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October 2, 2024

Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy,
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

RE: RIN 0955-AA06

Dear Dr. Tripathi,

On behalf of the 29 member companies of the HIMSS Electronic Health Record (EHR) Association, we appreciate the opportunity to provide input on Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. While we continue to support the nation's goals of advancing interoperability, transparency, and access to electronic health information, we have significant concerns about the impact this proposed rule will have on health IT developers, the healthcare providers we serve, and ultimately, the safe and efficient delivery of patient care.

The scope of new and expanded software requirements in HTI-2 significantly adds to the already substantial regulatory burdens imposed by ASTP, other federal agencies, and states, placing considerable strain on health IT developers. In fact, compliance requirements have become so onerous that even ASTP has acknowledged a projected 12% decrease in certified products as EHR developers opt out of the Certification Program, noting they also expect the burden of complying with HTI-2, particularly on the heels of HTI-1, to drive some smaller EHR developers out of business entirely. Regulations having this level of negative market impact for health IT developers also inherently mean disruption and stress for providers who currently rely on those solutions to participate in various payment programs, so this seems highly problematic.

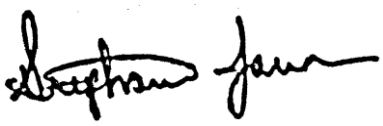
Moreover, further increased regulatory burdens on developers – those who are not driven out of business – would, in many cases, translate into higher prices passed along to providers as they keep up with mandated upgraded technology, which will trickle down to impact care delivery and operations. The development burden also detracts from developers' ability to focus on innovation and "delighters" for customers, effectively stunting growth and innovation in the industry.

For years, the EHR Association has implored ASTP and CMS to create staggered timelines between deadlines for CMS programs requiring upgraded CEHRT and ASTP requirements for developers to provide the updates. These concerns have gone unanswered, leaving providers without a sufficient runway for the implementation / adoption of updates and forcing developers to deliver significantly earlier than ASTP's adopted deadlines. This has also led to very frustrated provider organizations as they are forced to make upgrades much more frequently than they otherwise would based on their own strategic roadmaps.

On a positive note, we are strongly supportive of ASTP's proposal to expand the program to include criteria for both payers and public health agencies (PHAs), which could significantly enhance data exchange. To ensure the success of these efforts, however, agencies like the CDC and CMS must adopt appropriate incentives or mandates to drive adoption and use by PHAs and payers, or the program will not take off in any way as to positively impact the ease of data exchange with those entities.

We appreciate the opportunity to provide these detailed comments and look forward to continued collaboration to improve patient care.

Sincerely,



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Overview: Burden

In addition to the detailed feedback that follows, it is essential to highlight the broader burden imposed by the wide array of proposals in the HTI-2 proposed rule on health IT developers, especially in the context of today's increasingly complex regulatory landscape. When ASTP moved away from an edition-based certification program structure in the HTI-1 Final Rule, the expectation as explained to the market was that certifications would be more frequent but smaller and more focused. HTI-2 explicitly does not align with this vision. The scope and volume of requirements have actually grown, with the proposal exacerbating the strain on developers.

The quick transition from the HTI-1 Final Rule to the HTI-2 Proposed Rule—just seven months apart—has placed significant strain on health IT developers. This rapid cadence is not sustainable, particularly when the rules contain such a high volume of requirements. This pace of change, coupled with the complexity of the proposals, adds layers of burden that are difficult and expensive to complete effectively.

Key Areas of Burden and Conflict

- **Overwhelming Regulatory Obligations**: Developers are not only dealing with rapidly expanding requirements from ASTP but also face extensive obligations from other federal agencies and state governments. The sheer volume makes it difficult to prioritize and allocate resources efficiently (see the EHR Association's State Requirements Tracking). This cannot be overstated.

- **ICD-11 Transition**: The transition to ICD-11 could potentially fall within the HTI-2 deadline time frame and would require a massive undertaking dependent on the same development resources, adding to the cumulative burden on developers.

- **Cybersecurity Threats**: As the industry faces constant and evolving cybersecurity threats, developers are required to invest heavily in maintaining secure systems. This is a critical obligation that cannot be ignored, but it must be recognized as an added challenge against competing regulatory demands.

- **Impact on Smaller Developers**: For smaller developers with fewer resources, keeping up with the rapid, expanding certification demands is even more difficult. In some cases, developers, particularly those serving niche markets like pediatrics, may opt out of maintaining certification altogether if the effort outweighs the necessity.

- **Innovation Delays**: The increased complexity of regulations and the fact that government mandates are detracting from our ability to deliver "delighters" and innovative solutions, particularly in emerging areas like AI and machine learning, is problematic. We are not able to

focus resources where customer demand is growing most rapidly because of ASTP regulations, which seems counter to ASTP's goals.

- **Healthcare Provider Burden**: As noted, the burden on health IT developers translates directly into additional costs and pressures for healthcare providers, as well as systems that are forced to incorporate new functionality in a user-friendly way as much as possible, impacting patient care and operational efficiency. As the complexity of compliance increases, so does the strain on the providers who rely on these systems.

We want to reiterate comments made in previous rounds of rulemaking regarding the timeline for provider adoption. As we highlighted in both HTI-1 and in subsequent communications, the policy that sets the same timeline for provider adoption enforced by CMS inherently means that developers must deliver well before the ASTP's stated date to support customers effectively. We are not, in fact, able to take the time allowed in ASTP's regulations because ASTP and CMS are not working together to deploy regulations that reflect the reality of software development and deployment. This discrepancy compresses development time and places additional stress on an already strained process.

The EHR Association strongly urges ASTP to work more effectively and pragmatically with CMS to adopt a different policy that allows for more practical timelines for both developers and providers.

170.315(a)(2) - Revised Computerized Provider Order Entry – Laboratory Criterion

The EHR Association generally supports the adoption of LOI (Laboratory Order Interface) and LRI (Laboratory Results Interface) standards for laboratory orders and results reporting but recommends a modular approach to implementation. This would allow for incremental adoption without requiring a complete overhaul of existing interfaces. For example, beginning with modular capabilities and progressing to full adoption as an optional pathway would be more practical. Additionally, it is important to clarify whether the focus of these standards is intended to be cross-organizational or within an organization. For intra-organizational applications, the primary emphasis should be on the consistent use of vocabulary from the analyzer to the LIS (Laboratory Information System) and then to the EHR, rather than mandating LOI and LRI standards internally.

We also recognize that laboratory orders and results are currently shared using a variety of HL7 v2 versions and implementations. Mandating the latest versions of LOI and LRI across the board would likely not result in widespread conversion in a short time frame. Instead, it would impose significant costs on both health IT developers and healthcare providers, without a clear benefit. Therefore, we recommend a stratified adoption approach that emphasizes key LOI and LRI capabilities within the appropriate contexts, allowing older interfaces to be replaced gradually in production as needed, rather than as a prerequisite for using Certified EHR Technology (CEHRT).

To that end, the EHR Association suggests the following adjustments to the criteria and proposes separating any laboratory requirements into a distinct criterion if the intent is to enable certain non-public health laboratories to certify their capabilities for sending and receiving laboratory orders and results:

- **Ordering Provider—Internal Laboratory**: No requirement to use either LOI or LRI. Depending on settings and configurations, not all data required by LOI or LRI needs to be included, as some of this information may already be communicated through other means (e.g., initial ADT feeds to maintain relevant demographic data) or may not be necessary for the lab to perform the tests. In such cases, relevant data for external reporting, such as electronic laboratory reporting (ELR), can be obtained through alternative channels.

- **Ordering Provider—External Laboratory (Non-Public Health)**: Support specific LOI profile components for orders that are likely to result in public health reporting as part of current version interfaces. While some health IT systems may face challenges in supporting capabilities from newer versions, this should not be a significant concern given the construction of HL7 v2.

- **Ordering Provider—Public Health Laboratory**: Support LOI as required for Electronic Test Orders and Results (ETOR).

- **Public Health Laboratory—Ordering Provider**: Support LRI as required for ETOR.

- **Other Laboratory—Ordering Provider**: Optional support for LRI.

170.315(b)(1) - New Imaging Requirements for Health IT Modules: "Care Coordination - Transitions of Care - Create"

First, we note that the new C-CDA specification at 170.205(a)(1) is mentioned only in the preamble and not in the proposed rule language. We believe that this is an error with the proposed regulation text that needs to be corrected as part of the final rule when published.

The EHR Association remains supportive of the ongoing evolution and adoption of USCDI versions, including USCDI v4. We continue to advocate for a clear, reliable, and consistent process for the adoption of new USCDI versions, ensuring that the health IT community can plan and implement updates effectively.

Additionally, we reiterate our comments elsewhere in this comment letter regarding the proposed adoption of the imaging links requirement and strongly recommend ASTP withdraw the proposal to adopt that requirement as part of the ToC criterion from the final rule.

170.315(b)(2) - Care Coordination - Clinical Information Reconciliation and Incorporation - Reconciliation

The EHR Association has significant concerns regarding the proposal to adopt the entire USCDI v4, as the scope of data for clinical information reconciliation. Expanding to all ~114 data elements in USCDI v4 would be an unrealistic expectation, particularly given that current reconciliation requirements are limited to just three of the data classes. Supporting USCDI v4 for outbound exchange will already be a considerable challenge within the proposed timeline, and expanding this further for reconciliation is unrealistic.

Instead, we recommend a more focused and clinically impactful approach. The scope for clinical reconciliation should be limited to high-priority clinical data elements that will deliver the most value for

care coordination. Specifically, we propose focusing on the following data elements for reconciliation: Problems, Allergies & Intolerances, Medications, Immunizations, Procedures, and Clinical Notes. This represents a more modest—and achievable—expansion in scope while still aligning with critical areas of patient care and balancing the need for meaningful data reconciliation with the practical realities of implementation within the proposed time frame.

Additionally, although automation can be valuable in certain contexts—particularly for large organizations managing significant volumes of incoming data—it is premature to mandate automated reconciliation at this time. Clinical information reconciliation is a technically and clinically complex activity that requires medical decision-making by a clinician and discussion with an individual patient. Automatic reconciliation will require the health IT system to make those medical decisions instead–with significant risks to patient safety and patients' ability to direct their own healthcare. We recommend allowing health IT developers and their customers to determine how reconciliation occurs based on their specific workflows and needs. Instead of prescribing "how" reconciliation must happen, the focus should remain on "what" data needs to be reconciled to ensure flexibility and avoid unnecessary burden on developers and providers.

