Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Bonnie L. Harkless
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development—C
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

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

Dear Ms. Harkless:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the 2009 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.

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, we continue to believe more can be done to streamline the process, as well as to improve transparency and clarity for manufacturers. BIO is encouraged by CMS' recent guidance regarding the assignment of unique codes to single source drugs and biological products for the purposes of

[1] 72 Fed. Reg. 39812 (July 20, 2007)

accurate and separate payment under Section 1847A of the Social Security Act (SSA). We urge the agency to continue to implement the policy of assigning unique, permanent codes to all innovative drugs and biological products to ensure appropriate and timely patient access to novel treatments.

Despite these improvements, BIO is concerned by CMS' recent attempts, in certain instances, to inappropriately address coverage and payment issues in HCPCS coding decisions. 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.[2] Accordingly, BIO requests that CMS modify the 2009 HCPCS application to remove certain requirements that are neither appropriate nor relevant to the performance of the specific functions of the coding process. In addition, BIO asks CMS to clarify that it will apply consistent application requirements to both drugs and biological products.

BIO also is concerned that CMS' proposed revisions to the HCPCS application form will complicate the process and further burden manufacturers rather than "streamline[] the form into a user-friendly application" and "refine" the questions as the agency asserts.[3] CMS would benefit greatly from additional public input on these issues; however, we are concerned that many stakeholders missed the revised application form entirely as it was modified through a proposed information collection through the Paperwork Reduction Act of 1995 rather than posted 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 asks CMS to consider reissuing the proposed form for additional public comment.

I. CMS Should Not Require Data on Medical Outcomes with HCPCS Applications for Drugs and Biologicals

BIO is concerned by CMS' proposed revisions to the 2009 HCPCS application form that would require manufacturers to submit detailed and

[2] HCPCS Level II Coding Procedures, available at: http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/LevelIICodingProcedures113005.pdf.
[3] 72 Fed. Reg. at 39812-13

comprehensive information on clinical outcomes. Specifically, Question 7B of the proposed HCPCS application would require applicants to describe in detail "claims of significant therapeutic distinction" for their products compared to other items, as well as specify how their products result in a "significantly improved medical outcome or significantly superior clinical outcome" compared to currently coded products. According to the application, in complying with this requirement, CMS would expect applicants to include copies of articles that result from a "systematic analysis" of the available literature, as well as address "unfavorable" studies with "rebuttal or explanation."

Requiring the submission of such extensive information on clinical outcomes is inappropriate for the HCPCS coding process and would result in an unnecessary burden on both manufacturers and the agency. 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 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 access to medically necessary care by ensuring that reimbursement is appropriate for each brand.

Congress endorsed this view when enacting the Average Sales Price (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.[4] Thus, in the context of HCPCS coding applications for single source drug and biological products, evidence of "superior clinical

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

outcomes" in the medical literature is irrelevant to the performance of the HCPCS Workgroup's function in assigning unique codes.

BIO also is concerned that the estimated hour and cost burden of the new form is understated, particularly given the substantial additional requirements the revised form would impose. Many of our members report that they currently cannot complete the form in 11 hours and clearly will not be able to do so in the future if required to conduct a "systematic analysis of the available literature" and to provide "appropriate rebuttal or explanation" of unfavorable articles among other new requirements.

Therefore, BIO strongly urges CMS to eliminate the requirement that applicants submit detailed data on clinical outcomes with HCPCS applications and continue to rely on FDA approval and classifications to determine whether a product requires a unique code. Alternatively, in light of the recent guidance on Section 1847A, CMS should clarify that this requirement does not apply to coding requests for drug and biological products.

II. CMS Should Not Require Information on Product Pricing or Cost with HCPCS Applications

Similarly, BIO questions the information sought by Question 14 of the proposed 2009 HCPCS application form, which requires applicants to submit the "Manufacturer's Suggested Retail Price" or "list price" for the item. CMS states that it is necessary to collect this information to "ensure that the appropriate pricing and payment is assigned for the product."

However, as noted above, the agency clearly acknowledges that coding decisions are made separately from both coverage and payment determinations. Thus, the purpose of CMS requesting this information in the HCPCS application is unclear—the HCPCS Workgroup is not tasked with assigning payment amounts to the codes that it establishes. Indeed, payment rates for most drugs and biological products in Medicare are based on ASP or, for new therapies, Wholesale Acquisition Cost (WAC) per the requirements under Section 1847A of the SSA. Therefore, BIO urges CMS to eliminate requests for pricing and cost in the 2009 HCPCS application form and to leave payment decisions to others within the agency.

III. CMS Should Apply Consistent HCPCS Application Requirements for Drugs and Biological Products

As mentioned above, BIO greatly appreciates CMS' efforts to date to improve the process for assigning HCPCS codes, such as eliminating the requirements for FDA approval by the application date and for collecting marketing data. These improvements help important new drugs and biological products obtain permanent codes and have improved patient access to care accordingly.

However, BIO requests clarification from CMS 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). In the past, CMS has consistently applied the same standards for accepting HCPCS coding applications for manufacturers of both drugs and biologicals. However, BIO is concerned that recent actions by the agency have generated confusion and uncertainty among prospective applicants regarding the requirements for biological products. Such uncertainty can be reduced by making certain clarifications to the 2009 HCPCS application.

For example, Question 12 of the proposed application form references the fact that marketing data are not required for drugs, but does not mention that this policy also applies to biologicals. To reduce confusion, CMS should confirm that coding requests for biologicals are entitled to the same requirements as drugs, specifically with respect to acceptance after the FDA approval deadline and waiving of the marketing data requirement. Drugs and biologicals are treated similarly in all other aspects of the Medicare program, and the definitions of these terms are the same in the SSA.[5] The term "drugs and biologicals" is used consistently in the main statutory benefit category,[6] the statutory provisions on payment,[7] and within the Medicare Claims Processing Manual.[8] There is no valid basis upon which CMS could distinguish drugs from biologicals for purposes of the HCPCS

[5] SSA § 1861(t) (defining the term drugs or biologicals).
[6] SSA § 1861(s)(2)(A), (B).
[7] SSA § 1842(o)(1).
[8] CMS, Medicare Claims Processing Manual, Chapter 17, "Drugs and Biologicals" (July 23, 2007).

application process, and we ask CMS to clarify that they will be treated similarly in the 2009 HCPCS application.

In addition, we ask that CMS eliminate the term "biologic," and instead use the terms "biological" and "biological product." The SSA consistently uses the term "biological" as do Medicare regulations and guidance.

IV. 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.

Respectfully submitted,

/s/

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