Responses to Comments
CMS-10224

CMS received a total of 8 comments in reaction to the HCPCS information collection posted in the July 20, 2007 Federal Register. The majority of these comments expressed concerns about the content of question 7b of the information collection. CMS also received comments regarding the FDA 510K requirement, sales volume, estimated time burden, and equal treatment of applications for HCPCS codes for drugs and biologicals.

Question 7B

Comment

CMS received 7 comments that the requirement for detailed clinical data is more appropriate in the coverage context and that it is inappropriate for HCPCS coding decisions. Moreover, the HCPCS application should focus on distinct features of the product that applicants believe necessitate a unique code. Of these 7 comments, 3 suggested the removal of question 7b altogether, and 3 commenters suggested a revision of question 7b to remove the requirement for clinical studies. Question 7b currently reads: “Identify significant differences between this item and other products listed above. (Include differences in item cost; material; product design; how it is used; differences in function/treatment provided to a patient; clinical indication; and clinical outcome. Claims of significant therapeutic distinction when compared to the use of other, similar items, must be described in detail. Articulate the clinical theory behind the claim, including differences in the product or its operation as it compares to currently coded products. Specify how the product results in a significantly improved medical outcome or significantly superior clinical outcome. (Please refer to the HCPCS decision tree for additional information.) Provide the best available information related to your claim. Include copies of all articles that result from your systematic analysis of the available literature. Information submitted should be as complete as possible. Unfavorable articles should be provided with any appropriate rebuttal or explanation. If the articles submitted cause you to exceed the overall 40-page limit, then submit one reference copy of each article with 35 copies of the application.”

Response

Some of the concerns raised about clinical outcomes data are misguided. As stated in the language of question 7b, this information only applies to those applicants who choose to make a claim that their product has a superior clinical outcome when compared to similar products already described by existing codes. Coverage decisions are made separate and apart from coding decisions. When an applicant chooses to state a claim of superior clinical outcome as a basis for a coding distinction, CMS expects the applicant to substantiate the claim. The language of item 7b serves as a guide to applicants toward the validation of such claims. CMS disagrees with the removal of question 7b from the HCPCS application, as this would eliminate an opportunity to distinguish products on the basis of significant therapeutic distinction for applicants who choose to do so.

Comment
CMS received 2 additional comments that the "significant therapeutic distinctions" as a criterion creates a new and improper substantive standard as part of the HCPCS process and is not consistent with past practice.

Response
The request for studies that demonstrate superior clinical outcome is not a "new standard". This requirement has been a long-standing part of the existing criteria and decision making process. As documented in the Level II Coding Procedures, an existing code adequately describes an item in a coding request when the existing code describes products that function similar to the item in request and when there are no significant therapeutic distinctions from the item in the coding request. This criterion was clarified and illustrated in the publication of the HCPCS Decision Tree and Definitions on the HCPCS website at: www.cms.hhs.gov/medhcpcsgeninfo.

Comments
CMS received 2 comments stating that most companies that manufacture Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) generally do not conduct studies that are accepted in journals that are "peer reviewed", and that support documentation from different sources that reach the same conclusion strengthens the overall validity of the evidence and should be substitutable. Examples of such support documentation proposed by the commenter include individual physician or clinician letters, field trials, case studies and etc.

Response
As documented in the Definitions and Clarifications of the Decision Tree, "requests for modifications to the HCPCS Level II code set based on claims of significant therapeutic distinction (significantly improved medical benefit) when compared with the use of other, similar items are reviewed on a case-by-case basis, taking into consideration clinical information provided by the applicant and other commentators that supports or refutes the claim(s) made by the applicant. In submitting a request, an applicant should provide the best available information supporting his or her claim." Randomized, controlled clinical trials are not a specific requirement. Peer-reviewed literature is also not a specific requirement. Rather, we ask for descriptive material, that supports the applicants claim of significant therapeutic distinction. Understandably, greater weight is given to more methodologically rigorous and scientifically reliable evidence.

