

**Requests for OMB Review and Approval For
Office of the National Coordinator for Health Information
Technology
National Survey of Health Information Exchange Organizations
(HIO)**

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October 3, 2018

**Supporting Statement for
Office of the National Coordinator for Health Information
Technology
National Survey of Health Information Exchange Organizations
(HIO)**

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Office of the National Coordinator for Health Information Technology is seeking the approval for a new information collection request item the “National Survey of Health Information Exchange Organizations (HIO).

Electronic health information exchange (HIE) is one of three goals specified by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act (42 U.S.C. 17901 and 17903) to ensure that the \$30 billion federal investment in electronic health records (EHRs) results in higher-quality, lower-cost care. The ability of providers to share data electronically is a core goal of HITECH and a central feature of a high-performing healthcare delivery system. Greater EHR adoption without data flowing between systems substantially limits quality and efficiency gains as well as reduces the value of the health IT investment.

There is growing consensus that achieving broad-based HIE is one of the most difficult components of HITECH. This is because successful HIE at scale involves coordination between many stakeholders, including but not limited to federal and state policymakers, healthcare delivery organizations, EHR and HIE vendors, and specific organizations supporting HIE, such as health information organizations (HIOs) and health information service providers (HISPs). Further, the issues requiring coordination are diverse, spanning technical standards, consent regulations, business models and incentives, workflow integration, trust and governance, and information privacy and security.

Three HIE issues have proven particularly challenging. First, in the domain of technical standards for transporting and codifying health information, ensuring that vendors 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 opportunities for conformance failure exist. ONC recently developed a standards measurement framework which identified the need to measure the implementation and use of standards.¹ Such assessment is necessary to inform policy and private-sector efforts to promote better coordination among stakeholders on standards selection and conformance. While EHR vendors report some information about standards included in CEHRT products, HIOs are in a unique position to provide insights into how standards are being implemented in the ‘real world’ by EHR vendors and the providers they work with.

A second key HIE challenge is information blocking. As defined by ONC, information blocking occurs when persons or entities *knowingly and unreasonably interfere* with the exchange or use of electronic health information. Anecdotal reports suggest that some EHR vendors and healthcare providers (typically hospitals and health systems) have engaged in information blocking behaviors. The assumption is that they engage in information blocking because they believe that it allows them to reap economic benefits, but these practices harm public good and substantially limit HIE efforts and the value to be gained from EHR adoption. While the concept of information blocking has gained broad awareness, data to inform an understanding of information blocking prevalence, forms, and viability of solutions is scant. One of the key challenges to collecting such data is that the two key stakeholders believed to engage in information blocking – vendors and healthcare providers – are not likely to honestly report on whether they are engaging in it, and information blocking is not readily observable in existing datasets because it occurs in the form of provider and vendor business practices. HIOs are therefore in a unique position to provide data on information blocking because these third-party organizations routinely observe the business practices of providers and vendors as part of their efforts to enable HIE among providers in a geographic region that use diverse EHR systems. Our research team successfully surveyed HIO leaders in the recent past to collect a set of baseline data on information blocking.^{2,3,4,5,6} We found

¹ The Office of the National Coordinator for Health Information Technology. “Proposed Interoperability Standards Measurement Framework,” (April 2017).

² Adler-Milstein J, McAfee AP, Bates DW, Jha AK. “The State of Regional Health Information Organizations: Current Activities and Financing,” **Health Affairs** 27, no. 1 (2008): w60-w69 (published on-line 11 December 2007; 10.1377/hlthaff.27.1.w60)

³ Adler-Milstein J, Bates DW, Jha AK. “U.S. Regional Health Information Organizations: Progress and Challenges,” **Health Affairs** 28, no. 2 (2009): 483–492; 10.1377/hlthaff.28.2.483.

⁴ Adler-Milstein J, Bates DW, Jha AK. “A Survey of Health Information Exchange Organizations in the United States: Implications for Meaningful Use,” **Ann Intern Med** (2011); 154: 666-671.

⁵ Adler-Milstein J, Bates DW, Jha AK. “Operational Health Information Exchanges Show Substantial Growth, But Long-Term Funding Remains A Concern,” **Health Affairs** 32, no. 8 (2013): 10.1377/hlthaff.2013.0124.

