The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) Announces Special Emphasis Notice (SEN) Interest in Projects to Demonstrate the Readiness of FHIR®-based Subscriptions Capability as a Foundational Health IT Capability for Improved Interactivity with Third Party Applications (apps), and Identify and Test Innovative Technical Approaches that Would Inform Future Changes to the Trusted Exchange Framework and Common Agreement™ (TEFCA™) Infrastructure to Increase Adoption of Individual Access Services (IAS)

Notice Number: NAP-AX-22-001

Key Dates
Release Date: January 15, 2025
Expiration Date: April 25, 2025

Issued by
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP), U.S. Department of Health and Human Services (HHS)

Purpose

This notice announces ASTP's interest in funding projects under the Leading Edge Acceleration Projects (LEAP) in Health Information Technology (IT) funding opportunity (see NAP-AX-22-001 at https://grants.gov/search-results-detail/341131 in fiscal year 2025 to explore ways to: 1) Demonstrate readiness of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources (FHIR®)-based Subscriptions capability as a foundational health IT capability for improved interactivity with third-party applications, and 2) Identify and test innovative technical approaches that would inform future changes to Trusted Exchange Framework and Common Agreement ™ (TEFCA ™) Infrastructure to increase adoption of Individual Access Service (IAS).

Areas of Interest

ASTP is the principal federal entity charged with coordination of nationwide efforts to implement and advance the use of health IT and the electronic exchange of health information. The Office of the National Coordinator for Health Information Technology was created in 2004 through Executive Order 13335[1] and legislatively authorized in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009,[2] ASTP is at the forefront of the federal government's health IT efforts and is a resource to the entire health IT

[1] https://www.govinfo.gov/content/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf
[2] https://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf

and healthcare community to support the adoption of health IT and the promotion of nationwide health information exchange to improve healthcare.

The goal of the LEAP in Health IT funding opportunity is to address well-documented and fast emerging challenges inhibiting the development, use, or advancement of well-designed, interoperable health IT, which are scalable across the healthcare industry. Solutions are expected to further a new generation of health IT tools and inform the development, implementation, and refinement of health IT standards, methods, and techniques towards enabling widespread adoption of health IT tools to improve healthcare outcomes.

It is critical for the health IT field to be able to innovate and leverage the latest technological advancements and breakthroughs to optimize real-time solutions, especially in areas where health IT has potential to improve the health and healthcare for individuals and populations.

The descriptions provided for the two areas of interest, Area 1 and Area 2, include ways applicants may approach developing a project. The areas of interest have been assigned numbers for ease of reference, not for prioritization. While there are many challenges associated with the use of health IT, ASTP identified these two areas of interest as 2025 priority areas.

In fiscal year 2025, ASTP seeks applications pursuant to the LEAP in Health IT notice of funding opportunity for projects that address one of the following areas of interests:

- **Area 1:** Demonstrate readiness of FHIR®-based Subscriptions capability as a foundational health IT capability for improved interactivity with third-party applications.
- **Area 2:** Identify and test innovative technical approaches that would inform future changes to the TEFCA infrastructure to increase adoption of IAS.

ASTP expects to issue one cooperative agreement award per area of interest of up to $1 million per award, totaling up to $2 million for the two awards in fiscal year 2025. Please note that all applicants must explicitly state the area of interest for which they are applying. Applications that do not clearly state their intended area of interest will **not** be considered. Eligible applicants may apply for more than one area of interest; however, a separate application is required for each area. Except for the specific areas of interest listed above and described below for fiscal year 2025, and the desired expertise noted for each area of interest described below, all other requirements and application review information described in the LEAP in Health IT Notice of Funding Opportunity (NOFO) (NAP-AX-22-001 at https://grants.gov/search-results-detail/341131) shall apply, with the exception of the applicant capabilities. Specific merit review criteria for the applicant capabilities, as part of this SEN, are provided below:

- For area of interest 1: Demonstrate readiness of HL7® FHIR®-based Subscriptions capability as a foundational health IT capability for improved interactivity with third-party applications.
    - Applicant and their proposed project team should demonstrate familiarity with and understanding of the following:
        - Experience with developing applications using HL7® FHIR® Release 4.0.1.

