EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

550 W Van Buren Street, Suite S1110
Chicago, IL 60607

@EHRAssociation | ehra.org

December 2, 2024

Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy,
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, DC 20024

Re: Draft Federal FHIR® Action Plan

Dear Dr. Tripathi,

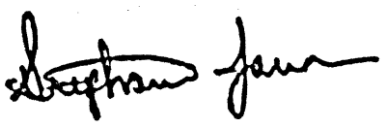
On behalf of the 29 members of the HIMSS Electronic Health Record (EHR) Association, we appreciate the opportunity to provide feedback on the Draft Federal FHIR® Action Plan ("draft action plan"). The EHR Association is dedicated to improving the quality and efficiency of healthcare through the development and adoption of interoperable health information technology standards. We appreciate that the draft action plan seeks to promote a unified approach to FHIR development and deployment, which will be crucial for advancing interoperability and enhancing patient care across the healthcare ecosystem.

We commend ASTP's commitment to transparency and the visibility provided into current and future FHIR goals, including details on proposed specifications and maturity considerations. The draft action plan's focus on interagency alignment is critical, and we fully support this goal as it will enable the industry to progress cohesively, avoiding the challenges that arise from conflicting priorities or divergent standards.

While the action plan centers on FHIR, we encourage ASTP to reference the broader health IT landscape and identify situations in which alternative standards, such as HL7v2 or CDA, may better address specific use cases.

Our specific comments follow. We appreciate your consideration of our feedback and stand ready to further discuss any of these topics. The EHR Association remains committed to collaborating with ASTP, CMS, and other key stakeholders to advance interoperable, efficient, and patient-centered healthcare.

Sincerely,



Stephanie Jamison
Chair, EHR Association
Greenway Health

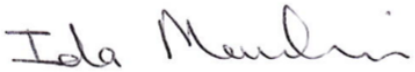
Leigh Burchell
Vice Chair, EHR Association
Altera Digital Health

HIMSS EHR Association Executive Committee

David J. Bucciferro
Foothold Technology

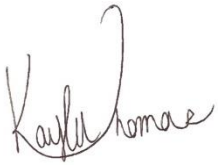
Danielle Friend
Epic

Cherie Holmes-Henry
NextGen Healthcare



Ida Mantashi
Modernizing Medicine

Shari Medina, MD
Harris Healthcare



Kayla Thomas
Oracle Health

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 29 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Introduction

The FHIR standard offers more granular data specifications leading to a shared foundation for data exchange. Its versatility supports multiple workflows through a unified approach to interoperability.
The timeline graphic that shows the progression of FHIR versions, federal initiatives, and regulations is indeed valuable for context. However, we note that labeling only FHIR R5 as "Trial Use" may be misleading. Currently, FHIR R4 is also designated for trial use as a standard, while FHIR R6 will still be designated for many resources for trial use.

To improve clarity, we suggest removing the "Trial Use" designation specifically for FHIR R5 and instead clarifying in the document that FHIR R6 is the next target release. Additionally, while the FHIR Subscriptions R5 Backport Implementation Guide (IG) may appear to be based on FHIR R5, it is, in fact, a FHIR R4 IG, drawing inspiration from capabilities envisioned in FHIR R5/R6, not structure. This may lead to significant changes and upgrades when transitioning to FHIR R6, highlighting the importance of clear guidance around version-specific implementation requirements.

We also recommend clarifying that FHIR supports a diverse range of use cases across the spectrum of data exchange needs, from highly granular, discrete data to extensive data sets. FHIR's structure enables these exchanges through various methods—such as messages, documents, queries, or RESTful APIs—while maintaining consistency in data definitions, vocabulary, and formats.

FHIR Ecosystem

Implementation Guides developed by HL7's Da Vinci Project Accelerator will reduce prior authorization burden on both payers and providers, augment payers' ability to share data with patients, reduce reporting burden, and provide greater continuity for patients changing insurance coverage.
We agree with the intention of highlighting the impact of HL7's Da Vinci Project Accelerator, but suggest revising the statement to read, "Implementation Guides developed by HL7's Da Vinci Project Accelerator will *enable* reducing prior authorization burden…" as the guides themselves will not directly reduce the burden. Instead, these guides provide the framework and standards necessary to support the development of solutions that may deliver these benefits.

