The Office of the National Coordinator for Health Information Technology (ONC) Announces Special Emphasis Notice (SEN) Interest in Projects to Develop Innovative Ways to Evaluate and Improve the Quality of Healthcare Data Used by Artificial Intelligence (AI) tools in Healthcare and Accelerate Adoption of Health Information Technology in Behavioral Health

Notice Number: NAP-AX-22-001

Key Dates Release Date: May 13, 2024 Expiration Date: July 12, 2024

Issued by

Office of the National Coordinator for Health Information Technology (<u>ONC</u>), U.S. Department of Health and Human Services

Purpose

This notice announces ONC'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 2024 to explore ways to evaluate and improve the quality of healthcare data used by artificial intelligence (AI) tools in healthcare and develop health IT tools and resources to enhance technologies in behavioral healthcare settings.

Areas of Interest

ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. Created in 2004 through Executive Order 13335¹ and legislatively authorized in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009,² ONC is at the forefront of the federal government's health IT efforts and is a resource to the entire health IT 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.

¹ https://www.govinfo.gov/content/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf

² <u>https://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf</u>

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 two areas of interest, area 1 and area 2, include ways in which 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, ONC identified these two areas of interest as 2024 priority areas.

In fiscal year 2024, ONC 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: Develop innovative ways to evaluate and improve the quality of healthcare data used by artificial intelligence (AI) tools in healthcare
- Area 2: Accelerate adoption of health information technology in behavioral health

ONC 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 2024. 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 2024, and the required 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 is provided below:

- For area of interest 1: Develop innovative ways to evaluate and improve the quality of healthcare data used by artificial intelligence (AI) tools in healthcare:
 - Applicant and their proposed project team must demonstrate familiarity with an understanding of the following:
 - The EO 14110, the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence
 - The ONC HTI-1 final rule, specifically the requirements for Predictive DSI
 - Experience evaluating and developing improvement strategies for data quality
 - Experience in developing and deploying AI tools using data derived from EHRs
- For area of interest 2: Accelerate adoption of health information technology in behavioral health:
 - Applicants and their proposed team must demonstrate familiarity with the following:

- Health IT standards and health IT technology including content and exchange standards and implementation specifications
- Behavioral healthcare systems and technology
- Behavioral healthcare settings and their interoperability gaps and needs

Area 1: Develop innovative ways to evaluate and improve the quality of healthcare data used by artificial intelligence (AI) tools in healthcare

Goal

The goal of this area of interest is to develop scalable solutions that can evaluate and improve the quality of healthcare data available in electronic health records (EHRs) that are used by artificial intelligence (AI) tools. This goal aligns with the intentions of Executive Order 14110 (EO 14110) *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*³ and ONC's Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule.⁴

Background

Responsible Artificial Intelligence

For this area of interest, AI is, as defined by EO 14110's definition for AI (as set forth in 15 U.S.C. 9401(3)), "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action." The performance behavior of such computational processes is typically not deterministic or static and can evolve based on inputs. AI systems can substantially assist or replace discretionary decision making.

AI has the potential to usher in a new era in human progress. Advancements in AI have the potential to drive the biggest technological shifts we will see in our lifetimes and will have positive impacts on the way essential services are provided to people, including healthcare. At the same time, irresponsible use of AI could exacerbate societal harms such as discrimination, bias, and disinformation.

EO 14110 directs the U.S. Department of Health and Human Services (HHS) to "prioritize grantmaking and other awards...to support responsible AI development and use, including...prioritizing the allocation of 2024 Leading Edge Acceleration Project cooperative agreement awards to initiatives that explore ways to improve healthcare-data quality to support the responsible development of AI tools for clinical care, real-world-evidence programs, population health, public health, and related research."³

³ <u>https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/</u>

⁴ <u>https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-an</u>

EHR Data in Artificial Intelligence

Clinical decision support (CDS) provides timely information, usually at the point of care, to help inform decisions for patient care.

