

September 17, 2007
Reference No.: FASC07061

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

**RE: Comments on Information Collection Request for Healthcare
Common Procedure Coding System**

Dear Ms. Harkless:

The Plasma Protein Therapeutics Association (“PPTA”) submits these comments in response to the information collection request related to the Healthcare Common Procedure Coding System (“HCPCS”) modification process that was issued in the Federal Register on July 20, 2007 (72 Fed. Reg. 39812). Although not published in the Federal Register, this information collection request pertains to the draft HCPCS application that would be used for the calendar year 2009 HCPCS code cycle. It is on this draft document that PPTA comments. For reasons discussed in more detail below, we urge the Centers for Medicare and Medicaid Services (“CMS”) to revise the application to ensure that drugs and biologicals are treated similarly in the HCPCS process, to eliminate aspects of the application that are more appropriate for the agency’s coverage or payment policies, and to clarify the pricing information sought in the application.

PPTA is the association that represents the manufacturers of plasma protein therapies, all of which are considered biological products. These therapies, which include albumin, blood clotting factor, alpha-1 antitrypsin, and intravenous immunoglobulin, are used to treat a variety of orphan diseases and serious medical conditions for a very small, fragile patient population in the United States. PPTA members produce more than 80 percent of the plasma protein therapies for the U.S. market and more than 60 percent of such therapies for global consumption. Our members are constantly striving to develop new therapies to improve the clinical options for the pertinent patient populations and thus often approach CMS about a new or revised HCPCS code.

I. Drugs and Biologicals Should be Treated the Same in the HCPCS Process

In the draft HCPCS application, there are references to drugs, biologics and biologicals. These various references, with no clear statement as to whether references to drugs are considered to include biologicals, are confusing. CMS should simplify and clarify the application to be clear that any reference to “drug” is also a reference to “biological” as well. In addition, CMS should discontinue the use of the term “biologic,” as that term has no meaning in Medicare, which instead uses the “term biological.”¹

Below are specific examples of the concerns that we have with the draft application:

- *Timing of Food and Drug Administration (“FDA”) Approval* – In a few places, the document indicates that, while an application for a code in 2009 would be due on January 3, 2008, for a drug, the FDA approval can be submitted after that date and no later than March 31, 2008. For all other items, FDA approval would have to be submitted with the application such that approval would need to be obtained by January 3, 2008.
- *Need for Post Approval Marketing Experience* – The draft document requires the applicant to submit three months of marketing experience after FDA approval for all “non-drug” items, and that marketing data is not required for “drugs,” making no mention of biologicals in referencing marketing data. Yet, the very next sentence states that date of first sale should be provided for drugs or biologicals.
- *HCPCS Category* – The draft document lists “Drug/Biologic” as one category.

The first two items above create ambiguity as to whether, for applications involving biologicals, the FDA approval can be submitted after the application due date and no later than March 31, 2008, and whether marketing data would not be needed for such an application. PPTA believes that there should be no question that applications for biologicals should be treated the same as drugs on these points – that FDA approval should be accepted up to March 31, 2008 and that there is no requirement for marketing data. Drugs and biologicals are treated similarly consistently in the Medicare program. Indeed, the definitions of these terms are exactly the same in the Medicare statute.² Further, the main statutory benefit category for drugs and biologicals links these terms together and applies the same coverage standards.³ Likewise, the statutory provisions on payment consistently refer to drugs or biologicals.⁴ The agency also has established a specific chapter in the Medicare Claims Processing Manual (Chapter 17) devoted to “drugs and biologicals.”

¹ See Social Security Act (“SSA”) § 1861(t) (defining the term drugs or biologicals) (emphasis added).

² See id.

³ See SSA § 1861(s)(2)(A), (B) (covering drugs and biologicals that are not usually self-administered by the patient as incident to a physician’s service).

⁴ See SSA § 1842(o)(1).

