

State Health Information Exchange Cooperative Agreement
National Survey on Health Information Exchange in Clinical Laboratories

Information Collection Request

Supporting Statement, Part A

Submitted by:

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A. Justification

A1. Circumstances Making the Collection of Information Necessary

The Office of the National Coordinator for Health Information Technology's (ONC) Office of Economic Analysis, Evaluation, and Modeling in the Department of Health & Human Services (HHS) requests Office of Management and Budget (OMB) approval to conduct a national survey of clinical laboratories to assess laboratory information exchange capacity, as part of the evaluation of the State Health Information Exchange (HIE) Cooperative Agreement Program. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 seeks to improve American health care delivery and patient care through an unprecedented investment in health information technology. The provisions of the HITECH Act are specifically designed to work together to provide the necessary assistance and technical support to providers, enable coordination and alignment within and among states, establish connectivity to the public health community in case of emergencies, and assure the workforce is properly trained and equipped to be meaningful users of electronic health records (EHRs). Combined, these programs build the foundation for every American to benefit from an EHR, as part of a modernized, interconnected, and vastly improved system of care delivery.

The State HIE Program, created under Section 3013 of the Public Health Service Act (PHSA), as amended by the American Recovery and Reinvestment Act (ARRA) of 2009, directed the Secretary of HHS to provide funding to states and territories in the United States to "facilitate and expand the secure, electronic movement and use of health information among organizations according to nationally recognized standards."¹ The appropriate and secure electronic exchange and consequent use of health information to improve the quality and coordination of care is a critical enabler of a high performance health care system. In support of the State HIE Program, ONC's Office of Economic Analysis, Evaluation and Modeling is conducting a legislatively mandated program evaluation study. There are three aims to the evaluation: 1) characterize the different approaches that states are using to enable information exchange; 2) assess the progress of states and the factors that are associated with more sophisticated information exchange; and 3) assess the effectiveness of the State HIE Program to expand the secure exchange of health information. To assess progress of HIE, the evaluation will include the three priority areas for information exchange described in the Centers for Medicare and Medicaid Services' (CMS) final rule for stage one meaningful use requirements: e-prescribing, receipt of structured laboratory results, and sharing patient care summaries across unaffiliated organizations.² While ONC utilizes Surescripts data to monitor e-prescribing and pharmacy capacity for information exchange and results from the National Ambulatory Medical Care Survey (NAMCS) Electronic Medical Record Supplement and the American Hospital Association Information Technology supplement to assess information exchange across provider organizations, there are currently no reliable data sources available assessing or monitoring laboratory information exchange across the United States.

Based on 2007 data from the CMS Online Survey, Certification, and Reporting (OSCAR) database, the Centers for Disease Control and Prevention (CDC) estimates that approximately 6.8 billion laboratory tests are performed annually in the U.S.³ These laboratory tests are a critical element in patient care

¹ Office of the National Coordinator. (2009). American Reinvestment and Recovery Act of 2009 – Title XIII – Health Information Technology, subtitle B – Incentives for the Use of Health Information technology, section 3013 – State Grants to Promote Health Information Technology, State Health Information Exchange Cooperative Agreement Program, Funding Opportunity Announcement. Department of Health and Human Services.

² Office of the National Coordinator. (2010). State Health Information Exchange Cooperative Agreement Program Information Notice. Department of Health and Human Services.

³ The Lewin Group. Laboratory Medicine: A National Status Report. May 2008. Available at <http://www.futurelabmedicine.org/reports/laboratorymedicine-anationalstatusreportfromthelewingroup.pdf>.

significantly influencing 70 to 80 percent of clinical decisions.⁴ Further, laboratory test results are a key component of a longitudinal EHR. However, these results are not often readily accessible, affecting providers' ability to follow-up on test results, affecting the quality of care delivered, and patient safety and satisfaction.⁵ In addition, there is evidence of unnecessary and duplicate testing among providers in different locations.⁶ Communication and the subsequent exchange of information among provider offices and clinical laboratories are integral to combat these inefficiencies. Bi-directional interoperability, or the ability to support seamless exchange of information between laboratory information systems and EHRs (primarily laboratory test results), and EHRs and laboratories (primarily laboratory orders) can "reduce medical errors, increase appropriate testing and reduce unnecessary testing, and improve quality and efficiency of health care."^{7,8} Despite the importance of laboratory information exchange, there are no comprehensive data sources providing insight into the capacity of laboratories to exchange clinical data, nor are there resources detailing the frequency of electronic information exchange among laboratories with healthcare providers.

