not yet been implemented could overwhelm hospitals and health systems, which face multiple priorities and must focus first on patient care. **Therefore, the FAH encourages ASTP to limit the scope of its final rule, reconsider the proposed timelines for provisions that are finalized, and refrain from adding new functions to the definition of the Base EHR.**

United States Core Data for Interoperability (USCDI): ASTP adopted USCDI v1 in the *21st Century Cures Act* Final Rule (2020). USCDI is considered the minimum data needed for interoperability and includes a range of data elements and vocabulary standards but is regularly expanded upon by ASTP through a public process. ASTP proposes to adopt USCDI v4, which includes additional data elements and updated standards.

The FAH supports the use of USCDI, which aligns the scope and standards for the health information gathered and shared to support patients. **However, the FAH recommends that ASTP hold off on establishing a date for moving to USCDI v4 until developers, hospitals, health systems, and other health care providers have implemented and assessed success with USCDI v3, which itself includes well over 100 data elements.** We note that the HTI-1 final rule does not require use of USCDI v3 until January 1, 2026, when the currently adopted version of USCDI is retired. ASTP proposes to retire USCDI v3 on January 1, 2028, effectively requiring use of USCDI v4 on that date.

Rather than finalizing a date to move to USCDI v4, the FAH encourages ASTP to focus on the following improvements to how data in USCDI can be leveraged:

- Identify an appropriate vocabulary standard for all USCDI v4 elements where there are none. This would provide a more reliable and efficient method for tracking medication fill status, adherence, and other core data elements that currently have no vocabulary standard.
- Evaluate the feasibility of capturing data in a structured manner through the use of Natural Language Processing (NLP) or other tools to reduce the burden of data capture.
- Develop workable solutions to advance technology that supports data segmentation for privacy.

As recognized by ASTP, the USCDI standard does not just determine the data elements and vocabulary standards used in certified health IT, it also flows into eight additional certification elements (including, among others, clinical information reconciliation, decision support, information sharing requirements, and application programming interfaces, or APIs). Changing the data that is used in these other functions has operational implementations beyond the initial burdens of purchasing and deploying updated technology and training staff on how to use it. For example, USCDI v4 introduces a number of sensitive data elements (such as data related to behavioral health, reproductive health, and gender identity) that pose operational challenges to ensure confidentiality and meet legal requirements. Certified health IT cannot yet easily segment data for privacy reasons, making it complex and difficult for hospitals and health systems to comply with existing laws protecting sensitive data, which can vary across jurisdictions, when managing an API or responding to requests for information. Sharing sensitive data also requires developing policies and procedures, training, and documentation systems to handle appropriately.

Diagnostic Imaging Hyperlink

ASTP proposes to add a requirement for certified health IT to provide “imaging links” to support sharing digital images with patients and others legally allowed to access clinical data. The functional requirement would enable electronic viewing or retrieval of one or more images over a network that is accessible via hyperlink.

Access to, and sharing of, diagnostic images can be challenging, given the variability of diagnostic images themselves and the complex technical systems needed to view them. The FAH understands the desirability of allowing patients and other caregivers to easily access diagnostic imaging. However, images are contained in many disparate systems. For example, an ultrasound may be taken in a physician’s office, while more advanced CT scans or MRIs are performed in a hospital outpatient setting. ASTP should not underestimate the complexities of operationalizing this requirement, as well as the security concerns it raises.

Even with vendor support, existing healthcare infrastructures may face significant challenges in implementing these changes. It is crucial to establish a clear and well-defined standard before requiring certification for this functionality. This will ensure that all stakeholders have a shared understanding of the requirements to facilitate compliance.

Given the importance of patients’ access to their own information, the FAH recommends that this requirement only apply to inclusion of a hyperlink within an internal

system (such as patient portal) to an internal resource. Patients should not have to leave the portal to see the image. **We strongly advocate avoiding external redirects, as this can negatively impact patient engagement.** In addition, providers should not be expected to send links to external parties that do not have organizational credentials as doing so represents a significant security issue.

Clinical Information Reconciliation and Incorporation (CIRI)

ASTP proposes to expand the number and types of data elements that health IT certified to this CIRI criterion would be required to reconcile and incorporate from the current three elements (problems, medications, and allergies) to all USCDI data elements (which number well over 100). Alternatively, ASTP proposes to expand this capability to a total of nine data classes that include many data elements beyond those currently required. ASTP also proposes new functional requirements to enable user-driven automatic data reconciliation and incorporation.

