Supporting Statement for Electronic Transactions and Supporting Regulations in 45 CFR Part 162

A. Background

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3306 (c)(2) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automation collection techniques.

Therefore we solicited public comments on each of these issues for the information collection requirements discussed below.
The information collection requirements and associated burdens in 162.1002, 162.1202, 162.1302, 162.1402, 162.1502, 162.1602, 162.1702, 162.1802 and 162.1902 are subject to the PRA. The burden for these standards is addressed under OMB approval number 0938-0866.

We are submitting a copy of this PRA Package to the regulations sections to OMB for its review of the request for a one year extension to the expiration date.

This submission contains the approved information collection requirements in CMS-0009-F and CMS-0013-F. The purpose of this collection review is to extend the original PRA Package expiration date for one year. The use of these standards will improve the Medicare and Medicaid programs and other Federal health programs as well as private health programs, and the effectiveness and efficiency of the health care industry in general, by simplifying the administration of the system and fostering and increase in EDI for exchanging healthcare information.

Relationship of the ICD-10 codes to Version 5010.

Version 5010 supports the use of the ICD-10 code set by making available a qualifier to indicate that an ICD-10 code is being reported. Like ICD-9, ICD-10 codes are reported in claim and payment transactions, as well as eligibility

inquiries and responses and requests for referrals and authorizations. In Version 5010, the number of codes required in any given transaction does not change. It is possible that a fewer number of codes in a given transaction may be necessary to report the same information reported with ICD-9 codes because ICD-10 codes are more specific.

For implementation of ICD-10, we anticipate a decrease in productivity for approximately six months or less during transition. Such decreases in productivity may be mitigated because the guidelines and instructions for use of the codes that accompany ICD-10 have also been adopted.

ICD-9-CM Coordination and Maintenance Committee

The ICD-9-CM/PCS Coordination and Maintenance Committee1 was created in 1985 as an open forum for proposals to update ICD-9-CM. Responsibility for maintenance of the ICD-9 code set is divided between the National Center for Health Statistics (NCHS) for classification of diagnoses (Vol. 1 and 2), and by the Centers for Medicare & Medicaid Services (CMS) for procedures (Vol. 3), with both agencies co-chairing the Committee meetings.

The ICD-9-CM Coordination and Maintenance Committee accepts suggestions for modifications from both the public and private sectors. Interested parties may submit recommendations for modifications, including a description of the code(s) being requested, and rationale for why it is needed, prior to a scheduled meeting.

These meetings are open to the public; comments are encouraged both at the Committee meetings and in writing. No decisions are made at the meetings; proposals are considered, and final decisions are made by the Director of NCHS and the Administrator of CMS. Final decisions made after the fall meeting generally become effective October 1 of the following year.

Increased advances in technology and improvements in healthcare business processes have fostered development of EDI standards to facilitate efficient and effective flow of administrative operations. Adopting the 5010 versions of the standards and the required code sets, as well as the standard for Medicaid subrogation greatly improves EDI standardization for healthcare transactions.

B. Justification

1 The Committee will be renamed the ICD-10-CM/PCS Coordination and Maintenance Committee with the implementation of the ICD-10-CM and ICD-10-PCS code sets.

1. Need and Legal Basis

The Congress, recognizing the need to simplify the administration of health care transactions, enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, on August 21, 1996. Title II, Subtitle F of this legislation directs the Secretary of the Department of Health and Human Services to develop unique standards for specified electronic transactions and code sets for those transactions. It also authorizes the Secretary to update existing standards and adopt new standards. The purpose of this Subtitle is to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care industry in general through the establishment of standards and requirements to facilitate the electronic transmission of certain health information.

Subtitle F defines various terms and imposes several requirements on health plans, health care clearinghouses, and certain health care providers concerning the electronic transmission of health information. This Subtitle also requires that the Secretary adopt standards for financial and administrative transactions, and data elements for those transactions to enable health information to be exchanged electronically. The following transactions are covered:

a. health claims or equivalent health encounter information,

b. health plan enrollments and disenrollments,

c. health plan eligibility,

d. health care payment and remittance advice,

e. health plan premium payments,

f. health claim status

g. referral certification and authorization

h. coordination of benefits.

i. health care claims attachments

j. first report of injury

k. Medicaid subrogation for retail pharmacy claims

The Standards for Electronic Transactions final rule (Transactions Rule)

published August 17, 2000, adopted standards for these electronic transactions (with the exception of (l) and (j) which will be proposed at a later date). Subsequent to the Transactions Rule, CMS-0003-P and CMS-0005-P proposed modifications to the adopted standards essential to permit initial implementation of the standards throughout the entire healthcare industry; CMS-0003/0005-F added revisions to two standards (at 45 CFR 162.170 and 162.1802) that were left out of the proposed rule.