170.315(b)(3) - Revised Electronic Prescribing Certification Criterion

The EHR Association is supportive of including the revised Electronic Prescribing criterion in the Base EHR. As it is already part of CEHRT through the eRx Promoting Interoperability measure, this inclusion aligns with the foundational elements of a Qualified EHR and makes sense for Base EHR requirements.

However, we strongly recommend deferring the adoption of electronic Prior Authorization (ePA) transactions as part of this criterion for the Base EHR in this rulemaking. Future regulations should adopt role-based criteria for providers, payers, and pharmacies—following the same structure proposed for non-Rx ePA. This approach would ensure that each of these stakeholder groups is adequately prepared to implement ePA. Once payers and pharmacies have sufficiently adopted and implemented these systems, the provider-focused criterion can be reconsidered for inclusion in Base EHR.

Requiring ePA transactions solely on the provider side without corresponding requirements for payers and pharmacies would not lead to the intended goals and would lead to unnecessary development efforts for health IT developers. The burden on developers would be significant, while at the same time, there is no commensurate requirement that the other stakeholders also adopt the same standardized approach. The requirement should be well-rounded and consistent across the industry, or it should be delayed.

This staged approach would ensure a more comprehensive and functional ePA system, aligning with the broader goals of streamlining care coordination and reducing administrative burden across the healthcare ecosystem.

170.315(b)(4) - New Real-Time Prescription Benefit Criterion

For RTPB to be effective, the payer side must have established functionality first. Without this foundational infrastructure, requiring RTPB in Base EHR certification would place an undue burden on providers and developers without ensuring that payers are equipped to support it. ASTP should

prioritize working with CMS to ensure that regulations governing payers enforce a similar requirement so that industry readiness happens consistently and collective value can be achieved.

The EHR Association recommends adopting the RTPB criterion as part of the overall certification program but excluding it from the Base EHR definition until a corresponding role-based criterion, similar to that suggested for ePA transactions under 170.315(b)(3), with separate criteria for providers and payers, has been adopted and successfully implemented. This phased approach ensures that all stakeholders are prepared and able to contribute to the system's functionality.

Additionally, we support maintaining t January 1, 2028 deadline for RTPB adoption rather than matching CMS's January 1, 2027 deadline for Part D plan sponsors. The 2028 timeline provides sufficient time for both payers and providers to prepare, ensuring a smoother and more effective implementation.

170.315(b)(10) - Electronic Health Information (EHI) Export – Single Patient EHI

The EHR Association is supportive of the proposal to afford exemptions for modules that do not involve human end-user interaction and only store a copy of EHI that is also stored in other modules certified for EHI export under 170.315(b)(10). However, we believe that the proposed exemptions do not go far enough. There should be a full exemption from both the single patient and patient population export requirements for such modules.

Simply offering the option for developers to provide assistance with the single patient export does not offer significant relief for products where the imposition of EHI Export requirements feels like an overreach. The core goal of this requirement is to ensure that patients and healthcare providers can access their EHI without restriction. If the EHI is already readily accessible via a "connected" certified health IT module that is certified for EHI Export, then it seems reasonable that modules described in the proposal should be fully exempt from both single patient and patient population EHI export requirements.

We urge ASTP to expand the proposal to fully exempt certified health IT modules in this scenario from both the single patient and patient population EHI Export requirements.

170.315(b)(11) - Decision Support Interventions – Decision Support Intervention Selection And Source Attributes

This criterion serves as an example of the "hidden work" that accompanies updates to USCDI versions. While updates to USCDI may appear to have an impact purely on interoperability, they often have broader implications due to the manner in which USCDI is cited as a standard throughout various parts of the program, including 170.315(b)(11). Specifically, it necessitates expanded support for enabling "selection" of DSIs and additional data elements to be exposed as part of source attributes to maintain compliance with the DSI criterion.

The EHR Association is not requesting changes to this specific criterion but emphasizes the need for ASTP to educate themselves on the broader set of impacts updates to USCDI have on developers. Updating to a new version of USCDI involves more than just adjustments to the interop layer; it requires a wide range of development work in multiple areas of our solutions. Aggressive timelines for USCDI

adoption can therefore pose significant challenges for developers and their customers, who are in turn obligated to implement these changes.

We encourage ASTP to therefore ensure that timelines are realistic and provide adequate time for implementation across the industry.

170.315(d)(7) - Health IT Encryption

The EHR Association has concerns regarding the proposed server-side encryption requirements, particularly based on where server-side encryption is performed and controlled away from the scope of the certified technology applications. The certified application itself does not need to support encryption, provided the server side manages encryption and the application does not write data to persistent storage outside of server control. Flexibility is essential, and a risk-based approach should be considered to account for use-case specificity and special needs.

We are concerned that adopting the requirement as proposed may expand the scope of certified software to include the storage mechanism, which would be inappropriate, especially in cases where storage may be on-premises and managed by the customer. Requiring encryption at the server level in such scenarios could impose unnecessary burdens without improving overall security.

We suggest that ASTP/ONC adopt this proposal with some specific changes outlined below. At the same time, we recommend issuance of additional sub-regulatory guidance on best practices for server-side encryption, aligning with existing HIPAA Security Risk Assessment (SRA) requirements that are already mandated under CMS Promoting Interoperability programs. This would allow for parties who host certified technology other than the certified developers themselves to be better equipped to do so with proper encryption techniques.

1. Update the requirement to clarify that it does not apply when the certified developer is not taking on the database administrator or technology hosting responsibilities where server-side encryption would be managed/owned.

2. Revise the proposed deadline for the requirement to adopt it no sooner than January 1, 2027 in order to provide appropriate time for developers to ensure compliance across their products.

170.315(d)(9) - Trusted Connection

The EHR Association supports the adoption of the FIPS 140-2 update across the program. This is a logical step in ensuring security standards remain up to date with the latest advancements.

In alignment with our recommendations for the adoption of the FIPS 140-2 October 2021 release elsewhere in our comments, we are fully supportive of applying this updated standard to the 170.315(d)(9) criterion.

170.315(d)(12) - Protect Stored Authentication Credentials

The EHR Association supports the proposed requirement to protect stored authentication credentials as a general security enhancement measure. Adopting these requirements is a logical step to strengthen

the security posture across certified health IT systems, and we believe this can be achieved without imposing a significant burden on developers or providers.

We recommend that ASTP adopt this requirement as proposed, with special emphasis on clarifying that the requirement would not apply in cases where authentication credentials are not locally stored—such as when they are managed externally or sourced from third-party identity providers.

170.315(d)(13) - Multi-Factor Authentication

The EHR Association is supportive of the proposed requirement for Multi-Factor Authentication (MFA) in the isolated use cases identified, particularly the 170.315(b)(3) criterion related to Electronic Prescriptions for Controlled Substances (EPCS), which aligns with existing DEA regulations. The scope defined by ASTP for MFA adoption is sensible and represents an appropriate entry point for MFA within the health IT certification program.

We recommend adopting the requirement as proposed, with a key consideration for scenarios in which customers may integrate a third-party identity provider (IdP) for patient portal or FHIR API patient authentication. In such cases, the certified health IT module may not be able to control the availability of MFA. This should be acceptable so long as the health IT developer offers an IdP that supports MFA, giving customers the option to use it at their discretion.

Additionally, we request clarification on the term "user" in the proposed regulation text regarding who must have the ability to configure (enable/disable) MFA. For the 170.315(g)(10) and 170.315(e)(1) criteria, it is unclear whether "user" includes patients. Under existing guidance for other Privacy & Security criteria, "user" generally excludes patients. However, in this instance, it may be appropriate to allow patients to determine whether MFA is enabled for their personal accounts.

170.315(e)(1) - Patient Engagement - View, Download, and Transmit to 3rd Party - View

The EHR Association reiterates its support for the adoption of USCDI v4 and continues to advocate for a clear, reliable, and consistent process for adopting new USCDI versions.

Again, we highlight a gap concerning the new C-CDA specification at 170.205(a)(1), which is mentioned only in the preamble and not in the proposed regulation text for 170.315(e)(1). We believe that this is an error with the proposed regulation text that needs to be corrected as part of the final rule when published. Additionally, we reiterate our comments elsewhere in this comment letter regarding the proposed adoption of the imaging links requirement and strongly recommend ASTP withdraw the proposal to adopt that requirement as part of the VDT criterion from the final rule.

170.315(f)(1)-(29) - General Public Health

The EHR Association notes that several public health-related criteria lack clarity regarding their intended focus—whether they are provider-focused, Public Health Agency (PHA)-focused, or could apply to both roles. We recommend that ASTP adopt a more explicit naming convention for the criteria, specifying the roles relevant to each capability. For example, Immunization Reporting - Provider for 170.315(f)(1) and Immunization Reporting - PHA for 170.315(f)(21). Each criterion would then describe only the capabilities relevant to the designated role.

This approach would eliminate the need to use terms like “bi-directional” within individual criteria, as the paired criteria would collectively address all bi-directional capabilities. This method would reduce confusion regarding which health IT is expected to support what functionality while allowing health IT that can support both provider and PHA roles to be certified accordingly.

170.315(f)(1)-(29) - General Public Health - Advancing Standards

The EHR Association understands and agrees that advancing standards is important to improve the quality and quantity of necessary data sharing across the public health ecosystem. However, we note that in several criteria, the proposals introduce new standards even where the existing standard has only recently been adopted and still provides sufficient capability to meet the intended goals. For example, in the case of Cancer Registry Reporting, the current standard remains effective, but changing to a new standard would deliver minimal additional value for the providers using the software despite the resources it would take to develop it.

In other cases, such as laboratory ordering and reporting, we suggest that the adoption of new standards can be focused through modular capabilities or targeted toward specific new use cases, given the large installed base of existing systems. This approach would ensure smoother transitions without disrupting established workflows and infrastructures.

While we will provide more detailed feedback on specific proposals, we generally recommend that in the public health space—where resources are limited—a more gradual glidepath be adopted. This would prioritize data quality over the immediate adoption of new formats purely for the sake of “new” while ensuring that the focus remains on the substance of data exchange rather than the mechanics.

170.315(f)(1)-(29) - Public Health Reporting through TEFCA

The EHR Association notes the various suggestions aimed at supporting public health reporting through TEFCA. However, we would like to point out that TEFCA currently lacks any guidance or roadmap for HL7 v2-based exchange, which is widely used for existing public health reporting, particularly in laboratory result transmissions.

Before any decisions are made regarding the rerouting of laboratory results reporting through TEFCA, we recommend addressing two key questions:

1. What is the value proposition of rerouting laboratory results through TEFCA, especially when the existing HL7 v2 messaging framework functions well for public health reporting?