        - Familiarity with HL7® FHIR® Subscriptions capability.
        - Experience with engaging health IT standards community
        - Experience with developing patient-facing apps using HL7® FHIR®

- For area of interest 2: Identify and test innovative technical approaches that would inform future changes to the TEFCA infrastructure to increase adoption of IAS.
    - Applicant and their proposed project team should demonstrate familiarity with and understanding of the following:
        - TEFCA, including its technical and the policy components.
        - Understanding of IAS in TEFCA.
        - Understanding of health IT networks
        - Developing patient-facing apps using HL7® FHIR®

Area 1: Demonstrate readiness of HL7® FHIR®-based Subscriptions capability as a foundational health IT capability for improved interactivity with third-party applications.

Goal

The goals of this area of interest are first, to demonstrate that HL7® FHIR®-based Subscriptions[3] is a foundational capability that supports a broad array of essential health information interoperability needs via HL7® FHIR®-based application programming interfaces (APIs)[4]. Projects should, through their implementation, demonstrate whether the implementation specifications developed by the standards community[5,6] for HL7® FHIR®-based Subscriptions capabilities are ready to be widely implemented by health IT developers, and to be made available to third-party client applications.

Background

HL7® FHIR® is a widely used, open standard for exchanging health information that is based on modern internet technology approaches. Due to substantial efforts made over the last decade, the HL7® FHIR® standard has matured since it was first created in 2012[7] and is now broadly adopted by the health IT industry.[8] HL7® FHIR® was incorporated into the ONC Health IT Certification Program[9] to support essential provisions of the 21st Century Cures Act[10] in 2016.

[3] https://hl7.org/fhir/r4/subscription.html
[4] https://hl7.org/fhir/R4/
[5] Argonaut FHIR Accelerator https://github.com/argonautproject/us-core-patient-data-feed/blob/main/spec.md#patient-data-feed-subscriptions.
[6] FHIR Subscriptions R5 Backport https://build.fhir.org/ig/HL7/fhir-subscription-backport-ig/.
[7] http://hl7.org/fhir/directory.html
[8] https://www.healthit.gov/buzz-blog/health-it/achieving-a-major-milestone-health-it-developers-certify-to-cures-update
[9] https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf
[10] https://www.congress.gov/bill/114th-congress/house-bill/34

As a result, HL7® FHIR®-based APIs have become more prevalent and now offer a new baseline for accessing and exchanging electronic health information (EHI) nationwide. This includes the establishment of HL7® FHIR® Release 4.0.1 [11] as the current, mature foundational version that health IT developers are relying on in the United States. HL7® FHIR® Release 4.0.1 was released in 2018 and has evolved into a mature standard for the health IT industry. While a newer version of the base standard, HL7® FHIR® Release 5 (R5), has been balloted, HHS has to date adopted implementation specifications through rulemaking (ASTP's Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)[12] Final Rule and CMS' Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program (Interoperability and Prior Authorization Final Rule[13]) that are based on HL7® FHIR® Release 4.0.1.

The health IT standards community has extended the HL7® FHIR® Release 4.0.1 specifications to address more advanced health IT use cases using an open standards approach and more advanced capabilities within FHIR®. One such capability is HL7® FHIR® Subscriptions,[14] which is a HL7® FHIR® standards framework that is used to establish proactive event notifications from a HL7® FHIR® server to another system. One example of use of such a capability would be to enable consumer applications to be notified when specific changes occur in a HL7® FHIR® server's data, which can be particularly useful in scenarios requiring timely updates (e.g., laboratory results) to be pushed from electronic health records (EHR) technologies to patients' applications on their phones instead of requiring patients to keep querying for the information from their patient portals. The HL7® FHIR® Subscriptions framework has been designed to support many other use cases in population health and research initiatives where there is a need for greater interactivity between HL7® FHIR servers and client applications. While the FHIR-based Subscriptions capability has shown great promise in meeting healthcare organizations' technology needs, Subscriptions are presently not widely made available in EHRs nor used broadly by client applications.[15]

A focused effort is needed to demonstrate that HL7® FHIR®-based Subscriptions can be a foundational capability for the modern digital health system in the US. This would include ensuring specifically that the application of the HL7 FHIR Subscriptions framework to US Core Resources (e.g., patient, observation, medication request) can be widely adopted by EHR

[11] https://hl7.org/fhir/R4/
[12] https://www.federalregister.gov/documents/2023/04/18/2023-07229/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and
[13] https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability
[14] https://build.fhir.org/ig/HL7/fhir-subscription-backport-ig/
[15] https://ehrintelligence.com/news/api-adoption-slow-widespread-fhir-uptake-expected-by-2024; Maisel, N. (2022, September 16). Uptake of FHIR: Where are We Today and What are the Challenges that Lie Ahead?

developers for meeting multiple customer needs and readiness of third-party client applications to take advantage of this capability to provide superior end user experience.

