

**Requests for OMB Review and Approval For
Office of the Assistant Secretary for Technology Policy and Office of
the National Coordinator for Health Information Technology
National Survey of Health Information Exchange Organizations**

Submitted By:

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Supporting Statement for Office of the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology National Survey of Health Information Exchange Organizations

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Office of the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) is seeking the approval for a revision to collection of the “National Survey of Health Information Exchange Organizations (HIOs)”, OMB No. 0955-0019 Exp 11/30/2025.

Electronic health information exchange (HIE) was one of three goals specified by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act to ensure that the \$30 billion federal investment in certified electronic health records (EHRs) resulted in higher-quality and lower-cost care. Subsequent legislation and regulations have continued to prioritize the sharing of data electronically across EHRs and other health information systems. Health information exchange organizations (HIOs) facilitate electronic exchange of health information across disparate providers, labs, pharmacies, public health departments, health plans, and other stakeholders. The [State HIE program, funded by HITECH](#), supported states to engage state, regional, and local HIOs to develop governance, policies, technical services, business operations, and financing mechanisms for HIE during the performance period (which ended in 2014). [Evaluations of the State HIE program](#) indicated though progress was made overall, variability exists across states in the abilities of organizations enabling HIE (and in particular HIOs) to support exchange within their respective states.

Since prior to HITECH, there has been substantial ongoing assessment of trends in the capabilities of HIOs to support clinical exchange through nationwide surveys of HIOs. These surveys have collected data on organizational structure, financial viability, geographic coverage, scope of services, scope of participants, perceptions of information blocking, and participation in national networks and the [Trusted Exchange Framework and Common Agreement \(TEFCA\)](#). Each of these topics will be useful to construct a current and more comprehensive understanding of HIOs’ role in health information exchange.

The most recently conducted survey, in 2023, was funded by ASTP/ONC (OMB # 0955-0019). The 2023 national HIO survey sought to assess the existing capabilities and examine the evolution of these organizations. With the COVID-19 pandemic, we updated

the most recent round of the survey to assess the capabilities of HIOs to support public health data exchange and public health agencies' informational needs. There is a need to continue the survey of HIOs to help ASTP/ONC better understand ongoing national health IT priorities such as information blocking, implementation and use of standards, role of HIOs in supporting interoperability and their experiences with and participation in TEFCA. We also plan to continue to assess the capacity of these organizations to support future public health emergencies.

We have revised the survey to better understand the role of HIOs in supporting public health data exchange and response to pandemics, removing specific questions about the COVID-19 public health emergency, which ended May 2023. HIOs, given their unique role in convening data across stakeholders in their region, may be able to support linking data from disparate sources together to help monitor strategies to prevent and response to public health emergencies. HIOs may also be able to leverage clinical and demographic data they have access to with other data to monitor community/state-level vaccination rates, transmission rates, and breakthrough infection rates among subpopulations (e.g., immunocompromised), along with supporting providers meeting public health reporting requirements via electronic means (rather than paper-based).

The newly revised survey will also provide new insights into HIOs' use of artificial intelligence (AI) and provision of data for the development and training of AI programs, an emerging health care technology topic. New questions will help inform AI governance policies adopted by ASTP/ONC and HHS more broadly. For instance, ASTP/ONC's HTI-1 final rule adopts the Decision Support Interventions (DSI) certification criterion to reflect contemporary functionalities and configuration requirements and this survey has been updated to reflect up to date terminology and policies for health information exchange programs and regulations. It is important this survey comprehensively measure the status of these critical capabilities across HIOs.

There are an array of policy efforts that are primed to leverage the results from the survey. ASTP/ONC and the Centers for Disease Control (CDC) continue to implement recommendations from the Health IT Advisory Committee Public Health Data Systems Task Force, which recommended key data types to be updated using published standards and implementation guides and that the deployment of these data types prioritize demographic and social determinants of health. ASTP/ONC and CDC also continue to partner on important ways to implement public health data modernization and enable greater interoperability of public health data across the care continuum. TEFCA went live and began live exchange in 2023. HIOs are key, potential participants and/or qualified health information networks (QHINs), and understanding their plans to participate in and experiences with TEFCA is crucial given their current role in facilitating HIE across the nation. This survey will be essential to understand the experiences of all players in nationwide information exchange and how to update the program over time. In October 2023, Executive Order 13960 "Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government" mandated federal agencies to prioritize and adopt AI governance policies to both advance the emerging technology as well as to prevent

potential harm. ASTP/ONC pursues multiple AI policies and projects, and this survey can help inform the ASTP/ONC about HIOs AI capabilities and use.