2. If there is indeed value, what requirements will QHINs need to meet to support HL7 v2 messaging? This would involve QHINs converting HL7 v2 messages into XCDR, which then would need to be extracted and passed along by the receiving QHIN, where the public health agency is connected. This seems to introduce extra complexity without delivering a clear benefit.

Given these concerns, we recommend that ASTP and the Recognized Coordinating Entity (RCE) consider selectively endorsing existing technologies (such as HL7 v2) to continue operating under the TEF Common Agreement, similar to the manner in which eCR reporting is enabled under Carequality.

170.315(f)(1)-(29) - Public Health Authority and Registry Certification Criteria

The EHR Association appreciates the addition of PHA and Registry-focused certification criteria that other agencies and jurisdictions can incorporate into their programs. These criteria represent an important step in strengthening public health reporting infrastructure.

However, we are concerned that the definitions of filtering and validation requirements within these criteria may inadvertently lead to unnecessary rejections of data or provide an incomplete perspective on the available data. While health IT systems can capture data with the appropriate quantitative or qualitative values, real-world workflows often result in missing or incorrect data. If filtering and validation criteria are too rigid, they could prevent valuable data from being used, simply because it does not meet predefined standards. Data receivers, such as PHAs and registries, need sufficient flexibility to consider all received data, ensuring that filtering and validation requirements do not limit the usability of the data or result in unnecessary rejections.

We recommend that ASTP and other regulatory bodies ensure that public health reporting systems are designed with this flexibility in mind to avoid compromising the completeness and value of the data used for public health analytics.

170.315(f)(1) - Immunization Registries - Bi-Directional Exchange

The EHR Association notes that this criterion would require provider health IT to support incoming immunization queries using the guides referenced. We suggest that the requirement to support HL7 v2-based query responses for immunization data should be withdrawn entirely. Instead, we recommend building on FHIR US Core-based queries, which offer more modern and flexible standards for data exchange.

Specifically, the 170.315(g)(10) and 170.315(g)(20) criteria should enable the relevant queries by PHAs or other requesters, such as patients, to streamline and modernize the exchange process.

While we generally support the adoption of new standards and versions, this must be done in a way that ensures immunization registries are on the same timeline for adoption as providers. This will ensure that the upgraded reporting can be adopted effectively across the ecosystem, preventing discrepancies between the capabilities of provider systems and the readiness of registries to receive and process the new data. We encourage ASTP to coordinate with their CDC counterparts on mechanisms to enable such alignment.

170.315(f)(2) - Syndromic Surveillance - Transmission to Public Health Agencies

The EHR Association generally supports the introduction of a new version of the standard for syndromic surveillance. However, we offer the following considerations in the context of evolving needs for syndromic surveillance reporting.

There is a growing interest and need for additional clinical data to be shared as part of syndromic surveillance reporting, whether jurisdictions require identified or de-identified patient data. While we acknowledge the importance of these data needs, the traditional method of communication via HL7 v2 ADT messages is becoming increasingly less suited to support these expanded data requirements.

We strongly urge ASTP to collaborate with the CDC to establish a syndromic surveillance reporting model similar to eCR (electronic Case Reporting), utilizing a FHIR-based format, and potentially, for a transitional period, a CDA-based format as well. These formats would enable the sharing of richer clinical data sets without being constrained by ADT message formats and events. Adopting this approach would also provide consistency across reporting events and data expressions, reducing the mapping complexities and anomalies that arise from the differences in underlying standards. We also encourage ASTP to consider extending deadlines for ambulatory practices to comply with these standards, as there is currently very minimal adoption of existing technologies for this type of reporting and to allow for development time to incorporate these standards with existing reporting capabilities.

While we recommend modeling syndromic surveillance after the structure of eCR, we want to clarify that it should not be integrated as part of eCR itself. Syndromic surveillance has distinct requirements and use cases that necessitate a separate, tailored approach. Further, we note that for syndromic surveillance to be successful, we believe that ASTP must work more closely with the CDC to ensure that the implementation of any such reporting model is managed effectively. The eCR certification process to date has been slow and burdensome, and we hope that any similar approach undertaken for syndromic surveillance will be managed more cohesively across all relevant HHS agencies.

Additionally, we note the substantial variations in reporting requirements across public health jurisdictions. As evidenced by the challenging eCR process still underway, certification to a single standard does not sufficiently reduce the effort required to conform to these jurisdiction-specific needs. Therefore, we recommend considering whether an immediate upgrade within the same standard is necessary or whether efforts should begin to shift the reporting approach towards an eCR-style model as outlined above. This shift would better meet the evolving needs of public health reporting while improving consistency and efficiency.

170.315(f)(3) - Reportable Laboratory Results - Transmission to Public Health Agencies

The proposed January 1, 2028, deadline for phasing out the ELR IG and transitioning to the LRI standard may not be feasible for all stakeholders. Given the complexities involved, we recommend considering a longer transitional period during which both ELR and LRI are allowed, providing flexibility and minimizing disruptions. A phased approach would ensure that organizations have sufficient time to adopt LRI while continuing to meet their current reporting obligations.

We suggest that the requirements for laboratory orders from providers be addressed under 170.315(a)(2). This would allow for distinctions regarding the standards or components that must be supported when laboratory orders involve tests that may need to be reported to public health. Further, there is no known use case in which providers would be recipients of laboratory orders, aside from receiving status updates on orders they placed. Therefore, filtering and validation of incoming lab orders should not be a requirement for providers. Any status tracking related to laboratory orders should be handled within 170.315(a)(2).

The 170.315(f)(3) criterion should focus solely on provider laboratory results reporting to public health agencies. Providers should use either the current ELR IG or the most up-to-date LRI guide, which includes all relevant ELR requirements. We recommend that 170.315(f)(3) highlight the specific components of the LRI guide that enable ELR and must be supported for laboratory results reporting.

For clarity, we suggest that 170.315(f)(3) not address inbound laboratory results, as this should be managed by 170.315(a)(2). Additionally, the receipt of laboratory results from public health laboratories under ETOR should adhere to the LRI standard, in line with the requirements for receiving laboratory results under 170.315(a)(3).

We propose adding a new criterion, such as 170.315(a)(22), to address the specific responsibilities of standalone laboratories. This criterion would outline how laboratories should receive orders using the LOI standard and generate laboratory test reports using the LRI standard. This would apply to both provider-focused interactions and public health reporting, using a role-based approach similar to that proposed for public health and payer interactions. This addition would create greater clarity on how data holders interact within the broader health IT ecosystem.

We agree that troubleshooting interoperability errors is an important goal. However, this task is typically performed by technical or administrative staff. The regulatory expectation should outline that these tasks are not meant to be carried out by clinical users.

We are concerned about the increasing number of required fields in public health jurisdiction-specific reporting, particularly related to demographic data. We urge ASTP to work with all jurisdictions to ensure that HL7 v2 fields can be marked as required but remain empty when the data is unavailable. Without that shared understanding, requiring fields serves as a barrier to exchange instead of encouraging it.

170.315(f)(4) - Cancer Registry Reporting - Transmission to Public Health Agencies

The EHR Association acknowledges the importance of supporting Cancer Registry Reporting, and we offer the following recommendations to ensure that the standards adopted facilitate the broadest possible adoption while balancing the state of readiness of available technologies.

Given the current reliance on CDA-based reporting for cancer registries, we suggest that 170.315(f)(24) should require support for CDA-based submissions, with the option to support FHIR-based submissions as well. This approach would allow organizations to continue focusing on the widely adopted CDA-based standard while enabling FHIR-based reporting to mature and solidify before becoming mandatory. Such a phased approach would ensure a smoother transition without compromising current reporting capabilities.

At this time, FHIR Cancer Pathology has not yet seen sufficient maturity or adoption to warrant inclusion in certification requirements. Given the lower priority and the current state of development, we recommend that FHIR Cancer Pathology not be a requirement for certification under this criterion.

Additionally, because cancer reporting is not always managed by the ordering provider, we suggest splitting this criterion into two distinct parts: one addressing provider-focused capabilities and a separate criterion focused on laboratory-focused capabilities. This separation would better accommodate scenarios where the laboratory is external, particularly in ambulatory settings, and ensure that both provider and laboratory roles are clearly addressed within the certification program.

170.315(f)(5) - Electronic Case Reporting - Transmission to Public Health Agencies

The EHR Association acknowledges the proposal to switch fully to FHIR-based eICR support by January 1, 2028. However, we see no clear benefit to discontinuing the generation of CDA-based eICR at this time. Both FHIR-based and CDA-based eICR formats cover the same content, and a format switch does not offer a sufficient advantage to justify the effort required for this transition.

Therefore, considering the comparable functionality between the two formats, we recommend continuing to support both FHIR and CDA-based eICR submissions, allowing for greater flexibility while enabling organizations to adopt FHIR at their own pace. A forced transition to FHIR does not provide the same tangible improvements as other proposed enhancements in this rule, and maintaining CDA-based reporting alongside FHIR would help ensure a smoother transition process.

170.315(f)(6) - Antimicrobial Use and Resistance Reporting - Transmission to Public Health Agencies

The EHR Association acknowledges the proposed timeline for implementing R3 by January 1, 2027, while recognizing that the NHSN currently requires R3 for ARO numerator and denominator reporting and R1 for AUP. Additionally, NHSN has signaled its intent to begin using R4 in CY 2025.

To facilitate a more streamlined transition, we recommend that ASTP align the timeline for certification versions with the cadence used by CMS for eCQM reporting specifications, where new versions are introduced for certification and subsequently used in annual reporting. Specifically, we suggest that ASTP work with the CDC to require R3 for all ARO and AUP components by January 1, 2026. This would align with current adoption and ensure that all stakeholders can utilize a single version for reporting.

Furthermore, we propose introducing R4 in the 2026 Standards Version Advancement Process (SVP), with an expectation for its use in CY 2027. This glidepath would be most sensible for establishing initial alignment of all involved parties (CDC/NHSN, ASTP, HIT developers, and healthcare providers) to then shift into the CMS eCQM model of annual specification update via SVAP on a go-forward basis.

170.315(f)(7) - Health Care Surveys - Transmission to Public Health Agencies

The EHR Association recommends maintaining flexibility in the certification criterion by allowing healthcare surveys to be submitted using either the CDA-based report or the FHIR-based report. While we support the gradual transition to FHIR, it is important to maintain CDA-based submissions to ensure continuity during the adoption process. A full migration to FHIR-based reporting should be considered at a future point when public health agencies are actually prepared to support and utilize the FHIR format.

We also encourage ASTP and the CDC to focus primarily on driving public health agency adoption of these standards before adopting new versions. The Standards Version Advancement Process (SVAP) can be leveraged to allow organizations to advance to more current versions as needed, without imposing the burden of mandatory upgrades that may not be widely adopted or utilized by public health agencies.