EHR implementation and technology resources used to support clinical decision making have continued to evolve and expand across the health IT ecosystem. Predictive models can be used to inform decision makers, including clinicians, payers, researchers, and individuals, and to aid decision making through CDS integrated in EHR systems. EHRs are the most used data in predictive modeling for healthcare.⁵

The National Academy of Medicine (NAM) described in a 2019 report how predictive models and other forms of AI have the potential to represent the "payback" of using EHRs "by facilitating tasks that every clinician, patient, and family would want, but are impossible without electronic assistance."⁶

In many cases, EHRs are key enablers of these predictive models, often providing the data used to build and train algorithms and serving as the vehicle to influence day-to-day decision making for patient care.⁷ Both structured and unstructured data generated by, and subsequently made available through, EHRs power the training and real-world use of predictive models. EHRs are also often the vehicle or delivery mechanism for predictive model outputs to reach users, such as clinicians, through clinical decision support.^{8, 9}

The NAM report also identified a crucial "need to present each healthcare AI tool along with the spectrum of transparency related to the potential harms and context of its use. Evaluating and addressing appropriate transparency, in each sub-domain of data, algorithms, and performance, and systematically reporting it, must be a priority."⁶

⁵ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8832418/</u>

⁶ Michael Matheny, et al., Artificial intelligence in health care: the hope, the hype, the promise, the peril, WASHINGTON, DC: NATIONAL ACADEMY OF MEDICINE (2019).

⁷ See, e.g., Burdick, Hoyt, et al. "Effect of a sepsis prediction algorithm on patient mortality, length of stay and readmission: a prospective multicentre clinical outcomes evaluation of real-world patient data from US hospitals." *BMJ health & care informatics* 27.1 (2020).

⁸ Fox, A. NextGen introduces AI-enabled ambient listening that syncs with EHR. Healthcare IT News. October 11, 2023. <u>https://www.healthcareitnews.com/news/nextgen-introduces-ai-enabled-ambient-listening-syncs-ehr</u>.

⁹ Miliard, M. Oracle Cerner adds generative AI to its EHR platforms. September 19, 2023. <u>https://www.healthcareitnews.com/news/oracle-cerner-adds-generative-ai-its-ehr-platforms.</u>

ONC's Role in Improving Data Quality in Health IT for AI

On January 9, 2024, ONC published the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)"10 final rule. The HTI-1 final rule established first of its kind transparency requirements for artificial intelligence (AI) and other predictive algorithms that are part of certified health IT certified to the decision support interventions certification criterion in 45 CFR 170.315(b)(11).¹¹ HTI-1 also emphasized the need for predictive decision support interventions (predictive DSIs) to be fair, appropriate, valid, effective and safe (FAVES) when it comes to their development and use. Evaluating Predictive DSIs while they are under development, before they are deployed, and during their use is acknowledged as a best practice.¹² However, not all healthcare organizations will have the resources and tools to thoroughly complete these tasks, especially on an ongoing basis. Developing standards-based tools to commoditize the evaluation, improvement, and governance of predictive DSIs may help increase trust and safety in AI. For example, evaluating existing AI tools can identify bias and address mistrust between AI and clinicians, as well as other limitations.¹³ Solutions to improve the evaluation of predictive DSIs and other decision-based algorithms can improve the safety and security of AI tools as aligned with EO 14110.

The HTI-1 final rule requires developers of health IT that are certified to the decision support interventions criterion to adhere to ongoing maintenance of certification requirements to attest that their DSI "source attribute" information is up to date. The final rule also requires developers that certify their health IT Module to the decision support interventions criterion to implement risk management practices. HTI-1 identifies 31 source attributes that health IT modules certified to the Predictive DSI criterion must support and keep information complete and up to date¹⁴. These source attributes will provide the transparency necessary for healthcare organizations and clinical users to better determine whether their Predictive DSIs are FAVES and create a consistent, industry-wide baseline for responsible AI development.

