## Supporting Statement for 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 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 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 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 code set. Modifications to the HCPCS are initiated via 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 authority to maintain and distribute HCPCS Level II Codes. As a result, the National Panel was dissolved 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. Until 2019, the Workgroup was comprised of representatives of the major components of CMS, Medicaid and private insurers, as well as other consultants from pertinent Federal agencies. In 2018, CMS' restructured the HCPCS workgroup as an internal workgroup comprised of federal government employees who represent the major components of CMS, as well as federal employees from pertinent Federal agencies, including but not limited to the Department of Veterans Affairs and the Defense Department.

Prior to 2020, CMS received and reviewed HCPCS Level II code applications and typically made related coding changes annually, including releasing updated coding files. However, CMS's quarterly systems release process gave CMS the flexibility to review applications and make codes effective quarterly in response to claims processing needs, which it used in very limited circumstances. In November 2019, CMS announced updates to our HCPCS Level II coding procedures to enable shorter and more frequent HCPCS

Level II code application cycles beginning in January 2020 as part of our initiative to facilitate launching new products into the marketplace for providers and patients. Specifically, we implemented a process whereby HCPCS Level II code applications for DMEPOS items and services are submitted and reviewed no less frequently than bi-annually; and HCPCS Level II code applications for drug and biological products are submitted and reviewed no less frequently than quarterly.
Prior to 2020, we included code applications for drug and biological products in the HCPCS public meeting process, even though not required under section 531(b) of BIPA. In order to achieve the additional time savings necessary to implement coding for the majority of drug and biological products for which we receive code applications on a quarterly cycle, in November 2019, we updated our HCPCS Level II coding procedures such that beginning January 1, 2020, we no longer conduct public meetings as part of our HCPCS Level II code application process for drug and biological products. Although code applications for drug and biological products are no longer included in the public meetings, the 2020 coding procedures do provide an opportunity for applicants to resubmit a code application for a drug or biological product in a subsequent quarterly coding cycle, which offers individual applicants who are dissatisfied with our coding decisions in one quarterly cycle an opportunity to reapply in the next or a subsequent quarterly cycle.

## 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 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 code set. 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.

### 2. Information Use rs

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

Prior to the COVID-19 public health emergency, all submitters were required to submit to CMS 1 signed original and 25 copies by US mail of their application and supporting documentation using the form published on the website. CMS is now requiring all HCPCS Level II applicants to send the completed application and supporting documents to CMS using an encrypted email.

CMS is currently building a secure internet based electronic system that we anticipate will begin accepting electronic applications in July 2021 and for subsequent HCPCS Level II coding cycles. Applicants will be able to access the HCPCS Level II application on a designated website through CMS.gov. We are working to enhance the user interface to reduce burden and provide a more convenient way for our applicants to submit HCPCS code applications. Once the online application is drafted we will submit a revised PRA package.

## 4. Duplication of Efforts

This data does not contain a 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).
No comments were received for both comment periods.

## 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:**
15 minutes – to read application instructions and questions
2hrs – 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.

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 2019 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 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

We anticipate more HCPCS Level II applications will be submitted since we are coding more frequently but believe the burden will decrease slightly since we are now receiving applications via secure email as discussed above. We had previously estimated 100 applications per year and have increased our estimate to 150 applications per year. The hourly wage has also increased.

We estimate the current total annual cost to be $166,110 (1500 hours x $110.74/hour). Previously the annual cost was estimated at $115,676.00 (1100 hours x $105.16/hour). This shows an increase of $50,434.

### 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

The expiration date will be updated upon approval on the bottom left side of the application.

### 18. Certification Statement

There are no exceptions to the certification statement.

## C. Collections of Information Employing Statistical Methods

No statistical methods are employed.