170.315(f)(8) - Birth Reporting - Transmission to Public Health Agencies

If an updated version of this IG is published prior to the publication of a final rule, and made available to the public, it would be our intent to consider adopting the updated IG if it best aligns with and supports effective implementation of this proposed certification criterion.

We note that the adoption of this standard is still in its early phases, with limited participation from stakeholders. Given this, the EHR Association again recommends caution in adopting a newer version too quickly, as widespread readiness and support for its implementation may not yet be in place.

Ensuring that sufficient time is provided for organizations to adopt and operationalize the current standard is critical for the success of any new IG. A more measured approach would allow for the gradual scaling of the new standard, ensuring that all stakeholders can effectively implement the changes without disruption.

We request comment specifically on whether the content specified in the IG can be exchanged using transport mechanisms defined in § 170.315(g)(10) and in the proposed § 170.315(g)(20) certification criteria

The EHR Association has concerns regarding the potential inclusion of data that is not supported by 170.315(g)(10) or 170.315(g)(20) into the USCDI or USCDI+ domains, which is in turn included in 170.315(g)(10) and/or 170.315(g)(20). We suggest that any data from 170.205(v) - FHIR Vital Records and Birth and Fetal Death Reporting 1.1.0 should only be considered for inclusion in USCDI and USCDI+ if it is not required to be managed by all certified health IT systems.

Further, certification to 170.315(g)(10) and 170.315(g)(20) should be scoped specifically to the data that certified health IT systems, including specialty EHRs, are already managing. This approach would ensure that health IT systems are only responsible for handling data that is relevant to their scope of certification, preventing unnecessary burdens for systems that do not manage certain types of data.

The same approach should be taken with Vital Records Death Reporting, which is also an important part of the vital records landscape, affecting many of the same users and systems.

As an alternative to the IG proposed above, we propose, and seek comment on, adoption of an interim standards-agnostic functional criterion for electronically transmitting medical and health information from birth certificate reports to PHAs based on the data elements outlined in CDC National Vital Statistics System's "Guide to Completing the Facility Worksheets for the Certificate of a Live Birth and Report of Fetal Death."

As noted in our earlier comments, we believe that now is not the appropriate time to introduce a mandatory standards-based requirement for birth reporting within the certification program. However, recognizing the interest in advancing this capability, we suggest that a functional requirement be introduced, which includes a recommended implementation guide. Once the implementation guide has been further developed and supported by wider adoption, the most current version can then be incorporated into the certification criteria. This allows for flexibility during the early stages of adoption, providing room for adjustments as the field matures. Ideally, the implementation guide and/or standard

should clarify whether this requirement is for hospitals only or if ambulatory practices also have reporting obligations for this criterion.

We further seek comment on the potential benefits and risks of adopting a functional approach, particularly as CDC's NCHS has retired and will not be actively updating the HL7 Version 2.6 Implementation Guide: Vital Records Birth and Fetal Death Reporting, Release 1 STU Release 2 and the HL7 CDA R2 Implementation Guide: Birth and Fetal Death Reporting, Release 1, STU Release 2 - US Realm standards

The EHR Association appreciates the concerns surrounding the retirement of the HL7 Version 2.6 Implementation Guide for Vital Records Birth and Fetal Death Reporting, as well as the HL7 CDA R2 Implementation Guide. In light of these developments, we suggest focusing on a functional requirement with a recommended implementation guide, as outlined in our previous comments.

Finally, we request comment on whether a functional approach—if adopted—should be time-limited and require a transition to a standards-based approach as of a specific timeline.

By focusing on the readiness and proven adoption of the guide, we can avoid the risks associated with prematurely enforcing standards that may not yet have broad usage or support. We recommend that the adoption of a required implementation guide should be based on maturity and demonstrated adoption wider than the current implementations, rather than setting an arbitrary timeline for this transition.

170.315(f)(9) - Prescription Drug Monitoring Program (PDMP) Databases – Query, Receive, Validate, Parse, And Filter

The EHR Association appreciates and strongly supports the goal of making discrete PDMP data available to providers, as this would significantly enhance their ability to make informed clinical decisions when they are authorized to access such data. For consistency across systems, we recommend that the NCPDP SCRIPT standard be used, particularly as efforts continue to develop a FHIR-based exchange method for PDMP data.

Additionally, we raise concerns about the requirements for validation, parsing, and filtering. These capabilities should be tailored to the specific needs and focus of the data receiver and how that data is best utilized in their respective environments. Therefore, the EHR Association suggests these criteria not be included in the final rule, as they could introduce unnecessary complexity without clear benefits across varying use cases.

We also note that our member companies have been forced to spend an increased volume of time trying to juggle requirements related to both certification and the CDC's modernization work (i.e., eCR) versus the public health jurisdictions' lagging efforts to do the work on their sides to complete the effort. Accordingly, we have real concerns regarding the readiness of PDMP registries to support discrete data exchange, as currently, only approximately 13 out of 50 states support some form of discrete data sharing. To accommodate this disparity in readiness, we recommend that these criteria be introduced as optional, allowing health IT systems in states without this capability to defer implementation until PDMP registries are better prepared.

170.315(f)(8), (9),(21)-(29) - Target Dates

The EHR Association notes that several provider-focused criteria and all PHA- and Registry-focused criteria under 170.315(f)(8), (9), (21)-(29) do not currently have target dates for implementation. We strongly recommend that ASTP collaborate closely with agencies and states planning to create incentives for certification to these new criteria, ensuring that target dates are aligned across the board. Without clear timelines, there is a risk that health IT developers will build capabilities that remain unused, while efforts that could have been directed toward other essential capabilities are put on hold.

Furthermore, we are concerned with the near-annual updates to reporting versions, particularly when these updates do not demonstrate clear added benefits to providers. The readiness of the receiving party is crucial in this regard. Misalignment between provider capabilities and the readiness of PHAs or Registries to receive updated data can result in unnecessary fragmentation, forcing developers to support multiple reporting versions concurrently. This introduces complexity and adds to the burden of maintaining certification across different versions in the Certified Health IT Product List (CHPL).

We urge ASTP to ensure that target dates are established and coordinated with both providers and PHAs, reducing uncertainty and improving alignment to facilitate smoother adoption and implementation of these new certification criteria.

170.315(f)(21) - Immunization Information – Receive, Validate, Parse, Filter, and Exchange – Response

The EHR Association acknowledges that certain workflows and interactions could benefit from population-level queries by providers to immunization registries. The progress made by the Helios project in this area is promising. However, we believe that provider-focused health IT should not be required to support population-level queries, as their workflows typically do not necessitate this functionality. Providers can adequately meet their needs using single-patient queries.

At the same time, we recognize that population-level or bulk queries can be valuable for certain PHA workflows. Therefore, we support the availability of this capability from immunization registries. However, before adopting population-level querying as a certification requirement, we strongly recommend resolving issues related to cohort/patient matching. Until this is addressed, we believe that this capability should not be included in the current version of the certification program.

Regarding the implementation of SMART Health Cards, we note that this would require support for the HL7 FHIR SMART Health Cards: Vaccinations and Testing implementation guide, which is not yet published. In the absence of this guide, we do not support the introduction of SMART Health Cards into the certification program. If the guide is published, we recommend that supporting SMART Health Cards be an optional capability rather than a mandatory one.

Additionally, we would like to highlight the substantial variation in demographic data requirements across different jurisdictions. We request that ASTP work with immunization registries to align these requirements more closely. A more standardized approach to demographics would improve patient matching and overall data quality across jurisdictions.

Finally, we reiterate our general concerns about filtering and validation in public health reporting, as outlined in our broader comments on public health criteria. These concerns should be addressed to ensure that important data is not unnecessarily excluded or rejected.

170.315(f)(22) - Syndromic Surveillance – Receive, Validate, Parse, and Filter
170.315(f)(23) - Reportable Laboratory Test Values/Results – Receive, Validate, Parse, and Filter
170.315(f)(24) - Cancer Pathology Reporting – Receive, Validate, Parse, and Filter
170.315(f)(28) - Birth reporting – Receive, validate, parse, and filter
170.315(f)(29) - Prescription Drug Monitoring Program (PDMP) Data – Receive, Validate, Parse, Filter Prescription Data, Support Query and Exchange

The EHR Association reiterates our general concerns regarding filtering and validation, as outlined in our broader public health-focused comments. Specifically, rigid filtering and validation requirements can lead to unnecessary rejections of data or an incomplete view of the data available, particularly given the variations in data completeness and quality across different jurisdictions and workflows.

We emphasize the need for flexibility in filtering and validation criteria to ensure that important data is not excluded or rejected while allowing for variability in real-world data. This flexibility is crucial to supporting meaningful public health reporting and ensuring that public health agencies can make the best use of the data they receive.

170.315(f)(29) - Prescription Drug Monitoring Program (PDMP) Data – Receive, Validate, Parse, Filter Prescription Data, Support Query and Exchange

The EHR Association notes the ambiguity around whether a PDMP registry is expected to query the provider, and if so, what standard should be used for such queries. We recommend that any queries from PDMP registries to providers be conducted using FHIR-based APIs supporting 170.315(g)(10) and 170.315(g)(20).

Summary of Major Provisions - ONC Health It Certification Program Updates - New and Revised Standards and Certification Criteria – New Imaging Requirements for Health IT Modules

We propose, as explained in section III.B.6, to revise the certification criteria adopted in § 170.315(b)(1), (e)(1), (g)(9), and (g)(10) to include new certification requirements to support access, exchange, and use of diagnostic images via imaging links.

The EHR Association is supportive of the broader goal of expanding access to diagnostic images through certified health IT systems. However, it is clear to us that requiring support for imaging links in the current state is impractical and poses a significant security risk due to ongoing challenges related to authorization with third-party imaging vendors.

Certified developers would largely be dependent on these third-party vendors to meet the proposed requirement, and there are several issues with the current state of image link formatting and access. Specifically, most links present one of two significant issues:

1. Embedded Authentication Credentials: In some cases, authentication credentials are embedded directly in the link, allowing anyone with access to the link to view the images, creating a serious security vulnerability.

2. Prompted Authentication: In other cases, the link prompts for authentication credentials that the user is unlikely to have, rendering the link effectively useless.

Until a consensus standard for secure and reliable image link access is established, implementing this requirement would introduce more risk than benefit. Healthcare organizations will not be willing to expose their PACS and VNA systems to the public internet so that external providers can access them. It will also not be feasible for them to provide credentials to every external user who receives an imaging link.

