Supporting Statement

CMS HCPCS Modification to Code Set Form

(CMS-10224, OMB 0938-1042)

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. The
HCPCS Level II code set, also referred to as alpha-numeric codes, is a standardized coding system that is used primarily to identify items, supplies, and services not included in the HCPCS Level I Current Procedural Terminology (CPT®) codes, such as ambulatory services and durable medical equipment, prosthetics, orthotics, and supplies when used in the home or outpatient setting as well as certain drugs and biologicals. Because Medicare and other insurers cover a variety of these services and supplies, HCPCS Level II codes were established for assignment by insurers to identify items on claims. HCPCS Level II classifies similar items or services 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 code set. Modifications to the HCPCS are initiated via an application form submitted by any interested party. The purpose of the data provided is to inform CMS about the items and services for which a modification is requested so that the agency can reach a decision in response to the recommended coding action. Prior to the COVID-19 Public Health Emergency (PHE), applicants would download the application from the CMS website, complete the information and mail the paper application to CMS. During the COVID-19 PHE, CMS staff who process the applications were not in the office to receive the mailed applications, so CMS started requiring applicants to send the completed applications via encrypted email. Prior to the COVID-19 PHE, CMS began working on developing a secure web-based solution where applicants can complete the application online and submit directly to CMS. The electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), went live in August, 2021 and applicants were able to submit their applications for the fourth quarterly cycle of 2021. The HCPCS Level II application form designed for MEARIS™ is similar to the current OMB-approved paper application (CMS-10224, OMB-0938-1042).

We are not making any new changes to this package's requirements/burden or any information collection/reporting instruments or instructions. We are adding a supplemental document "Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures" for OMB- approval. The document includes background information on the HCPCS coding and outlines the HCPCS Level II coding process and criteria along with a timeline of the coding cycles.

B. Justification

1. Need and Legal Basis

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 code set 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 code set maintenance. The HCPCS code set maintenance is an ongoing process, as changes are implemented and updated quarterly (for drug and biological products) and biannual (for non-drug and non-biological items or services); therefore, the process requires continual collection of information from applicants on a quarterly and bi-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 code set. Applications have been received prior to HIPAA implementation and must continue to be collected to facilitate quality decisionmaking. 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 compliant with the August 2000 regulation by October 1, 2002.

2. Information Use

When an application is submitted in MEARIS™, the reviewers have real-time access to the application and accompanying materials to facilitate a timely review of the application. The review team reviews the material and provides comments at the HCPCS application review meetings. After the review meetings, preliminary decisions are posted to CMS' HCPCS website for non-drug and non-biological items and services as well as select drug or biological products and the 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 CMS's preliminary decision. The reviewers then meet again, taking into consideration all public feedback, and makes a final decision. Final decisions are released to the applicant and the public via a narrative summary document published to the HCPCS website, and all resulting modifications to the HCPCS codes are reflected on the HCPCS update files released to our claims processing contractors.

3. Use of Information Technology

Applicants are able to access the HCPCS Level II application via MEARIS™ on a designated website through CMS.gov. The electronic version of the HCPCS Level II application is the same as the version approved by OMB last year and we are not making any changes to the application. This secure online application maintained by CMS enables applicants to submit their responses to our application questions directly to CMS as opposed to downloading the application from CMS.gov, completing the application, and attaching the completed application and sending via email. We believe these changes have

no impact on the previously stated burden associated with this collection. Requests that are received and complete by the established deadlines will be included in the upcoming cycle; and requests that are received after the established deadline for any coding cycle, will be considered for inclusion in the next coding cycle.

4. Duplication of Efforts

These data do 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 that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register / Outside Consultation

The 60-day Federal Register notice published on 1/27/2023 (88 FR 5360).

No comments were received during the comment period.

The 30-day Federal Register notice published on TBD (88 FR).