Comment
CMS received 2 comments (both from pharmaceutical manufacturers), regarding the level of evidence requested in question 7b. One comment supported the request for clinical studies stating that this is a "significant step forward", while the other comment disagreed with the request, arguing that the requirement of such extensive information on clinical outcomes would result in an unnecessary burden on both manufacturers and the CMS. In addition, we received 1 related comment that stated that the request for a

"systematic analysis of the available literature," would impose a disproportionately heavy burden on smaller medical technology companies.

<u>Response</u>
Only a portion of all applicants choose to make a claim of significant therapeutic distinction. The request for clinical outcomes data applies only to these applications. Drugs and biologicals that are subject to ASP pricing are not subject to the requirements of submission of clinical outcomes data to substantiate superior clinical outcomes. CMS will continue to ensure that accurate codes are available to promote appropriate, separate payment for singles source drugs and biologicals under Section 1847A of the Social Security Act. However requests to establish unique codes for drugs or biologicals that are not subject to ASP pricing that make claims of significant therapeutic difference or superior clinical outcome when compared to similar products already coded will need to substantiate those claims. Revisions have been made to the language of question 7 to clarify that this requirement is not applicable to all applicants. In addition, in some cases, the entire body of available evidence does not exceed the existing 40-page limit for HCPCS code applications. In cases where pertinent reports that would substantiate a claim would exceed the 40-page limit, CMS is willing to accept one master copy of this supportive documentation.

<u>Question #5</u>

<u>Comment</u>
CMS received 2 comments that suggest a revision to question 5 to focus on technological differences, operational differences and distinct patient need. Question 5 currently reads: Describe the item fully in general terminology. What is it? What does it do? How is it used? Describe the patient population for whom the product is clinically indicated. Descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles on the item may be included in the information packet submitted for review, but they do not replace the requirement to fully respond to this question and fully describe the item.
For drugs and biologicals, include: A) indications for use, B) action, C) dosage and route of administration, D) package insert and, E) how supplied.

<u>Response</u>
The proposed revision to question 5 suggests a policy change related to decision-making criteria to focus on technological differences (a different method to get the same result) and distinct patient need (distinct patient population) instead of significant therapeutic differences. CMS will not be addressing changes to the decision-making criteria as this topic is not within the scope this information collection. This information collection serves to gather the data necessary to make determinations using the long-standing decision criteria.

<u>Question #11</u>

<u>Comment</u>

CMS received one comment raising concerns with the request for a 510K summary for items approved using the 510k process, stating: "If the purpose is to check for FDA approval, then the manufacturer should be able to state whether their device has been approved and when.

Response
Item 2 of the Alpha-Numeric Coding Recommendation Format for the 2009 Update states: "If the item identified in this recommendation is health care device or product, identify the device(s)/product(s) that have been determined by the FDA to be substantially equivalent." CMS considers the FDA approval type and classification of products as appropriate information to considered as part of the review process.

Question #12

Comment
CMS received 2 comments to revise question #12 to include, and consider, sales trend reports and product feasibility studies in addition to marketing activity.

Response
Information provided in question 12 helps us to avoid the inefficiency and administrative burden of assigning distinct codes for items or services that are rarely furnished or for which we expect to receive few claims. There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug/biological products, so that the adding of a new or modified code enhances the efficiency of the claims processing system and justifies the administrative burden of adding or modifying a code. The proposed revision to question 12 suggests a change in policy regarding the volume and marketing criteria as defined in the HCPCS Decision Tree. The purpose of this information collection is to formalize the data and information needed to make HCPCS coding decision. We are not proposing to revise long-standing decision criteria.

Question #14

Comment
CMS received 2 comments to revise the application to ensure that drugs and biologicals are treated the same; 2 related comments to clarify what information CMS seeks related to drugs or biologicals and 1 related comment that expressed concern about the request for a MSRP or list price for a product that has not yet been marketed.