Key Objectives

There are three key objectives in this area of interest, as follows:

1. Advance and mature existing HL7® FHIR®-based Subscriptions capability for readiness to be widely adopted by health IT developers.

2. Demonstrate how use of Subscriptions capability can lead to beneficial interactive data exchange between EHRs and third-party client applications.

3. Demonstrate how a HL7® FHIR®-based Subscriptions specification can be a foundational health IT capability to support a modern API-based digital health care system in the United States.

Applicants should achieve these three goals by developing a solution that is inclusive of the following considerations:

- **Standards-Based Solution:** Design a technical solution or technical solutions that utilize Subscriptions specification that is based on HL7® FHIR® Release 4.0.1 and supported by recognized standards development organizations (SDOs). Alternatively, utilize the HL7® FHIR® Subscriptions R5 Backport implementation guide[16] that supports HL7® FHIR® Release 4.0.1 and/or Argonaut US Core Patient Data Feed: Subscriptions for the technical solution.[17]
- **Interoperable with Third-Party Applications:** The technical solution or technical solutions should be readily interoperable with any third-party client applications developed by organizations unaffiliated with the organization that provides the server that meets HL7® FHIR® specifications used to initiate Subscriptions notifications.
  Foundational Capability: The technical solution or technical solutions should be use-case agnostic, to demonstrate the versatility of the FHIR based Subscriptions capability. This could include providing the HL7® FHIR® Subscriptions capability on multiple data elements from United States Core Data for Interoperability that address diverse types of use cases, using the same technical solution and specification.

For an award in this area of interest, applicants are encouraged to include a coalition of key interested parties who will be directly involved in the project such as EHR vendors, developers of consumer health applications and members of the health IT standards community. Applicants should include letters of commitment from interested parties, including, but not limited to, those mentioned above.

[16] https://build.fhir.org/ig/HL7/fhir-subscription-backport-ig/
[17] https://github.com/argonautproject/us-core-patient-data-feed/blob/main/spec.md#patient-data-feed-subscriptions

Applicants have flexibility to propose activities that achieve the goals and objectives of Area 1, which could include (not required), for example:

- By implementing a technical solution, identifying, and resolving any shortcomings of existing specification developed by the standards community (including but not limited to HL7® FHIR® Release 4.0.1, HL7® FHIR® Subscriptions R5 Backport implementation guide[18], and Argonaut US Core Patient Data Feed: Subscriptions).
- Demonstrating how the developed technical solution or solutions can be used by appropriate communities to encourage adoption of the capability by health IT developers.
- Enhancing underlying specification used in the project (including but not limited to HL7® FHIR® Release 4.0.1, HL7® FHIR® Subscriptions R5 Backport implementation guide[19], and Argonaut US Core Patient Data Feed: Subscriptions) to improve use by implementers including client applications and facilitate broader adoption of the capability.

The proposal developed by the applicants are required to demonstrate readiness of HL7® FHIR®-based Subscriptions capability but will not be required to be open source as long as the Subscriptions capability is using open standards developed by standards development organizations, such as HL7®, for interoperable health information exchange between clients and servers.

Applicants for an award in this area of interest shall include, at minimum, the following elements in their technical solution:

- The technical solution must be based on the HL7 ®FHIR® Release 4.0.1 standard.
- The technical solution must demonstrate and pilot HL7® FHIR® based Subscriptions specification using a server and an unaffiliated third-party application acting as the Subscriptions client.
- The technical solution must include at least one use case that demonstrates beneficial interactive exchange with third-party client applications over query-based exchange.

Additionally, the application shall also include, at a minimum:

- Plans for encouraging acceptance of any update and modifications (e.g., identification and fixing of errors, updating the specifications with any changes) to existing technical specifications (including but not limited to HL7® FHIR® Release 4.0.1, HL7® FHIR® Subscriptions R5 Backport implementation guide[20], and Argonaut US Core Patient Data Feed: Subscriptions) by the standards community.
- Plans for facilitating/fostering widespread adoption of the Subscriptions capability in the health IT industry.