Additionally, there are limitations when it comes to viewing diagnostic-quality images. If the device (monitor or other display equipment) does not support the standards for diagnostic-quality images, such as DICOM, the user may be unable to view the images properly, even if authentication issues are resolved.

Given these challenges, we strongly recommend that ASTP defer the adoption of this requirement at this time. Instead, efforts should focus on spurring modernization by encouraging imaging vendors to adopt standardized authorization mechanisms, such as a token-based approach that ensures that only those who are appropriately authorized can access and view the images.

170.315(G)(6) - Consolidated CDA Creation Performance

The EHR Association wishes to highlight what we believe to be errors in the proposed regulation text for the 170.315(g)(6) criterion. First, in the preamble, it is specifically referenced that the intent is for the C-CDA Edition 3 specification proposed for adoption at 170.205(a)(1) to be cited as part of the criterion for the standard by which USCDI v4 data is represented. However, that standard is not cited anywhere in the proposed text.

Second, the preamble also references that the adoption of the new USCDI v4 standard proposed at 170.213(c) and the C-CDA Edition 3 standard proposed for adoption at 170.205(a)(1) would become effective as of January 1, 2028. However, the proposed regulation text does not include such a date reference - only the existing reference to the January 1, 2025 deadline for other changes adopted with the HTI-1 final rule is included. These errors should be corrected in the final rule.

170.315(G)(9) - Application Access—All Data Request

The EHR Association wishes to reiterate our recommendations outlined elsewhere in this comment letter for both supporting the adoption of USCDI v4 and for withdrawing the proposed adoption of support for imaging links as both apply to the 170.315(g)(9) criterion.

Additionally, we highlight that the same presumed errors as identified above for the 170.315(g)(6) criterion also appear to apply to the proposed regulation text for the 170.315(g)(9) criterion. Equivalent corrections should be made in the final rule.

170.315(G)(10) - Standardized API for Patient and Population Services

The EHR Association reiterates several key points that directly impact the 170.315(g)(10) criterion. First, we continue to support the ongoing, reliable, and consistent adoption of USCDI data classes. We are in favor of adding USCDI v4 and reaffirm our position that there should be a clear, reliable, and consistent process for the adoption of new USCDI versions, ensuring alignment with industry standards and operational realities.

Regarding the imaging links requirement, consistent with our comments elsewhere in this letter we strongly recommend withdrawing the proposed requirement from the (g)(10) criterion in the final rule.

We also support the adoption of dynamic registration with some caveats. While we are tentatively supportive of UDAP v1, there is ongoing development of the specification that ASTP should monitor to ensure timely pivots to newer versions as they are adopted. While this could be achievable through SVAP, the pace of updates may present a challenge. We also emphasize the importance of flexibility, particularly the ability to support only the trust communities we choose, and assert that developers should have the option to force dynamic registration paths when apps do not align with preferred validation pathways.

In terms of FHIR Subscriptions, we reiterate our comments in the modular API criteria section of this comment letter recommending that developers certifying to 170.315(g)(10) and/or 170.315(g)(20) be required to support at least three subscription topics of their choice across both 170.315(g)(10) and 170.315(g)(20). Requiring support for all proposed subscriptions across specific FHIR resources would be far too burdensome and inefficient to adopt at this stage as many of those would not have immediate use cases.

Regarding the adoption of SMART v2.2, we reiterate that token revocation for clinician launch scenarios must be handled by system administrators and not by clinicians themselves. The same applies to authorization processes, which should be managed administratively rather than at runtime, as is currently the case for patient users.

In addition, we offer the following comments specific to the 170.315(g)(10) criterion:

- We support the adoption of CDS Hooks for “patient-view” and “order-sign” use cases, with the caveat that flexibility must be maintained in how systems implement these features from a user experience (UX) perspective, including both synchronous and asynchronous workflows.

- Additionally, we are supportive of the adoption of Bulk Data v2 with the exception that we recommend deferring “_since” requirements to allow time for more maturation of the operations with industry standards groups. Today, the “_since” parameter is not well-defined, and we believe US Core is the appropriate venue to have a more detailed review and guidance developed. That includes the existing Bulk FHIR project happening this year through the HL7 Argonaut Project.

- Lastly, we request clarification on the inclusion of a "read and search" API requirement for system applications under (iii)(B)(1). We understand this to be a single-patient equivalent API requirement for system apps in alignment with the existing Bulk API requirement, and request confirmation of this interpretation.

170.315(G)(20) - Standardized API for Public Health Data Exchange

The EHR Association recommends starting with US Core to support public health data exchange use cases, rather than moving directly to the U.S. Public Health Profiles Library (USPHPL). US Core is already a requirement for other certification criteria, and we believe that the immediate goals of public health data exchange can be achieved using US Core alone. By starting with a widely adopted standard, we can streamline the implementation process and build a more cohesive framework for future public health data exchange.

Regarding the inclusion of Bulk API, we recommend excluding it from public health data exchange requirements for now. While the Helios project is making progress on bulk querying by providers from Public Health Agencies (PHAs), Bulk API still requires significant manual pre-setup to define the appropriate group and scope of data. As such, it is not yet ready to meet the complex needs of public health reporting. Instead, the focus should be on improving Bulk API before mandating its use for these scenarios.

Additionally, the use cases for FHIR Subscriptions in public health are not clearly defined at this time. In line with our recommendation on Subscriptions in general and 170.315(g)(10) specifically, we recommend that developers certifying to 170.315(g)(10) and/or 170.315(g)(20) be required to support at least three subscription topics of their choice across both 170.315(g)(10) and 170.315(g)(20). Scaling back subscription requirements to a limited set of high-priority use cases will reduce the burden on developers and ensure that the technology is used where it can provide the most value. As part of HTI-2, it would be beneficial to prioritize use cases that promote industry consistency, with the potential for future expansion through a standardized process like US Core.

Overall, 'Subscriptions' does not seem to align well with what we understand the primary intent of 170.315(g)(20) to be – a supplement for initial reporting under the (f) criteria. Therefore, we recommend a more measured approach to Subscription requirements, focusing on practical and immediate needs for public health data exchange.

170.315(G)(30) - Patient Access API

The EHR Association requests clearer language regarding the scope of 170.315(g)(30) – particularly whether this criterion is intended solely for payer actors and is optional. It is important to confirm that 170.315(g)(30) is not expected to be relevant to providers, as they have their own patient access API requirements under 170.315(g)(10).

To ensure clarity and avoid confusion, we recommend that ASTP provide clear guidance on the specific actors and contexts to which each regulation applies. Defining which criteria apply to providers, payers, or other actors will help ensure proper implementation and compliance across different sectors of the healthcare system.

170.315(G)(31) - Provider Access API – Client
170.315(G)(32) - Provider Access API – Server

The EHR Association suggests replacing the terms “Client” with “Provider” and “Server” with “Payer” in the naming of these API components for clarity and alignment with the roles involved.

For 170.315(g)(31), we recommend aligning with CMS’s existing requirements. While 170.315(g)(32) and other HTI-2 criteria for payers exist, these are currently optional and do not carry enforceable requirements for payers. Therefore, we suggest continuing with an optional path forward, as these capabilities are still evolving. For example, PDex 2.0 should remain optional or recommended at this stage due to its limited known production use. This approach allows for further experience and future adoption while recognizing that it is not yet ready for full implementation.

We agree with naming US Core and Bulk Data, as these are consistent with existing provider API support under HTI-1 and match CMS’s requirements, providing a foundation for continued alignment between ASTP and CMS regulations.

170.315(G)(34) - Prior Authorization API – Provider
170.315(G)(35) - Prior Authorization API – Payer

The EHR Association recommends ASTP follow CMS’s approach by not requiring specific standards for the Prior Authorization API at this time. Instead, we suggest maintaining a functional requirement that allows for the optional but strongly recommended use of the implementation guides, while still requiring that it be based on FHIR R4. Ultimately, it will be critical for both health IT developers and payers to adopt a common standard and Implementation Guide. However, the current guides have not been deployed at scale or tested sufficiently to be required. Locking in on an immature standard would not allow the industry to make adjustments as needed, which will likely occur at a more rapid pace than the SVAP can accommodate. Instead, we recommend starting with the implementation guides, working with DV to gather insights, and quickly incorporating those learnings into the next version. This flexibility will enable providers and payers to adapt to evolving standards while allowing these processes to mature. In future iterations of the HTI framework, ASTP can lock into a well-matured and widely agreed-upon set of guidance, including a specific standard.

As outlined in our prior feedback to both ASTP and CMS, prior authorization is a highly interactive and complex workflow that requires proper integration into provider workflows, which often involve multiple health IT systems beyond just EHRs. While we support the ability to use FHIR-based apps to provide different levels of integration, there are several key complexities that need to be addressed:

- The connection of Coverage Requirements Discovery (CRD) with various trigger events to initiate prior authorization, particularly in both clinician and back-office/administrative workflows.

- The integration of Document-Based Requirements (DTR) into the workflow to manually collect data that is not yet automatically retrievable.

We acknowledge that the CMS objective is to facilitate the submission of a prior authorization request, which suggests that CRD-based and/or Prior Authorization Support (PAS)-based interactions are the

most relevant. Rather than requiring support for all guides and interactions, we recommend that ASTP allow health IT systems and providers the flexibility to grow and expand as their needs evolve. Early feedback from initial implementations has shown that CRD alone can provide substantial value, while others may choose to focus on PAS to support their workflows.

Additionally, the proposed rule outlines six specific hooks to support. While all are reasonable in themselves, not all EHRs may need to support every hook (e.g., appointment scheduling is highly likely to be handled in other systems). We suggest allowing for flexibility and focusing on an initial core set of hooks that can expand over time as workflows develop.

170.315(G)(36) - Provider Directory API – Health Plan Coverage

The EHR Association requests confirmation that the Provider Directory API – Health Plan Coverage is expected to apply only to payer actors and is optional. We understand that this requirement is not intended to be implemented by providers or for providers to ingest this information from a payer.

170.315(J)(1) - Functional Registration

The EHR Association is supportive of the inclusion of functional registration maintenance as a necessary measure to account for edge cases. However, we emphasize the need to limit the reliance on functional registration over time, as the industry moves towards adopting more trusted and standardized approaches.

We believe that as health IT systems increasingly adopt trusted registration methods, such as dynamic registration, ASTP should focus on encouraging the exclusive use of these approaches. Functional registration should remain in place as proposed to accommodate edge cases, but we reiterate our recommendation made under the dynamic registration proposals, which suggests allowing developers the flexibility to require dynamic registration for apps that do not follow their preferred registration paths. This includes instances where apps might be part of a developer program that offers value-added services for app validation during registration.