The FAH recommends that ASTP refrain from expanding the CIRI requirements beyond the three data classes required as part of the current certification criterion’s functionality. We strongly encourage ASTP to strengthen the existing clinical reconciliation requirements for problems, medications, and allergies before introducing additional data elements for incorporation into a patient’s medical record.

While there are potential benefits from having the ability to reconcile and incorporate additional data classes and elements, hospital and health systems experience significant challenges in the practical adoption and utilization of this functionality. The variability in data quality and payloads from outside data sources pose substantial hurdles for reconciliation and storage. This reality necessitates a more focused approach, prioritizing usability and process efficiency over the breadth of technical capabilities and data reconciled.

Further, the FAH disagrees with ASTP’s secondary proposal to mandate “automatic reconciliation and incorporation, without manual review, for each of the applicable USCDI data elements.” Automated integration and reconciliation of any clinical data could introduce data quality issues and inaccuracies within a patient’s chart. The potential downstream impacts of sharing erroneous or inaccurate information could also be detrimental to the quality of a patient’s health information, which would ultimately impede healthcare treatment, payment, and operations.

Revised Electronic Prescribing Certification Criterion

The FAH supports the proposed revision of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 into the electronic prescribing criterion. This update would enhance prescription transactions' security, efficiency, and interoperability. The proposed transition timeline provides a reasonable timeframe for health IT developers to update their systems and ensures a smooth transition to the newer standard. Finally, removing optional transactions would streamline the certification process and promote consistency across certified health IT modules.

Real-Time Prescription Benefit

ASTP proposes a “Real-Time Prescription Benefit” certification criterion to enable the exchange of patient eligibility, product coverage, and financial information for a chosen product and pharmacy so that prescribers can have access to and share with their patients both coverage and out-of-pocket cost information at the point of care. ASTP also points to specific standards that would support this functionality.

The FAH strongly supports creating this functionality in certified health IT as a tremendous benefit for patients, such as helping them understand their out-of-pocket costs and determine whether prior authorization is required. Assuming the technology will work effectively and provide accurate information, this is a tool that also would give clinicians access to crucial inputs that they have long wanted to use in shared clinical decision-making.

Standardized API for Patient and Population Services and Modular API Capabilities

ASTP proposes to require support of several updated standards and new functionality within the existing standardized API for patient and population services with an implementation date of January 1, 2028. ASTP also proposes to create a new constellation of certification requirements to support modular API capabilities that would include both updates to existing requirements and the introduction of more advanced capabilities. These proposals are in addition to new requirements finalized in HTI-1 that have yet to be implemented.

The FAH supports the direction of the proposals to enhance API granularity, enabling users to request specific data points rather than requiring the retrieval of entire datasets. This approach can improve efficiency and reduce unnecessary data transfer. However, the large volume and generally tight timeframes for the proposed new functionality, on top of the new requirements in HTI-1, may strain the ability of health IT vendors to adopt and test new API versions effectively. As a result, developers may not have sufficient time to implement necessary changes and ensure the seamless integration of updated APIs. For their part, providers have many priorities and demands on their resources and have not seen significant uptake of the APIs they currently have in place.

To mitigate these challenges, the FAH recommends that ASTP limit the scope and slow the pace of new requirements. ASTP can help avoid costly out-of-cycle installations and upgrades by allowing reasonable implementation timelines. These considerations are particularly relevant to rural, ambulatory, and safety net providers, who may have more constrained resources.

The FAH also offers the following observations on the proposed updates to the standardized API for patient and population services:

- The inclusion of subscriptions and Query parameters will be beneficial.
- “Write” capabilities for APIs must include consideration of security concerns and data quality issues. Hospitals and health systems do not want to incorporate poor-quality data in the medical record as it could jeopardize clinical decision making. Further, bad actors could attempt to use these capabilities to introduce malware.

- The growing amount of data available through the API, coupled with the limited technical abilities to segment data, make it difficult to comply with existing law, including abiding by minimum necessary requirements and protections for sensitive data.