FHIR Ecosystem - Core Components

While a newer version of the base standard, FHIR Release 5 (FHIR R5), has been balloted, all implementation specifications adopted by federal regulations (ASTP's HTI-1 and CMS' Interoperability and Prior Authorization Final Rule) are based on FHIR R4.
While FHIR R5 has been published and is available–not just balloted–we suggest ASTP clarify that there are no plans to promulgate adoption of FHIR R5 at any scale and instead, FHIR R6 will serve as the next core standard once it is available and supported by the necessary, updated implementation guides. Providing a clear signal to the industry to avoid expending resources on any wide-scale adoption of FHIR

R5 would be beneficial, as it helps to set realistic expectations and prevents unnecessary investments in a version that will not receive broad support. This would also echo expectations discussed in the HL7 community and formally document ASTP's expectations. It would also be helpful for ASTP to reinforce that any new development efforts should continue to align with FHIR R4 specifications until the planned transition to FHIR R6.

If the information required to be exchanged for a use case can be accomplished by USCDI, then using US Core IG will provide the easiest and lowest-cost approach. There is also considerable knowledge of US Core IG and support within the standards community and health IT developers to ensure successful implementation, including any modifications if necessary.

We recommend clarifying that USCDI defines the scope of the data elements to be exchanged but does not include the interoperability standards used to accomplish this exchange. Standards such as FHIR, C-CDA, HL7 v2, and NCPDP provide the technical framework necessary to enable interoperability for data within the USCDI scope. We suggest rephrasing to, "If the information required to be exchanged for a use case *is within the scope of a USCDI version published at least in SVAP*, then using US Core IG provides a straightforward and cost-effective approach."

While Bulk IG provides a consistent health IT implementation of API-enabled access service for multiple patients, there are performance and scalability challenges that have been identified that are being addressed by health IT developers.

While we acknowledge that the Bulk IG offers a consistent implementation framework for API-enabled access to multi-patient data, we suggest clarifying that it is specifically designed to handle large-scale, multi-patient data sets. Not every multi-patient data exchange requires the use of the Bulk Data format; rather, it is most beneficial for scenarios involving extensive data retrieval across numerous patients.

As a result, Bulk IG performance and scalability should be considered depending upon the use case application. Developers should review the latest information from the health IT developer and standards community before embarking on adopting the IG.

We agree that Bulk IG performance and scalability should be evaluated based on the specific use case application. To further enhance implementation, we recommend encouraging developers and government agencies to build on top of Bulk FHIR with a defined implementation guide for their given use case. This approach has proven successful in areas like UDS+, where defined implementation guides allow for more precise tuning of expectations and performance improvements within the specific constraints of a given workflow.

Standard / Specification: HL7® FHIR® CDS Hooks 2.0 (CDS Hooks IG)

As noted in our feedback to the HTI-2 proposed rule, 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.

Standard / Specification: HL7® FHIR® Subscriptions R5 Backport Implementation Guide (Subscriptions IG)

The EHR Association appreciates the proposal to adopt the HL7 FHIR Subscriptions Framework and the R5 Backport IG as a baseline standard for FHIR-based API subscriptions. However, we recommend that ASTP focus on prioritizing specific use cases 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 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. 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 efficiency and focus on what matters most to their operations.

FHIR Ecosystem - Payment and Health Quality Components

The EHR Association notes the absence of the payer-provider query use case within the FHIR Ecosystem Payment and Health Quality Components. This use case is relevant for functions such as prior authorization and claims submissions, particularly for follow-up queries to request additional information. We recommend that ASTP consider including the Da Vinci Clinical Data Exchange (CDex) implementation guide, which is in early adoption and plays a crucial role in supporting general queries as well as specific workflows like ePrior Authorization. Including CDex would strengthen interoperability for payer-provider interactions and enhance the efficiency of data exchange in payment and quality-related processes.

Further, we recognize the value of the HL7® FHIR® Da Vinci Implementation Guides (IGs) in advancing interoperability; however, we suggest that the current versions of several guides are not yet sufficient for large-scale implementation. For each of the following IGs, we recommend waiting for the next version, which should address key requirements necessary to fully support their intended APIs. We also strongly encourage implementers to work closely with the Da Vinci Project to identify further updates that will be necessary to evolve these guides for full, scalable operational use. Currently, these guides have not been proven out at scale, and feedback from early adopters will be essential to refine their application and ensure effectiveness in real-world settings.

Standard / Specification: HL7® FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide (PDex IG)

We suggest that PDex 2.0 is insufficient for large-scale implementation and recommend delaying until the next version, which is anticipated to include the remaining requirements necessary to fully support the Provider API. Implementers should collaborate with the Da Vinci Project to refine PDex for scalable use, as it has yet to be validated at scale.

Standard / Specification: HL7® FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide

We recommend beginning implementation with the next version, which should include the necessary requirements to support the Prior Authorization API.

Standard / Specification: HL7® FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide

We suggest that DTR 2.0 is also insufficient for comprehensive implementation, recommending that the next version—including additional requirements to fully support the Prior Authorization API—would be a more appropriate starting point.

