July 26, 2004

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
Mail Stop C5-01-14
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: HCPCS Process Recommendations

Dear Mr. Kuhn:

The Biotechnology Industry Organization ("BIO") appreciates this opportunity to present our concerns regarding the Healthcare Common Procedure Coding System ("HCPCS") coding process. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial, and environmental biotechnology products. Our members are keenly interested in the HCPCS process because these codes are central to coverage and reimbursement for medical technology, and therefore are essential to ensuring patient access to care.

BIO supports the comments submitted by the Advanced Medical Technology Association ("AdvaMed") on June 10, 2004. We share AdvaMed's concerns about the current process for adding, deleting, and revising Level II codes, but are writing separately to highlight our particular concerns with respect to biological products. We believe the current system for revising HCPCS codes lacks the openness, appropriate application requirements, timely procedures, and appeal mechanisms that are essential to ensure that the codes used throughout the U.S. health care system reflect the current state of medical technology.

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I. The HCPCS National Panel should comply with the Federal Advisory Committee Act's requirements for open meetings and public information disclosure.

The current process for reviewing requests for HCPCS code changes fails to provide interested parties with sufficient information and opportunity to comment on the development of the coding system. The HCPCS National Panel, the body that maintains the HCPCS level II permanent codes created for use of all private and public health insurers, operates with too much secrecy and too little opportunity for public input. First, the National Panel meets in private and does not provide transcripts of its meetings, effectively shielding its deliberations from public view. Second, the National Panel provides limited information about its meetings to the public. The agendas posted on CMS' HCPCS website[1] describe only the name of the product for which a code is sought, not enough to clearly describe the issues involved in each decision. Third, the National Panel does not make its decisions or the rationales behind them publicly available, leaving many interested parties unaware of the outcome of a request.

These procedures not only deny our members an essential opportunity to participate in the coding process, they also appear to violate the Federal Advisory Committee Act ("FACA").[2] We believe the HCPCS National Panel is subject to FACA because it is an advisory committee used by CMS to obtain advice or recommendations for the agency, and it is not comprised wholly of officers or employees of the Federal government.[3] As a FACA-governed body, the National Panel is required to provide advance notice of its meetings;[4] make the agenda, minutes, and transcripts of its meetings available to the public;[5] hold open meetings;[6] and provide opportunity for public comment.[7] We urge CMS to ensure

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1 http://www.cms.hhs.gov/medicare/hcpcs/.

2 5 U.S.C. App. 2.

3 See 5 U.S.C. App. 2, § 3(2).

4 5 U.S.C. App. 2, § 10(a)(2).

5 5 U.S.C. App. 2, § 10(b).

6 5 U.S.C. App. 2, § 10(a)(1).

7 5 U.S.C. App. 2, § 10(a)(3).

that the National Panel complies with FACA by opening up the HCPCS coding process to provide more public input.

We recommend the following changes to the HCPCS National Panel's procedures to help our members and other interested parties better understand the National Panel's deliberations:

1. Open the National Panel's meetings to the public.

2. Expand the agenda information provided on CMS' website to include a brief summary of the issue being considered and the non-confidential and non-proprietary parts of submitted code applications.

3. Release the National Panel's decisions and a brief summary of its reasoning to the public through the CMS HCPCS website.

II. The HCPCS coding application should not require inappropriate information that impedes access to new technologies.

The application for HCPCS modifications requires applicants to accumulate 6 months of marketing data before submitting an application,[8] causing delays in the issuance of new codes, in turn blocking access to new technologies and discouraging innovation. Although we appreciate CMS' concern for minimizing the administrative burden of changing HCPCS codes, we urge CMS to recognize the costs to providers and payers of delays in establishing permanent codes. The current system requires providers and payers to adjust to at least one change in coding for each new technology – from a miscellaneous J-code to a permanent code, with the possible interim step of a C-code – with each change requiring widespread provider education and computer reprogramming to ensure that claims continue to be processed. Using a miscellaneous code also requires providers to submit additional information and slows payment.

These administrative burdens may discourage providers from offering new therapies to their patients, denying patients the benefits of advances in medical technology. Over time, innovation will suffer if patients are unable to try new therapies due to the coding system's failure to appropriately recognize them. When a therapy already has undergone years of clinical studies and review to

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8 See http://www.cms.hhs.gov/medicare/hcpcs/2005alpha.pdf.

obtain Food and Drug Administration ("FDA") approval, Medicare beneficiaries' access to it should not be unnecessarily delayed further by a lack of an appropriate code.