With respect to the modular API capabilities, the FAH believes that this approach could make long-term sense but should not be pursued until we have an ecosystem of apps that have proven to be useful.

Security-Related Proposals

The FAH supports both of ASTP's proposals regarding security-enhancing tools:

- Encryption of personally identifiable information stored on end-user devices and on servers using updated encryption algorithms, and
- The addition of specific requirements to support multi-factor authentication for certain functionality.

Protecting against cyberattacks that can disrupt care and put patient health care information at risk is a key priority for FAH members. They are working continually to strengthen their cyber defense systems and welcome the addition of tools to certified health IT that will advance their efforts to defend patients against criminal actors.

Computerized Provider Order Entry - Laboratory Criterion

The FAH supports ASTP's proposal to require new functionality for creating and transmitting laboratory orders, as well as receiving and validating laboratory results. We believe that this will contribute to standardizing laboratory reporting, and we foresee this functional requirement as a positive step forward for laboratory provider order entry.

Public Health Data Exchange

The HTI-2 proposed rule includes a number of proposals meant to facilitate the sharing of information across provider organizations and PHAs. Since the beginning of the meaningful use program, eligible hospitals and clinicians have adopted technology that allows standardized electronic reporting of a variety of indicators to PHAs as a condition of the Medicare PIP/MIPS. However, the capabilities of PHAs to receive that data electronically has varied considerably and there has been no national policy to support certification of the health IT used by PHAs. Generally, the health IT used by PHAs is not yet universally capable of receiving the information that provider systems have been certified to send.

In order to improve this mismatch in capabilities, ASTP proposes a suite of criteria that would update the certified health IT used by hospitals and health systems, and required under the Medicare PIP/MIPS, while also developing certification criteria for health IT that could be voluntarily adopted by PHAs. ASTP separately proposes certification criteria for a Standardized API for Public Health Data Exchange (Provider) to be included in the definition of Base EHR, and hence required to meet the CEHRT requirements under the Medicare PIP.

Certified Health IT for PHAs. The FAH is supportive of steps that will decrease the burden and improve the efficiency of public health reporting. The COVID-19 pandemic highlighted the shortcomings of the public health community to be able to leverage IT solutions to gather and share critical information during an emergency and FAH members report that onboarding to PHA electronic reporting systems is currently slow and challenging. The burden for providers that operate in multiple jurisdictions is particularly high as each PHA may have unique onboarding and data reporting requirements. Moving quickly to improve the capacity of PHAs to support standards-based transactions is crucial to ensuring that the country does better in future public health emergencies. **Therefore, the FAH urges ASTP to work with the Centers for Disease Control and Prevention (CDC) and other agencies to accelerate the modernization and standardization of IT capabilities across PHAs, including by requiring the use of certified health IT.** ASTP and CDC must also evaluate whether PHAs are adequately financed or staffed to adopt these new technologies and map them to existing policy and program requirements. We note that PHAs may need a much longer timeline to successfully transition to effective use of certified health IT to receive reporting data. CDC and PHAs should also prioritize moving toward a universal set of standardized reporting requirements.

Measure-specific Criteria. The FAH also offers these comments on the specific certification criteria proposed by ASTP that are related to specific types of public health reporting measures.

- **Immunization Registries—Bi-directional Exchange:** The FAH appreciates ASTP's efforts to improve immunization reporting and believe that revising the current HL7 V2.5.1 immunization implementation guides (IG) is necessary to further standardize public health reporting. While this proposal is a positive step for public health reporting, we seek additional clarity on the proposed functional requirement for receiving patient-level immunization-specific queries and requests from external systems. The FAH specifically requests additional clarification regarding the value of adding this functionality and proper defining of an "external system." In addition, we agree with ASTP's approach to add a new certification criterion to require receipt, validation, and parsing of immunization data. However, we believe this should not be EHR-centered, and consumers should have the ability to utilize other platforms to meet this requirement. Given that bi-directional immunization reporting is a requirement for the PIP, many providers fulfill this requirement using alternative platforms. As such, requiring this functionality from the EHR system may not properly align with CMS's approach.
- **Syndromic Surveillance:** The FAH supports ASTP's initiative to update the current HL7 implementation guide for syndromic surveillance reporting and we also believe it would be appropriate to expire existing standards based on the proposed expiration date. While we appreciate the criterion's focus on new functionality to validate, parse, and filter data, it may not be advantageous for larger-scale facilities. We would appreciate further clarification on the care setting(s) for which ASTP envisions this functionality to be valuable.
- **Reportable Laboratory Results:** We support ASTP's efforts to improve reportable laboratory results and believe updating the current standards is necessary for public

