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

A. Background

This submission contains information collection requirements in HCFA-0149-F, CMS-0003-P, CMS-0005-P, and CMS-0003/0005-F. The purpose of this collection is to establish standards for electronic transactions and for code sets to be used in those transactions. The use of these standard transactions and code sets would improve the Medicare and Medicaid programs and other Federal health programs and private health programs, and the effectiveness and efficiency of the health care industry in general, by simplifying the administration of the system and enabling the efficient electronic transmission of certain health information.

There were about 400 formats for electronic healthcare claims in use in the United States. This lack of standardization made it difficult to exchange data efficiently and reduced the efficiencies and savings for health care providers and health plans that could be realized if transaction formats were standardized. Adopting national standard electronic data interchange formats for health care transactions would greatly decrease the burden on health care providers and their billing services, as would standardized data content.

B. Justification

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. 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 claims attachments

j. first report of injury

The Standards for Electronic Transactions final rule (Transactions Rule) published August 17, 2000 adopted standards for these electronic transactions (with the exception of (I) and (j), which will be published 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.

2. Information Users

Health plans, health care clearinghouses, and health care providers who choose to conduct transactions electronically, will use these standards for the electronic exchange of medical, billing, and other information within the health care system in a fast and cost effective manner. The information will be 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.

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.

4. Duplication of Similar Information

These standards will replace through standardization, rather than duplicate, existing electronic formats for these transactions. The standards will replace paper formats to the extent that providers who are now using paper transactions elect to begin transmitting their information electronically.

5. Small Businesses

Small businesses are not significantly affected by this collection.

6. Less Frequent 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 timely.

7. Special Circumstances

There are no applicable special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day FR notice published on December 14, 2007.

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 proposed applicable transaction standards from each of these organizations.

9. Payment/Gift To Respondent

There will be no payments/gifts to respondents.

10. Confidentiality

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 will be collected on sexual behavior and attitudes, religious beliefs, and other matters commonly considered private.

12. Burden Estimate (Total Hours & Wages)

Discussion: As referenced in the proposed rule, the emerging and increasing use of health care EDI standards and transactions has raised a question of the applicability of the PRA. While public comments suggested that the use of an EDI standard might not be an information collection under the PRA, the Office of Management and Budget concluded that 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. OMB has concluded that the scope of its review under the PRA would be 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. For example, if OMB concluded under the PRA that a different standard would substantially reduce administrative costs as compared to an established industry standard, the Secretary would be required to reconsider its decision under the HIPAA standards. The Secretary would be required to make a new determination of whether it is appropriate to adopt an established industry standard or whether it should enter into negotiated rulemaking to develop an alternative standard (section 1172(c)(2)(A)).

The burden associated with these requirements, which is subject to the PRA, is the initial one-time burden on the entities identified above to modify their current computer system requirements (see below). However, the burden associated with the routine or ongoing use of these requirements is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

The one-time burden referenced above was an estimate of 2.6 million health plans/sponsors and 800 thousand health care providers. The estimated burden is 10 hours at $300 per entity, for a total burden of 34 million hours and $1.02 billion in costs. These estimates were first published in the proposed rule. We received no comments on the burden estimates, and included them in the final rule without change.

The one-time burden associated with the requirements for proposed rules CMS-0003-P and CMS-0005-P and final rule CMS-0003/0005-F has been satisfied. Accordingly, we have only one token burden hour assigned to this information collection. The satisfaction of the burden was reflected in our regulation entitled: "Health Insurance Reform: Standards for Electronic Transactions" published in the Federal Register on August 17, 2000 (65 FR 50312).

13. Capital Costs (Maintenance of Capital Costs)

The one-time start-up costs are reported in B. 12. above. 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 include the costs to the Federal government. 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 one-time burden associated with this collection has already been satisfied and is reflected in the adjusted amount of total annual hours.

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.