Given the importance of laboratory results to support clinical care delivery, one of the priorities of the State HIE Program is for states and state designated entities to promote the electronic exchange of structured test results from clinical laboratories to healthcare providers. To gain a comprehensive understanding of the baseline level of laboratory information exchange and to assess progress over time, both national and state level information is needed regarding the baseline capacity for clinical laboratory information exchange.

There are approximately 225,000 laboratories in the United States and territories according to the CMS Clinical Laboratory Improvement Amendments (CLIA) database.⁹ Collecting information from all laboratories would be burdensome, costly, and time-consuming. This survey will collect key information from a relatively small sample of laboratories to provide estimates of the status of electronic capabilities and practice. A sample size of 13,957 laboratories, resulting in at least 4,963 completed surveys, will provide accurate estimates of information exchange capacity of laboratories at the national level and in the 50 states, D.C., and Puerto Rico. A mail out/mail back mode of survey administration will be used, followed by email reminders and telephone non-response follow-up.

This OMB package is for approval of Wave 1 and Wave 2 of the survey. Wave 1 will be conducted early in 2013 and seeks to establish the baseline; Wave 2 is planned for 2014 and will provide sufficient measures to assess improvements. At this time, the content of both Wave 1 and Wave 2 will be the same.

⁴ American Health Information Community. Letter to the Honorable Michael O. Leavitt. 2006. Available at <http://www.hhs.gov/healthit/ahic/materials/meeting04/ehr/EHRDraftRecs.doc>.

⁵ Poon EG, Wang SJ, Gandhi TK, Bates DW, Kuperman GJ. Design and Implementation of a Comprehensive Outpatient Results Manager. *Journal of Biomedical Informatics*. 2003; 36: 80-91.

⁶ Weydert JA, Nobbs ND, Feld R, Kemp JD. A Simple, Focused, Computerized Query to Detect Overutilization of Laboratory Tests. *Archives of Pathology & Laboratory Medicine*. 2005; 129: 1141-1143.

⁷ Eisenberg JM, Williams SV, Garner L, Viale R, Smits S. Computer based Audit to Detect and Correct Overutilization of Laboratory Tests. *Medical Care*. 1977; 15(11): 915- 921.

⁸ The Lewin Group. Laboratory Medicine: A National Status Report. May 2008. Available at <http://www.futurelabmedicine.org/reports/laboratorymedicine-anationalstatusreportfromthelewingroup.pdf>.

⁹ Clinical Laboratory Improvement Amendments (CLIA). (2011). Overview. Available at <https://www.cms.gov/clia/>.

A2. Purpose and Use of Information Collection

ONC is at the forefront of the administration's health IT efforts, and is a resource to the entire health system to support the adoption of health IT and the promotion of nationwide HIE to improve health care.

The goal of the survey is to assess laboratory information exchange capacity and activity at the state and national levels. Results will provide crucial information about laboratories across the United States, including the volume of laboratory information exchange, laboratory information exchange standards, current systems and technical architecture, and barriers and facilitators of laboratory information exchange. In particular, data will be used to generate general estimates for two key performance measures:

1. Percentage of laboratory facilities *within each state* that are able to send structured laboratory results electronically to ordering providers, overall and separately for hospitals and independent laboratories. Percentage of laboratory facilities *nationally* that are able to send structured laboratory results electronically to ordering providers overall and separately for hospitals and independent laboratories.
2. Percentage of laboratory results *within each state* that are currently being sent electronically in coded format to ordering providers, overall and separately for hospitals and independent laboratories. Percentage of laboratory results *nationally* that are currently being sent electronically in coded format to ordering providers, overall and separately for hospitals and independent laboratories.

The survey is integral to nationwide efforts to promote electronic laboratory information exchange, as it will yield invaluable information on laboratory information electronic exchange capacity and activity at the state and national levels. ONC will use these findings to develop a comprehensive understanding of the baseline level of laboratory information exchange in order to inform program activities to promote laboratory information exchange and provide more targeted assistance to states and territories in developing their laboratory information exchange strategies. The information will also be used by states and territories to refine their approaches to promoting laboratory information exchange. As time and program funding are limited, it is critical that they have access to quality and comprehensive information in order to quickly refine their interventions. Finally, the information will be used to assess the effectiveness of the program in facilitating the electronic exchange of laboratory information, a critical aspect of clinical care. Ultimately, the information will guide ONC and other federal agencies on future policy for laboratory information exchange.