health reporting. We also believe aligning with the proposed updates would be feasible given the proposed expiration dates. Although we are in favor of updating the current standards, we also believe implementing the new proposed functionality would be challenging due to its attributes. **We urge ASTP to present use cases that illustrate the value and benefits of requiring this functionality. We request further clarification on the significance of receiving this data and would appreciate additional information regarding the specific care settings where ASTP anticipates this functionality to be beneficial.**

Standardized API for Public Health Data Exchange: ASTP proposes a standardized HL7 FHIR-based API for public health data exchange that would be included in the Base EHR definition, and therefore be required for eligible hospitals and clinicians under the Medicare PIP/MIPS, beginning January 1, 2028.

The FAH supports the concepts behind ASTP’s proposal, which could be a positive step forward in enhancing public health data exchange, if appropriately designed and resourced. We also emphasize the importance of conducting comprehensive performance testing of this type of API and the ability of PHAs to query them, as the existence of functionality alone does not ensure optimal performance.

While APIs are a promising approach for public health reporting, most PHAs currently lack sophisticated technical capability, and will not universally have the ability to use a provider API to request needed information for the foreseeable future. While the ability to access FHIR-based APIs is included in the certification criteria for health IT used by PHAs, adoption of that technology is not required, and the timeline for widespread deployment of that technology across PHAs is unknown. At a minimum, routine use of provider APIs by PHAs will require the following steps:

- ASTP establishing the PHA certification program, including the creation of testing tools.
- Health IT companies making the decision to undertake certification and modify or develop products that will meet the certification requirements.
- PHAs having sufficient funding and staffing to upgrade to certified systems, while maintaining the ability to receive reports via current methods, with significant time needed to design and implement a transitional cross-over plan.
- PHAs having sufficient funding, staff and time to assess a myriad of non-technical issues, including the scope and format of reporting requirements across programs, and whether certified products can be tailored to accommodate them.

Therefore, the FAH urges ASTP to refrain from including the Standardized API for Public Health Data Exchange in the Base EHR until such time as the public health community has widely adopted health IT certified to support their capabilities, perhaps through a specific requirement from CDC or another federal agency. In the current state, providers are still waiting to be onboarded to many existing PHA systems, such as electronic lab reporting, and the road to use of a FHIR-based API is long and uncertain.

In the interim, ASTP could keep the provider-side API certification requirements as optional (not included in the BASE EHR), so that providers in areas with more advanced PHAs can voluntarily adopt technology with these capabilities. In this way, the community could learn from voluntary adoption so that all PHAs and providers can successfully adopt standardized FHIR-based exchange in a coordinated manner.

US Public Health Profile Library: ASTP proposes to include the United States Public Health Profiles Library Implementation Guide (USPHPL IG) implementation guide in its certification requirements, as a means to automatically include new use cases in public health exchange certification criteria. **Given the above considerations, it is premature to tie the PH API to the USPHPL.**

Payer and Provider APIs

ASTP proposes to adopt a suite of APIs intended to support exchange of information between payers and providers, as well as payers and patients, and payer to payer. The following technologies would be required of hospitals and health systems in order to interact with payer systems:

- Provider Access API client functionality and associated standards, which would allow attributed providers to ask for certain clinical and claims data (minus payment information) held by the payer.
- Prior Authorization API functionality and a suite of associated standards that would allow providers to request coverage requirements, submit needed documentation for authorizations, and receive notification back from the payer on authorization status.

ASTP proposes to include these functions in the Base EHR definition, which means eligible hospitals and clinicians would need to adopt them by the proposed implementation dates of January 1, 2027 (Prior Authorization APIs) and January 1, 2028 (Provider Access API – client) in order to comply with the Medicare PIP/MIPS requirements to use CEHRT.

Prior authorization API: The FAH understands the motivation for these proposals and believes that ASTP is moving in the right direction, particularly for patient and provider access. With respect to prior authorization, hospitals and health systems currently manage across scores of payer/plan combinations that each have different medical policies and documentation requirements, and face growing burdens related to managing authorizations. It is crucial to improve the PA process, and automation may well be a key part of the solution.