There are five key areas that require broader assessment: (1) organizational demographics, including services provided; (2) public health; (3) implementation/use of standards; (4) network-to-network connectivity and TEFCA; and (5) information blocking, including technical capabilities offered by HIOs and the challenges they face in supporting electronic health information exchange.

Organizational demographics, which include HIOs' overall HIO capabilities, including services provided is critical to assess. With many options available for how providers, public health agencies, labs, and other key health care stakeholders can engage in HIE, and a growing number of newer approaches scaling rapidly, it is critical to track how HIOs are positioning themselves. Thus, collecting the latest data on HIO services including those related to AI, sustainability, and related issues such as governance and use cases, this survey will provide important insights into the evolution of our national HIE infrastructure. In turn, results will reveal gaps that require renewed policy attention. Collecting current data on HIO sustainability will also reveal whether these efforts are continuing the trend that began in 2015 of aligning their value proposition with new models of care delivery and payment. That is, with the rise of alternative HIE approaches (particularly those provided by EHR vendors), HIOs may no longer be able to sustain themselves by only supporting simple HIE transactions that move data across organizations. Instead, they may need to demonstrate added value through functionalities and analytics that support health system transformation efforts (e.g., ADT notifications, PDMP integration and alerting, quality reporting, MIPS, etc.). Understanding the specific approaches to sustainability pursued by HIOs today in the context of delivery system reform efforts will demonstrate not only to their viability but also the infrastructure to support broader health policy and public health goals.

Continuing to track HIOs' capabilities to facilitate public health exchange between health care providers and public health agencies is crucial to inform ongoing public health data modernization and planning and preparation for future public health emergencies. In alignment with CDC's Data Modernization Initiative (DMI), ASTP/ONC has made substantial investments in the public health IT infrastructure and workforce training (e.g. PHIT program). HIOs, given their unique role in convening data across stakeholders in their region, may be able to support linking data from disparate sources together to help monitor the use of strategies to prevent and respond to public health emergencies. We have revised the survey to better understand the role and capabilities of HIEs and HIOs in supporting public health data exchange reporting and response to pandemics.

Measuring the implementation/use of standards for transporting and codifying health information, ensuring that HIOs adopt and conform to standards is critical to enable the sharing of information across systems and to ensure that information can be easily integrated once received. There are often multiple standards available to accomplish the same HIE use case and, even when the same standard is selected, there is often ambiguity

and optionality in the implementation guide that result in poor standards conformance. Unfortunately, when implementing standards, there is little room for flexibility and even one small difference in how a standard is implemented results in failure. It is therefore critical to assess not only which standards are being implemented but the extent to which implementations use the same implementation guide and where there are gaps in conformance. Such assessment is necessary to inform policy and private-sector efforts to promote better coordination among stakeholders on standards selection and conformance. Specifically relevant to public health emergencies, it is critical to assess which standards are in use for tracking lab test results. Standards used to encode laboratory test results can be difficult to implement though ultimately coded results would be helpful to public health reporting and surveillance. Examining the extent to which HIEs have these data encoded and the barriers associated with this process would be informative to ASTP/ONC's efforts related to enabling lab interoperability. Collecting data on standards from HIOs provides important information on both HIO activities and how HIOs are responding to standards development and implementation approaches by developers of certified health IT and other HIE vendors. The results from this survey could help inform future standards development efforts.