ONC also intends to link survey responses from hospital laboratories to data ONC obtains from the American Hospital Association's Annual Survey. This linkage will enable ONC to better understand hospital and area characteristics of the surveyed entity, without burdening them with additional questions. Having these data will allow ONC to understand if factors such as hospital bed size, teaching status, whether the hospital is part of a network of hospitals or single entity, and EHR adoption status affect a hospital's capability to exchange laboratory test results electronically.

A3. Use of Improved Information Technology and Burden Reduction

This study will rely on data gathered from self-administered hardcopy surveys of key informants (i.e. Laboratory Managers or Directors and Laboratory Information System Specialists) at the sampled laboratories. Employing a hard copy questionnaire will be most effective since completion of survey

questions will likely require consultation with more than one respondent. Respondents will also be contacted via email and phone and survey responses can be provided by mail, phone or fax. Data collection costs are reduced by reducing the number of response modes (e.g., not conducting web or personal visit data collection). Consultations with grantees who have conducted state-based surveys with clinical laboratories have indicated that the majority of laboratory staff is expected to prefer filling out a hard copy questionnaire.

All respondents will be mailed an advance invitation letter informing them of the purpose and importance of the survey. The advance letter will be followed by a mailed packet. The packet will contain a cover letter, a hard copy questionnaire and a postage paid return envelope. In order to maximize the response rates to the survey, non-responders will be mailed a reminder packet, a post card reminder, and a final reminder packet if needed. The reminder packets will again include cover letters stressing the importance of the survey and urging participation, hardcopy versions of the questionnaire, and postage paid return envelopes. For cases where an email address is also available, periodic emails encouraging response during the data collection period will also be sent to respondents. Finally, non responders will be contacted by telephone and respondents may complete the survey at that time over the telephone if desired.

There will be two versions of the questionnaire – one for hospital-based laboratories and one for independent laboratories. Based on information contained in the sample file about the laboratory classification, each sampled laboratory will be assigned to the “hospital laboratories” group or the “independent laboratories” group. Dividing the sample in this way will ensure that respondents receive the appropriate version of the questionnaire. While the content of the two questionnaire versions are similar, customizing these questionnaires to hospitals and independent laboratories will alleviate respondent burden by ensuring that respondents only receive the questions that are appropriate to their type of laboratory and are not asked to answer questions that are not applicable. In addition to minimizing respondent burden, this should also help reduce any potential nonresponse by limiting the number of survey questions.

The survey will have a centralized case management system (CMS), linked to locating and receipt control systems for all mailings and returns of completed hardcopy questionnaires, emails and phone calls which will allow for the review of case status at any time. This will allow for effective follow-up, including ensuring that respondents do not receive any additional mailings once a hardcopy questionnaire is received.

A4. Efforts to Identify Duplication and Use of Similar Information

The purpose of this survey is to collect national and state -level data from clinical laboratories to assess laboratory information exchange capacity and activity. A review of the literature and discussions with key informants did not identify any other efforts to collect data of this scale and focus. No other known projects assessing the capacity of laboratory information exchange of this scale have been funded by the federal government or private entities.

A5. Impact on Small Businesses or Other Small Entities

No information will be collected from small businesses or other small entities.

A6. Consequences of Collecting the Information Less Frequently

The design of the survey requires only two data collection activities per respondent within a two year time frame. It is critically important to survey laboratories at baseline and follow-up in order to assess changes in the level of laboratory information exchange across the United States. Without collecting these data, the evaluation will lack essential information about laboratory information exchange activity and capacity.

The federal government will find enormous benefit in having national and state level estimates particularly in regards to efforts to promote laboratory information exchange capacity. Survey results will enable ONC to best promote laboratory information exchange, inform states, D.C. and Puerto Rico of approaches to enhance laboratory information exchange efforts, and augment program evaluation efforts to assess the effectiveness of the State HIE Program on facilitating electronic laboratory information exchange. In addition, results will be used by ONC and other federal agencies to inform policy decisions regarding laboratory information exchange.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No special circumstances apply; this request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2).