In 1999, representatives from CMS and Medicaid agencies began working closely with the National Council for Prescription Drug Programs (NCPDP) to develop a standard electronic format that could be used to facilitate the electronic transmission of pharmacy subrogation claims from Medicaid agencies to other payers. Due to the lack of standardization and the number of different formats in use, CMS-0009-F adopted a standard transaction for the Medicaid subrogation of retail pharmacy claims.

2. Information Users

Health plans, health care clearinghouses, and health care providers who choose to conduct transactions electronically, must use these standards for the electronic exchange of medical, billing, and other information within the health care system in an efficient and cost effective manner. The information is used to submit health claims or equivalent health encounter information; carry out health plan enrollments and disenrollments; determine health plan eligibility; send and receive health care payment and remittance advices; transmit health plan premium payments; determine health claim status; provide referral certifications and authorizations; and coordinate the benefits for individuals who have more than one health plan. Medicaid agencies and other health plans use and benefit from the adoption of the Medicaid subrogation transaction for retail pharmacy claims. Its use reduces administrative costs by eliminating multiple formats and methods of performing retail pharmacy subrogation, and facilitates electronic data interchange (EDI).

3. Improved Information Technology

The transaction standards specified in Subtitle F apply exclusively to electronic transactions. The benefits of the electronic transfer of this information are a substantial reduction in handling and processing time, the elimination of the inefficiencies associated with the handling of paper documents, a reduction in administrative burden, lower operating costs, and improved data quality and standardization.

4. Duplication of Similar Information

These standards replace through standardization, rather than duplicate, existing

electronic formats for these transactions. The standards replace paper formats and older versions of the standards to the extent that providers who are now using paper transactions and prior versions elect to begin transmitting their information electronically..

5. Small Businesses

Small businesses are not significantly affected by this collection.

The information that is collected is used to carry out administrative and financial health transactions. To the extent that information on claims status, enrollment, eligibility, etc. are not provided as required and in an acceptable format, the payment of health care claims cannot be made efficiently and timely.

7. Special Circumstances

There are no applicable special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day FR notice published on
In the course of the development of the transaction standards, exhaustive consultations took place with a number of outside organizations, including those with whom consultation is required by Subtitle F. These include the National Uniform Billing Committee, the National Uniform Claim Committee, the Workgroup for Electronic Data Interchange, the American Dental Association, the National Council for Prescription Drug Programs, and the National Committee on Vital and Health Statistics. We have obtained endorsement for the adopted applicable transaction standards from each of these organizations.

9. Payment/Gift To Respondent

There will be no payments/gifts to respondents.

10. Confidentiality

Individual identifiable information is collected and transmitted in the conduct of the electronic standard transaction standards adopted by the Secretary.

Section 1177 of Subtitle F provides severe penalties for the wrongful disclosure of individually identifiable health information. These include fines of not more than $50,000 and imprisonment for not more than 1 year; $100,000 and 5 years, if the offense is committed under false pretenses; and $250,000 and 10 years, if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or

malicious harm.

11. Sensitive Questions

No information is collected on sexual behavior and attitudes, religious beliefs, and other matters commonly considered private.

12. Burden Estimate (Total Hours & Wages)

Discussion: The emerging and increasing use of health care EDI standards and transactions has raised a question of the applicability of the PRA. This regulatory requirement (which mandates that the private sector disclose information and do so in a particular format) does constitute an agency sponsored third-party disclosure as defined under the Paperwork Reduction Act of 1995 (PRA).

HIPAA mandates the Secretary to adopt standards that have been developed, adopted, or modified by a standard setting organization, unless there is no such standard, or unless a different standard would substantially reduce administrative costs. The scope of the PRA is limited to the review and approval of this regulatory requirement, that is, the Secretary's decision to adopt or reject an established industry standard, based on the HIPAA criterion of whether a different standard would substantially reduce administrative costs.

The burden associated with these requirements, which is subject to the PRA, is the initial one-time implementation burden spread over a period of three years for certain health care providers, health plans and clearinghouses to modify their current computer system requirements. Even though implementation of the Version 5010 standards represents an upgrade from the previously adopted Version 4010/4010A, we determined that there is no burden beyond that associated with the routine or ongoing use of these standards.