⁶ Adler-Milstein J, Lin SC, Jha AK. “The Number of Health Information Exchange Efforts is Declining, Leaving the Viability of Broad Clinical Data Exchange Uncertain,” **Health Affairs** 35, no. 7 (2016): 1278-1285; 10.1377/hlthaff.2015.1439

that half of respondents reported that EHR vendors routinely engage in information blocking, and one-quarter of respondents reported that hospitals and health systems routinely do so. Collecting a second round of data from HIOs on information blocking will allow an assessment of trends as well as facilitate collection of new data on topics specifically relevant to current efforts to target information blocking, including those that are part of 21st Century Cures.

Information blocking stems from the prevalence of perverse incentives, in which stakeholders perceive more harm than benefit from engaging in HIE. In particular, when providers fail to perceive a strong business case to engage in HIE, they do not demand improved HIE capabilities from their EHR vendors and have a hard time justifying substantial investment in third-party approaches to HIE. With many options available for how to engage in HIE, and a growing number of newer approaches scaling rapidly, it is critical to track how various approaches are faring. HIOs in particular occupy a unique niche in the landscape of HIE approaches because they are community oriented and typically work to connect providers using disparate EHR vendors. Thus, collecting the latest data on HIO sustainability, and related issues such as governance and use cases, will provide important insights into the evolution of our national HIE infrastructure. In turn, this will reveal gaps and areas that might 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) and the requirements for greater interoperability proposed by the Trusted Exchange Framework and Common Agreement (TEFCA), 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. Understanding the specific approaches to sustainability pursued by HIOs today in the context of support for delivery system reform efforts will therefore speak not only to their viability but also to the infrastructure to support broader health policy goals.

2. Purpose and Use of Information Collection

The ultimate goal of this project is to generate the most current national statistics and associated actionable insights to inform policy efforts in the following key domains:

- (1) Implementation of and use of standards to enable exchange and interoperability
- (2) Information blocking practices undertaken by provider organizations and health IT developers
- (3) HIO sustainability and related demographics, including stakeholder participation and geographic coverage, maturity and scope of exchange, financial, challenges to development, that capture the role of HIOs in supporting exchange and interoperability, along with delivery system reform efforts (e.g. MIPS)

- (4) Trusted exchange of health information to support the ability of stakeholders to access, exchange, and use relevant electronic health information across disparate organizations nationally

Collecting timely, national data from HIOs in the three domains of standards, information blocking, and sustainability is therefore valuable to inform both HIE-specific policy efforts as well as broader health system reform efforts. By developing a survey instrument addressing these topics, collecting national data from a census of HIOs (and related HIE efforts), and analyzing the data to identify important new insights, the proposed project fills a critical gap in current knowledge and will provide policymakers with actionable results to inform progress towards greater interoperability and exchange of clinical data.

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 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 attempt 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 accuracy of branching and skip logic, accuracy of piped text, clarity of question display, and adherence to other survey usability guidelines.

In addition, in order 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, with the support of the Robert Wood Johnson Foundation, conducted a survey of HIO leaders bi-annually. Most recently, 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 ONC staff.

The Robert Wood Johnson Foundation is no longer funding the bi-annual survey. However, repeating elements of this survey with a larger sample of HIO leaders would

provide ONC with robust nationally representative estimates of potential information blocking practices.

To avoid duplication, ONC conducted an open solicitation of bids to administer the survey and selected a team comprised of the three organizations that have conducted past national HIO surveys (Dr. Julia Adler-Milstein in collaboration with the Strategic Health Information Exchange Collaborative and the eHealth Initiative). The selected team agreed that they will only conduct a single survey to ensure no duplication. ONC will also communicate with grantees and other contacts to ensure there will not be duplication in the future.

5. Impact on Small Businesses or Other Small Entities

Information being requested or required has been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Information Less Frequent Collection

The survey of HIO leaders has occurred almost bi-annually since 2005 with the most recent survey conducted in 2015. Data collection will occur once in the 2018-2019 period.