It is also important to assess approaches to HIE coordination at the federal level. The number of HIE networks has grown from just a handful of local HIOs a decade ago to nearly 100 disparate networks at the local, regional, and national levels. The result is that health care providers must use a variety of different networks and methods to exchange health information, increasing the complexity and costs of health information exchange. Current efforts, notably the Trusted Exchange Framework and Common Agreement (TEFCA), seek to better coordinate varied approaches to HIE. The goal of TEFCA is to establish universal governance for nationwide connectivity, simplify connectivity, and enable individual access to their health information. Since participation in TEFCA is voluntary, it is critical to assess how HIOs anticipate participating in TEFCA, and their engagement in related activities such as connecting to each other, to gain insight into progress towards nationwide connectivity under TEFCA.

Finally, recently implemented federal regulations prohibiting information blocking should result in more HIE engagement and a more rapid growth of HIOs. HIOs offer a key source of data to inform an understanding of whether information blocking is happening and the extent to which different forms of information blocking may be persisting among developers of certified health IT and provider organizations. Information blocking findings from the 2019 HIO survey helped establish baseline levels prior to enforcement of the new rules. Results showed that over half of HIOs reported that some, most, or all EHR developers engage in information blocking. In terms of frequency, the majority of HIOs also indicated that EHR vendors sometimes, often, or routinely engage in information blocking. The most common type of information blocking behavior EHR vendors engaged in was setting unreasonably high prices, which 42% of HIOs reported routinely observing. These findings on how and when information blocking occurs informed the implementation of the 21st Century Cures Act and have potential to inform future policy initiatives.

The timely collection of national data from our survey will assess current capabilities to support effective electronic information sharing within our health care system. Further, data collected in other topic areas, such as on TEFCA, public health and information blocking, offer the opportunity to assess the impact of recent policies to increase the flow of information across the health care system. The HIO survey results will inform potential modifications to the rules and related activities.

2. Purpose and Use of Information Collection

The goal of this project is to generate the most current national statistics and actionable insights to inform policy efforts. The timely collection of national data from our survey will assess current capabilities of HIOs to support effective electronic information sharing within the U.S. health care system.

Our survey will accomplish this goal by asking HIOs to report current activities in the following key areas:

1. HIO sustainability and related demographics and services that capture the role of HIOs in supporting exchange and interoperability
2. Public health information sharing capabilities
3. Implementation of and use of standards to enable health information exchange and interoperability
4. Planned and current participation in TEFCA and current engagement with inter-HIO and national network connectivity
5. Information blocking practices undertaken by provider organizations and health IT developers

By updating the survey instrument to assess these timely topics from a national census of HIOs, the proposed project fills a critical knowledge gap and will provide policymakers with actionable results to inform progress towards greater interoperability and health information exchange.

3. Use of Improved Information Technology and Burden Reduction

This study will rely on data gathered from a self-administered, web-based survey of leaders of Healthcare Information Exchange Organizations. The survey will be administered electronically to alleviate burden on the respondents. The web-based survey permits respondents to complete the instrument at their preferred time. Respondents who begin the survey and are unable to complete it in one session will be able to save their responses and resume work on the survey at a later time.

We will be using the web-based survey tool Qualtrics©. This tool has been used previously for past surveys of HIOs and it has strong capabilities to support complex survey design (e.g., branching logic) as well as respondent communication and tracking. The tool will be extensively tested to ensure the accuracy of branching and skip logic, accuracy of piped text, clarity of question display, and adherence to other survey usability

guidelines.

In addition, to increase response rate, respondents will also be offered the option to complete the survey via MS Word or over the phone with a Research Assistant or Project Manager if they prefer that to the online platform.

4. Efforts to Identify Duplication and Use of Similar Information

Dr. Julia Adler-Milstein is a leading researcher and expert on HIOs. She has led numerous national surveys of HIOs over the past two decades. She has published more than 30 peer-reviewed publications from these surveys in leading journals, such as Health Affairs and the Journal of the American Medical Informatics Association. Dr. Adler-Milstein, with the support of the Robert Wood Johnson Foundation, has conducted a survey of HIO leaders bi-annually, and published key findings in a series of publications in Health Affairs. The Robert Wood Johnson Foundation no longer funds the bi-annual survey. Separately, in 2015, Dr. Adler-Milstein conducted a survey consisting of 60 leaders of HIOs regarding information blocking practices. This survey was independently funded with some consultation provided by ASTP/ONC staff. Most recently, with support from ASTP/ONC, Dr. Adler-Milstein conducted a national survey of HIOs in 2019 and 2023. Papers that describe these results were published in the Journal of the American Medical Informatics Association ([April 2021](#)) and in Health Affairs ([May 2021](#)).