Standard / Specification: HL7® FHIR® Da Vinci—Prior Authorization Support (PAS) FHIR IG

Finally, we recommend that PAS 2.0 is insufficient for effective implementation, and suggest waiting for the next version, which should include the requirements needed to fully support the Prior Authorization API.

FHIR Ecosystem - Care Delivery and Engagement Components

Standard / Specification: HL7® FHIR® SMART Health Cards: Vaccination and Testing Implementation Guide

We note that the HL7 FHIR SMART Health Cards: Vaccinations and Testing Implementation Guide has not yet been published. While the existing draft guide can be used for initial pilot projects, we recommend clarifying that it is still in the ballot process and remains unpublished. If the guide is published by the time the FHIR Action Plan is formally released, this status can be updated accordingly.

Standard / Specification: HL7® FHIR® International Patient Summary Implementation Guide (IPS FHIR IG)

The EHR Association supports the emphasis on the HL7® FHIR® International Patient Summary (IPS) Implementation Guide as a promising foundation for advancing global health data exchange. While early in its adoption, IPS FHIR IG offers a standardized, interoperable set of FHIR resources that enable cross-border data sharing between patients and clinicians. The specification's alignment with the US Core IG and its use of well-defined international terminologies strengthen its potential to facilitate seamless information exchange on a global scale.

Standard / Specification: HL7® FHIR® At-Home In-Vitro Test Report Implementation Guide: The At-Home In-Vitro Test Report IG version 1.0.0 has been balloted and is a "framework" for future reporting of self-test results into electronic health record (EHR) systems.

While we recognize the potential value of the At-Home In-Vitro Test Report IG as a framework for reporting self-test results into electronic health record (EHR) systems, we suggest that the current focus should be on hubs or intermediaries that manage the sharing of at-home test results. Direct integration with individual EHRs remains a more distant prospect, and it may be premature to include this specification as a fully realized solution for reporting. We recommend either removing this from the immediate implementation list or indicating it as an early concept or pilot stage that will require further development before widespread adoption becomes feasible.

FHIR Ecosystem - Public Health and Emergency Response

The EHR Association recognizes the importance of establishing efficient, interoperable systems for public health and emergency response, especially as public health agencies increasingly seek to query for additional data in response to case reports or investigational follow-ups. We believe there is a valuable opportunity to align query methods between payers, providers, and public health agencies to create a consistent approach across these stakeholders. We suggest that ASTP, in collaboration with public health initiatives like HELIOS, explore the Da Vinci CDex guide as a potential framework for FHIR-based queries in public health contexts.

Standard / Specification: HL7® FHIR® Implementation Guide: Electronic Case Reporting Implementation Guide (eCR IG)

The EHR Association supports the long-term goal of migrating case reporting from CDA-based to FHIR-based formats for Initial Case Reports and Responsibility Reports (eICR/RR). However, as outlined in our feedback on the HTI-2 NPRM, we recommend prioritizing the adoption of case reporting while maintaining CDA as a viable option beyond the timeline proposed by ASTP for discontinuing CDA-based eICR/RR.

Standard / Specification: HL7® FHIR® Central Cancer Registry Reporting Content Implementation Guide

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 ASTP 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.

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.

Standard / Specification: HL7® FHIR® Cancer Pathology Data Sharing Implementation Guide

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 stated as ready for adoption.

Standard / Specification: HL7® FHIR® Vital Records Birth and Fetal Death Reporting (BFDR) Implementation Guide

The EHR Association notes the early stage of adoption and therefore emphasizes the need for further maturation before the guide is ready for large-scale adoption. We recommend that the FHIR-based

guide, combined with our recommendation to use a functional requirement within ASTP's certification program as described in our HTI-2 feedback, provide flexibility to refine the guide. Once it is deemed sufficiently mature, its adoption at scale can then be required.

Standard / Specification: HL7® FHIR® Health Care Surveys Content Implementation Guide

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 and reflect the state (or lack) of readiness within the public health technology space. 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.

Standard / Specification: HL7® FHIR® Implementation Guide: Profiles for Transfusion and Vaccination Adverse Event Detection and Reporting (Transfusion and Vaccination AE IG)

The EHR Association acknowledges the importance of the Transfusion and Vaccination Adverse Event Detection and Reporting use case and recognizes its potential to enhance patient safety. However, given the breadth of other HTI-2-related public health priorities, we suggest that this use case is not the most critical for immediate advancement. Instead, we recommend focusing on preparing this use case for future adoption, ensuring it is well-defined and ready to be implemented when public health resources and priorities allow.

Standard / Specification: HL7® FHIR® US Public Health Profiles Library Implementation Guide (USPHPL IG)

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.