A8. Comments in Response to Federal Register Notice/Outside Consultations

Comments in Response to Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the *Federal Register* on 6/20/2012 page 37047 announcing ONC's intention to request an OMB review of data collection activities and providing a 60-day period for public comments.

During the 60-day comment period, one set of comments was received from the American Clinical Laboratory Association (ACLA) on 8/17/2012. These comments are summarized below and are provided in their entirety in Attachment D.

Many of the ACLA comments are consistent with recommendations NORC received from consultations with experts as well as findings from the cognitive interviews. The following key changes were made based on the results from the cognitive interviews and discussions with experts:

- Added a question that clarifies whether the respondent is reporting for a single laboratory or multiple laboratories
- Expanded the response categories for the laboratory's organizational affiliation and the job title of the respondent
- Included a question that provides details on the kinds of clinical pathology tests performed by the laboratory
- Used the phrase 'ordering practitioners' rather than 'providers'
- Added instructions defining 'lab tests' and 'electronically in a structured format'

Other changes as described below were made in response to the ACLA comments. *“Billable” tests.*

ONC agrees with ACLA’s suggestion to remove the word “billable” in describing a laboratory test that is (1) ordered by a provider; (2) performed on received specimens; and (3) finalized and results have been produced. NORC has removed references to “billable” tests and now refers to “final test results” throughout the survey instrument. In addition to meeting the criteria above, final test results describes that the laboratory has incorporated and calculated reference data to produce the results referenced. This change is consistent with the recommendations from the cognitive interviews, in which respondents were confused by the term “billable” tests, and thus ONC recommended changing it to “final test results.”

Addressing Wave 2 sample

ONC agrees with ACLA’s suggestion to use the same sample for Wave 2 of the survey in order to measure progress made in exchanging health information. Rather than including this information on the survey instrument itself, NORC proposes addressing it in the cover letter, which will accompany the survey instrument.

LIMS/LIS Questions

ACLA expressed concern that the LIMS/LIS questions diverge from the purpose of this survey, which is to measure exchange. ONC suggests retaining these questions as they serve two important purposes in the survey. First, there may be an association between the systems that labs have purchased and electronic capability. In other words we may see trends where certain labs are more or less likely to be involved in electronic exchange depending on their LIS/LIMS. Secondly from a survey design perspective the questions on LIS/LIMS serve a priming effect. These questions are presented early on the survey so get survey respondents comfortable with the survey and prepare them for the more detailed technical questions on standards and system capabilities that follow later in the survey instrument. This information could help us see if there is a relationship between electronic connectivity and certain systems.

Providing write-in answers for final test results

ACLA suggested that their members would object to writing in the number of final test results sent in 2012, but they would be willing to select a corresponding range. ONC agrees with this comment and retained an option for respondents to respond to this item by selecting a range that best represents the volume of test results.

Unlinking references to SNOMED and LOINC

Previous to ACLA’s comment about unlinking questions on SNOMED and LOINC, ONC removed all references to SNOMED. In discussions, experts suggested that SNOMED and LOINC are two different concepts. Since the real focus is understanding lab capabilities around the delivery of structured lab results which in the recent certification and standards criteria for meaningful use stage 2 has been specified to include LOINC, the questions have been revised to focus on LOINC only. To eliminate confusion and increase survey efficiency, NORC is only asking questions about LOINC.

National survey's relationship to state surveys

ACLA inquired how the goals of the national survey compare with surveys conducted by states and what role the survey will play in the future. Grantees of the State HIE Program have been involved in efforts to understand the landscape of laboratory exchange within their state, identify gaps in exchange capability, and promote the electronic exchange of test results by targeting and supporting laboratories that lack this capability. These efforts enable states to set goals related to the exchange of structured lab data and perform targeted outreach during the short duration of their grant period. The methods used by grantees to collect information are not consistent across states, preventing the aggregation of data on the key measures required for ONC to evaluate health information exchange in clinical laboratories nationally. To balance the needs of the grantees supported by the State HIE Program and this information collection effort, ONC has encouraged grantees to focus their monitoring and outreach efforts on labs they have previously identified as not sending structured results to providers electronically, and those not using LOINC vocabulary coding. This balance will minimize respondent burden and provide ONC with important measures not captured by the grantees, including national data on systems and technical architecture, detailed information on volume of lab exchange, messaging and vocabulary standards, barriers to laboratory information exchange, and implementation of guidelines and regulations.