In addition, CMS appears to have added a new requirement that would further delay access to new therapies. The current description of the HCPCS process on the CMS HCPCS website states that a therapy must account for 3 percent or more of the outpatient use for that type of product in the national market before a new code can be sought.9 This requirement, if applied to drugs and biologicals, would trap many new therapies in a vicious cycle: the therapy would not be used without a new code, but cannot receive a new code until it is used by enough providers.

We therefore recommend that CMS:

1. Eliminate the requirement for 6 months of marketing experience before submitting an application for a new or revised HCPCS code; and,

2. Eliminate the requirement for 3 percent share of the market before submitting an application for a new or revised HCPCS code.

III. The HCPCS coding process should be more timely.

The current HCPCS coding process is unnecessarily long, causing significant delays in the issuance of new codes. At present, the HCPCS system is updated only once a year after a prolonged review process. Applications that are received by April 1 of the current year are eligible for inclusion 9 months later in the January 1 update of the following year. When the additional 6 months for gathering marketing data is added to the 9 month review process, the time between FDA approval and issuance of a new code stretches to at least 15 months and can reach up to 27 months. For example, a therapy approved by the FDA on October 2, 2004 would not be eligible to apply for a new HCPCS until it has had 6 months of marketing experience, so its manufacturer could not apply until April 2, 2005. Because this therapy would have missed the April 1, 2005 cut-off for consideration for the January 1, 2006 update, the earliest the therapy could be represented by a new code is January 1, 2007; 27 months after the FDA approved it. Although we recognize that the National Panel has at times allowed manufacturers to

9 http://www.cms.hhs.gov/medicare/hcpcs/codpayproc.asp (updated July 16, 2004).

supplement their marketing data if the end of the 6 month period is close to the HCPCS deadline, these timeframes still are much too long.

As we discussed above, delays in creating new codes impose administrative burdens on providers and payers, harming patient access to vital new therapies. While therapies wait for specific codes, providers must bear the extra costs and payment delays of using miscellaneous codes and C-codes. These costs discourage providers from making new therapies available to their patients, limiting patients' choices and denying access to important advanced treatments. These costs and risks could be avoided if specific HCPCS codes were issued sooner.

We therefore urge CMS to revise the HCPCS process to permit the issuance of new codes and updates to the system on a quarterly basis.

IV. The HCPCS system should have an established mechanism for appealing a National Panel decision.

In the recently updated description of the HCPCS coding application process, CMS states:

> A requestor who is dissatisfied with the Panel's decision may submit a new request asking the Panel to reconsider and re-evaluate the code request. At that time, the requestor should include new information or additional explanations to support the request. This is not an appeal process per se, but an entirely new submission asking for a coding change, which we believe is an even more complete avenue of appeal.[10]

Although we applaud CMS for providing this clarification of the process for requesting reconsideration of a denial, we strongly believe that a fair and timely appeals process also is needed. The current re-submission process lacks clear instructions and deadlines. Furthermore, this process does not require the National Panel to provide a clearly stated basis for its initial decision in a timely fashion to help the applicant prepare its appeal. This process also could unfairly provide a second review only to applications for which significant new information is available and not applications whose initial submission was complete. As CMS

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[10] Id.

acknowledges, the current process is "not an appeals process per se;" it is merely a rehearing by the same body after an apparent wait of another whole year. This process does not assure applicants of a fair and timely review, and its slowness and lack of clarity could exacerbate problems with access to new drugs and biologicals.

We recommend that CMS create a meaningful appeals process that includes:

1. Timely hearing of appeals, with clearly stated deadlines for submitting appeals;
2. Timely provision of a clear statement of the basis for the initial denial;
3. Opportunity to appeal decisions without a requirement to submit new or different information;
4. Opportunity for an in-person presentation;
5. Identification of the individual(s) or organization(s) hearing appeals; and,
6. Identification of the final authority on appeals.

Conclusion

BIO appreciates the opportunity to comment on our concerns regarding the HCPCS coding process. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions in the final rule. Please feel free to contact me at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted by,

/s/

Michael Werner,
Chief of Policy
Biotechnology Industry
Organization