In addition to these survey efforts, Civitas Networks for Health (CIVITAS) (formally known as Strategic Health Information Exchange Collaborative (SHIEC)) has conducted an annual survey of its membership that includes more than 70 HIOs. CIVITAS presented their 2019 survey results at the 2020 ASTP/ONC annual meeting.

CIVITAS and ASTP/ONC collaborated on the 2023 survey and agreed to collaborate on future proposed surveys to reduce duplication and build on each other's separate efforts to produce a comprehensive measurement strategy. CIVITAS did not separately conduct their annual survey in 2023.

ASTP/ONC considers it critical to continue supporting the HIO survey to examine how HIOs have evolved and the role they play in enabling interoperability and the success of various policy initiatives. This information will be key to informing policy strategies to advance the exchange of health information and support public health efforts going forward. Furthermore, repeating elements of the 2023 survey can provide insights into the implementation of the TEFCA and information blocking rule, as well as the evolution of standards and public health exchange.

5. Impact on Small Businesses or Other Small Entities

Health information exchange organizations vary in size; it is possible that some may be considered small businesses. The survey is voluntary, and the information being requested or required has been held to the absolute minimum required for the intended

use of the data.

6. Consequences of Not Collecting the Information

The survey of HIO leaders has occurred almost bi-annually since 2005 with the most recent survey conducted in 2023. Data collection will occur once every two years beginning late 2024/early 2025.

If information is not collected in 2024, ASTP/ONC will lack the needed information to understand the current state of HIOs to support public health preparedness, limiting our ability to tailor investments in public health data infrastructure in the near-term that could impact our ability to improve information exchange to support public health. Information that will be gathered in this survey is critical to construct a current and comprehensive picture of HIOs' role in facilitating exchange and ensuring rapid access to important health care data and information when it matters most, including vital data to address public health emergencies. Broader ASTP/ONC efforts, particularly around TEFCA, information blocking, and AI governance, also require timely data on the current state of HIOs. Additionally, this information is critical to guide ASTP/ONC's efforts to support CDC's Data Modernization Initiative.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection request is fully consistent with the guidelines. There are no special circumstances required for the collection of information in this data collection.

8. Comments in Response to the Federal Register Notice/Outside Consultation

The 60-day FRN soliciting public comment on this survey data collection, required in 5 CFR 1320.8(d), was published in the Federal Register on December 19, 2023, at 88 FR 87788. There were no comments received from the public.

9. Explanation of any Payment/Gift to Respondents

As with prior years, respondents will be offered a small incentive (\$15) for completing the screening questions that enable us to determine whether they are operational, planning, or defunct and a larger incentive (\$100) for completing the entire survey if they are eligible (i.e., not defunct). We have found with previous surveys that financial incentives help improve response rate.

10. Assurance of Confidentiality Provided to Respondents

We will not make ANY individual responses to questions publicly available or attribute responses to any specific organization. These data will only be presented in aggregate and may be published in a peer-reviewed journals and shared on the ASTP/ONC website.

The information for this study is being collected by the Division of Clinical Informatics & Digital Transformation, Department of Medicine, University of California, San Francisco (UCSF), on behalf of ASTP/ONC and in partnership with CIVITAS. Based on

the UCSF’s Human Research Protection Program Institutional Review Board (IRB) review, an exempt certification was granted for this study (#23-39652).

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked in this data collection.

12. Estimates of Annualized Hour and Cost Burden

We will target sending the survey to approximately 100 key senior respondents from HIOs such as executive directors who will be knowledgeable about the topic areas covered in the survey. We assume an 85% response rate of 100 respondents. The survey was pre-tested with a total of five separate respondents, from which we derived the 45-minute burden per respondent burden estimate.