[18] https://build.fhir.org/ig/HL7/fhir-subscription-backport-ig/
[19] https://build.fhir.org/ig/HL7/fhir-subscription-backport-ig/
[20] https://build.fhir.org/ig/HL7/fhir-subscription-backport-ig/

Area 2: Identify and test innovative technical approaches that would inform future changes to the TEFCA infrastructure to increase adoption of IAS.

Goal

The goal of this area of interest is to explore and test innovative technical approaches that could be applied to the technical infrastructure used for IAS exchange in TEFCA. These approaches would ideally lead to increased participation of IAS Providers,[21] improved responses for IAS requests from responding nodes, and markedly increase the number of individuals using TEFCA to access their EHI. We expect that TEFCA partners, including Qualified Health Information Networks (QHINs),[22] Participants,[23] and Subparticipants[24] may also be informed by the technical approaches identified through this area of interest.

Background

TEFCA[25] is a pivotal initiative aimed at improving the exchange of health information across different networks using health IT, ensuring that health data can flow securely and efficiently across the country.

The 21st Century Cures Act[26] required the National Coordinator to "develop or support a trusted exchange framework, including a common agreement [TEFCA] among health information networks nationally." One of the key goals of TEFCA is to enable individuals to gather their electronic health care information, or EHI. TEFCA is currently operational and actively facilitating exchange of EHI.[27]

---

[21] IAS Providers include QHINs, Participants, and Subparticipants that offer Individual Access Services (IAS). https://rce.sequoiaproject.org/wp-content/uploads/2024/01/Draft-TEFCA-Glossary-508-Compliant.pdf

[22] QHINs, to the extent permitted by applicable Standard Operating Procedure(s) (SOPs), are a Health Information Network that is a U.S. Entity that has been Designated by the Recognized Coordinating Entity ® (RCE) and is a party to the Common Agreement countersigned by the RCE. https://rce.sequoiaproject.org/wp-content/uploads/2024/01/Draft-TEFCA-Glossary-508-Compliant.pdf.

[23] Participants, to the extent permitted by applicable SOP(s), are a U.S. Entity that has entered into the Terms of Participation (ToP) in a legally binding contract with a QHIN to use the QHIN's Designated Network Services to participate in TEFCA Exchange in compliance with the ToP. https://rce.sequoiaproject.org/wp-content/uploads/2024/01/Draft-TEFCA-Glossary-508-Compliant.pdf.

[24] Subparticipants, to the extent permitted by applicable SOP(s), are a U.S. Entity that has entered into a ToP in a legally binding contract with a Participant or Subparticipant to use the Participant's or Subparticipant's Connectivity Services to participate in TEFCA Exchange in compliance with the ToP. https://rce.sequoiaproject.org/wp-content/uploads/2024/01/Draft-TEFCA-Glossary-508-Compliant.pdf.

[25] https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca

[26] https://www.congress.gov/bill/114th-congress/house-bill/34

[27] https://www.healthit.gov/buzz-blog/tefca/what-makes-tefca-different-new-standard-operating-procedure-strengthens-trust

IAS[28] is one of the six currently authorized TEFCA Exchange Purposes[29] that is designed to empower patients to easily access to their EHI. It enables individuals to connect to a single IAS Provider in TEFCA and use the IAS Provider service to retrieve their EHI from all participating organizations that are connected to TEFCA.

For patients, IAS can empower them to easily retrieve their EHI from a single application provided by a QHIN, Participant, or Subparticipant connected to TEFCA, without having to individually connect to all the health care provider portals that may contain their EHI. Even if patients do not remember where all of their EHI is located, they can retrieve their EHI through IAS as long as the organization holding the information is a TEFCA QHIN, Participant, or Subparticipant.

Adoption of IAS in TEFCA has been slow and limited to date. While the TEFCA Recognized Coordinating Entity (RCE) [30] has not published information on the number of IAS Providers or number of individuals using the IAS Exchange Purpose, anecdotal evidence suggests that IAS adoption has not scaled significantly since TEFCA went live in December 2023.[31] There are a limited number of IAS Providers and individuals that used TEFCA to access and gather their health information.

The broader health IT community has also raised several potential technical challenges that could hinder the broader availability and adoption of IAS. Those challenges include, but are not limited to, patient matching issues which can limit providers from matching patient records across different systems and organizations, and burdens on individuals using the IAS Provider service. These challenges must be addressed to fully realize the potential of TEFCA for enabling patient access.