The source attributes can be categorized into following:¹⁵

- Details and output of the predictive algorithms
- Purpose of the intervention
- Cautioned out-of-scope use of the intervention
- Intervention development details and input features
- Process used to ensure fairness in development of the intervention
- External validation process
- Quantitative measures of performance
- Ongoing maintenance of intervention implementation and use
- Update and continued validation or fairness assessment schedule

¹⁰ <u>https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and</u>

¹¹ https://www.hhs.gov/about/news/2023/12/13/hhs-finalizes-rule-to-advance-health-it-interoperability-andalgorithm-transparency.html

¹² https://www.fda.gov/media/153486/download

¹³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9875857/

¹⁴ https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1 DSI fact%20sheet 508.pdf

¹⁵ <u>https://www.healthit.gov/sites/default/files/page/2023-12/HTI-1_DSI_fact%20sheet_508.pdf</u>

The resulting information transparency is expected to increase public trust and confidence in these technologies so that the benefits of these technologies may expand in safer, more appropriate, and more equitable ways. Developers of health IT certified with health IT modules certified to the 45 CFR 170.315(b)(11)- DSI criterion, will need to update their health IT to meet these requirements and provide the updated certified health IT to customers by December 31, 2024.

Key Objectives

This area of interest is focused on the development of scalable solutions to evaluate and improve the quality of healthcare data available in EHR technologies used by AI tools. Applicants may propose approaches that are targeted for health IT developers, healthcare providers, or both. Applicants must identify and explore specific requirements related to EO 14110 and the HTI-1 final rule's "source attributes" as part of proposing solutions to address this area of interest. Applicants will also need to describe ways to scale their proposed solution across the health IT industry.

Applicants have wide flexibility to propose evaluation and improvement activities related to data quality and AI tools. This could include a deep focus on a consistent and repeatable testing approach for AI. Applicants, under this award, are also expected to actively participate in relevant standards-based AI development activities related to healthcare, including supporting advancement within the standards community that enables other developers to implement the solutions developed as part of this activity in their own environment.

Applicants can seek the expertise of the health IT community and healthcare organizations to work together to explore the activities listed in this area of interest.

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 health IT developers, EHR vendors, standards development organizations, healthcare providers, payers (e.g., Medicare, commercial healthcare insurers), public health agencies, and health information networks (HINs). Applicants should include letters of commitment from key stakeholders.

An applicant's proposal must not rely on proprietary technology.

Applicants for an award in this area of interest shall demonstrate familiarity with and understanding of the following:

- EO 14110, the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence
- ONC HTI-1 final rule and specifically the requirements for Predictive DSI
- Experience evaluating and developing improvement strategies for data quality
- Experience in developing and deploying AI tools using data derived from EHRs

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

- Propose at least one activity related to the goal and key objectives of Area 1.
- Provide a detailed project plan and explanation of how the applicant intends to meet the goal of this area of interest.

Area 2: Accelerate adoption of health information technology in behavioral health

Goal

The goal of this area of interest is to support the development of lightweight health information technology (IT) solutions, using open standards, that can enhance health IT capabilities in behavioral health settings with limited technical and financial resources and improve care coordination between behavioral health and clinical healthcare settings. This goal supports ONC's mission to create systemic improvements in healthcare through access, exchange, and use of data. It aligns with the objective of reducing the technology gap between behavioral healthcare providers and physical healthcare providers, as outlined in the U.S. Department of Health and Human Services (HHS) Roadmap for Behavioral Health Integration¹⁶ and the President's Strategy to Address our National Mental Health Crisis.¹⁷

Background

The Role of Health Information Technology in Behavioral Health

To unlock the full power of information to improve individual health and well-being, electronic health information must be available when and where it matters most. Improving the secure availability and use of electronic health information allows individuals to take ownership of their health, partner with their healthcare providers and others on care preferences and decisions and reach their health and quality of life goals.

This is especially true in the behavioral health setting, where patients with behavioral health disorders have been found to have higher rates of physical illnesses including cardiovascular disease, diabetes, and respiratory diseases.¹⁸ It is important that patients' electronic health information is interoperable between behavioral health and clinical healthcare settings to support positive healthcare outcomes for patients. Interoperability between behavioral health and clinical health and clinical health and clinical healthcare settings also promotes patient engagement, which is critical for patient and family customer experience and direct engagement in care.

