Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

December 10, 2007

BY FACSIMILE TRANSMISSION

Carolyn Lovett
OMB Human Resources and Housing Branch
Executive Office Building, Room 10235
Washington, DC 20503

Re: CMS–10224 (Agency Information Collection Activities: Proposed Collection; Comment Request; HCPCS Level II Code Modification Request Process)

Dear Ms. Lovett:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the 2010 Healthcare Common Procedure Coding System (HCPCS) Level II Modification Process.[1] 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 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations.

BIO appreciates this opportunity to comment on proposed revisions to the HCPCS application process. For years, BIO has expressed concern that CMS' process for granting HCPCS codes is too long and cumbersome and delays patient access to care. Although we appreciate the improvements CMS has made to the coding process, including several of the proposed revisions to the 2010 application form, we continue to believe more can be done to streamline the process, as well as to improve transparency and clarity for manufacturers. Most of all, BIO strongly urges the agency to continue to implement the policy of assigning unique, permanent codes to all

[1] 72 Fed. Reg. 63611 (November 9, 2007)

innovative drugs and biologicals to ensure appropriate payment under Section 1847A of the Social Security Act (SSA) and allow for timely patient access to novel treatments.

BIO continues to believe that CMS would benefit greatly from additional public input on changes to the HCPCS coding process. However, as was the case with the release of the draft 2009 HCPCS application form in July, we are concerned that many stakeholders missed the revised 2010 request form entirely as it was again issued through a Paperwork Reduction Act of 1995 notice without being announced on the HCPCS section of CMS' Web site or communicated to interested parties through email list serves or other means. Given the importance of the issues involved and the potential burden on applicants, BIO again asks CMS to consider reissuing the proposed 2010 form for additional public comment. We also request that, in proposing future updates to the HCPCS process, CMS undertake additional outreach efforts to notify stakeholders of its plans, which would improve the public dialogue with the agency.

BIO supports several of CMS' proposed revisions to the 2010 HCPCS application form, and encourages the agency to adopt them in the final version. Specifically, BIO applauds CMS for clarifying that HCPCS application requirements apply equally to both drugs and biologicals. BIO also appreciates that CMS proposes to exempt drug and biological coding applicants from completing questions about cost and pricing that are irrelevant to the assignment of HCPCS codes to such therapies. Finalizing these changes will reduce uncertainty for manufacturers, and contribute to the agency's stated goal of streamlining the request form into a more "user-friendly application."[2]

However, BIO remains concerned by elements of the proposed 2010 HCPCS application form that request detailed clinical data demonstrating "superior clinical outcomes." CMS' own description of the HCPCS coding process clearly states that HCPCS "is not a methodology for making coverage or payment determinations" and that coding decisions are made "independent" from coverage and payment processes.[3] Detailed clinical

[2] 72 Fed. Reg. at 63612
[3] HCPCS Level II Coding Procedures, available at: http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/LevelIICodingProcedures113005.pdf.

information demonstrating superior medical outcomes is not relevant to coding assignments for drugs and biologicals. Accordingly, BIO requests that CMS modify the 2010 HCPCS application to further clarify that applicants requesting HCPCS codes for drugs and biologicals are not required to submit such information.

In addition to the specific comments below, BIO also notes that in 2009, the January 3rd submission deadline falls on a Saturday. Thus, BIO encourages CMS to accept applications until Tuesday, January 6, 2009. This would allow applicants an additional day, Monday, January 5, to compile and submit their HCPCS applications, as the preceding week includes the New Year's Day holiday on Thursday.

I. CMS Should Finalize Revisions to the HCPCS Request Form Clarifying that Application Requirements Apply Equally to Both Drugs and Biologicals.

BIO applauds CMS for clarifying in the proposed 2010 HCPCS request form that the coding application requirements apply equally to both drugs and biological products by inserting the term "biological" in certain places throughout the form. In previous written comments submitted to CMS, BIO requested written clarification from the agency that HCPCS coding requests for biological products licensed by the FDA under section 351 of the Public Health Service (PHS) are subject to the same requirements as drugs approved under section 505 of the Food, Drug, and Cosmetic Act (FDCA).[4] BIO particularly supports the proposed revisions to Question 11 of the request form, which make it clear that applicants seeking HCPCS codes for biologicals can submit FDA approval documentation after the January 3rd submission deadline, until March 31, 2009. We also strongly support the language added to Question 12 clarifying that the submission marketing data is not required for biological coding applications. BIO urges CMS to finalize these changes in the 2010 HCPCS request form.