Outside Consultations

ONC and our contractor, NORC at the University of Chicago, consulted with many subject matter experts, survey methodologists and sampling statisticians within our respective organizations. Representatives from the Laboratory Corporation of America (LabCorp) and Quest Diagnostics Incorporated (Quest) discussed draft survey questions with us. Representatives from states that previously conducted statewide surveys of their laboratories provided input on the survey instruments. In addition, the data collection methodology, sampling design and survey instruments were developed with input from subject matter experts at the College of American Pathologists and HLN Consulting including the following two individuals:

Ron Ranauro
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Gregory J. Farnum
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gfarnum@hln.com

A9. Explanation of any Payments/Gifts to Respondents

No incentive is proposed for this project. Respondents will be offered a report of the survey findings, which should be of interest to Laboratory Managers and their staff.

A10. Assurance of Confidentiality Provided to Respondents

Participation in this survey is voluntary. Responses by laboratories will be kept private to the extent allowed by law. Under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c), respondents will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information will not be used or disclosed for any other purpose. Data will be collected in conformance with the Privacy Act of 1974

As required by Federal law and ethical research standards, all projects involving primary data collection (or identifiable secondary data) must undergo review by NORC's Institutional Review Board (IRB), which is registered with the HHS Office of Human Research Protection (OHRP). In turn, OHRP has the right to audit NORC's IRB records or any study's procedures at any time to assure that they are in compliance with the federal regulations regarding research with human subjects.

During data collection, our Federal contractor, NORC at the University of Chicago, will incorporate numerous safeguards for the data. Each sampled laboratory will be assigned a unique identifier, and this identifier will be used on all hardcopy survey materials. While collecting data, information that could identify a particular sampled laboratory or respondent, such as contact information, will be stored in a separate file from the survey response data collected for that case.

The electronic systems for data collection and data storage at NORC are on a local area network (LAN). All systems used to store electronic survey data are secure by design and protected by passwords only available to authorized survey staff.

All of the survey's data collection and processing sites are located in highly restricted areas that are readily protected by security systems, including video cameras or the previously mentioned keycard systems or trained guards. Only those employees who have read and signed a copy of NORC's confidentiality pledge (or their escorted guests) are allowed on the premises. All of NORC's employees sign a confidentiality pledge at time of hire. All completed hardcopy survey questionnaires will be stored in locked file cabinets accessible only to authorized project staff.

As is done with many surveys of businesses and establishments, the instrument design has taken into consideration possible concerns respondents may have regarding proprietary information. Response options have been provided that permit the respondent to report ranges and estimates rather than reporting of actual figures or numbers.

A11. Questions of a Sensitive Nature

The survey questionnaire will ask respondents about the lab's electronic transfer of health information. None of the questions in the questionnaire are considered to be of a sensitive nature. The two versions of the survey questionnaires can be seen in Attachments A and B.

A12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized respondent burden for the proposed project.

The burden hours are based on an estimated length of approximately 20 minutes per completed survey for the hospital laboratories and independent laboratories and approximately 10 minutes for the LabCorp and Quest laboratories. We expect 4,963 respondents to complete the survey in Wave 1 and 4,420 to complete the survey in Wave 2. The estimated annualized respondent burden is 1,489 hours.

EXHIBIT 1. ESTIMATED ANNUALIZED RESPONDENT BURDEN

Forms	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden (in hours) per Response	Total Burden Hours
Hospital-Based Laboratory Survey on Health Information Exchange	Hospital-Based Laboratories	2,729	1	20/60	910
Independent Laboratory Survey on Health Information Exchange	Independent Laboratories	1,963	1	17.70/60	579
Total		4,692	1	19.04/60	1,489

Exhibit 3 shows the estimated annual cost to respondents based on the amount of time required from individuals and the average hourly wage obtained from the 2010 U.S. Bureau of Labor Statistics. For those respondents that agree to participate, it is estimated that the total time required to complete the survey will be approximately 20 minutes on average, and approximately 10 minutes for the LabCorp and Quest headquarters to provide responses for all of their laboratories.

EXHIBIT 3. ESTIMATED ANNUAL COST TO RESPONDENTS

Type of Respondent	Total Burden Hours	Average Hourly Wage Rate* (in dollars)	Total Respondent Cost
Wave 1 (2013) Survey	1,570	\$30.02	\$47,131

*As of June 2010, the average hourly earnings for the general public group is \$30.02. (U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, June 2010)

A13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no capital or maintenance costs involved in collecting the information. Other than their time to complete the surveys, estimated in Exhibit 3, there are no direct monetary costs to respondents.