Exhibit 1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Executive Director	HIO Survey	100	1	45/60	75
Total					75

Exhibit 2. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Executive Director	75	\$124.47	\$9335.25
Total			\$9335.25¹

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no annualized capital/startup or ongoing operation and maintenance costs involved in collecting the information.

14. Annualized Cost to Federal Government

The estimated cost to the Federal Government for the *2024 Health Information Organization (HIO) Survey and Civitas Member Survey* data collection activities is

¹Based on US Bureau of Labor Statistics mean hourly wage for Chief Executives (<https://www.bls.gov/oes/current/oes111011.htm>).

\$279,295.00 over 2 years or \$139,647.50 annually. The contractual costs to the University of California, San Francisco (UCSF), for data collection activities associated with this submission is \$225,395.00 over two years or \$112,697.50 annually. The cost of federal employees providing oversight and some analysis is \$53,900.00 over 2 years or \$26,950.00 annually.

15. Explanation for Program Changes or Adjustments

This a revision to OMB No. 0955-0019 Exp 11/30/2025. We have updated the number of respondents based on the most recent available estimates, which reflects the consolidation of HIOs over time. The survey instrument has been updated but requires similar response time as the previous instrument.

16. Plans for Tabulation and Publication and Project Timeline

ASTP/ONC and UCSF will jointly conduct three types of analyses based on the survey results. First, we will describe response rate and assess longitudinal trends in the number of HIOs in the U.S. Since 2006 we have tracked the number of operational, planning, and defunct efforts. These analyses will enable us to assess whether the number of HIOs has continued to decline since its peak in 2011 or is leveling off at a stable level.

Second, we will conduct descriptive analyses that provide national estimates on survey items. These have traditionally comprised most of our results and they describe U.S. HIO characteristics. This includes general demographics – such as the number and types of participants engaged, the types of data exchanged, the HIE services supported, and geographic coverage – as well as specific measures in the key areas of interest. For example, in the public health capabilities area, we will calculate the proportion of HIOs that are supporting state public health agencies in various ways (e.g., test result reporting, immunization tracking and reporting, etc.). In the standards area, we will calculate the prevalence of adoption of each standard and the associated implementation guide – overall as well as by specific characteristics such as geography or HIO type. In the information blocking area, we will calculate the proportion of respondents who indicated that information blocking was routine, occasional, and rare as well as, for each form of information blocking, the proportion of respondents who indicated it occurred “routinely/often”, “sometimes”, and “rarely/never”. In the sustainability area, we will calculate the overall proportion of HIOs that are financially sustainable (using our previous definition of revenue from participants that is equal to or greater than operating costs) and then examine other measures of sustainability, such as the proportion of respondents reporting different barriers to progress, engaged in different governance models, supporting different models of payment and delivery reform efforts.

Finally, we will conduct more advanced bivariate regression analyses that will identify factors associated with key measures of “success” or “sophistication”. These may include support for public health reporting, use of particular standards, reporting of infrequent information blocking, achievement of financial sustainability, and support for value-based payment. Predictors will include various HIO and contextual demographics.

Peer-reviewed papers were published in the Journal of Medical Informatics Association and Health Affairs using the 2019 HIO survey results on two key topics: [information blocking practices](#) associated with electronic exchange of health information and the current state of HIOs and [their role in supporting exchange](#), including factors associated with planning to participate in TEFCA, a major ASTP/ONC initiative. These findings were also presented at conferences such as Academy Health and AMIA, and a [blogpost](#) was published as well to widely disseminate findings. Given that the national HIO maturity has increased and TEFCA is now live and operational, analyses can further shed light on how information blocking practices, support for exchange, and TEFCA have evolved. We will also be able to examine factors associated with greater support for public health reporting capabilities.

We will conduct preliminary analyses and solicit input internally within ASTP/ONC, federal partners (such as CDC), and CIVITAS to ensure that they reflect the expertise from these organizations. The results will be published, similar to the 2019 findings, in peer-reviewed publications or other public documents, shared via conferences and through blog posts to ensure they are widely disseminated.

The project timeline is two years, starting in August of 2023 and ending in August of 2025. Data collection will occur over three months and is scheduled to begin immediately upon receiving OMB approval.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

All data collection materials will display the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.