Response
CMS has revised its application to ensure that biologicals are treated the same as drugs with respect to questions 11 through 14. Specifically, we will be extending the FDA approval until March 31st for biologicals; and will not require pricing, sales and marketing data, or percentage of use for biologicals.

Attestation Comment

Comment
CMS received 2 comments to add an attestation statement for manufacturers who are not the submitter of the HCPCS application, instead of a letter of support from the manufacturer.

Response
Presently, CMS requires a letter of support from the manufacturer when the applicant is not the manufacturer. CMS has revised the information collection to include the proposed attestation statement for manufacturers. We would appreciate additional input regarding the addition of an attestation statement from the manufacturer versus a letter of support from the manufacturer.

Additional Rationale for Questions

Comment
CMS received 2 comments to group questions 4, 6, 10 and 13 together since they address meeting the definition of durable medical equipment.

Response
CMS has provided rationale and justification for each question included in the HCPCS application. However, the HCPCS code set is not based solely on the needs of Medicare, and as such, the questions are not intended to address Medicare benefit policies. HCPCS Level II is a national code set that addresses the needs of all payers, Medicare, Medicaid and Private Insurers. CMS will consider this recommendation as a simple matter of reformatting, however it is not CMS' intent to use the application or process to make Benefit Category Determinations.

Rationale for Q #12 - #13

Comment
CMS received 2 comments that request clarification of the administrative burden mentioned in the rationale for questions #12 and #13. These questions currently read:

12. "When was the item/product marketed in the United States?
(**Note** Marketing data is not required for drugs and biologicals. For all non-drug and biological items, the applicant must submit 3 months of marketing experience following the FDA approval date.) For drugs or biologicals, please provide date of first sale. Prior to submitting this coding recommendation, what is the total number of units sold in the U.S. and the total dollar amount in sales (Medicare, Medicaid and private business)? Do not estimate or provide projections - the information provided must represent actual volume of sales for the product for the period of time indicated."

13. “Identify the percent of use of the item across the following settings for all non-drugs/biologicals”

Physician's Office: _______
Freestanding Ambulatory Care Clinics: _______
Patient's Home by patient: _______
Patient's Home by Health Care Provider: _______
Nursing Home/Skilled Nursing Facility: ________
Hospital Inpatient Facilities: ________
Hospital Outpatient Facility: ________
Other- (identify): _________
TOTAL VOLUME OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100%

<u>Response</u>
Information provided in questions 12 and 13 helps us to avoid the inefficiency and administrative burden upon insurers of having distinct codes for items or services that are rarely furnished or for which we expect to receive few claims. Such practice is contrary to administrative simplification. There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug/biological products, so that the adding of a new or modified code enhances the efficiency of the claims processing system and justifies the administrative burden of adding or modifying a code. Information regarding percentage of use in various settings is of equal importance as HCPCS Level II codes identify items that are use outside of physician’s offices. A code is not established for an item that is used only in the inpatient setting or for an item that is not diagnostic and therapeutic in nature.

<u>Time Estimate Burden</u>

<u>Comment</u>
CMS received 3 comments that the amount of time to prepare the HCPCS application has been dramatically underestimated; and that the collection of clinical outcomes data will increase this burden.

<u>Response</u>
None of the comments received offered an estimate of the time it takes to complete a code application. CMS will consider data regarding the time estimate burden when provided by the commentors. Please note that if you have not conducted clinical studies on your product we are not requiring you to do so for the purposes of submitting an application. The time estimate is burden was calculated by allotting 10 hours for the completion of the application, 10 minutes for copying, 40 minutes for collating, and 10 minutes for packaging.

<u>Not Within Scope</u>

<u>Comment</u>
CMS received several comments regarding the HCPCS decision-making criteria.

Response

CMS would like to thank you for these comments. However, they are outside of the scope of this particular information collection and we will not be addressing them in this document.