# ICD-10 Industry Readiness Assessment

## Request for OMB Review

## Supporting Statement

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Submitted by:

Denise M. Buenning, MsM
Acting Deputy Director
Office of E-Health Standards and Services (OESS)
Centers for Medicare & Medicaid Services (CMS)
Denise.Buenning@cms.hhs.gov
410-786-6711

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## A. Justification

### A.1. Circumstances Making the Collection of Information Necessary

Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, enacted on August 21, 1996. Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled ‘‘Administrative Simplification.’’ Part C of title XI of the Act now consists of sections 1171 through 1180, which define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and certain health care providers concerning the transmission of health information. Specifically, HIPAA requires the Secretary of HHS to adopt standards that covered entities are required to use in conducting certain health care administrative transactions, such as claims, remittance, eligibility, and claims status requests and responses.

As part of addressing these requirements, on January 16, 2009, HHS published two final rules (74FR3296 and 74FR3328; included as Appendixes A-1 and A-2): adopting by regulation sets of standards for HIPAA transactions ICD-10 standards for coding diagnoses and inpatient hospital procedures and Version 5010/D.0 standards for eight types of electronic health care transactions (such as claims, eligibility inquiries, remittance advices). The first rule mandates concurrent adoption of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for diagnosis coding, and the International Classification of Diseases,

Tenth Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding. The new codes would replace the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Volumes 1 and 2, and the International Classification of Diseases, Ninth Revision, Clinical Modification (CM) Volume 3, for diagnosis and procedure codes, respectively. Covered entities that use these code sets include health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction for which HHS has adopted a standard. The ICD-10-CM code set is maintained by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC) for use in the United States. It is based on ICD-10, which was developed by the World Health Organization (WHO) and is used internationally. The ICD-10-PCS code set is maintained by the Centers for Medicare & Medicaid Services (CMS).

To support the new ICD-10 coding system, the other HIPAA final rule published January 16, 2009, mandates updating two sets of standards, the Accredited Standards Committee X12 Version 4010/4010A1 (Version 4010/4010A1) for health care transactions, and the National Council for Prescription Drug Programs Version 5.1 (Version 5.1) for pharmacy transactions, with Version 5010 and Version D.0, respectively. Covered entities that use these transaction standards include health plans, health care clearinghouses, and certain health care providers. The rule also proposes the adoption of a standard for the Medicaid pharmacy subrogation transaction.

The final rules set compliance dates of January 1, 2012, for Version 5010/D.0 standards (other than the Medicaid pharmacy subrogation standard, for which HHS proposes a

compliance date two years after the effective date of the final rule, except for small health plans, which would have an additional year to comply) and October 1, 2013, for ICD-10 standards.

Now that the Version 5010 deadline has passed, CMS estimates that 98 percent of HIPAA-covered entities are Version 5010-compliant as of July 2012. (Systems must be Version 5010-compliant to accommodate the specificity of ICD-10 codes.)

On September 5, 2012, HHS published a final rule (Appendix A-3), extending the deadline for ICD-10 compliance by one year, to October 1, 2014.

CMS has developed an education and communication campaign to support the adoption of and transition to Version 5010 and ICD-10. Initiated in 2009, the education and communication activities are targeted toward the millions of professionals across the health care industry who must take steps to prepare for the implementation of the new codes and transaction standards. The stakeholders in the ICD-10/Version 5010 transition are a large and diverse group encompassing all segments of the health care industry including, but not limited to, health care providers, commercial and Government health plans, and software vendors and clearinghouses. The challenge is to 1) help the health care industry understand the value of the transition to ICD-10 code sets, 2) encourage stakeholders to keep moving forward with transition efforts even as the deadline potentially shifts, and 3) lead them to the tools and resources they need to integrate the code sets and achieve timely compliance. Meeting this challenge will require additional information from the various affected entities to determine what education is needed and what types of communication techniques will be most effective.

CMS is requesting Office of Management and Budget (OMB) approval to conduct survey research to monitor the health care industry's preparation for the transition to ICD-10. This proposed data collection focuses specifically on ICD-10, as CMS education and communications outreach for Version 5010 is expected to end in summer 2012. The aggregated data obtained through the survey will help inform CMS outreach and education efforts to help affected entities (health care providers, health plans, clearinghouses, and their vendors) meet interim milestones and achieve timely compliance so that they can continue to process HIPAA transactions and provide patient care without interruption.

