Version 5010/ICD-10 Industry Readiness Assessment

Request for OMB Review

Supporting Statement

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A. Justification

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 electronic transmission of health information. Specifically, HIPAA requires the Secretary of HHS to adopt transaction standards that covered entities are required to use in electronically 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 adopting by regulation sets of standards for HIPAA transactions (Appendix A): ICD-10 standards for coding diagnoses and inpatient hospital procedures and Version 5010/D.0 standards for eight types of electronic health care transactions (claims, eligibility inquiries, remittance advices, etc.). 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 Center for Medicaid & Medicare 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. HIPAA transactions not meeting the standards by those dates will be not compliant and rejected. The final rules also outlined interim milestones that organizations should meet in order to achieve compliance by the required dates. For Version 5010/D.0, these interim milestones include completing internal testing and being able to send and receive compliant transactions by December 2010, commencing external testing with trading partners by January 2011, and completing that testing and moving into production by the compliance date of January 1, 2012. Entities cannot implement ICD-10 standards until they are in compliance with

Version 5010/D.0; the interim milestone for ICD-10 is to begin compliance activities (gap analysis, design, development, internal testing) by January 2011.

CMS has developed an education and communication campaign to support the adoption of and transition to Version 5010/D.0 and ICD-10. The education and communication activities will be targeted towards the millions of professionals across the healthcare industry who must take steps to prepare for the implementation of the new codes and transaction standards. The stakeholders in Version 5010/D.0 and ICD-10 implementation 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 help the health care industry understand the value of the transition to ICD-10 code sets and Version 5010 transactions and 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 awareness of, and preparation for, the transition to Version 5010 and ICD-10. The proposed data collection focuses specifically on Version 5010 and ICD-10, and not on D.0. 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 then vendors who service them) meet interim milestones and achieve timely compliance so that they can continue to process HIPAA transactions without interruption.

2. Purpose and Use of Information Collection

Findings from "Version 5010/ICD-10 Industry Readiness Assessment" will be used by CMS to understand each sector's progress toward compliance with each set of standards and to determine what

communication and educational efforts can best help affected entities obtain the tools and resources they need to integrate the code sets into their electronic transaction processing and achieve timely compliance with Version 5010 and ICD-10. Insights gleaned from the proposed research will be valid for education and outreach purposes only, and will not be used for other policy-related purposes.

3. Use of Improved Technology and Burden Reduction

Data collection for the surveys of payers, providers and vendors will use a web-based self-administered survey. Because use of computers and the Internet is likely to be universal among managers charged with overseeing their organizations' transitions to new electronic transaction standards, 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 collections and cleaning.

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.

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 most are either non-profits 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.

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 Version 5010 and ICD-10 codes and standards. The data collection is planned for summer 2011; not conducting the data collection would compromise CMS's ability to provide a maximum amount of education and support to affected entities so that they can achieve timely compliance with federal regulations.

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

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

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 March 3, 2011, (76 FR 13415), soliciting comments on the requested data collection activity. As part of questionnaire

development, the contractor reviewed qualitative research that had been conducted with health care providers, payers, and vendors responsible for implementing Version 5010 and ICD-10 transaction processing in their organizations.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

The contractor will take several steps to ensure 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 introduction (Appendix D) will 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 sub-contractor'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.

11. Justification for Sensitive Questions

The questionnaire does 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 compliance dates. Introductory emails and the questionnaire itself will assure respondents that information is confidential and responses will be examined only in aggregate.

12. Estimates of Annualized Burden Hours and Costs

Table A.2 presents estimates of burden hours for completing the survey of Version 5010 and ICD-10 readiness 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. The questionnaire is expected to take 15 minutes to complete.

Table A.2 Estimated Annualized Burden Hours

Forms	Type of Respondent	Number of Respondents	Numbers of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Self-administered questionnaire	Payers	100	1	.25	25
Self-administered questionnaire	Providers	400	1	.25	100
Self-administered questionnaire	Vendors	100	1	.25	25
Total					150

Table A.3 presents estimates of the cost burden for completing the Version 5010 and ICD-10 readiness survey. It shows the type of respondents, the total burden hours, the estimated wage rate, and the total respondent costs for the data collected. The cost per questionnaire was computed using

an average hourly wage rate of $45.44 ($45.44*0.25 = $11.36) [1] per response. Data collection for this study will be conducted over a six-week period in the summer of 2011.

Table A.3 Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Payers – directors or higher at health insurance companies, managed care organizations, and pharmacy benefits managers	25	$45.44	$1,136
Providers – hospital and pharmacy chain administrators, health care practice managers	100	$45.44	$4,544
Vendors – managers at health IT system developers, billing services and clearing houses	25	$45.44	$1,136
Total			$6,816

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.

14. Annualized Cost to the Federal Government

The total value for the surveys of payers, providers and vendors regarding their 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

[1] The median hourly wage rate for general and operations managers according to the Bureau of Labor Statistics' *May 2009 National Occupational Employment and Wage Estimates* is $44.55 [http://www.bls.gov/oes/current/oes_nat.htm#(5)]. The estimated wage calculation for burden estimates includes a 2 percent inflation rate: $44.55 * 1.02 = $45.44.

facilities; and indirect costs for fringe benefits, general and administrative costs, and fees. The estimate also includes federal government oversight.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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

Table A.4 shows the timeline for the data collection and delivery of results for the survey.

Table A.4: Project Timetable

Task Name	Weeks After OMB Approval
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

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

The OMB expiration date will be displayed on the self-administered questionnaire (Appendix D).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.