June 24, 2013

Mr. Jonathan Blum, Director
Center for Medicare Management
Centers for Medicare and Medicaid Services
Hubert H Humphrey Building
200 Independence Avenue, SW
Mail Stop 314G
Washington, DC 20201

Re: Seeking HCPCS System Improvements

Dear Mr. Blum:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing to raise several concerns regarding the current process for adding, deleting, categorizing, and revising Level II codes under the Healthcare Common Procedure Coding System (HCPCS) and to provide our recommendations for improving this process. We appreciate the opportunity to submit feedback on these issues.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

We are pleased that CMS has implemented some changes that have improved the HCPCS system—including holding public meetings, restructuring the operation of the former HCPCS National Panel, and modifying the application for HCPCS codes. Though these changes have improved the process for acquiring HCPCS codes, other changes would make the system work more effectively, namely:

- Modifying the marketing and percentage share requirements
- Increasing transparency
- Improving the temporary code system
- Improving descriptor specificity
- Improving the time frame for issuing HCPCS codes
- Creating a formal appeal process

I. Drop Volume and Marketing Requirements
The HCPCS application requires manufacturers to have three months of marketing experience prior to submitting a request for coding consideration and following FDA approval for marketing. In addition, sales of the product must represent 3-percent or more of the outpatient use for that type of product in the national market. AdvaMed recommends that CMS eliminate both of these requirements.

The three-month marketing requirement poses a serious obstacle to code assignment for many new technologies. The lack of appropriately descriptive HCPCS codes can interfere with accurate reporting for payment and quality purposes and/or can hamper Medicare patient access to medical devices and technologies. This CMS marketing requirement is not applied to all products approved by the FDA. For example, the manufacturer of a new drug or biological that is approved by the FDA is not required to provide three months of marketing data in order to apply for a HCPCS code. The marketing data requirement for devices is particularly concerning because it lengthens the coding process from 12 to 15 months, creates an onerous and unnecessary delay in collecting accurate data, and impacts beneficiary access to new technologies. We urge CMS to drop this requirement or, at a minimum, allow the submission of 3 months of marketing data following the application deadline.

Similarly, requiring that an individual device or product represents 3-percent or more of the claims volume for the affected patient population is another requirement that potentially compromises patient access to new technologies. As practitioners and providers increase their use of electronic medical records and measurement of efficiency and quality gains more importance, it is essential that coding keeps pace with advances in technology. Adoption of new products is often dependent on the availability of new codes. A product’s attainment of the market share required for a code may be difficult to track due to the lack of a code. Further, as health systems move toward more personalized medicine, the 3-percent requirement could also preclude the issuance of new codes for a new product that is targeted toward a small subset of the population. Lastly, CMS has not provided guidance regarding how the three percent market share requirement should be calculated. AdvaMed urges CMS to remove this requirement.

II. Improve Process for Issuing HCPCS Codes
AdvaMed appreciates CMS’s public HCPCS meetings which allow interested stakeholders to comment on proposed HCPCS coding decisions in a public forum. We appreciate the staff resources required to plan and prepare for the meetings. However, AdvaMed believes that the overall HCPCS process could benefit from increased transparency.

The process used by CMS and the HCPCS Workgroup to evaluate HCPCS applications
and to develop findings is not transparent. Additionally, there is no process for appealing the Workgroup’s decision to not grant a request. AdvaMed recommends that CMS focus on the transparency of the process and the information that is provided to HCPCS code applicants.

CMS has outlined criteria for determining the need for a new or revised code as well as the criteria for code deletion. CMS has also identified the reasons which can be cited by the HCPCS Workgroup in letters regarding final decisions on a HCPCS application. CMS requires that a decision letter include, though it is not limited to, at least one of the enumerated responses it has identified as a basis for denying or approving an application. Some of the responses identified for use in the event of application denial include the following:

- A new code is not needed because an existing code describes the product;
- Insufficient sales volume to assign a new code; or
- Revisions do not improve the descriptor.

According to CMS policy the HCPCS Workgroup is not required to provide additional details or other explanation regarding why or how the conclusion to deny an application request was reached. Without this information many manufacturers submit a revised application, containing new information and additional explanations, without fully understanding the deficiencies in their initial submissions. This frequently results in prolonged efforts to obtain new codes or to revise or delete existing codes. AdvaMed recommends that the application approval process be more transparent by providing detailed explanations regarding the basis for the agency’s decision.

III. Improve Temporary Code System Process
AdvaMed urges CMS to issue more refined standards that outline the appropriate use of temporary codes. Currently, CMS relies on temporary HCPCS codes for various purposes. Some temporary codes are assigned pursuant to notice-and-comment rulemaking while others are not. Circumstances arise wherein stakeholders could use a temporary code while awaiting a permanent code. However, no formal or recognized mechanism exists for stakeholders to request a temporary code. AdvaMed recommends that CMS create such an option and urges the agency to provide the public with a clear rationale in cases when the request for a temporary code is denied.

IV. Improve the Specificity of HCPCS Codes
HCPCS codes should be sufficiently detailed to achieve the goals of appropriate coding—accurate identification and classification of items and services used for patient care. Accordingly, it is imperative that code descriptors accurately describe the products they identify. Many existing HCPCS code descriptors lack sufficient detail to accurately describe a new technology. This is often problematic and could adversely impact use of the new technology and interfere with tracking of both new and older products. Moreover, the lack of sufficient detail leads to difficulties in assessing the use of items
and services that are best suited for a particular patient.