## A.2. Purpose and Use of Information Collection

Findings from the ICD-10 industry readiness assessment will be used by CMS to understand each sector's progress toward compliance and to determine what communication and educational efforts can best help affected entities obtain the tools and resources they need to achieve timely compliance with ICD-10. Insights gleaned from the proposed research will be valid for education and outreach purposes only, and will not be used for policy purposes.

## A.3. Use of Improved Technology and Burden Reduction

Data collection for the readiness assessment of payers, providers, and vendors will use a web-based self-administered survey. Because use of computers and the Internet is widespread among managers charged with overseeing their organizations' transitions to new ICD-10, we believe this method of data collection will be the most comfortable and least burdensome for respondents.

In addition, web-based data collection will provide the highest quality data while minimizing the costs and time for data collection, processing, and analysis. Compared to self-administered paper-and-pencil surveys, web-based surveys improve data quality in two ways: the instrument can be programmed to provide prompts for valid responses, and respondent-entered data eliminates errors that can occur when responses collected via paper-and-pencil are entered into an electronic data file for analysis. Web-based survey administration also minimizes the time necessary for data collection and cleaning.

### A.4. Efforts to Identify Duplication and Use of Similar Information

The proposed information collection activity does not duplicate any other effort and will provide unique information unavailable from any other source. Through a data collection conducted in 2011 under OMB Approval No. 0938-1149, CMS garnered valuable insights via an online survey of stakeholders affected by the Version 5010 and ICD-10 transitions. These insights guided outreach and led to development of specific messages and tactics for small clinical practices, for example. Now that the ICD-10 deadline is potentially changing, feedback from industry indicates that many organizations are putting their transition efforts on hold, meaning that responses to the 2011 survey about preparedness and projected timing for reaching specific ICD-10 milestones no longer apply. New data collection efforts—with instruments that account for the likely extension of the ICD-10 deadline, as well as the passing of the Version 5010 deadline—are required in order to guide CMS outreach and education planning.

## A.5. Impact on Small Businesses or Other Small Entities

Survey respondents will be employed by a mix of small and large businesses. Many health care providers (hospitals and practitioners) can be considered small businesses because they are either nonprofits or meet the Small Business Association's size standard for small businesses. Most pharmacy benefits managers and clearinghouses are not small businesses; health plans are a mix of large and small businesses, as are software vendors.

The survey instrument and procedures for completing the instrument are designed to minimize burden on all respondents and will not have a significant impact on small businesses or other small entities.

## A.6. Consequences of Collecting the Information Less Frequently

This is the only data collection that will gather input from a substantial sample of payers, providers, and vendors on their readiness to implement ICD-10 codes. Because the ICD-10 transition requires extensive preparation and planning for HIPAA-covered entities, CMS is requesting approval to conduct the data collection twice annually in 2013 and twice annually in 2014. CMS is submitting two variations of the readiness assessment questionnaire – one version to be used in advance of the compliance deadline, and one version to be used after the deadline has passed. The data collection to be conducted after the compliance deadline is intended to guide CMS in providing intensive education and outreach to noncompliant entities. Conducting the data collection less frequently would compromise CMS's ability to provide timely education and support to affected entities so they can achieve compliance with federal regulations.

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

There are no special circumstances related to the proposed data collection.

## A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Appendix B contains the 60-day notice which appeared in the Federal Register on August 10, 2012, (Volume 77, Number 155, p. 47852), soliciting comments on the requested data collection activity. [XX] public comments were received in response to that notice.

As part of questionnaire development, the contractor reviewed qualitative research that had been conducted with health care providers, payers, and vendors responsible for implementing ICD-10 codes in their organizations.

## A.9. Explanation of Any Payment or Gift to Respondents

Survey participants will not be offered a financial incentive for taking the assessment.

## A.10. Assurance of Confidentiality Provided to Respondents

The contractor will take several steps to assure respondents that the information they provide will be kept private to the extent allowed by law and will be used for research purposes only. The questionnaire introductions (Appendices D-1 and D-2) inform respondents that data will be aggregated in reports, that no individual-level data will be reported, and that their participation in the study is voluntary. Survey data will be collected and stored on the survey vendor's servers in accordance with the company's information security policy, which ensures the confidentiality, integrity, and availability of all data and information owned, managed by, or

supplied by clients to the survey vendor, and the Information Security Management System (ISMS) that implements the policy. The vendor's ISMS has received ISO 27001 certification and is maintained and continuously improved by means of internal audits, corrective and correction actions, learning from experiences of security issues, and advising all those involved of every improvement.