Health information technology, including EHRs, have been key tools developed by industry to support interoperability of health information across multiple healthcare settings, facilitating care coordination and improving patient engagement.

¹⁶ <u>https://www.hhs.gov/about/news/2022/12/02/hhs-roadmap-for-behavioral-health-integration-fact-sheet.html</u>

¹⁷ <u>https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/01/fact-sheet-president-biden-to-announce-strategy-to-address-our-national-mental-health-crisis-as-part-of-unity-agenda-in-his-first-state-of-the-union/</u>

¹⁸ <u>https://www.healthit.gov/sites/default/files/bhandhit_issue_brief.pdf</u>

Health IT Gaps in Behavioral Healthcare Settings

There are large gaps in health IT adoption between behavioral healthcare providers and nonbehavioral healthcare provider. Specifically, psychiatrists (58%) and psychiatric hospitals (67%) have lower certified EHR adoption than physical health providers (86%).¹⁹ One of the key reasons for the lack of adoption of health IT in behavioral healthcare settings has been due to lack of government programs specifically targeting health IT for behavioral health providers. For example, behavioral health providers did not receive the same incentives (as hospitals and ambulatory care providers) for EHR adoption under the HITECH Act.²⁰ As a result, certified EHR technologies that have been widely adopted for clinical care have not been adopted at the same rate in behavioral health settings.²⁰

Given this technology gap, behavioral healthcare providers also have gaps in areas of basic health IT capabilities and functions, especially in interoperability and patient engagement functionalities. For example, only about 30% of psychiatric hospitals report having the capability to send health records electronically, compared to more than 70% of general hospitals.²¹ Similarly, only about 30% of residential treatment centers report they can electronically send referrals, compared to about 65% of multi-setting mental health facilities. ²¹

There have been few programs that have specifically targeted health IT for behavioral health providers and general funding programs haven't provided the necessary flexibility for use of funds for health IT. As a result, behavioral healthcare settings lack adoption of certified EHRs, and other health IT tools to help integrate clinical information across the various healthcare settings and provide integrated behavioral health care for patients.²⁰

To bridge the technology gap between behavioral healthcare providers and physical healthcare providers, and to help reduce the barrier to health IT adoption in behavioral healthcare settings, HHS published the HHS Roadmap in September 2022 to advance the President's Strategy to address the National Mental Health Crisis. The HHS Roadmap highlights current programs and activities within HHS to help strengthen system capacity in behavioral health settings.²²

One of the programs includes expansion of the United States Core Data for Interoperability (USCDI) data standard²³, which sets the technical and policy foundation for the access, exchange, and use of electronic health information to support nationwide, interoperable health information exchange. The USCDI is a standard developed by ONC on behalf of the U.S. Department of Health and Human Services (HHS) to serve as a baseline set of data elements for health information exchange and to inform interoperable health IT implementations.

¹⁹ Myrick KL, McNeal M, Yin X. Table 1. Percentage of office-based physicians using any electronic health record (EHR) system and physicians that have a certified EHR system, by selected specialty: National Electronic Health Records Survey, 2019. National Center for Health Statistics. July 2022. and HRSA 2020 Uniform Data Set.

²⁰ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6568002/pdf/nihms-1031682.pdf</u>

²¹ National Mental Health Services Survey: 2020

²² https://aspe.hhs.gov/sites/default/files/documents/4e2fff45d3f5706d35326b320ed842b3/roadmap-behavioralhealth-integration.pdf

²³ <u>https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi</u>

USCDI version 1²⁴ (USCDI v1) was adopted as a standard in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (Cures Act Final Rule).²⁵ Since then, ONC has released four more versions of USCDI, three of which have been approved under the ONC Standards Version Advancement Process (SVAP).²⁶ The SVAP permits health IT developers with health IT products certified under the ONC Health IT Certification Program (Certification Program) to voluntarily update their conformance to newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405). To further advance interoperability, ONC included USCDI v3 in the Certification Program in the recently finalized HTI-1 Final Rule.²⁷ Participants in the Certification Program may adopt USCDI v3 now, and starting in 2026, USCDI v3 will be the baseline requirement in the Certification Program.