The one-time burden referenced above is an estimate of 25% to 50% of the original cost to implement Version 4010/4010A of the standards. For 4,786 health plans/sponsors, 5,764 hospitals, 427,430 physician practices (includes dentists and pharmacists) and 162 clearinghouses (includes Practice Management Vendors, Hospital Information System Vendors, Claims Related Transaction Vendors and Clearinghouses) for a total of 438,142 entities. The average estimated burden per health plan is $1,006,686 for the three year implementation period. This equals the equivalent of 8.5 FTEs for the three year implementation period at an average salary of $50 per hour and a total of 53,751 hours. The total estimated burden per hospital is $202,116 for the three year implementation period. This equals the equivalent of 4 full-time employees (FTEs) for the three year period at an average salary of $50 per hour and a total of 25,224 hours. The average estimated burden per provider practice is

$2,344 for the three year implementation period. This equals the equivalent of less than one FTE for the three year implementation period at an average salary of $50 per hour and a total of 293 hours. It should be noted that the estimated costs for provider practices is small by comparison with other entities because the total number of entities used in the calculations includes dentists and pharmacies and is significantly higher than the total number for other entities. Also we determined that a significant portion of provider costs will be borne by their vendors. The average estimated burden per clearinghouse is $993,827 for the three year implementation period. This equals the equivalent of 17 FTEs for the three year implementation period at an average salary of $50 per hour and a total of 105,541 hours.

Cost estimates for the clearinghouse segment include practice management vendors, claims vendors, hospital information system vendors, as well as clearinghouses. The cost estimates for hospitals include nursing homes, home health companies, and mental health and substance abuse facilities. Cost estimates for health plans/payers include government plans.

Calculations for these burdens are derived from a combination of industry surveys and the historical costs for implementing Version 4010/4010A of the HIPAA implementation guides. Since the costs vary by the size of the provider practice, hospital and health plan, and whether implementation of the standards is conducted internally or outsourced to vendors or clearinghouses, average costs were calculated to determine an estimated total burden for these types of entities. Total costs are based on a three year implementation period and include the following estimated total costs:

- Providers/Hospitals- $2.167 million
- Health plans- $2.061 million
- Clearinghouses- $137 million

The total estimated costs for of the estimated 438,142 covered entities for the three year implementation period is $4.365 million.

The costs associated with this burden are based on the most current industry information that could reasonably be obtained. They represent estimates compiled in a report on research conducted by The Gartner Group in 2007 and 2008.

The one-time burden associated with the requirement to adopt a standard for Medicaid Pharmacy Subrogation is estimated to range between $50,000 to $150,000 for State plans at 10% for State responsibility and 90% Federal government.

13. <u>Capital Costs (Maintenance of Capital Costs)</u>

The one-time start-up costs reported in B. 12 above are not considered because the implementation date for the adopted electronic transaction standards was January 1, 2012. Since the burden associated with the routine or ongoing use of these requirements is exempt from the PRA, there are no ongoing operational or maintenance costs associated with this collection.

14. Cost to Federal Government

The one-time costs reported in B. 12 above included the costs to the Federal government, but are not considered because the implementation date for the adopted electronic standards was January 1, 2012. Since the burden associated with the routine or ongoing use of these requirements is exempt from the PRA, there are no ongoing costs to the Federal government.

15. Program Changes

The burden associated with this collection is increasing due to new requirements and the additional burden associated with updating compliance with the existing requirements.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

We are not seeking this exception.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

This section is not applicable.

Copy of the Statute Requiring the Collection

P.L. 104-191, Title II, Subtitle F

Section 1173 (a) STANDARD TO ENABLE ELECTRONIC EXCHANGE

(1) IN GENERAL - The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for -

(A) the financial and administrative transactions described in paragraph (2); and

(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

(2) TRANSACTIONS - The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

(A) Health claims or equivalent encounter information

(B) Health claims attachments

(C) Enrollment and disenrollment in a health plan

(D) Eligibility for a health plan

(E) Health care payment and remittance advice

(F) Health plan premium payments

(G) First report of injury

(H) Health claim status

(I) Referral certification and authorization

Section 1173 (f) TRANSFER OF INFORMATION AMONG HEALTH PLANS - The Secretary shall adopt standards for transferring among health plans appropriate standard data elements needed for the coordination of benefits, the sequential processing of claims, and other data elements for individuals who have more than one health plan.