A14. Annualized Cost to the Government

Exhibit 4 shows the estimated annualized cost to the government. The estimated total cost for all survey design, data collection, data processing, tabulation, estimation and analysis activities is \$1.35 million. The estimated annualized cost to the government is \$675,000.

EXHIBIT 4. ESTIMATED ANNUALIZED COST TO THE GOVERNMENT

	(a)	(b)	(c) (a/b = c)
	Total Government Cost	Total Number of Years	Total Estimated Annualized Cost to the Government
Totals	\$1,350,000	2	\$675,000

A15. Explanation for Program Changes or Adjustments

No change is requested. This submission to OMB is an initial request for approval for a new collection of information.

A16. Time Schedule, Publication and Analysis Plans

Survey data will be collected in the baseline year (Wave 1) and follow-up (Wave 2) of the survey. Analysis will begin shortly after the Wave 1 data are collected from the hardcopy surveys to produce a report. An additional report will be produced following the completion of Wave 2 data collection. Exhibit 5 provides an estimated schedule for data collection, analysis and publication for the two waves of the survey, using a target OMB approval date of 12/14/2012. If approval is received after that date, the timetable will shift accordingly.

EXHIBIT 5: TIMETABLE FOR DATA COLLECTION AND PUBLICATION FOR OTHER DATA COLLECTION EFFORTS

Activity	Estimated Start Date	Estimated End Date
Wave 1 Data Collection (Baseline)	1/16/2013	5/3/2013
Data Cleaning and QA	5/4/2013	6/6/2013
Analysis of Wave 1 Data	6/9/2013	7/8/2013
Development of report for Wave 1 Data	7/11/2013	8/5/2013
Wave 2 Data Collection (Follow-Up)	1/6/2014	4/18/2014
Data Cleaning and QA	4/21/2014	5/16/2014
Analysis of Wave 2 Data	5/17/2014	6/3/2014
Development of report for Wave 2 Data	6/6/2014	6/27/2014

Analysis of the Wave 1 data will entail two tracks. First, univariate statistics will be generated and examined at the national level as well as for each state and laboratory category. They will include two key measures of interest identified earlier:

1. Estimated percentage of laboratory facilities within each state that are able to send structured laboratory results electronically to ordering providers, overall and separately for hospitals and independent laboratories. Estimated percentage of laboratory facilities nationally that are able to send structured laboratory results electronically to ordering providers, overall and separately for hospitals and independent laboratories. Confidence intervals at the 95% confidence level for estimated percentages will also be provided.
2. Estimated percentage of laboratory results within each state that are currently being sent electronically in coded format to ordering providers, overall and separately for hospitals and independent laboratories. Estimated percentage of laboratory results nationally that are currently being sent electronically in coded format to ordering providers, overall and separately for, hospitals and independent laboratories. Confidence intervals at the 95% confidence level for estimated percentages will also be provided.

3. Estimated percentages and confidence intervals at the 95% confidence level will also be derived for other data elements collected from the survey instrument.

Analysis of the primary survey measures will entail both cluster analysis and discriminant analysis. One area of interest will be classification of states in terms of high, medium, and low information exchange capability and utilization, for which cluster analysis will be applied in an attempt to establish state groupings. A second area of interest will be determinants of information exchange capability and utilization, for which discriminant analysis will be applied to assess the multiple variables associated with laboratories, both from the CLIA database and from the survey, and identify that subset of predictor variables.

Analysis of the Wave 2 data will entail the same tracks as those in Wave 1, with additional analyses intended to assess change between Waves 1 and 2. First, comparisons between Wave 1 and 2 will be made based on the full sample from each Wave. Such comparisons will provide an indication of the overall change in percentages for each population (e.g., state x category, national for each category, state). Second, comparisons of results for consistent reporters (i.e., laboratories reporting in both Waves 1 and 2) will be carried out to understand the nature and determinants of the changes occurring between Waves 1 and 2. Such analyses can leverage the full set of information reported in both Waves 1 and 2 to develop measures of change.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

ONC does not seek this exemption.

A18. Certifications

ONC certifies that the collection of information encompassed by this request complies with 5 CFR 1320.9 and the related provisions of 5 CFR 1320.8(b)(3).