

Non-Substantive Change Request to CMS-10224, OMB 0938-1042

This is a non-substantive change request to Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Level II Code Modification Application Form (CMS-10224) to allow CMS to collect HCPCS Level II Code Modification requests in an electronic application intake system on the CMS-10224 form. The Form (CMS-10224) is currently near completion and is anticipated to go live in the electronic application intake system in mid-June, 2021 in time for the second bi-annual application cycle. If we do not implement the system by mid-June, it will delay implementation until the next bi-annual cycle, which will cause cost overruns in our contract with the system developer.

The electronic form is essentially identical to the paper application form (CMS-10224, OMB 0938-1042) except for a few minor, non-substantive changes to either accommodate the web format or further provide simplification or clarification of the existing questions. We are not requesting any new information. The modifications to the form include:

- (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 are grouped under “Drug or Biological Products” 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 questions 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 the related questions are placed together, under the same tab
- (4) The questions in the Durability section are reworded to make them more concise and explicit to assist the applicants in formulating 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

Please refer to our crosswalk document for a more detailed comparison of the differences between the paper and electronic application. We consider all of the changes to be non-substantive since they do not constitute changes to the intent or substance of the HCPCS Level II application, but only simplify or clarify the content and streamline the reporting process. These changes have no impact on the previously stated burden associated with this collection.