BIO also supports CMS' proposed revision to Question 14 of the draft HCPCS request form that exempts drugs and biological coding applicants

[4] BIO Letter to CMS regarding CMS–10224 (Agency Information Collection Activities: Proposed Collection; Comment Request; HCPCS Level II Code Modification Request Process, September 18, 2007, available at: http://bio.org/healthcare/medicare/20070918.pdf.

from providing information regarding the "Manufacturer's Suggested Retail Price." As BIO noted in its previous comments, the HCPCS Workgroup is not tasked with assigning payment amounts to the codes that it establishes for drugs and biologicals, and thus, pricing information is unnecessary to the coding process. Indeed, payment rates for most drugs and biological products in Medicare are based on Average Sales Price (ASP) or, for new therapies, Wholesale Acquisition Cost (WAC) per the requirements under Section 1847A of the SSA. Therefore, BIO supports CMS' proposal to eliminate requests for pricing data for drugs and biologicals in the 2010 HCPCS application form, and urges the agency to finalize this proposal.

In addition, we applaud CMS for incorporating BIO's suggestion of eliminating the term "biologic" in places where it appeared throughout the HCPCS application form and replacing it with the term "biological." Doing so improves consistency between the HCPCS application process and other Medicare regulations and guidance, as well as the SSA, which all use the term "biological."

II. CMS Should Not Require Data on Clinical Outcomes with HCPCS Applications for Drugs and Biologicals.

BIO remains concerned by CMS' request in Question 7 of the draft 2010 HCPCS request form for detailed information on clinical outcomes. In comments to the draft 2009 HCPCS application form, BIO noted that requiring the submission of extensive information on clinical outcomes for drug and biological coding applications is inappropriate for the HCPCS coding process and would result in an unnecessary burden on both manufacturers and the agency.[5] It is not the role of the HCPCS Workgroup to determine whether a drug or biological demonstrates, "significantly superior clinical outcomes" compared to existing therapies when evaluating a coding request. BIO has long held the position that biological products and drugs without therapeutic equivalents in the Food and Drug Administration's (FDA) Orange Book are not interchangeable, and because of this, they should not be grouped together within HCPCS codes based on arbitrary, undefined distinctions that the agency cannot apply consistently. Creating unique HCPCS codes for each brand of a drug or biological product, based on classifications by the FDA, helps protect beneficiary

[5] BIO Letter to CMS, September 18, 2007, available at: http://bio.org/healthcare/medicare/20070918.pdf.

access to medically necessary care by ensuring that reimbursement is appropriate for each brand.

Congress endorsed this view when enacting the ASP reimbursement methodology in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). According to CMS' recent guidance enacting those provisions, in order to facilitate accurate and separate payment under Section 1847A, the agency now determines whether a new drug or biological requires the assignment of a unique code based upon the lack of therapeutic equivalents listed in the FDA Orange Book and the date of first sale.[6] Thus, in the context of HCPCS coding applications for single source drug and biological products, evidence of "superior clinical outcomes" in the medical literature is irrelevant to the performance of the HCPCS Workgroup's function in assigning unique codes.

While BIO acknowledges that CMS has proposed several revisions to Question 7 in the draft 2010 HCPCS request form that are apparently intended to clarify the question, we strongly urge the agency to more explicitly state that coding applications for biologicals and drugs without therapeutic equivalents listed in the FDA Orange Book are not required to submit data demonstrating "superior clinical outcomes." Specifically, BIO requests that CMS further clarify that manufacturers requesting codes for biologicals and drugs without therapeutic equivalents, as identified in Question 7A, are not required to complete Questions 7B and 7C.

III. Conclusion

BIO appreciates the opportunity to offer these comments. We look forward to continuing to work with the agency to identify and implement enhancements to the HCPCS process that improve patient access to innovative therapies. Please feel free to contact me at 202-312-9281 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

[6] CMS guidance (April 24, 2007), available at: http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/code_Def.pdf.

Respectfully submitted,

/s/

John Siracusa
Manager, Medicare Reimbursement
& Economic Policy