In accordance with the survey vendor's policies, identities of respondents will not be available at any time to CMS or the prime contractor.

## A.11. Justification for Sensitive Questions

The questionnaires do not contain any sensitive items. It is possible that some respondents may be concerned that truthful answers may indicate to CMS they are behind schedule and unlikely to meet the ICD-10 compliance date. Introductory emails and text on the questionnaires will assure respondents that information is confidential and responses will be examined only in aggregate.

## A. 12. Estimates of Annualized Burden Hours and Costs

Table A.1 presents estimates of annualized burden hours for completing the survey among payers, providers, and vendors. It shows the type and expected number of respondents, frequency of response, the hours per response, and the total burden hours for the data collected in each year. The questionnaires are expected to take 10 minutes to complete. We anticipate the survey will be conducted twice in 2013 and twice in 2014, with 204 annual burden hours.

The respondent mix for each fielding will be 400 providers, 100 payers, and 100 vendors. Anticipated fielding dates are outlined in Section A.16, Project Time Schedule.

**Table A.1. Estimated Annualized Burden Hours for the ICD-10 Readiness Assessment**

| Forms | Type of Respondent | Number of Respondents | Numbers of Responses per Respondent | Average Burden Hours per Response | Total Burden Hours |
|---|---|---|---|---|---|
| Self-administered questionnaire | Payers | 200 | 1 | .17 | 34 |
| Self-administered questionnaire | Providers | 800 | 1 | .17 | 136 |
| Self-administered questionnaire | Vendors | 200 | 1 | .17 | 34 |
| Total | | | | | 204 |

Table A.2 presents estimates of the cost burden for completing the ICD-10 readiness survey. It shows the type of respondents, the annualized burden hours, the estimated wage rate, and the total respondent costs for the data collected. The cost per questionnaire is $8.01, computed using an average hourly wage rate of $47.09 ($47.09 * 0.17 = $8.01 per response)[1].

**Table A.2. Estimated Annualized Burden Costs**

| Type of Respondent | Annual Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Payers – directors or higher at health insurance companies, managed care organizations, and pharmacy benefits managers | 34 | $47.09 | $1,601.06 |
| Providers – hospital and | 136 | $47.09 | $6,404.24 |

[1] The median hourly wage rate for medical and health services managers according to the Bureau of Labor Statistics' *May 2011 National Occupational Employment and Wage Estimates* is $46.17 [http://www.bls.gov/oes/current/oes_nat.htm]. The estimated wage calculation for burden estimates includes a 2 percent inflation rate: $46.17 * 1.02 = $47.09.

| | | | |
|---|---|---|---|
| pharmacy chain administrators, health care practice managers | | | |
| Vendors – managers at health IT system developers, billing services and clearing houses | 34 | $47.09 | $1,601.06 |
| Total | | | $9,606.36 |

## A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate in the study.

## A.14. Annualized Cost to the Federal Government

The total annualized cost of the surveys of payers, providers, and vendors about their ICD-10 readiness is $268,500.00. The estimate is based on the contractor's costs for collecting and tabulating survey data, including labor and other direct costs for computer, telephone, postage, reproduction, and survey facilities; and indirect costs for fringe benefits, general and administrative costs, and fees. The estimate also includes federal government oversight.

## A.15. Explanation for Program Changes or Adjustments

This is a revision to an approved data collection.

The survey instrument (Appendix D-1) is based on a previously approved instrument used under OMB Approval No. 0938-1149 as described in Section A.4. The originally approved instrument included questions about Version 5010 that are no longer relevant and thus have been deleted. The originally approved instrument was also based on an October 1, 2013, transition date, which HHS extended to October 1, 2014, in a final rule published on September

5, 2012, as described in Section A.1 above. The revised survey has been revised to account for the new deadline and to add text that clarifies three questions. A second survey instrument (Appendix D-2) is also based on the previously approved instrument, but is further modified for the final data collection, to occur after the ICD-10 compliance deadline. Text in the second survey is reworded to account for the fact that respondents should already be ICD-10-compliant by the fielding date.