Key Objectives

As described in the Background Section, TEFCA is currently operational and actively facilitating exchange of EHI among QHINs, Participants, and Subparticipants using established technical infrastructure and Standard Operating Procedures that define the contours of IAS exchange. Any changes to the technical infrastructure in TEFCA would need to be well-tested in a sandbox environment, demonstrated to meaningfully add value over existing approaches, and be likely to be embraced by partners currently participating in TEFCA.

Based on these considerations, there are three key objectives in this area of interest, as follows:

---

[28] https://rce.sequoiaproject.org/wp-content/uploads/2024/08/XP-Implementation-SOP-IAS.pdf

[29] TEFCA Exchange Purpose refers to the reason (e.g., treatment, payment, IAS, government benefits determination, healthcare operations, public health), that organizations connected to TEFCA are allowed to request or respond, as authorized by a Framework Agreement. https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca

[30] https://rce.sequoiaproject.org/

[31] https://rce.sequoiaproject.org/rce/faqs/#IsTEFCAExchangeHappeningToday

- Identify technical barriers that impede entities that could be IAS Providers from participating in TEFCA and offering services to individuals.

- Develop and test non-proprietary innovative technical solutions to the identified technical barriers.

- Demonstrate the technical solutions to the identified barriers that can be made to the technical infrastructure used for IAS exchange in TEFCA.

Applicants have flexibility to propose activities that achieve the goals and objectives of Area 2, which could include (not required), for example:

- Improvements to the technical requirements for IAS Providers and any related standard operating procedures that would increase utilization of patient facing applications under TEFCA.

- Implementing new ways to perform identity proofing, verification, resolution, and overall identity management of individuals in the context of TEFCA exchange that could simplify the process for individuals to use IAS Provider services.

- Identifying a method of replacing demographics-based patient matches with non-proprietary deterministic approaches that could be broadly adopted within TEFCA.[32]

Applicants for an award in this area of interest shall include the following in their application:

- Describe in detail one or more technical barriers currently impeding entities that could be IAS Providers from participating in TEFCA; or that impede QHINs, Participants, or Subparticipants from becoming IAS Providers and offering IAS services to individuals; or both.
- Describe in detail a technical solution to the technical barrier(s), including:
    - Provide sufficient details on the technical solution to demonstrate it is based on non-proprietary technologies.
    - Provide a detailed plan on how the applicant intends to test the solution.
    - Provide a detailed plan describing how the solution will be demonstrated in a manner that would be informative to future changes to technical infrastructure used for IAS exchange in TEFCA.

- Identify an approach to improve IAS exchange while adhering to data security and privacy standards, including ensuring consistency for covered entities' compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule where applicable, its implementing regulations, and other relevant regulations.

[32] The awardee may ultimately propose additional changes to the existing SOPs if project work uncovers an unmet need, inconsistency, or need for clarification.

- Provide details of any changes that the applicant believes might be needed to TEFCA SOPs related to IAS exchange to implement the technical solution.

Further Guidance

Unless otherwise indicated in this Notice, all requirements, instructions, and terms and conditions of the LEAP in Health Information Technology (IT) funding opportunity (NAP-AX-22-001 at https://grants.gov/search-results-detail/341131) will apply to applications submitted and awards made in response to this Notice.

Application Submission and Special Application Receipt Date. Information about the application process can be found at https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information or https://grants.gov/search-results-detail/341131.

An informational session will be held on March 6, 2025. Further details about the informational session – including the date, time, and instructions for joining – are available at: https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information.

Although not required, applicants are strongly encouraged to submit a non-binding e-mail letter of intent to apply for this funding opportunity. This letter of intent will assist ASTP in planning for the application review process. When submitting your letter of intent, please identify which area of interest your organization plans to apply for. The letter of intent is requested by 11:59 P.M. Eastern Standard Time on March 27, 2025. Interested organizations can send the letter of intent to ASTP-LEAP@hhs.gov. Please identify the name of the applicant organization, the city and state in which the applicant organization is located, the intended area(s) of interest, and the Notice of Funding Opportunity title and number.

Submit applications focused on the areas of interest identified in this Notice by **NOON Eastern Standard Time on April 25, 2025. This Notice will expire on April 25, 2025.**

Inquiries

Please direct all program related inquiries to:

Alison Kemp
LEAP Program Manager
Assistant Secretary for Technology Policy (ASTP)
Email: ASTP-LEAP@hhs.gov

Please direct all grant related inquiries to:

Carmel Halloun

Grants Branch Chief
Assistant Secretary for Technology Policy (ASTP)
Email: ASTPGrants@hhs.gov