9. Payments / Gifts to Respondents

HCPCS Level II codes are reported on a claim when CMS or other insurers have a claims processing need to identify a particular item on service on a claim in order to make a payment for that item or service that is not described adequately by any other code set. The existence of a code does not guarantee Medicare payment.

CMS maintains the HCPCS Level II code set, as designated by the Secretary of HHS; for use
by all government and non-government insurers in identifying products on electronic medical claims forms, as designated under HIPAA. The HCPCS Level II code set is in the public domain and may be freely downloaded, used and distributed. HCPCS Level II codes that begin with the letter "D" are an exception. Codes that begin with the letter "D" comprise the Current Dental Terminology (CDT) code set, which is copyrighted, maintained and published by the American Dental Association, completely separate and apart from CMS' HCPCS Level II codes of other letter designations.

10. Confidentiality

"CMS pledges privacy to the extent provided by law."

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates

We estimate the average response time to be 10 hours. The time estimate for preparation of the HCPCS Application is based upon the professional judgment of staff members at the Centers for Medicare and Medicaid Services. It is estimated that there are 250 applications filed annually at an average response time of 10 hours per filing. Therefore, we have calculated the burden as follows: 250 responses x 10 hours per response = 2500 burden hours (annual). Previously, approximately 150 applications were filed annually.

The estimated maximum of requests for modification to the HCPCS is 250 per cycle year. The estimated time to read, execute, and submit this form is 10 hours.

Time to fill out application (Electronic version):
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/paste and/or type in responses

2 hrs. – to proof and edit
Total – 10 hrs.

The applicants are no longer required to make 25 copies of the completed application and mail them to CMS as the application process is currently completely online.

We believe Medical and Health Service managers will be responding to the information collection requirements. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2021 http://www.bls.gov/oes/current/oes_md.htm) for Category 11-9111 (Medical and Health Services Managers), the mean hourly wage for a Medical and Health Services Manager is
$57.61. We have added 100% of the mean hourly wage to account for fringe and Overhead benefits, which calculates to $115.22 ($57.61+ $57.61). We estimate the total annual cost to be $288,050 (2500 hours x $115.22/hour).

13. Capital Costs

The application is available online on a designated website through CMS.gov. 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

The calculations for CMS employees' hourly salary were obtained from the Office of Personnel Management 2023 General Pay Table for the Washington DC Metro Area here: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2023/generalschedule.

We estimate that approximately 250 HCPCS Level II applications are submitted on an annual basis, and that it takes 35 hours per application for review by the subject matter experts and management, for a total of 8,750 hours per year. The annual burden to the Federal Government including the cost of CMS employees' time is calculated to be $523,027.50, as reflected in the table below:

HCPCS Level II Subject Matter Experts and Management Review	Hours	Costs
3 GS-12 step 5: 3 x $51.15/hr x 917 hours	2,750	$140,713.65
5 GS-13 step 5: 5 x $60.83/hr x 1,000 hours	5,000	$304,150
1 GS-14 step 5: 1 x $71.88/hr x 500 hours	500	$35,940
2 GS-15 step 5: 2 x $84.55/hr x 250 hours	500	$42,275

TOTALS	8,750 hours	$523,078.65

15. Changes to Burden

We estimate the current total annual cost to be $288.050 (2500 hours x $115.22/hour). Previously, the annual cost was estimated at $166,110. The number of applications being filed have increased from 150 to 250 annually for this PRA package. The current annual cost to the government is estimated to be $523,078.65.

The intent and substance of the electronic HCPCS Level II Code Modification Application form is similar to the paper survey and the current HCPCS Level II electronic application that received OMB-approval through the non-substantive change request. We are submitting the HCPCS Level II procedures document as a supplemental document for OMB approval with this package.

16. Publication / Tabulation Dates

The application is available online on a designated website through CMS.gov. The dates and deadlines will be changed quarterly and bi-annually to reflect the upcoming coding cycles. 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

The existing PRA package will expire on 07/31/2023. The PRA expiration date will be displayed on the application welcome page for the applicants.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methodsu

No statistical methods are employed.