Supporting Statement for CMS HCPCS Modification to Codeset Form

A. Background

Each year, in the United States, health care insurers process over 5 billion claims for payment. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential. The Healthcare Common Procedure Coding System (HCPCS) Level II Code Set is one of the standard code sets used for this purpose. Level II of the HCPCS, also referred to as alpha-numeric codes, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulatory services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used in the home or outpatient setting. Because Medicare and other insurers cover a variety of these services and supplies, Level II HCPCS codes were established for assignment by insurers to identify items on claims. HCPCS Level II classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. For each alpha-numeric HCPCS code, there is descriptive terminology that identifies a category of like items.

As technology evolves and new products are developed, there are continuous changes to the HCPCS codeset. Modifications to the HCPCS are initiated via application form submitted by any interested stakeholder. These applications have been received on an on-going basis with an annual deadline for each cycle. The purpose of the data provided is to educate the decision-making body about products and services for which a modification is requested so that an informed decision can be reached in response to the recommended coding action. Historically, use of Level II of the HCPCS began in the 1980's under the authority of the Alpha-Numeric HCPCS Editorial Panel (National Panel), a tripartite membership comprised of the Health Insurance Association of America, the Blue Cross and Blue Shield Association and the Health Care Financing Administration. Each member of the National Panel reviewed the applications, received input from their organizations, brought forth recommendations at panel meetings, and voted on a final decision. Modifications to the code set were only made if there was a unanimous agreement amongst all three voting members of the National Panel. However, in October 2003, the Secretary of Health and Human Services delegated CMS authority to maintain and distribute HCPCS Level II Codes. As a result, the National Panel was delineated and CMS continued with the decision-making process under its current structure, the CMS HCPCS Workgroup (herein referred to as "the Workgroup". CMS' HCPCS Workgroup is an internal workgroup comprised of representatives of the major components of CMS, Medicaid and private insurers, as well as other consultants from pertinent Federal agencies. Currently the application intake is paper-based. However, the process has grown and HCPCS staff is exploring electronic processes for the collection and storage of applications.

B. Justification

1. Need and Legal Basis

In October 2003, the Secretary of Health and Human Services (HHS) delegated authority under the Health Insurance Portability and Accountability Act (HIPAA) legislation to Centers for Medicare and Medicaid Services (CMS) to maintain and distribute HCPCS Level II Codes. As stated in 42 CFR Sec. 414.40 (a) CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes. The HCPCS codeset has been maintained and distributed via modifications of codes, modifiers and descriptions, as a direct result of data received from applicants. Thus, information collected in the application is significant to codeset maintenance. The HCPCS codeset maintenance is an ongoing process, as changes are implemented and updated annually; therefore, the process requires continual collection of information from applicants on an annual basis. As new technology evolves and new devices, drugs and supplies are introduced to the market, applicants submit applications to CMS requesting modifications to the HCPCS Level II codeset. Applications have been received prior to HIPAA implementation and must continue to be collected to ensure quality decision-making. The HIPAA of 1996 required CMS to adopt standards for coding systems that are used for reporting health care transactions. The regulation that CMS published on August 17, 2000 (45 CFR 162.10002) to implement the HIPAA requirement for standardized coding systems established the HCPCS Level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions. HCPCS Level II was selected as the standardized coding system because of its wide acceptance among both public and private insurers. Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002.

Prior to the delegation of authority of the HCPCS codeset maintenance to CMS, CMS' contracted with Jing Xing Technologies, Inc. (JXT) to review, analyze and recommend improvements in the HCPCS process. The report prepared by Jing Xing recommended revising the HCPCS process to be more open and transparent to industry stakeholders. In response to those recommendations, CMS' Council on Technological Innovation (CTI) has instituted a number of improvements to the HCPCS process to improve coding decisions, particularly for new technology, as well as provide for more transparency in decision-making. Specific process refinements include public notification of CMS' preliminary decisions, and a new opportunity to respond to CMS' preliminary decisions at a public meeting before a final decision is reached by the workgroup. As part of this new open process, we have received feedback on the nature of the application; and have streamlined the form into a user-friendly application. The content of the material is the same, but the questions have been refined in accordance to comment received from industry members; and the level of necessity of the information required to render quality coding decision as determined by the CMS workgroup. We now feel confident that the application is ready to be presented for OMB approval. We are also preparing a system of records (SOR) notice.

2. Information Users

When an application is received, HCPCS staff distributes the material to all workgroup members. Workgroup members review the material and provide comments at the HCPCS workgroup meetings. After the workgroup meets, preliminary decisions are posted to CMS' HCPCS website and all requests are placed on a HCPCS Public Meeting Agenda. At the HCPCS Public Meetings, the requester, as well as all other interested parties, can provide comments in reaction to the workgroup's preliminary decision. Then the workgroup meets again, taking into consideration all public feedback, and makes a final decision. Final decisions are released to the applicant via letter; and all resulting modifications to the HCPCS codes are reflected on the HCPCS update.