170.315(J)(2) - Dynamic Registration

The EHR Association is tentatively supportive of UDAP v1 for dynamic registration, but we emphasize that there is still ongoing development in this area. We recommend that ASTP closely monitor the evolving specifications to ensure the ability to pivot and adopt newer versions as they become available. This could be achieved through SVAP, though the pace of updates may present challenges.

We are highly supportive of maintaining flexibility for developers to choose and support only the trust communities they prefer. Additionally, we assert that developers should have the right to enforce a dynamic registration path when an app does not follow the preferred registration path, such as joining a developer program that includes value-added services for app validation. This ensures that developers retain control over which apps integrate with their systems, supporting enhanced security and functionality.

170.315(J)(5) - Asymmetric Certificate-Based Authentication for Patient Access.

The EHR Association is supportive of and appreciates the alignment of asymmetric certificate-based authentication with the TEFCA framework. We believe that this approach offers a robust security model for patient access, and the consistency with TEFCA is a positive step toward broader interoperability and security.

However, we note that as this model is implemented in practice through TEFCA, there may be important clarifications and changes that need to be addressed. It is critical that these developments are closely monitored to ensure that the implementation remains consistent and provides the best possible outcomes for both security and usability. Any emerging insights or adjustments should be reflected in future iterations of the certification criteria to ensure the most effective and secure application of asymmetric certificate-based authentication.

170.315(J)(6) - Smart App Launch User Authorization

The EHR Association is supportive of the goal to implement approaches for token revocation in the SMART App Launch framework. However, we recommend ASTP adopt flexibility to allow token revocation for clinician-facing apps to be managed by IT administrators rather than clinical end-users, if preferred by the developer and their customers. This approach is more practical and aligns with existing workflows in healthcare organizations, where IT departments typically manage security-related functions. By centralizing token management with IT, organizations can ensure a more streamlined and secure process, while reducing the burden on clinical staff.

170.315(J)(8) - Asymmetric Certificate-Based System Authentication and Authorization

Again, we support and appreciate the alignment of asymmetric certificate-based system authentication and authorization with the TEFCA framework. We note that as this model is implemented in practice, particularly within TEFCA, there may be important clarifications and changes that require adjustment. It is essential that these developments are closely monitored to ensure the continued effectiveness and scalability of the system as it expands across various healthcare environments.

170.315(J)(9) - Smart Patient Access for Standalone Apps (Smart App Launch 2.2)

The EHR Association is supportive of the addition of SMART v2 Scopes (permission-v2) and requests clarification that this applies specifically to US Core-defined scopes. We recommend that the ongoing expansion of scopes be delegated to US Core and related standards, allowing for iterative additions as new use cases emerge. This will ensure that the scope definitions evolve in a structured and manageable way.

It is also important to keep the defined set of scopes at a level that is most usable for patients. Overly granular scopes may become burdensome and confusing for patients to manage. For example, distinguishing between broad categories such as vital signs and laboratory results is helpful, but narrowing it down too much—such as to only vital signs on a specific day—may create unnecessary complexity for the patient.

We also request that ASTP clarify that implementers can and should have the flexibility to create patient-friendly names for scopes, without needing to expose patients to the technical details or API terms behind those scopes. This approach would greatly enhance the user experience by making permissions more understandable and accessible to patients.

170.315(J)(11) - Asymmetric Certificate-Based Authentication for B2B User Access

The EHR Association is supportive of and appreciates the alignment of asymmetric certificate-based authentication for B2B user access with the TEFCA framework. As with other TEFCA-aligned initiatives, we recognize that putting this approach into practice may yield important clarifications and changes. These developments should be closely monitored to ensure consistency and to achieve the best possible implementation outcomes.

We request that ASTP clarify that while this section references B2B interactions, the requirement is specifically intended to apply to clinician access user scenarios. The use of the term "B2B" may be misleading in this context, and clear guidance confirming its focus on clinician access will help ensure accurate implementation.

170.315(J)(22) - Verifiable Health Records

The EHR Association recommends that ASTP withdraw the verifiable health records proposals at this time, as the specifications are not yet fully published. Additionally, the bundles referenced in the regulation text do not all appear in the build-status version of the implementation guide (IG). For any bundles to be cited in the regulation, they must be: (1) part of a published IG, and (2) discretely specified in that IG.

Given the significant volume of work involved and the relative lack of perceived value for Smart Health Cards at this stage, the current proposal does not warrant the level of effort required for implementation. Looking ahead, we encourage ASTP to consider using Smart Health Links in future regulations rather than Smart Health Cards. Smart Health Links do not face the same data volume limitations that are inherent in Smart Health Cards due to the constraints of QR code technology.

170.315(J)(23) - Subscriptions - Client
170.315(J)(24) - Subscriptions - Server

We propose that Health IT Modules certified to § 170.315(j)(23) and § 170.315(j)(24) demonstrate support for FHIR-based API subscriptions according to the HL7 FHIR Subscriptions Framework. We specifically propose the adoption of the Subscriptions R5 Backport Implementation Guide version 1.1.0 (Backport IG) in § 170.215(h)(1) as a baseline standard conformance requirement in § 170.315(j)(23) and § 170.315(j)(24)

1. *Conformance to the "R4/B Topic-Based Subscription" profile detailed in the as specified in the Backport IG. This includes the need to demonstrate support for "must support" elements.*

2. *Adoption of both the Patient-Update and Encounter-Create Subscription topics as minimum requirements for server support.*
3. *Conformance to the R4 "Server CapabilityStatement" included in the Backport IG.*
    a. *Server support of create, update, and delete interactions for Subscription resources (create and delete are currently optional).*
4. *Server support of id-only payload notification bundles.*
5. *At a minimum, support of the REST-hook Subscription channel as a means of notifying subscribers of the availability of new results.*

The EHR Association appreciates the proposal to adopt the HL7 FHIR Subscriptions Framework and the R5 Backport Implementation Guide (IG) version 1.1.0 as a baseline standard for FHIR-based API subscriptions. However, we recommend that ASTP focus on naming specific use cases to prioritize in HTI-2 to ensure industry consistency and to allow for future, regular expansion of these capabilities.

Given that there are not currently consensus use-cases for particular subscription topics that provide value for all stakeholders, we propose that ASTP/ONC instead begin by requiring developers to support at least three specific subscription topics of their choice, based on what would provide the most value to their customer base. These topics should not be limited to predefined resources but should instead allow developers to select one or more resources within the USCDI scope from either 170.315(g)(10) or 170.315(g)(20). For example, topics could include:

- Lab result finalization and amendments
- Inpatient stays that are extended
- Patient-Update
- Encounter-Create

We believe it is overly burdensome and inefficient to require support for all possible subscription topics. Instead, starting with a core set of high-priority use cases will ensure that the most valuable workflows are supported first, allowing provider organizations to maximize their efficiency and focus on what matters most to their operations.

We also recommend that ASTP implement a standardized process for expanding use cases, using industry-defined processes such as US Core. This would provide clearer definitions for topics, use cases, and workflow expectations while allowing the community to vote on and standardize these expansions over time.

We are supportive of moving forward with the R5 Backport IG as proposed, given that it is stable and in use. While there are some changes expected in R6, they are far enough away that it makes sense to adopt R5 in the interim.

170.315(j) - Modular API Capabilities Certification Criteria

We propose to adopt fourteen new modular API technology certification criteria in § 170.315(j) at (j)(1)-(2), (5)-(11), and (20)-(24).

In addition to our specific comments on the 170.315(j) criteria outlined above, the EHR Association expresses general support for the adoption of modular API technology certification criteria. This modular approach promotes inclusivity by opening the certification program to products supporting specific capabilities, providing more flexibility in how requirements are applied. It also avoids forcing developers to support capabilities that may not be applicable to their software or customer needs.

However, we remind ASTP that if all the "modular" criteria are cited within a single criterion – such as 170.315(g)(10) – the intended goal of modularity may not be fully realized. To maintain the flexibility and modularity intended, we ask ASTP to keep this perspective in mind when moving forward with future rulemaking.

170.315 (general - USCDI v4)

We propose to update the USCDI standard in § 170.213 by adding USCDI v4. We propose that as of January 1, 2028, any Health Modules seeking certification to certification criteria referencing § 170.213 would need to be capable of exchanging the data elements that the USCDI v4 comprises.

Further, we propose that Health IT Modules certified to certification criteria that reference § 170.213 would need to update their Health IT Modules to accommodate USCDI v4 data elements using the FHIR® US Core Implementation Guide Version 7.0.0 proposed in § 170.215(b)(1)(iii) and the HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes, Edition 3 - US Realm, proposed in § 170.205(a)(1)

The certification criteria that currently cross-reference to USCDI via § 170.213 are as follows:

1. *"Care coordination - Transitions of care - Create" (§ 170.315(b)(1)(iii)(A)(1) and (2));*
2. *"Care coordination - Clinical information reconciliation and incorporation - Reconciliation" (§ 170.315(b)(2)(iii)(D)(1)-(3));*
3. *"Decision support interventions – Decision support configuration" (§ 170.315(b)(11)(ii)(A) and (B), and (iv)(A)(5) – (13)));*
4. *"Patient engagement - View, download, and transmit to 3rd party - View" (§ 170.315(e)(1)(i)(A)(1) and (2), and (iii));*
5. *"Transmission to public health agencies – electronic case reporting" (§ 170.315(f)(5)(i)(C)(2)(i));*
6. *"Design and performance - Consolidated CDA creation performance" (§ 170.315(g)(6)(i)(A) and (B));*
7. *"Design and performance - Application access – all data request – Functional requirements" (§ 170.315(g)(9)(i)(A)(1) and (2)); and*
8. *"Design and performance - Standardized API for patient and population services – Data response" (§ 170.315(g)(10)(i)(A) and (B)).*

The EHR Association is supportive of the proposal to update the USCDI standard in 170.213 by adding USCDI v4. We believe that ongoing, reliable, and consistent adoption of USCDI data classes is essential

for fostering interoperability and improving health information exchange across the healthcare ecosystem.

We agree with the use of the FHIR US Core Implementation Guide Version 7.0.0 and the HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (Edition 3) as the foundational specifications for accommodating USCDI v4 data elements, as outlined in 170.215(b)(1)(iii) and 170.205(a)(1).

We further support the certification criteria that currently cross-reference USCDI via 170.213.

By maintaining a clear, reliable, and consistent process for adopting new USCDI versions, ASTP will help ensure that health IT developers can stay aligned with evolving standards and provide valuable improvements to data interoperability across the healthcare industry.