However, there has been very limited testing of the Da Vinci Project standards in the real world and across a range of clinical settings, provider types, and payers. Additional real-world testing is crucial if these technologies are to be used in the determination of whether patients can receive certain medications or treatments, which could be lifesaving.

Further, the FAH is concerned that payer adoption of certified technology is voluntary, and the CMS rules do not currently require payers to use many of the Da Vinci Project standards

that would be required of providers, particularly those related to prior authorization. **We believe that the same standards and approaches should be mandatory, rather than optional, for payers to guarantee consistency of the systems used to share information across payers and providers. Adopting a uniform standard will help prevent fragmentation and promote a more efficient healthcare ecosystem.**

Unless and until payers are required to use certified systems that rely on the same standards, it will not be possible to ascertain whether their tools work with certified provider systems, or if all payers will use them. Further, ASTP has yet to create a certification program for payer technologies and it is not clear whether any payer technology companies would want to seek certification or how long it would take them to develop compliant technology and have it certified. As a result, the timeline for use of prior authorization APIs is unclear.

Therefore, the FAH strongly urges ASTP to refrain from including the Prior Authorization API functionality in the definition of the Base EHR until all payers – commercial and governmental – are also required to adopt certified technology.

ASTP could keep the certification requirements as optional (and not included in the Base EHR) for voluntary use by willing provider and payer trading partners, so that the field can learn from their experience.

Additional considerations: Other, non-technical considerations must also be addressed before adopting prior authorization APIs. For example, health care providers have an obligation to share only the minimum necessary patient information. For the safety of our patients and their information, we request ASTP/ONC provide more guidance on how providers can anticipate and accommodate these requests, while maintaining standards for privacy and protection of patient information.

We strongly suggest that ASTP/ONC offer guidance on how data should be effectively shared between payers and providers, particularly regarding FHIR bulk data, given their differing implementation guides. Clear standards and expectations for addressing requests from different sources are crucial. Further, we seek clarity on how these API requests will impact the provider's access to their patient's information, particularly in terms of authentication and verification mechanisms.

Finally, prior authorization APIs will be automating decision-making about patient care, raising questions about which entity would bear responsibility to ensure that the resulting decisions do not result in illegal discrimination. **Given the complexity of patient situations and health care delivery, it is likely that not every case can be automated and there will always need to be a human in the loop for decision-making.**

Provider Directory API—Health Plan Coverage: The FAH is in favor of this proposal as it will allow patients to discover their in-network healthcare providers with the most accurate and up-to-date lists. We also support the alignment of this proposal with the CMS requirements for payers. We seek to understand how inclusion of coverage for patients not participating in the payer's current network will be included. Specifically, we encourage ASTP to provide clear safety and security requirements for this proposal. Additionally, we

encourage ASTP to align with CMS' payer requirements, particularly regarding the implementation deadlines.

Information Blocking Enhancements

ASTP proposes a set of changes to the information blocking regulations that the agency states are responsive to queries it has received from stakeholders and creates greater alignment with other regulatory requirements.

Interference: The FAH opposes ASTP's proposal to add a new section to the information blocking regulations that would codify that certain specific practices constitute "interference" for purposes of the information blocking definition. ASTP could, instead, consider providing additional examples in sub-regulatory guidance.

The proposal would lead to additional confusion, given that the agency states the codified examples would not be comprehensive. In addition, the inclusion of broad categories of activity as codified acts of interference would implicate many common practices that are not, in fact, information blocking. Finally, ASTP has consistently emphasized that the evaluation of a claim of information blocking will be based on facts and circumstances. Codifying certain activities as constituting a prima facie interference moves away from the historical approach.

Protecting Care Access Exception: ASTP proposes a new exception to the information blocking regulations that would apply to practices that otherwise would be considered information blocking when an actor is taking action the actor believes in good faith is needed to comply with OCR's rules regarding information related to reproductive health care. That is, the practice would reduce a risk of potential exposure to legal action (including investigation) against patients, health care providers, or those who help make providing or receiving care possible for purposes of reproductive health care that was lawful under the circumstances in which it was provided.