3. Use of Information Technology

All submitters are required to submit their application and supporting documentation using the form published on the website. Once completed, these forms are mailed to CMS in hard copy. Requests that are received and complete by the set deadline, will be included in the upcoming cycle; and requests that are incomplete or received after the set deadline for any coding cycle, will be considered for inclusion in the next cycle.

4. Duplication of Efforts

This data does not contain duplication of similar information.

5. Small Businesses

There will be minimal impact on small businesses as this process has been in place for years; and there is ample time allotted from the beginning of the cycle to the deadline to read, complete and submit a request.

6. Less Frequent Collection

This information is collected one time and a coding action is rendered. However, the requestor can choose to submit another application in a subsequent coding cycle.

7. Special Circumstances

There are no special circumstances. A request cannot be presented without an application submission. Each requestor must submit a complete application(s) by the set deadline in order to be considered for the coding cycle.

8. Federal Register / Outside Consultation

CMS contracted with Jing Xing Technologies, Inc. (JXT) to review, analyze and recommend improvements in the HCPCS process. Also, many industry members have shared common views on ways in which the process could be improved, with much focus given to the requested information that is collected via HCPCS application. There were many suggested revisions to the HCPCS application. Public comment has also been welcomed on CMS' HCPCS website @ www.cms.hhs.gov/medhcpcsgeninfo via email to

HCPCS@cms.hhs.gov. The 60-day Federal Register notice for this information collection published on July 20, 2007.

9. Payments / Gifts to Respondents

There are not payments or gifts to respondents.

10. Confidentiality

CMS will adhere to all statuses, regulations, and agency policies.

11. Sensitive Questions

Sensitive questions on the application form include those questions that are related to pricing and sales information that pertain to the product for which the request is being submitted. Questions of particular interest would include:
#12. When was the item/product marketed in the United States?
(**Note** Marketing data is not required for drugs. For all non-drug items, the applicant must submit 3 months of marketing experience following the FDA approval date.) Prior to submitting this coding recommendation, what is the total number of units sold in the U.S. and the total dollar amount in sales (Medicare, Medicaid and private business)? Do not estimate or provide projections - the information provided must represent actual volume of sales for the product for the period of time indicated.
#14. What is the Manufacturer's Suggested Retail Price (MSRP) or list price of the item? This question must be answered for all items, including drugs. In the case of drugs that have not yet been marketed, provide information regarding planned MSRP.

12. Burden Estimates

The estimated maximum of requests for modification to the HCPCS is 300 per cycle year. The estimated time to read, execute, and submit this form is 10 hours.

Time to fill out application:
15 minutes – to read application instructions and questions
2 hrs – to gather information in response to questions
2 hrs – to gather sales data and the percentage of use in each setting
1 hr – to gather product information and FDA documentation
2 hrs 45 min. – to copy and paste application, and type in responses
2 hrs – to proof and edit
Total – 10 hrs.

Cost to fill out application:
GS-14 Rate: $40/hr x 10 hrs. = $400.00

Time to run copies, collate & package materials:
35 copies = 10 minutes
Collate = 40 minutes
Package = 10 minutes
Total = 1 hour

Cost to run copies, collate & package materials:
GS-7 Rate: $18/hr x 1 hr = $18.00
Total number of pages - 20 pgs x 35 copies = 700 pgs
Total cost of paper - 700 pgs x .10/pg. = $70.00
Total Costs = $88.00

Cost to mail:
Based on one of the furthest points from CMS – California 96150
1000 pgs weighed = ~11 lbs.
Dimensions of box = 9x10x12
Carrier – United States Postal Service $22.05

GRAND TOTAL – $510.05

13. Capital Costs

The application is available online at www.cms.hhs.gov/medhcpcsgeninfo. Respondents will need a computer with internet access, which is publicly available. We do not anticipate any capital costs to the respondents.

14. Cost to Federal Government

There are no costs to the Federal Government to receive these application forms.

15. Changes to Burden

There are no changes to the burden. The HCPCS application has been streamlined and the number of questions have been minimized.

16. Publication / Tabulation Dates

The application is available at www.cms.hhs.gov/medhcpcsgeninfo . The dates and deadlines will be changed annually to reflect the upcoming coding cycle. Content of the material will remain the same, however questions may need to be revised periodically for clarity so that the respondent will know how to respond correctly.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

A. Collections of Information Employing Statistical Methods

No statistical methods are employed.