As noted above, even in the draft application with regard to inclusion of date of first sale, CMS would treat drugs and biologicals similarly (including with regard to submission of FDA approval and exclusion from requirement for submitting marketing data). Given that, there is no valid basis upon which CMS could treat drugs and biologicals differently for purposes of the HCPCS code application. PPTA requests that CMS revise the document to ensure that all references to drugs are also references to biologicals. Mechanically, this could be done by adding “or biologicals” in each place that “drugs” appears (as the agency did with respect to seeking date of first sale).

With regard to the HCPCS category in Item number 3J, it is unclear why CMS uses the term “biologic” when, as noted above, the Medicare statute consistently uses the term “biological.” In order to promote clarity in the terminology of the HCPCS application, PPTA suggests that CMS use the term “biological” instead of biologic in the listing of HCPCS categories.

II. Coverage

In item number 7B of the draft application, CMS specifies that claims of significant therapeutic distinction when compared to the use of other, similar items would have to be described in detail. The application also would require the applicant to articulate the clinical theory behind the claim, including by comparison to currently coded products. Further, applicants would have to specify how the products result in a significantly improved medical outcome or significantly superior clinical outcome. PPTA strenuously objects to the inclusion of these requirements, as they call for information that is, at most, relevant to Medicare coverage or payment policies, not to decisions on coding.

Indeed, these requirements are inconsistent with the agency’s own characterization of the HCPCS coding process. In the agency’s most comprehensive description of the HCPCS process available on its website,⁵ CMS explains that:

HCPCS is a system for identifying items and services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment.

⁵ This document is available at <http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/LevelIII CodingProcedures113005.pdf>.

Demonstrations of superiority of one product over other existing products are considerations for coverage or payment, not coding. For example, in determining whether a medical device is eligible for pass-through payments under the hospital outpatient prospective payment system, CMS requires the applicant to demonstrate that the device substantially improves the diagnosis or treatment of an illness or injury compared to existing devices.⁶ Similarly, for additional payments to be made for new technologies under the hospital inpatient prospective payment system, the technology must be shown to represent a substantial clinical improvement over existing technologies.⁷

As a result, the inclusion of the product comparison requirements with assessments of clinical comparisons to existing products and demonstration of clinical superiority or improvement, in the draft application is directly contrary to the agency's own statements as to the purpose of the HCPCS coding process. PPTA agrees with the agency that coding decisions should be made independent of coverage and payment decisions. Therefore, CMS should remove the portions of item 7B that seek information that relates to coverage and payment, but not coding (i.e., the third through the eighth sentences).

III. CMS Should Clarify What a Manufacturer's Suggested Retail Price is for a Drug or Biological

Item number 14 in the draft application asks for the Manufacturer's Suggested Retail Price ("MSRP") or list price of the item and makes clear that this request applies to drugs. Consistent with our recommendation in Section I above, PPTA believes that this requirement also would apply to biologicals and thus our member products. However, it is not clear to us what an MSRP is with respect to drugs or biologicals. Moreover, it is not clear why this construct is even relevant given that Medicare reimbursement for most drugs is tied to average sales price and for new products, CMS uses wholesale acquisition cost. Accordingly, PPTA asks that the agency clarify what information it seeks related to drugs or biologicals in item number 14 or tie the request to the type of information that is more relevant to Medicare reimbursement methodologies.

IV. Conclusion

PPTA appreciates the opportunity to comment on the draft HCPCS application for the 2009 coding cycle. We urge CMS to revise the draft document to make clear that biologicals and drugs are treated similarly in the HCPCS process and to eliminate the aspects of the application that seeks information that is relevant to coverage or

⁶ See <http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/catapp.pdf> (device pass-through application).

⁷ See http://www.cms.hhs.gov/AcuteInpatientPPS/Downloads/FY2009_New%20Technology%20App.pdf (new technology add-on application).

payment. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Julie Birkofer
Vice President, North America