AdvaMed is concerned that, in certain cases, the HCPCS codes are too broad. Frequently, requests for new or revised HCPCS codes are denied on the grounds that an existing permanent or temporary code describes the product. The breadth of some HCPCS descriptors frequently leads to denied requests for new codes for technologies that arguably should be distinguished, on the grounds of distinct relevant technical features, from existing technologies that are already assigned a HCPCS code.

AdvaMed urges CMS to:

- incorporate more transparency in the process for approving new codes and for modifying the descriptors of existing codes;
- provide an opportunity for stakeholder input when the agency revises an existing HCPCS descriptor;
- re-examine the criteria used to assign new HCPCS codes;
- provide detailed rationales regarding why the function and purpose of a given technology may be inadequate for assignment of a new HCPCS code.

V. Issue HCPCS Codes More Frequently
The current HCPCS review cycle runs from January 5th of each year through the following January 1st. Requests for new or modified HCPCS codes may be submitted at any time throughout the year. Requests that are received and completed by January 5th of the current year will be considered for inclusion in the next annual update (January 1st of the following year). However, requests received on or after January 6th, and requests received earlier that require additional evaluation, will be included in a later HCPCS update.

This timeline, combined with the requirement of three months of marketing data before an application may be submitted means that a new device approved by the FDA on October 15 of 2012, will not receive a new HCPCS code until January 1, 2014. A new device approved on October 15, 2012 will not have three months of marketing experience until January 15, 2013—making it ineligible to receive a new code in 2013. An application to obtain a HCPCS code for the device can, at the earliest, be submitted for consideration during the 2014 annual update. If a new HCPCS code was obtained during the 2013 update cycle, it would not be available for use until January 1, 2014 – nearly 27 months after the device received FDA approval.

This prolonged process for obtaining new codes is unnecessary; costly for physicians, providers and payers; and harmful to patients because it delays access to important new products and services. While a product that has yet to receive a permanent code can be billed using a miscellaneous code, the administrative costs associated with submitting and processing miscellaneous codes is higher than the costs of electronic processing of claims.
with unique codes. These issues often result in delays in adopting new technologies, thereby denying patients access to technologies from which they could benefit. The lack of unique codes also reduces CMS’s ability to monitor utilization and establish appropriate medical review policies. In an effort to alleviate these problems and to create increased beneficiary access to new technologies, AdvaMed recommends that the HCPCS process be revised to permit the issuance of new codes and updates quarterly.

VI. Implement a HCPCS Appeals Process
AdvaMed has concerns regarding the recourse that is available to applicants when a HCPCS application is denied. Once a decision is made to deny a HCPCS request there is no option for reconsideration other than re-applying and submitting new information at a later date. HCPCS codes are currently issued only once each year. Because of the absence of an appeals process, applicants who want to pursue a code for an application that was denied must wait until the next year and apply again during the next coding cycle, which means that another year lapses before the application is reviewed. AdvaMed recommends that CMS develop a process that would allow an applicant whose code request was denied to appeal the denial with the prospect, should the appeal be upheld, of assignment of a code during the same coding cycle.

In 2004, CMS indicated its intent to implement an appeals process as part of the HCPCS coding process. The process, planned for implementation in 2007, would have provided applicants whose applications were denied, the opportunity to have their applications reconsidered during the same coding cycle. The HCPCS Coding Procedures found on CMS’s website (revised September 6, 2012) indicate that, “CMS management is considering pilot-testing, a process by which denied applicants would be allowed an opportunity to have their application reconsidered during the same coding cycle.” CMS has yet to implement such a process.

AdvaMed believes that including a timely appeals process would be extremely valuable in providing applicants with an option for revisiting denied applications. We are concerned that continued delays in implementing an appeals process further complicates the ability of device manufacturers to obtain needed coding changes. AdvaMed is unaware of any change in CMS’s assessment of the desirability of an appeals process and is hopeful that the agency will commit the resources needed to bring this project to fruition.

AdvaMed urges CMS to move forward with its plan to develop a HCPCS appeals process that, in the event of a favorable outcome, would allow a requestor to obtain a code during the code cycle year in which the request was originally made. In order for the appeals process to work effectively, the basis for the initial denial should be clearly stated and provided to the applicant in a timely fashion. A meaningful appeals process should include the following:
clearly stated submission deadlines and timely hearings;
- elimination of the requirement to submit new or different information;
- an opportunity for an in-person presentation;
- identification of the person(s)/organization(s) hearing the appeals; and
- identification of the person(s)/organization(s) with final authority.

AdvaMed asks that CMS implement a HCPCS appeals process in the immediate future. We would further ask that the development and implementation of any such appeals process provide for stakeholder input.

VII. Conclusion
We appreciate your attention to these issues and we look forward to the opportunity to work with you. Please do not hesitate to contact my staff lead on this issue, DeChane Dorsey, at ddorsey@advamed.org or 202-434-7218 should you have any questions. Thank you and we look forward to your feedback.

Sincerely,

[Signature]

Ann-Marie Lynch
Executive Vice President,
Payment and HealthCare Delivery Policy

cc: Elizabeth Richter, Deputy Director, Center for Medicare Management