If information is not collected in 2018-2019, ONC will not have needed information to understand the current state of HIOs, information blocking behaviors, or a baseline for assessing the impact of current policy efforts (e.g., 21st Century Cures and TEFCA).

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 notice soliciting public comment on this survey data collection, required in 5 CFR 1320.8(d), was published in the *Federal Register* on October 15 2018, 83, FR 51962. There were no comments received from the public.

The National Survey of Health Information Exchange Organizations represents a collaboration among the Office of the National Coordinator for Health Information Technology (ONC) and the University of California, San Francisco (UCSF).

9. Explanation of any Payment/Gift to Respondents

As with prior years, respondents will be offered a small incentive (\$10) for completing the screening questions that enable us to determine whether they are operational, planning, or defunct and a larger incentive (\$50) 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 responses to questions publicly available or attribute responses to any specific organization. These data will only be presented in aggregate and will be published in a peer-reviewed journal and shared on the ONC website.

The information for this study is being collected by the University of California, San Francisco (UCSF) Center for Clinical Informatics and Improvement Research (CLIIR), on behalf of ONC. Based on the UCSF’s Human Research Protection Program Institutional Review Board (IRB) review, an exempt certification was granted for this study.

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 key senior respondents from Health Information Organizations such as Executive Directors who will be knowledgeable about the topic areas covered in the survey. If the appropriate respondent is identified at each organization, the survey should take on average about 20 minutes to complete.

The survey was pre-tested with 4 separate respondents from which we derived the 20-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	200	1	20/60	67
Total					67

Exhibit 2. Estimated Annualized Burden Costs

Type of	Total Burden	Hourly	Total Respondent Costs
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Respondent	Hours	Wage Rate	
Executive Director	67	\$90.00	\$6,030.00
Total			\$6,030.00

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 *National Survey of Health Information Exchange Organizations (HIO)* data collection activities is \$192,678 over 2 years or \$96, 339 annually. The cost to the University of California, San Francisco (UCSF), for data collection activities associated with this submission is \$189,077 over 2 years or \$94,538.50 annually. The cost of federal employees providing oversight and some analysis is \$3,600.30 over 2 years or \$1,800 annually.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Three types of analyses that will comprise the survey results will be conducted. First, response rates will be described and longitudinal trends in the number of HIOs in the U.S. will be assessed. Since 2005, the number of operational, planning, and defunct efforts have been tracked. 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 post-HITECH level.

Second, descriptive analyses will be conducted that provide national estimates on survey items. These have traditionally comprised the majority of the 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 domains of interest. For example, in the standards domain, we will calculate the prevalence of adoption of each standard and associated implementation guide – overall as well as by specific characteristics, such as geography or HIO type. In the information blocking domain, 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 domain, 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, more advanced bivariate and multivariate regression analyses that identify factors associated with key measures of “success” or “sophistication” will be conducted. These key measures will be developed by UCSF in consultation with ONC and may include: use of particular standards, reporting of infrequent information blocking, achievement of financial sustainability, and support for MIPS. Predictors will include various HIO and contextual demographics. Similar analyses have been performed in the past for two measures: (1) becoming operational and (2) becoming financially viable. We found that exchanging a narrow set of data and involving a broad group of stakeholders were independently associated with a higher likelihood of being operational. Involving hospitals and ambulatory physicians, and securing early funding from participants were associated with a higher likelihood of financial viability, while early grant funding seemed to diminish the likelihood. We expect to glean even more insights from performing similar analyses at a later stage of national HIO maturity. We will also be able to compare how these relationships have changed over time.

The final report will present these analyses, synthesize key themes across the analyses, and interpret their significance. The report will include a description of the methodology and response rates. UCSF will work with ONC to decide how best to divide up the results into publications or other public documents for dissemination. We will also develop associated dissemination and communication plans.

The entire project timeline is 2 years, starting in September 26, 2017 and ending September 25, 2019. This includes survey development, piloting the survey, OMB PRA clearance, fielding the survey, data quality assurance and analyses, creating a summary report, and creating analytic data files and documentation per our agreement with ONC. Data collection will occur over ~6 months and is scheduled to begin in Q1 2019 contingent 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.