The FAH agrees with and appreciates this proposal, as it would allow actors certainty that they will not be considered information blockers under certain conditions and scenarios related to seeking, obtaining, providing, or facilitating reproductive health care. In particular, actors must be able to act in good faith and presume that care was lawful unless they have actual knowledge that it was unlawful. **However, we ask that ASTP simplify the requirements of the exception so that providers acting in good faith are protected without having to engage in excessive documentation. We also ask ASTP to provide examples of where this exception would and would not be appropriate according to the threshold exceptions.**

We note that certified health IT does not yet include functionality to support data segmentation for privacy – that is, the ability to share some health information while withholding particularly sensitive information. ASTP requested information and made proposals in this area in its HTI-1 proposed rule, but did not finalize any requirements. Data segmentation is increasingly needed and the FAH urges ASTP to focus its efforts on advancing this high-priority functionality, despite the challenges in doing so.

Requestor Preferences Exception: ASTP proposes a new exception to the information blocking regulations that would apply to practices that otherwise would be considered information blocking when an actor honors a patient’s or other requestor’s preferences regarding the amount, timing, or conditions under which EHI is provided. ASTP proposes that these preferences would need to be expressed or confirmed in writing.

The FAH appreciates this proposal, as it offers actors certainty that they may limit the amount or timing of the release of EHI in certain conditions. Providers have found, for example, that some patients would prefer to wait to talk with a clinician before receiving test results or other information that may be life altering. This exception supports the ability to withhold information in such cases and may prompt clinicians to engage in conversations to ascertain patient preferences. **However, we urge ASTP to remove the condition that the preference be expressed in writing, as it may be received verbally, such as during a clinic visit. We also urge ASTP to ensure that use of the exception is workable, without the need for excessive documentation.**

Privacy Exception: The FAH agrees with ASTP’s proposal to update the sub-exception for unreviewable grounds and respecting an individual’s request not to share EHI within the Privacy exception.

Infeasibility Exception. The FAH supports ASTP’s proposed updates to the *segmentation condition*, *third party seeking modification use condition*, and *responding to requests condition* within the Infeasibility exception, which provides clarity and certainty in specific situations. In addition, we support extending the amount of time for the *responding to requests conditions* to a maximum of 30 days.

Certification to support compliance with information blocking rules: We note that the HTI-2 proposed rule does not include any certification requirements that would support health care providers in using any of the information blocking exceptions. **We urge ASTP to prioritize tools that support clinicians in documenting patient preferences, flagging sensitive data, and documenting professional opinions relevant to information blocking.**

TEFCA Proposals

The FAH supports ASTP/ONC’s proposed updates to the requirements under TEFCA participation for Qualified Health Information Networks (QHINs). However, we request additional guidance regarding how these changes will impact customers who rely on QHINs to exchange data.

In the proposed rule, the process for suspension of a QHIN is outlined in subpart D, and the provisions related to termination of a QHIN’s status are outlined in subpart E. In each of these subparts, **we seek additional clarity on the impact** to those utilizing a QHIN for data exchange purposes, especially regarding compliance reporting. For example, if a hospital is connected to a QHIN that is then suspended or terminated from QHIN status, what options are available for this hospital to ensure continued exchange of health information and compliance with the HIE Objective of PIP?

Additionally, we recommend that ASTP/ONC establish a definitive attestation submission schedule for applicable and relevant QHINs. We believe an attestation process would benefit all parties participating in the Common Agreement.

Definition of Base EHR

ASTP proposes to expand the definition of Base EHR, and therefore the definition of CEHRT under the Medicare PIP/MIPS. **For the reasons explained above, the FAH strongly opposes adding the following functionality to the definition of the Base EHR at this time because neither PHAs nor payers have a requirement to have or use compatible certified products.**

- Standardized API for Public Health Data Exchange; and
- Prior Authorization API.

We further recommend that ASTP specifically and separately identify **all** updates to the definition of the Base EHR in a single section of its rulemaking (including the preamble) so that eligible hospitals and clinicians have a clear understanding of how ASTP’s proposals would affect their obligations under the Medicare PIP/MIPS. This is particularly important in light of CMS’s recent decision-making to automatically align the definition of CEHRT with the Base EHR.

The FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership as we strive to advance the use of health IT to improve our nation’s health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

