



Office of the National
Coordinator for Health
Information Technology
U.S. Department of Health and
Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

January 30, 2021

Margo Schwab, Ph.D.
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Re: Under Approved Generic OMB Control No: 0990-0376, expiration date 07/31/2014; ICR
Reference No: 201106-0990-003
Request Approval to Administer Survey Questions Across Patient Population

Dear Dr. Schwab:

The Office of the National Coordinator for Health Information Technology (ONC), Office of the Chief Privacy Officer (OCPO), is requesting approval for administering a patient survey under Approved Generic OMB Control No. 0990-0376. Specifically, OCPO requests approval to conduct a survey and evaluate responses from the proposed information collection entitled, “Survey for Developing Education for Sharing Patient Medical Information.”

The specific survey and data collection methods proposed for coverage by Approved Generic OMB Control No: 0990-0376 are described below. .

Background

ONC serves as the principal advisor to the Secretary of the U.S. Department of Health and Human Services (HHS) on the development, application, and use of health information technology (health IT). ONC was originally created under Executive Order (EO) 13335, but has since been codified in law by the HITECH Act. The HITECH Act builds on EO13335 and establishes additional purposes for the ONC and duties for the National Coordinator. Chief among these new HITECH Act responsibilities are to: promote the development of a nationwide health IT infrastructure that allows for electronic use and exchange of information; coordinate health IT policy; and update the Federal Health IT Strategic Plan to meet the objectives specified in the HITECH Act. Meeting certain objectives such as “methods to foster the public understanding of health information technology” will require additional information from the public at large to determine what education is needed and what types of communication techniques will be most effective. Additionally, Section 3001(e) of the Public Health Service

Act authorizes the National Coordinator to, “appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.”

E-Consent Pilot Summary

ONC understands the challenges related to health information sharing and the issues of patient consent. Health Information Exchanges (HIE’s), along with the Regional Health Information Exchanges (RHIO’s), and the various participating health service providers, must be able to provide clear, comprehensive, succinct, meaningful and easily understood education on the issues of patient choice. From a national perspective, health reform in this country is heavily dependent upon the patient population recognizing, appreciating, and being willing to participate in the sharing of their health information. This is one of the key goals of the Federal Health Information Technology Strategic Plan and it is reinforced by recent Health Information Technology Policy Committee (HITPC) publications.

The scope of this project includes the responsibility of identifying the key informational elements required to educate patients, the challenge of developing key educational material and resources so providers can educate patients, the requirement to develop effective, efficient, and innovative means of delivering and communicating this information, and the need to assess how well a patient both understood and responded to the presented material.

This project has a three-phased approach to gather inputs from patients. Patient input will be solicited for Phase 1 via surveys. Phase 2 inputs will collect information from patients during focus groups. Selected patients will have an opportunity to evaluate the process and education content during Phase 3, immediately following the patient’s interaction with the E-Consent Trial.

Public Affected by this Project

Adult Health Care Consumers: We are proposing to distribute the survey among general adult health care consumers within an eight county region of Western New York (Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Niagara, Orleans, and Wyoming counties). This survey will use the clearest language possible to include responses from participants with low-health literacy, based off of demographic indicators. Additionally, our survey sample will be representative of the ethnic and socio-demographic characteristics of the target population.

Purpose of Survey

The purpose of the survey is to obtain information from adult health care consumers about information they deem necessary prior to giving informed consent to share their personal medical information across a network of providers. The key is to understand the information patients indicate they need to make a meaningful, informed decision regarding patient choice.

Survey Methodology

The methodological design of this proposed effort is consistent with the design of typical survey collection methods. The analysis will be both quantitative and qualitative.

Surveys will be administered via mailings to a representative sample (2,800 respondents) drawn from a Master Patient Index (MPI) comprised of 1.5 million registered adult health care consumers. This survey will use a targeted approach towards low-health literacy and use the clearest language possible. The survey will be distributed through the mail, and include a return-address, pre-paid postage return envelope in which the participants may return the completed survey. Survey responses will be anonymous and no personally identifying information will be captured from the survey instrument. The participant data will be pulled from the secure MPI and it will be stored in a secure environment. The data will be provided in an encrypted form to the vendor (North Delaware Printing) mailing out the surveys. The surveys will return directly to HEALTHeLINK (one of the partners on the project) and the responses will be analyzed.

The sampling methodology to select patients to provide input in Phase 1 includes the following. First, HEALTHeLINK will provide a master patient list which includes all actual and potential patients served by practices who are a part of HEALTHeLINK's MPI. Second, a random sample of patients will be selected to receive the survey in the mail ensuring a representative sample of the larger population in terms of gender, age, and residence location (urban, suburban, and rural).

In the survey, we will frame questions in a manner which allows us to individually identify information components which are of most important to health consumers prior to their agreeing to share their health information. This will be elicited via quick multiple choice response questions.

After completing the survey, respondents will be directed to place their responses in the provided, postage-paid envelope within a given timeframe. The responses will be collected and analyzed. This analysis will provide information regarding what patients regard as most important prior to agreeing to share their information and will provide valuable context for future focus groups.

Explanation of Payments/Gifts to Respondents

Our Team does not intend to compensate respondents for completing this survey. We expect to receive a statistically valid response from the mailing without providing compensation.

Estimates of Burden Hours

The table below shows the estimated burden for the proposed cognitive testing based on 2,800 mailed surveys, estimated to be 5 minutes in length.

Type of Respondent	Number of Responses	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Survey Respondents	2800	1	.0833	233

The table below shows the estimated costs for the proposed cognitive testing based on the estimated burden of 233 hours. The average salary for the general public group is \$30.02.¹

Type of Respondent	Total Burden Hours	Average Hourly Wage Rate (in dollars)	Total Respondent Cost
Survey Respondents	233	\$30.02	\$6,994.66

Cost to the Government

The total cost to the federal government for the survey is estimated to be \$4,210. This cost estimate includes the both the printing and mailing of the surveys.

Requested Approval Date: TBD

Attachment 1: Draft Survey for Developing Educational Material for Sharing Patient Medical Information

Attachment 2: Cover Letter

¹ U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, June 2010.