CMS received a total of 3 comments in reaction to the HCPCS information collection posted in the December 10, 2010 Federal Register. CMS received 1 comment regarding the durability of products (question #4), FDA 510K requirement (question #11), and estimated time burden. The other 2 comments were suggestions for an electronic application process.

Responses to Comments

Question 4

4a.) Is the item durable, if so, explain how it can withstand repeated use?

Specify whether the entire item or only certain components of the item can withstand repeated use:

4b.) If the entire item can withstand repeated use, then please specify the length of the time that the item can withstand repeated use.

4c.) If only certain components of the device can withstand repeated use, then please identify the individual components and the length of the time that the individual components can withstand repeated use.

4d.) Please provide detailed information on the warranty of the device such as the parts included under the warranty, the length of the warranty and the parts excluded from the warranty. In addition, please specify if the device includes any disposable components and the expected life or the replacement frequency recommended for the disposable components.

Comment

CMS received 1 comment that there has been limited direction on what is required for a product to be considered "durable" under the Medicare program. The commenter suggested that CMS avoid any changes until the terms used in expanded question 4 are defined with specificity.

Response

The original text of item 4 on the 2011 HCPCS application requests the applicant to explain if the item is durable and elaborate on how the item can withstand repeated use. We are not proposing to remove or revise the existing, general question about whether an item is durable and can withstand repeated use because it is relevant in determining whether there is a Medicare program need for a change to the HCPCS. The comments indicate that there is limited direction on what is required of a product to be considered durable. We are grateful to receive these comments because they underscore the need to add secondary questions related to durability of items coded under the HCPCS. Durable medical equipment is one of the main categories of Medicare covered items that are classified under the HCPCS, and therefore, information regarding durability of items classified under the HCPCS is critical in determining whether a change in the HCPCS is needed.

Information in response to the proposed, additional questions under item 4 on the 2011 HCPCS application is needed in order to support an applicant's claim that an item is durable. The information obtained from the answers to the secondary questions would include factual and readily available data about the product specifications and warranty which should remain consistent regardless of the criteria used by CMS to classify items as durable or nondurable. This information is necessary in determining whether there is a program operating need to establish a new HCPCS code or make coding changes for different categories of items. In most cases, applications for changes to the HCPCS that are related to equipment or supplies are submitted from manufacturers or on behalf of manufacturers of the equipment or supplies. We therefore believe that the burden for obtaining this additional information is insignificant since manufacturers of equipment or supplies are already very familiar with the equipment or supplies that they manufacturer.

Question #11

11a.) Provide the date that the item/product was cleared for marketing by the FDA. If the product is exempt from FDA review and classification, please explain the basis for the exemption.

b.) Attach copy of the FDA approval letter including the 510(k) summary for those items that are approved using the 510(k) process. Also, if an item is cleared using the 510(k)process, identify the HCPCS codes, if applicable, that describe the predicate products listed in the 510(k) submission and explain why these codes do not adequately describe the item that is the subject of the HCPCS recommendation. In other words, if an item is listed as being substantially equivalent to another item(s) in an application for FDA marketing clearance, why is it not equivalent or comparable for coding purposes?

Comment

CMS received 1 comment that question 11 has been expanded in a way that creates an unreasonable expectation that the applicant undertake a burdensome search of how predicate devices have been treated. The commenter suggested the deletion of the expanded question.

Response

The revision of question 11 incorporates part of the answers provided to questions 7A (Identify similar products and their manufacturers.) and 8C (Explain why existing code categories are inadequate to describe the item.). As such, this is not a new requirement and it should not create any undue burden to applicants. In fact, manufacturers that request clearance under the 510(k) process must list predicate products in their 510(k) summary when submitting their request to the FDA for marketing clearance. What is new here is that CMS is requesting the applicant to provide an explanation as to why items classified as equivalent by the FDA should not be identified in the same coding category.

Time Estimate Burden
Comment

CMS received 1 comment that the amount of time to prepare the HCPCS application is unrealistic; especially if the applicant is describing a claim of significant therapeutic distinction. The commenter suggested that it takes much longer than 10 hours to complete an application (taking into consideration conference calls; discussions of how to best answer questions; collection of payer information; hiring a consultant; joint efforts between FDA staff; and consulting with sales & marketing/reimbursement specialist).

Response
CMS is aware that some applicants hire consultants to prepare their applications. However, this is not a requirement of HCPCS applicants. Obtaining information necessary to answer questions 4 and 11, should not create any additional burden for the applicant. Applicants should already have this information prior to submitting a request. Information about product warranties is most often documented in the company's brochures and marketing materials when the product is endorsed. Having requested, and been granted, clearance under the 510(k) process, an applicant would need to be familiar with predicate products, as that is fundamental to the applicant's request. As such, CMS disagrees with the commenter that the time to prepare an application is unrealistic.

Not Within Scope
Comment
CMS received 2 comments proposing an electronic application process.

Response
CMS would like to thank you for these comments. CMS will consider electronic application intake.