170.404(b)(2) - User-Access Brands and Endpoints

We propose in our updated § 170.404(b)(2)(iii) to require that, by January 1, 2028, service base URLs and related API Information Source details, including each organization's name, location, and facility identifier, must be published in an aggregate vendor consolidated "FHIR Bundle" according to the Brands specification.

The EHR Association is supportive of adopting the User Access Brands and Endpoints specifications. These specifications provide a consistent representation of endpoints and metadata across developers, benefiting app developers and the general public. Additionally, they offer certified API developers a clear standard for formatting the required data, which promotes transparency and interoperability.

However, regarding the proposal to require the publication of trust community details alongside endpoints, we believe this is unnecessary and should be removed from the final rule. The UDAP Implementation Guide (IG) already requires trust community information to be published as part of the .well-known endpoint, as outlined in the specifications: UDAP Security IG - Discovery. Including trust community information again with the published endpoints would be duplicative and add unnecessary complexity, as this requirement is already addressed by existing standards.

170.407 - Conditions and Maintenance of Certification Requirements – Insights and Attestations

Overarching comments for Insights Condition and Maintenance of Certification

The EHR Association wishes to express its appreciation to ASTP for the continued responsiveness to feedback on the measures and metrics finalized in HTI-1, including several proposed updates in this proposed rule. However, it is still true that these ongoing adjustments are making it difficult for developers to understand the expectations of the program when planning development and, in some cases, require developers to completely rework or discard work in progress.

The following points are key considerations regarding the Insights Condition and Maintenance of Certification and the additional proposals under HTI-2 that we urge ASTP to take into account as the program is carried forward.

- **Stability in Final Rules**: It is crucial that whatever is included in the HTI-2 final rule be maintained without significant changes for at least the first year of reporting for each applicable measure. This should allow for minor clarifications that do not materially alter metrics but help guide developers. Consistent rules will allow developers to implement and comply without disruption.

- **Sufficient Time for Implementation**: We need adequate time to react to and implement the proposed metrics. Some of the current proposals impact metrics for year one, such as Immunizations Administered, or depend on other certification criteria updates proposed in this same proposed rule, like C-CDA Reconciliation and Incorporation. For these reasons, more time is required for the implementation of add-on metrics.

- **Provider-Specific Data Collection**: We continue to assert that the collection of healthcare provider-specific data for measurements is better directed at the provider entities themselves rather than the developers. This would ensure more accurate data collection and reporting.

- **Impact on Developer Resources**: The increasing complexity of these measures is pulling significant attention and resources away from the work we do to provide software and support that directly benefits our customers. The focus should be on building solutions that meet the needs of healthcare providers and patients, rather than being overly burdened by complex reporting metrics.

- **Potential Misinterpretation of Data**: There is an ongoing concern about how the data provided under these measures could be misconstrued, potentially painting a negative picture of EHR capabilities or an inappropriate generalization of provider usage. In reality, the gaps or failures in certain measures may not be due to system shortcomings but instead reflect complexities in real-world healthcare workflows. These nuances need to be better communicated to avoid unjust criticism of EHR systems.

We propose to add § 170.407(a)(1)(i)(D) to require developers of certified health IT to provide health care provider identifiers (e.g., National Provider Identifier (NPI), CMS Certification Number (CCN), or other type of unique national identifier) for providers included in the data submitted.

The EHR Association understands the intent behind requiring developers of certified health IT to provide healthcare provider identifiers such as NPI, CCN, or other unique national identifiers. However, we have significant concerns regarding the additional complexity and potential limitations this requirement would impose on measurement and reporting capabilities.

For many developers, submitting aggregated data without unique identifiers for the source healthcare providers is feasible. However, the requirement to disclose identifying information could result in contractual limitations, rendering many, if not all, healthcare providers ineligible for inclusion due to

privacy concerns and/or provider refusal. Furthermore, the inclusion of unique identifiers increases the sensitivity of the data, leading to heightened costs associated with storing and maintaining this sensitive information securely.

We also question whether this requirement constitutes an overreach of authority, as access to provider identifiers under the EHR Reporting Program may not align with the scope of the Cures Act. Requiring developers to submit this level of detail places an unreasonable burden on them, which could complicate compliance and reduce the effectiveness of the reporting program.

We strongly recommend that ASTP exclude the unique identifier requirement and revert to basic data submission. If the inclusion of unique identifiers is deemed necessary for reporting purposes, it would be more appropriate to collect this data directly from healthcare providers, such as through existing PI/MIPS submission processes, rather than from developers.

We seek public feedback on approaches to understand the types and number of providers that are included in the data submitted, relative to the broader population of providers using the products of a developer of certified health IT. We also request comments for alternatives that may shift measurement from provider-based measures to patient-centered measures such as percentage and/or number of encounters or patients included in the data.

The EHR Association continues to question the viability of requiring the submission of percentages of hospitals and clinicians represented in the data submissions for Insights. Identifying the number or percentage of individual hospitals and providers involved in these submissions is fundamentally infeasible for developers to determine reliably. This would essentially require each customer to provide these details to developers, which is not only an unreasonable ask but also imposes unnecessary burden on healthcare providers—Insights should never create additional burden for them.

We recommend that ASTP not adopt any requirement for supplementary information submission for Insights beyond the metrics themselves. This would entail withdrawing the existing requirement to submit percentages of hospitals and clinicians represented in our submission and declining to adopt any replacement that adds complexity without clear value.

As expressed in our general comments on Insights, the burden of this program is already growing for something that provides no direct tangible benefit to our customers. The existing requirement to supply provider-based percentages is completely infeasible, as developers do not have access to this granular information. Furthermore, the proposed patient-focused approach using counts of unique patients or encounters does not appear to offer any added value that would justify the additional burden and effort it would impose on developers.

If ASTP sees a need to provide supplementary information to help contextualize Insights data, the only functionally achievable option would be to require counts of unique patients in the total data submitted for each measure category. However, we reiterate that even this approach does not seem to provide enough value to justify the requirement.

We propose in § 170.407(b)(1)(ii) that the response a developer of certified health IT submits per the requirements of the Insights Condition, must be applicable to all their certified health IT as of January 1st of each year, beginning January 2026.

The EHR Association generally supports the policy of using January 1st as the date for determining the applicability of Insights Condition submissions for certified health IT modules. This provides a clear and sensible cutoff for each reporting cycle, rather than aligning with the August 31st date used for Real World Testing (RWT).

However, we request clarification from ASTP on how to handle scenarios where a certified health IT module that is active as of January 1st is fully withdrawn before the July submission date. In such cases, it does not seem relevant to require submission of measurements for a product that has been discontinued. Our assumption is that there would be no need or expectation for submitting data for a module that has been withdrawn after the January 1st cutoff but prior to the July submission deadline.

We ask that ASTP provide explicit guidance on this matter in the final rule to avoid any confusion regarding submission expectations for withdrawn health IT modules.

We also propose in § 170.407(b)(2) that if developers update their certified health IT using Inherited Certified Status after January 1 of the year prior in which the responses are submitted, a health IT developer must include the newer version of the certified Health IT Module(s) in its annual responses to the Insights Condition of Certification.

The EHR Association supports this as a logical approach to ensure consistency in reporting across different versions of health IT modules. However, we ask ASTP to acknowledge that versions of certified health IT modules that go live late in the year may only contribute data for a subset of the reporting year. While this is not a concern from a developer perspective, it is important for ASTP to align with this understanding to ensure that expectations around data completeness are clear and reasonable.

To improve alignment and consistency with ONC's other certification requirements, we propose to revise § 170.407(a)(1)(i)(B) to specify that documentation must be available via a publicly accessible hyperlink instead. We note that this applies to both required and optional documentation.

The EHR Association supports the proposal to revise 170.407(a)(1)(i)(B) to specify that documentation must be available via a publicly accessible hyperlink. This approach ensures consistency with other related certification program requirements, such as Real World Testing, and streamlines the documentation process for developers.

We request that ASTP provide a standard template for public documentation. While this template should remain optional, it would offer developers a clear and consistent format to work from when preparing required and optional documentation. The template should lay out all specific required documentation details as well as any optional or recommended elements for each measure category, ensuring that developers can meet the documentation requirements efficiently and comprehensively.

Therefore, we propose to revise § 170.407(a)(3)(i) to include both individuals and individuals' authorized representatives accessing their EHI (rather than just individuals alone).

The EHR Association supports the proposed revision to 170.407(a)(3)(i) to include both individuals and their authorized representatives accessing their EHI. This change simplifies the measure and more closely aligns it with the certification criteria requirements related to EHI access.

Given that our intent is to measure individuals' access to EHI (versus just authorizing access), we plan to update this definition in the measure specification sheet for this metric to further specify that access to EHI should be measured by counting the number of individuals where at least one FHIR resource was returned when using the "standardized API for patient population services" under § 170.315(g)(10) during the reporting period.

The EHR Association supports the proposal to measure individuals' access to EHI by counting the number of individuals where at least one FHIR resource was returned using the "standardized API for patient population services" under 170.315(g)(10) during the reporting period. This approach better aligns with the actual intent of the metric, focusing on the retrieval of data, rather than just authorizing access.

We expect to update the metrics for the proposed "C-CDA reconciliation and incorporation through certified health IT" measure, within the accompanying measure specification sheet to align with the proposed broader set of data referenced by the criterion specified in § 170.315(b)(2) if finalized as proposed.

The EHR Association strongly recommends that ASTP forgo the adoption of any new or revised metrics for the C-CDA Reconciliation measure as proposed in HTI-2. These changes are contingent upon the corresponding certification criterion at 170.315(b)(2) itself being updated. It would be inappropriate to revise Insights measures simultaneously with the criteria they are meant to measure. Therefore, any modifications to the measurement should be deferred to future rulemaking, after developers have had an opportunity to assess the impact of the updated criterion on system use.

Furthermore, as a default standard, any Insights measurement associated with updated certification criteria should not take effect until at least one year after the effective date of the changes. For example, if a criterion update becomes effective in 2028, the earliest an associated Insights metric should begin would be 2029. This provides a necessary buffer to allow healthcare providers to adjust to the new functionality gradually.

Given the lack of perceived value these metrics offer relative to the required effort from developers, we recommend that ASTP reconsider adding any revised or new metrics as part of this measure in HTI-2. The Insights metrics should not automatically expand with changes to certification criteria. Instead, there should be minimal expansion of Insights measurements, and ample opportunity for input from developers before any updates are adopted.

We also plan to make a technical update by revising the number of unique patients with an associated C-CDA document measure to instead capture the number of unique patients with an encounter and associated C-CDA document.

The EHR Association supports this update as a local change that is well-aligned with the structure of the preceding metrics.

