

May 28, 2024

Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:

<https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2>

Re: Federal Health IT Strategic Plan, 2024-2030

Dear Dr. Tripathi:

The Regenstrief Institute welcomes the opportunity to submit comments on the Office of the National Coordinator's draft 2024-2030 Federal Health IT Strategic Plan, published March 27, 2024.

The Regenstrief Institute is a local, national, and global leader with a vision to provide pioneering transformative, interdisciplinary solutions for a healthier and more equitable world. A key research partner to Indiana University, Regenstrief and its research scientists, we are responsible for a growing number of major healthcare innovations and studies. Regenstrief is also the steward for vocabulary standards Logical Observations Identifiers Names and Codes (LOINC®) and The Unified Code for Units of Measure (UCUM). A key part of our mission is to develop and advance the adoption of data standards that enable efficient transmission, understanding, and use of health data.

We appreciate the work that ONC and the federal agencies have devoted to this draft. Our comments are intended to augment ONC's efforts toward electronic health information (EHI) access, exchange and use. The Draft Strategic Plan outlines high-level goals and objectives but does not specify actions that federal agencies plan to undertake to achieve those goals. In the comments below, we focus on four specific recommendations to help ONC accomplish the four strategic goals and objectives in the 2024-2030 draft plan.

Comment 1: Data standards are the backbone for achieving the goals and objectives in the strategic plan.

Present funding for data standards limits the pace of improvements in healthcare IT and the improvements to healthcare and research as envisioned in the plan. Leading healthcare standards bodies must put together a patchwork of funding streams that may not fully align with the acceleration of improvements to healthcare. Our review of funding models for data standards organizations shows that historic models of membership, licensing, and project specific funding are not fully aligned with the current needs of patients, healthcare delivery, and research and in some cases not sustainable. Much funding is focused on project specific needs, e.g., health IT education, SDOH, advancement of FHIR. Funding for the maintenance of existing standards and the education, systems, and administration needed to support existing standards and their users is difficult to obtain. Standards bodies stand ready to carry out their central role in accelerating and achieving the vision of the Federal Health IT strategic

plan, but this will not happen without an aligned strategic approach to developing, maintaining, and supporting the users of health IT standards. We recommend that ONC and its Federal partners convene with health care standards bodies to develop a plan for health standards development that aligns with the Federal Health IT Strategic Plan and identifies the funding streams that will be available to support this work.

Comment 2. Advance standardization and interoperability of social determinants of health.

Regenstrief and ONC are closely aligned in advancing standardization and interoperability of social determinants of health so that health care providers and the patients they serve can benefit from data that provides a more complete view of a person's health.

In meeting this goal, we urge ONC and its Federal partners to leverage and continue to fund the collaborative work of Regenstrief and Health Level Seven® (HL7®) International's Gravity Project. Initiated in early 2024, the overall project goal is to identify and build a critical mass of standardized SDOH data elements to represent and exchange patient level social risk data documented across four clinical activities as applicable, including, screening, assessment/diagnosis, goal setting, and intervention and treatment.

Additionally, the HL7 Gravity project was named in the White House report, the U.S. Playbook to Address Social Determinants of Health, as the recognized source for nationally required SDOH data elements. This recognition highlights the cogency and importance of the Regenstrief and HL7 collaboration in supporting ONC with meeting this strategic goal.

Comment 3. Advance the collection and use of social determinants of health data to reduce health and healthcare inequities and disparities. Promote the safe and responsible use of AI tools.

Health equity has been a core value of the Regenstrief Institute since its inception. We have a strategic goal to expand our real-world data including SDOH and informatics presence as it relates to interventions, with a focus on translation of generalizable research findings into health systems and the local community. We also believe that to know how we can improve healthcare for marginalized groups, we must understand where and why inequalities exist. Our work focuses on identifying health disparities in the current healthcare system, discerning the causes of those disparities, and developing, testing and implementing solutions. In a world increasingly dependent on artificial intelligence, we also advocate for algorithmovigilance—monitoring machine learning to identify bias and prevent unintended consequences. We encourage ONC to leverage the breadth and depth of Regenstrief's expertise in meeting these goals in integrating social determinants of health into patient care and promoting health equity.

Comment 4. Promote interoperable and secure health information sharing through nationally adopted standards.

We applaud ONC on its progress in advancing interoperability now that the Trusted Exchange Framework and Common Agreement (TEFCA) is live. We believe TEFCA is one of the most significant milestones in the United States' health information exchange history and it sets the stage to engage more substantially in achieving semantic (or plug-and-play) interoperability of health data. We strongly

encourage ONC to prioritize semantic interoperability in its 2024-2030 strategic initiatives. Semantic interoperability depends on the computable and unambiguous representation of data and information. Understanding that the interaction of data structures and terminology is at the heart of enabling semantic interoperability, we ask ONC and its Federal partners to focus on and fund the development and support of open public repository of preferred detailed information models. ONC can draw upon the extensive expertise of Regenstrief along with a cadre of leading organizations in the health data standards community in supporting and facilitating widespread semantic interoperability.

Comment 5. Promote individual and population level transfer of health data.

Patient matching plays a critical role in patient safety and quality of care, and is important in promoting individual and population level transfer of health data. However patient matching has proven difficult to accomplish in the United States, the last developed country without a unique patient identifier. In the U.S., linking patient data is dependent on algorithms designed by researchers, vendors and others. Research scientists led by Regenstrief Institute Vice President for Data and Analytics Shaun Grannis, M.D., M.S., have developed an eight-point framework for evaluating the validity and performance of algorithms to match medical records to the correct patient. The framework’s approach to the creation of gold standard matching data sets necessary for record linkage encompasses technical areas including data preprocessing, blocking, record adjudication, linkage evaluation and reviewer characteristics. We encourage ONC to implement Regenstrief’s patient matching framework in accomplishing this goal.

We take a moment to share the depth and breadth of real-world experience that Regenstrief brings to these strategic recommendations. We come from many disciplines and backgrounds, united by a vision of pioneering transformative solutions for a healthier and more equitable world. Building tools, terminology standards and infrastructure, creating care models, and enabling research are the ways our dedicated investigators and staff commit to improving patients’ lives. We bring the depth and breadth of these and many other efforts to bear in our aforementioned comments and recommendations.

We look forward to partnering with ONC and its Federal partners to accelerate moving to a truly equitable health care system

If there are questions regarding our comments, please contact Marjorie Rallins, DPM, MS, Executive Director, Health Data Standards at mrallins@regenstrief.org or 317-274-9415.

We appreciate and look forward to continued collaboration with ONC.

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