The expansion in the availability of data captured by certified EHRs will enable EHR developers in the future to provide more targeted capabilities to support behavioral health providers, including more seamless integration of data between behavioral health and clinical care. Additionally, through other HHS incentive programs, described in the HHS Roadmap, including expansion of Substance Abuse and Mental Health Services Administration's Certified Community Behavioral Health Clinics,²⁸ and the Innovation in Behavioral Health (IBH) Model²⁹ through CMS, HHS is working towards increasing adoption of certified EHRs by behavioral healthcare providers.

Goal of Area 2: Developing Lightweight Health IT Solutions

In addition to encouraging the development of behavioral health specific capabilities in EHR technologies and incentivizing EHR adoption by behavioral health providers, the HHS Roadmap also identified the need for agencies to develop health IT solutions, especially targeted towards behavioral healthcare settings that have the least technical resources and lack funding for up-front health IT capital investments as well as on-going maintenance of health IT. These include, but are not limited to, residential treatment centers, substance use disorders/detoxification facilities and outpatient mental health facilities

The development of "lightweight" health IT solutions that can be adopted by behavioral healthcare providers with limited technical and financial resources is the goal of this area of interest.

²⁴ <u>https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf</u>

²⁵ https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperabilityinformation-blocking-and-the-onc-health-it-certification

²⁶ <u>https://www.healthit.gov/isa/standards-version-advancement-process</u>

²⁷ https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-andinteroperability-certification-program-updates-algorithm-transparency-and

²⁸ <u>https://www.samhsa.gov/certified-community-behavioral-health-clinics</u>

²⁹ <u>https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-advance-integration-behavioral-health</u>

Health IT developers have the potential to innovate and develop health IT solutions that deliver value in health care.³⁰ Key provisions of the 21st Century Cures Act have been implemented and are dramatically improving clinical interoperability, including rollout³¹ of standard application programming interfaces (APIs) across the industry using the mature HL7® Fast Healthcare Interoperability Resources (FHIR[®])³² interoperability standard based on modern internet technology approaches. This has created a climate of innovation by allowing technology developers to build to a common, industrywide specification. The Interoperability Standards Advisory³³ (ISA) provides a comprehensive compendium of all standards used in health care. Standards-based APIs and applications are the key foundations of lightweight solutions that would provide patients and behavioral health providers the enhanced access, functionality, ease of use for care coordination, and lower barriers to adopting health IT regardless of which technology platform they use.

One of the most mature examples of a lightweight solution is the "SMART on FHIR" approach that has been developed by the SMART program and originally funded by ONC.³⁴ The SMART approach enables FHIR to work as a "apps platform"³⁵ with the ability for the SMART application (app) to be connected into any certified EHR using a standard FHIR API and integrated into existing healthcare workflows, anywhere in the health system. The "apps" are readily substitutable for another, which makes them have the potential to enhance technology features and lower costs for healthcare settings.³⁴

"SMART on FHIR" app support is included within ONC's Health IT Certification Program and is well supported by major EHR products.³⁶ "SMART on FHIR" apps are already being used across various healthcare settings.³⁷ One example is the "Major Depression Outcomes App" that provides a "snapshot" view of a patient's depression symptoms and outcomes using scores from the Patient Health Questionnaire-9³⁸ and clinical data to calculate and display standardized depression outcome measures that a provider can use to monitor a patient's response to treatment over time.³⁹

³⁰ <u>https://www.healthaffairs.org/content/forefront/delivering-promise-health-information-technology-2022</u>

³¹ https://www.healthit.gov/buzz-blog/healthit-certification/on-the-road-to-cures-update-certified-api-technology

³² https://hl7.org/fhir/

³³ <u>https://www.healhit.gov/isa</u>

³⁴ https://www.hl7.org/fhir/smart-app-launch/

³⁵ <u>https://smarthealthit.org/about-smart-2/</u>

³⁶ https://onc-healthit.github.io/api-resource-guide/g10-criterion/#supported-search-operations-single-patient