In the HTI-1 Final Rule (89 FR 1326), we finalized the "use of FHIR in apps through certified health IT" in § 170.407(a)(3)(iv) ... We intend to make a technical update in the accompanying measure specification sheet to provide additional implementation information specifying that reporting by user type should be done according to three mutually exclusive categories: patient-facing only, non-patient-facing only, and both patient-facing and non-patient-facing.

The EHR Association supports the proposed update. We recommend that ASTP adopt this metric change as proposed, as it provides a structured approach to ensure that all developers are reporting consistently across all relevant API endpoints and user types.

We intend to add metrics to separately count the number of immunizations administered electronically submitted to IISs that returned with an acknowledgment with the error of severity level E during the reporting period overall, and by IIS and age category.

The EHR Association is supportive of the proposed new metric to track the number of immunization submissions returned with an acknowledgment if the severity level is E (error). This update provides clearer insight into immunization messaging transaction failures, offering a more detailed picture of data quality without imposing any additional burden on developers. As developers would already need to track such failures under the finalized metric specifications from the HTI-1 Final Rule, this proposed metric aligns well with existing processes.

We also intend to make another technical update to the measure specification sheet by adding metrics to separately count the number of immunizations administered that were electronically submitted to IIS where an acknowledgment from an IIS is not received by certified health IT overall, and by IIS and age category.

Although we are generally supportive of the proposed update, this is a new metric that would not have been tracked as part of the originally finalized measure. Therefore the EHR Association recommends delaying its implementation by one year, until 2027. This will give developers sufficient time to make the necessary updates to account for this new metric that was introduced late in the process.

We also request comment on the value and burden associated with reporting a count of the subset of messages sent to third-party intermediaries where the third-party intermediary does not provide an acknowledgment that the message was sent to an IIS.

The EHR Association does not believe there is significant value in requiring a dedicated metric for tracking messages sent to third-party intermediaries where no acknowledgment is received that the message was sent to an IIS. Given the expected low volume of such messages, it is unnecessary to

separately track this subset from the already proposed metric for messages that do not receive an acknowledgment. The addition of a separate metric for this scenario would only create additional burden without providing substantial benefit.

We intend to make a technical update that would clarify that the immunization administration submitted would include HL7 Z22 messages, and request comment on this approach. This aligns with the "immunization history and forecasts through certified health IT" measure specification sheet where we indicate that "the successful response received from IIS" includes HL7 Z42 and Z32 messages.

The EHR Association supports the proposed update to clarify that immunization administration submissions include HL7 Z22 messages. This additional point of clarity provides the necessary technical specificity for the scope of the metric and aligns with the successful response definition in the immunization history and forecasts measure specification sheet, which already includes HL7 Z42 and Z32 messages.

We plan to update this definition so that the number of immunization queries sent to IISs overall metric should be measured by only counting the total number of immunization queries sent to IISs during the reporting period. This metric no longer requires subtracting the number of acknowledgments with the error of severity level E.

We support the proposed update to the immunization queries metric to measure the total number of immunization queries sent to IISs during the reporting period, without requiring the subtraction of acknowledgments with error severity level E. The original structure of the metric, which tied successful submissions to acknowledgment responses, was inappropriate. The success of a query message submission should not depend on the receipt of an acknowledgment.

The EHR Association recommends that ASTP adopt this metric update as proposed.

We are adding separate metrics in the measure specification sheet which would report on the total number of queries responses that returned with acknowledgments that had an error of severity level E, overall and by IIS, during the reporting period.

The update does not impose additional developer burden, as these failures would already need to be tracked under the finalized metric specifications from the HTI-1 Final Rule. Therefore, the EHR Association is supportive of the proposed update. This change provides clearer details on immunization messaging transaction failures, which helps to paint a more comprehensive picture of data quality and transmission issues.

We plan to make a technical update in the accompanying measure specification sheet to create additional metrics which would report on the total number of queries sent but where no acknowledgment was received from the IIS overall, and by IIS.

This is a logical metric to add to the measure category. The EHR Association supports the proposed technical update to create additional metrics that report the total number of queries sent where no acknowledgment was received from the IIS.

We also plan to make a technical update to the definition of "queries sent" to IISs such that the definition of queries sent applies to HL7 Z34 and HL7 Z44 messages.

The EHR Association supports the proposed technical update to the definition of "queries sent" to IISs, specifying that it applies to HL7 Z34 and HL7 Z44 messages. This additional point of clarity provides important technical specificity for the scope of the metric, ensuring consistency and accuracy in reporting.

170.207(f) – Race and Ethnicity

We propose to revise § 170.207(f)(1) to include recent updates to the U.S. Office of Management and Budget's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15). In § 170.207(f)(1)(i) we propose to include The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997, with an expiration date of January 1, 2026, for adoption of that standard. In § 170.207(f)(1)(ii) we propose to include the U.S. Office of Management and Budget's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), as revised, March 29, 2024.

The EHR Association expresses concern regarding the proposed inclusion of the U.S. Office of Management and Budget's (OMB) Statistical Policy Directive No. 15 (SPD 15) as revised in March 2024. The new version of the standard is not yet ready for implementation by health IT systems, particularly within the proposed timeline for end of year 2025. This update would necessitate corresponding functional changes to the Patient Demographics and Observations criterion at 170.315(a)(5), specifically to consolidate race and ethnicity into a single concept.

The revisions adopted in this standard, especially the transition to a combined format for race and ethnicity, represent significant changes. Current downstream interoperability standards across the healthcare industry are based on the use of independent fields for representing these concepts. Adopting the proposed standard would create a disconnect between the standard version cited in USCDI and that referenced in the Patient Demographics and Observations criterion.

We recommend that ASTP adopt the new SPD 15 standard update with a deadline *no sooner than* January 1, 2028 and also ensure that proper alignment with the OMB standard version adopted in USCDI and with the functional requirements of the Patient Demographics and Observations criterion, particularly with respect to consolidating the race and ethnicity concepts, are accounted for as part of that adoption. This is critical to prevent downstream issues and inconsistencies in program requirements and to avoid disruptions in the interoperability of race and ethnicity data.

170.210(a) - Standards for Encryption and Decryption of Electronic Health

We propose to adopt the updated version of Annex A of the Federal Information Processing Standards (FIPS) 140-2 (Draft, October 12, 2021) in § 170.210(a)(3) and incorporate it by reference in § 170.299.

The EHR Association supports the proposal to adopt the updated version of Annex A of FIPS 140-2 (Draft, October 12, 2021). This update presents little or no burden for developers and is a sensible move to ensure the highest level of security by adopting the latest version of the standard.

We recommend that ASTP move forward with this proposal but suggest holding off on transitioning to FIPS 140-3 until there is more time to fully assess and consider the potential impacts of that transition on the health IT ecosystem.

Information Blocking Enhancements

171.104 - Interferences

(a) The following constitute practices that are likely to interfere with the access, exchange, or use of electronic health information (EHI) for purposes of § 171.103:

The EHR Association recommends that ASTP does not finalize a specific list of likely interferences for 171.103. We believe that codifying a list of interferences could detract from the effective evaluation of other potential interferences and place undue priority on the examples provided, limiting flexibility in addressing various situations.

The current guidance outlined through the preamble discussion and FAQs is sufficient for OIG and other stakeholders to make determinations on a case-by-case basis. There is no need to codify a list, and we encourage ASTP to avoid doing so. It is also unclear how a codified list serves ASTP or OIG's goals, as information blocking investigations will be too fact specific to rely on a codified list of interferences.

(4) Non-standard implementation. Implementing health information technology in ways that are likely to restrict access, exchange, or use of EHI with respect to exporting electronic health information, including, but not limited to, exports for transitioning between health IT systems.

The EHR Association has concerns about codifying non-standard implementation as a specific example of interference. There is a lack of clarity in what constitutes a "non-standard implementation," and this ambiguity creates challenges in applying such a rule consistently.

For instance, while there are cases where unexpected or non-standard practices clearly impede interoperability (e.g., writing medication prescriptions in a note rather than ordering them prevents e-prescribing), there are many gray areas in which industry consensus does not exist. For example, there is ongoing debate about whether medication administrations are classified as procedures. The term non-standard will not help clarify or resolve these nuanced cases.

Furthermore, this example references exports for transitioning between health IT systems, which is confusing given that EHI Export does not have a standard identified. Additionally, the concept of implementation versus client configuration is often blurred, and it is unclear to what extent EHR developers control implementation compared to the deployment decisions made by clients.

We recommend that ASTP refrain from codifying this specific practice and all interference examples.

171.204 - Infeasibility Exception - Responding to Requests Condition Modifications

We propose to modify the § 171.204(b) responding to requests condition by establishing different timeframes for sending written responses to the requestor based on the § 171.204(a) condition under which fulfilling the requested access, exchange, or use of EHI is infeasible.

The EHR Association appreciates ASTP's willingness to listen to stakeholder feedback and adjust the timeframes for sending written responses under 171.204(b). We believe that the proposed changes will address many of the timing challenges related to responding to requests for access, exchange, or use of EHI when infeasibility is claimed.

However, we request further clarity regarding situations involving patient portal or API access, specifically around the timing of the 10-day window to provide a written response to the request. For example, is this a one-time 10-day window or does it occur with each sign-on to the portal or API? There have been ongoing discussions in the industry and with our clients regarding how the 10-day window applies to patient portal and API log-ins. There are discrepancies in interpretation, with some viewing the 10-day window as preventing the use of the infeasibility exception, while others believe standard language in the patient portal satisfies the requirements, and still others require consent from each patient. We believe clarity around this point would go a long way toward alleviating provider concerns about the information released through the patient portal and APIs.

Additionally, we request clarification as to whether it is possible to provide an overarching notification of the segmentation ability and the claiming of the infeasibility exception, rather than handling it on an individual request basis.

171.304 - New Exception: "Requestor Preferences"

We propose in section IV.B.4, a new information blocking exception: "Requestor Preferences" in 45 CFR 171.304. This exception would stand separate from and independent of other exceptions and would apply where an actor honors or adheres to a requestor's preference(s) expressed or confirmed in writing for: (1) limitations on the amount of EHI made available to the requestor; (2) the conditions under which EHI is made available to the requestor; and (3) when EHI is made available to the requestor for access, exchange, or use.

The EHR Association recommends that ASTP refrain from adopting the proposed Requestor Preferences exception. We believe that this exception is unnecessary, as the ability to honor a requestor's preferences should already be covered under the existing Manner Exception. Creating a separate exception would impose additional documentation requirements without adding any meaningful value.

Furthermore, if ASTP does not finalize the list of interferences, including improper encouragement or inducement, the need for this exception is even less relevant. ASTP should avoid creating exceptions for the sake of having them.