## A.16. Plans for Tabulation and Publication and Project Time Schedule

The data will be analyzed using descriptive statistics and cross-tabulations to allow examination of progress by sector. Statistical comparisons among sectors will not be made and no weighting will be used.

Reports will include all necessary background information on the objectives, scope, and methodology of the project.

Table A.3 shows the timeline for the data collection and delivery of results for the survey.

**Table A.3. Project Timetable**

| **Task Name** | **Week** |
|---|---|
| *First Fielding: February 2013* | |
| Program the survey for fielding | 1 |
| Begin fielding first wave of survey | 2 |
| End data collection | 7 |
| Produce tabulations | 8 |
| Analyze data | 9 |
| Prepare report and present results | 10 |

We anticipate fielding the readiness assessment survey again in August 2013, February 2014, and October 2014 according to the timetable outlined above.

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

The OMB expiration date will be displayed on the self-administered questionnaires.

## A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

# B. Collection of Information Employing Statistical Methods

## B.1. Respondent Universe and Sampling Methods

### B.1.a. Respondent Universe

The respondent universe includes individuals at health care payers (health insurance companies, managed care organizations, and pharmacy benefits providers), health care providers (hospitals and large and small physician practices for this study), and vendors (health IT developers, clearinghouses, and third-party billers) who are responsible for managing the planning and implementation of their organization's ICD-10 transition. The total universe is unknown; estimates of the larger universes containing individuals responsible for planning and implementation of ICD-10 transitions are shown in Table B.1.

**Table B.1: Estimated Universe and Sample Sizes**

| Population | Size | Sample size |
|---|---|---|
| Providers | 4,000,000 | 400 |
| Payers | 57,000 | 100 |
| Vendors (HIT developers, clearinghouses, third-party billers) | 6,900 | 100 |

**B.1.b. Sampling Methods**

To ensure that information is obtained from all sectors needing to address the ICD-10 transition, the sample will be stratified based on the role of the respondent's organization: health care payer, health care provider, or vendors to payers or providers. The goal for each fielding is to obtain 400 completed surveys with representatives of health care providers (the largest and most diverse group) and 100 each with payers and vendors.

All samples will be convenience samples from established panels that have been constructed using association, state licensing, and publication data on the populations of interest. It would be cost-prohibitive to construct probability samples of such low-incidence populations. Every nth eligible panel member will be selected to achieve desired sample sizes. Given that the purpose of the survey is for directional guidance in education and communication efforts, we believe a convenience sample is appropriate.

More information about the panels to be used for this project is as follows:

- This project will utilize multi-mode health care panels. The Ipsos Healthcare Professional panel is comprised of hard-to-reach targets (such as hospital executives and administrators, nurses, and pharmacists), and includes more than 250 subspecialties. Individuals can be reached via different approaches, such as email, fax, direct mail, and phone. By using a multi-mode approach for this project, we combine postal mail and email to recruit the right individuals to participate in this research.
- The panels that will be used have purchased and licensed key association and governmental databases that verify essentials like a physician's practicing status. These verification resources include DEA number and AMA ME number to help to ensure validity.

- Recruitment to these panels is also done by a range of techniques: email invitation, affiliate networks, online recruitment, router assignment, and others. We use Captcha software to eliminate automatic registration (bots) of surveys, and also check for suspicious IP addresses to prevent them from joining the panels.
- Ipsos panel management protocols include a series of legitimacy checks as well, including name/address matching using external databases, digital fingerprinting, and TrueSample. Ipsos utilizes inbuilt criteria such as the exclusion of individuals who repeatedly fail to respond to survey invitations, as well as those who exhibit undesirable survey behavior (e.g., inconsistent response, straight-lining, speeding through).

More information about likely sources of samples per audience segment is described as follows:

- The majority or all completes for group 1 (provider community) will likely come from the Ipsos online e-mail panel
- The majority or all completes for group 2 (payer community) to come from direct mail-to-web
- The majority or all completes for group 3 (HIT developers, clearinghouses, and third-party billers) to come from direct mail-to-web

### B.2. Procedures for the Collection of Information

Upon OMB approval, the survey instrument will be programmed into the survey vendor's web hosting servers. The survey vendor, Ipsos, a leading market research firm, and contractor staff will then review the online version for accuracy and test it to ensure all skip patterns function as intended, items permit all valid responses and exclude invalid ones, items intended to accept multiple responses do so, etc.