³⁷ https://apps.smarthealthit.org/apps/featured

³⁸ https://www.apa.org/depression-guideline/patient-health-questionnaire.pdf

³⁹ <u>https://apps.smarthealthit.org/app/major-depression-outcomes-app</u>

Key Objectives

The objective of this area of interest is to design, develop, and pilot lightweight health IT solutions, such as SMART on FHIR apps, that can enhance health IT capabilities in behavioral health settings and improve care coordination between behavioral health and clinical healthcare settings. Applicants can achieve this objective by developing health IT solutions using FHIR-based tools and develop these solutions to meet the needs of behavioral healthcare providers with limited technical and financial resources. Applicants may consider utilizing standards identified in the ISA and data elements identified in the USCDI as part of their technical solution.

Applicants should consider the following list of activities to achieve the goals and objectives of Area 2:

- Design and develop one or more lightweight application(s), such as SMART on FHIR applications, and FHIR-based APIs, to solve a specific behavioral health use case or multiple use cases. The lightweight application must also enable a behavioral healthcare setting to access and integrate health information from other healthcare settings that use ONC certified health IT.
 - The application must be developed using open FHIR based APIs. Applicants may also consider the standards adopted in HTI-1 as applicable for the lightweight application to access data from ONC certified health IT.
- Pilot the application(s) at behavioral healthcare settings to make the application(s) ready for adoption by behavioral health providers.
 - Document approaches used for testing the application(s) at behavioral healthcare settings to make the tool production ready.
- Coordinate input and dialogue with health IT industry and behavioral healthcare community/providers to inform development of the application(s) and share lessons learned and best practices.

Applicants can seek the expertise of the health IT community and healthcare organizations to partner in implementing solutions for behavioral health interoperability and improving care coordination

An applicant's proposal shall not rely on proprietary technology.

Applicants for an award in this area of interest shall demonstrate, in their application, familiarity with and understanding of the following:

- Health IT standards and health IT technology, including content and exchange standards, and implementation specifications
- Behavioral healthcare systems and technology, behavioral healthcare settings, and interoperability gaps and needs

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

- Provide a detailed project plan and explanation of how the applicant intends to meet the goal and objectives of this area of interest. In the project plan, the applicant should:
 - Describe the attributes of the application(s) that make the solution "lightweight" in behavioral healthcare settings, including but not limited to the resources required to maintain and support the application in production.
 - Identify all the behavioral healthcare settings that the proposed solution is applicable, with preference given to under resourced providers who have generally lower adoption of health IT, such as residential treatment centers, substance use disorders/detoxification facilities and outpatient mental health facilities.
- Identify at least one behavioral healthcare clinical use case based on the challenges facing behavioral healthcare providers and provide an explanation on how the applicant plans to build a scalable lightweight tool or resource to solve the problem associated with the use case effectively.
- Identify at least one behavioral healthcare setting and a data exchange partner to test and pilot the tool associated with the use case(s) identified.
- Provide a plan for engaging with the open-source community for long-term sustainability of the tool(s)

Further Guidance

Unless otherwise indicated in this Notice, all requirements, instructions, and terms and conditions of the Leading Edge Acceleration Projects (LEAP) in Health Information Technology (IT) funding opportunity (NAP-AX-22-001 at <u>https://www.grants.gov/web/grants/search-grants.html?keywords=nap-ax-22-001</u>) 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 <u>https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information</u> or <u>https://www.grants.gov/web/grants/search-grants.html?keywords=nap-ax-22-001</u>.

An informational session will be held on May 21, 2024. 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 ONC 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 May 28, 2024. Interested organizations can send the letter of intent to <u>ONC-LEAP@hhs.gov</u>. 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 July 12, 2024. This Notice will expire on July 12, 2024.

Inquiries

Please direct all program related inquiries to:

Alison Kemp and Anastasia Perchem LEAP Program Manager Office of the National Coordinator for Health Information Technology (ONC) Email: <u>ONC-LEAP@hhs.gov</u>

Please direct all grant related inquiries to:

Carmel Halloun Grants Branch Chief Office of the National Coordinator for Health Information Technology (ONC) Email: <u>oncgrants@hhs.gov</u>