

**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. Level II of the HCPCS, 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 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, Level II HCPCS 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 stakeholder. 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 the 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"). Initially, CMS' HCPCS Workgroup was comprised of representatives of the major components of CMS, Medicaid, private insurers, as well as other consultants from pertinent Federal agencies. In 2018, CMS' restructured the HCPCS workgroup to be comprised of federal government employees who represent the major components of CMS and federal employees from pertinent Federal agencies, including but not limited to the Department of Veteran's Affairs and the Defense Department. Prior to the COVID-19 Public Health Emergency (PHE), applicants would download the application from the CMS website, complete the information and mail the application to CMS. During the COVID-19 PHE, CMS staff who process the applications are not in the office to receive the mailed applications, so CMS now requires 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™), is near completion and is scheduled to go live mid-June, 2021 to coincide with our second bi-annual coding 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 requesting a non-substantive approval because we believe the information we are collecting in the web survey remains the same as the paper form. The only minor changes made to the application form are to adapt to the web environment including the accommodation of yes/no questions that were previously implied in the paper application. For example, by responding to “no” in certain questions, an applicant can skip a question they would have seen on a paper application instead of just filling in a response of “N/A” as instructed in the paper application. We also did some reordering of questions to fit into the tab format of the application and for one question, we made it more clear as to what we meant by “is your item durable.” We clarified this question based on previous feedback from applicants about what it meant to be “durable” by asking the direct questions around what it means for an item to be “durable. For a complete breakdown of the changes made from the paper application to the online application, please see the crosswalk document. We believe the changes to the online applications have no impact on the data collection requirements or the burden associated with this collection. We also believe there is nothing new in the online application that a repeat applicant would not have seen in the paper application and its associated instructions. If we cannot go live with the system due to our PRA not being approved by mid-June 2021, it will delay our implementation by 6 months until the next bi-annual application cycle, which will cause cost overruns on our current fixed price contract.

## **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 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 drugs and biologicals) and Bi-Annually (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 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.

## **2. Information Use**

When an application is submitted in MEARIS™, the entire workgroup will have instant access to the application and accompanying materials to facilitate a more timely review of the application. 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 for non-drug/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 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 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 will be able to access the HCPCS Level II application, via the Medicare Electronic Application Request Information System™ (MEARIS™), on a designated website through CMS.gov. The electronic version of the HCPCS Level II application will be the same as the paper version except for a few minor non-substantive changes as described in question one above and in our crosswalk document. 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, and provides a more convenient way for our applicants to submit HCPCS code applications. Requests that are received and complete by the set deadline, will be included in the upcoming cycle; and requests that are received after the set deadline for any coding cycle, will be considered for inclusion in the next 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.

## **8. Federal Register / Outside Consultation**

The 60-day Federal Register notice published on September 12, 2019 (84 FR 48145). The 30-day Federal Register notice published on November 25, 2019 (84 FR 64898).

## **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 Level II HCPCS code set, as designated by the Secretary, HHS; for use by all government and non-government insurers in identifying products on electronic medical claims forms, as designated under HIPAA. The Level II code set is in the public domain and may be freely downloaded, used and distributed. Level II HCPCS 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’ Level II HCPCS 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 150 applications filed annually at an average response time of 10 hours per filing. Therefore, we have calculated the burden as follows: 150 responses x 10 hours per response = 1500 burden hours (annual).

The estimated maximum of requests for modification to the HCPCS is 150 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 2018 [http://www.bls.gov/oes/current/oes\\_md.htm](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 \$55.37. We have added 100% of the mean hourly wage to account for fringe and Overhead benefits, which calculates to \$110.74 (\$55.37 + \$55.37). We estimate the total annual cost to be \$166,110 (1500 hours x \$110.74/hour).

### **13. Capital Costs**

The application will be 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**

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

### **15. Changes to Burden**

We estimate the current total annual cost to be \$166,110 (1500 hours x \$110.74/hour). Previously, the annual cost was estimated at \$166,110 as well, therefore, there are no anticipated changes to the burden.

The intent and substance of the electronic HCPCS Level II Code Modification Application form is similar to the paper survey except for the following minor/non-substantive changes that we do not believe will impact the burden associated with the HCPCS Level II applications:

- 1) Question specific instructions, which were previously in the general instruction section, are now with their respective questions so applicants do not have to refer to a separate document or information tab to determine how to complete specific questions. In addition, some instructions are reworded for further clarification to aid applicants in providing appropriate information as required by CMS
- (2) HCPCS subcategories grouped under “Drug/Biologicals” and “Non-Drug and Non-Biological items or services” options to allow the system to know whether an application should be in a quarterly (drugs and biological products) or bi-annual (non-drug and non-biological items and services) application cycle and introduction of yes/no options to accommodate skip patterns in the electronic system
- (3) Existing questions, previously in paragraph form, are separated into individual fields to

ensure targeted responses from the applicants. The sequence of some questions has been changed so that related questions are placed together, under the same tab.

(4) The questions in “Durability” section are reworded to make them more concise and explicit in order to assist the applicants formulate more accurate responses

(5) Information currently supplied in the cover letter is now a separate question, as cover letters are no longer being required in the electronic system. In addition, the manufacturer’s attestation is no longer required in the electronic system.

**16. Publication / Tabulation Dates**

The application will be 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.

**18. Certification Statement**

There are no exceptions to the certification statement.

**C. Collections of Information Employing Statistical Methods**

No statistical methods are employed.