The survey vendor will then commence data collection by sending mail and email invitations to sample members. The mail samples will be sent survey invitations via traditional mail that ask potential respondents to go to the specific website and enter a code to complete the survey. Email samples will be emailed a survey invitation containing a link to the survey. (See Appendix C.)

The in-panel survey completion rates for projects of this type range from 60%-80%, depending to some extent on the particular subpopulation groups being included in the survey as well as the incentive structure and reminder mechanisms. While this rate cannot be guaranteed, we are aiming for approximately 80%.

The survey vendor will track responses on a daily basis and provide the contractor and CMS with periodic updates. Up to two follow-up emails will be sent; the first, approximately five days after the initial invitation is emailed; the second, approximately five days after that. No follow-up mailings will be sent to sample members initially contacted by postal mail, as the fieldwork period is fairly short. There is not sufficient time to send out a postal reminder without essentially sending it a day or two after the first invitation, which some potential participants would view negatively as overly aggressive.

### B.3. Methods to Maximize Response Rates and Deal with Nonresponse

As this is a convenience sample, there is no response rate for this research. Instead, we will provide a participation rate, per recommendations from the American Association for Public Opinion Research (AAPOR) Task Force (2010) and ISO 26362 (2009). Regardless of this, a number of methods of maximizing response will be employed in line with industry standards of

best practice. The email and mail invitations to participate in the survey, the introductory survey language, and the survey itself are designed to facilitate rapid understanding and promote compliance with and completion of the survey. The survey vendor utilizes best practices derived from mail and online surveys in its approach to initial contacts and all follow-on email reminders. The importance of the survey and the reasons each individual should participate will be emphasized in all contacts with sample members; the body of research around response has demonstrated that respondent understanding of the reasons for and importance of a survey are important factors in their likelihood of completing the survey.

The estimated time involved to complete the survey is stated in the invitation so that respondents will realize that it will take only a small amount of time. Invitations also succinctly describe procedures for maintaining the privacy of respondents (i.e., identities of individuals will not be released, identifying information will be stored separately from the survey responses, and all information collected will be analyzed in the aggregate). Reminders for survey completion will be sent only to those who have not completed it and will be worded in such a way that potential participants do not feel pressured.

Consistent with the calculations approved by AAPOR, participation rates for this study will be calculated as: “the number of respondents who have provided a usable response divided by the total number of initial personal invitations requesting participation” (per AAPOR guidelines on Non-Probability Internet Panels).

## B.4. Tests of Procedures or Methods to be Undertaken

The sampling and data collection procedures are used on an ongoing basis by the survey vendor and are refined and improved as needed. The survey questionnaire previously fielded in 2011 under OMB Approval No. 0938-1149 was pretested by several trade associations that represent the three audiences (providers, vendors, and payers). The organizations fielded the questionnaire among their members during a March-April 2011 time frame. No fielding difficulties were reported then or when the approved survey was fielded in November-December 2011. The information obtained through the readiness assessment survey fielded in November-December 2011 has been valuable in informing CMS outreach and education efforts.

## B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CMS's contractor, Ketchum, will contract with Ipsos to conduct the sampling, data collection and analysis for this study. Ipsos' efforts will be overseen by Dr. Clifford Young, Managing Director, Public Sector, Ipsos Public Affairs, USA. Dr. Young is a survey statistician and methodologist, trained in statistics and survey methods (MA and PhD) at the University of Chicago, and in survey sampling at the University of Michigan. He is expert in sampling and methodological design, and has led on more than 30 full samples and worked as lead survey methodologist on more than 50. Ipsos's Meghann Jones, Senior Research Manager, and Neale El-Dash, Director, will also lead this project. Ketchum's Christina Nicols, Vice President and Director of Research, will prepare a report of findings based on Ipsos data tables. Several Ipsos staff members with appropriate training are also available as needed to program

the questionnaire, perform statistical programming, prepare tables and summary statistics for reports, and assist in interpretation of the results of the quantitative analysis.

Rosali Topper, Health Insurance Specialist, of CMS will serve as the Technical Monitor and the federal agency personnel responsible for receiving and approving all contract deliverables. Ms. Topper's phone number is (410) 786-7260.