BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Statement to the Advisory Panel on Ambulatory Payment Classification Groups
March 5-7, 2008

The Biotechnology Industry Organization (BIO) appreciates this opportunity to testify before the Advisory Panel on Ambulatory Payment Classifications (APC Panel). 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 in the United States.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO is deeply concerned that the policies the Centers for Medicare and Medicaid Services (CMS) has adopted and is considering adopting for drug and biological therapies will harm beneficiary access and will discourage future innovation. Specifically, we are alarmed that the agency has set reimbursement for separately paid drugs and biologicals at average sales price (ASP) plus five percent, with the intention of dropping reimbursement to ASP plus three percent in 2009. Similarly, we are troubled by CMS's intentions to expand packaging and the agency's failure to pay appropriately for pharmacy services despite continued analysis and input from numerous stakeholders. We believe CMS's rate-setting methodology for drugs and biologicals and the services necessary to administer them is critically flawed and violates the clear language of the Social Security Act (SSA). It also fails to follow past recommendations of the APC Panel.

In order to preserve hospitals' ability to provide high quality drug and biological therapies to Medicare beneficiaries, BIO urges the APC Panel to make the following recommendations to CMS:

- Pay no less than ASP plus six percent for drugs and biologicals administered in the OPPS;
- Adjust payments to ensure that pharmacy service costs are adequately reimbursed; and
- Make separate payment for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting or alternatively, not increase the packaging threshold for these therapies.

I. <u>The APC Panel Should Recommend that CMS Pay No Less Than ASP Plus Six Percent for Drugs and Biologicals Administered in the OPPS.</u>

1201 Maryland Avenue, SW • Suite 900 • Washington, DC 20024-2149 • 202.962.9200 • Fax 202.488.6301 • www.bio.org

For 2008, CMS continues to use a flawed methodology to establish payment rates for separately paid drugs and biologicals that does not comply with the SSA's requirement to reimburse these therapies at the average acquisition cost for each drug for that year with an adjustment for pharmacy service costs.[1] CMS's methodology of estimating aggregate average acquisition and pharmacy service and handling cost substantially underestimates the actual costs of acquiring and supplying separately paid drugs and biologicals and produces inaccurate and unpredictable results on a drug by drug basis, and likely does so in the aggregate as well. In the Final Rule, CMS compares the estimated total costs of drugs, as derived from claims data, to total costs calculated using ASP and concludes that ASP plus three percent represents hospitals' aggregate average acquisition cost and pharmacy service costs.[2] The agency decided to transition to this rate and to reimburse separately paid drugs and biologicals without pass through status at ASP plus five percent for 2008.

There are several significant problems with CMS's methodology. First, CMS does not account for increases in ASPs in its analysis. Instead of comparing estimated costs to contemporaneous ASPs, CMS compares costs derived from charges in the 2006 claims data to ASPs effective in the fourth quarter of 2007. The charges in the 2006 claims data do not include the increases in the prices of drugs and biological products that occurred in 2007. Because many hospitals update their charges only once each year, the claims data also may not include price increases from 2006. As a result of this discrepancy, CMS's estimated aggregate cost as a percent of ASP is too low. The effect of this error can be seen in the difference between CMS's aggregate cost estimates in the proposed and final rules. When CMS compared the 2006 claims data to ASPs based on data from the fourth quarter of 2006, it concluded that the aggregate average acquisition cost to hospitals was ASP plus five percent. When CMS compared the same 2006 claims data to updated ASPs from two quarters later, the estimated cost decreased to ASP plus three percent. If CMS compared costs derived from the 2006 claims data to ASPs from earlier in 2006, it is possible that the effect of inflation on the aggregate estimated costs would be even larger.

Second, CMS uses the 'all-drug' average cost-to-charge ratio to estimate costs for the subset of separately-payable drugs. However, because the 'all-drug' average ratio can only accurately estimate costs for all drugs, this methodology is

---

1 SSA § 1833(t)(14)(A)(iii)(I).
2 72 Fed. Reg. 66580, 66763 (Nov. 27, 2007).

only valid if the cost estimate (relative to ASP) for the subset is the same as the estimate for all drugs. Any difference represents a bias in the methodology. In fact, two independent analyses estimate the costs for all drugs at between ASP+12.6 to 12.9 percent, compared to CMS' estimate of ASP+3 percent for the subset of separately payable drugs. Our own analysis also found that CMS' methodology produces estimated average unit costs, stated as a percentage of ASP, that range from ASP minus 97 percent to ASP plus 7179 percent. Clearly, then, the 'all-drug' average ratio leads to a biased estimate costs for the subset of separately payable drugs.

The aggregated estimated costs derived from CMS's methodology clearly are not the "average acquisition cost for the drug for that year" that Congress intended to serve as the basis for payment for drugs and biologicals under the OPPS. The SSA requires Medicare to reimburse specified covered outpatient drugs (SCODs) at the "average acquisition cost for the drug for the year," as determined by the Secretary using survey data.[3] If acquisition cost data are not available, the payment shall be set at the average price for the drug established under section 1842(o), 1847A, or 1847B (e.g., ASP plus 6 percent or the rates determined under the Competitive Acquisition Program).[4]

Since the GAO concluded its survey of acquisition cost in 2004, neither GAO nor CMS has conducted the subsequent periodic surveys required by the statute and therefore CMS does not have the data necessary to set payment at average acquisition cost. We understand that these surveys are difficult to conduct and generally have supported the use of ASP plus six percent as a proxy for acquisition cost instead of asking the agency to incur the administrative and financial burden of conducting additional surveys. We continue to believe that ASP plus six percent would be a reasonable payment for acquisition cost. We believe it is inconsistent with both the language and the intent of the statute to use aggregate costs derived from charges as a proxy for average acquisition cost and pharmacy service and handling costs for each drug when the methodology for calculating those costs is severely flawed and does not even approximate acquisition cost alone—much less acquisition *and* handling costs. Congress enacted these provisions because it disagreed with CMS's use of claims data to set payment rates for these drug and biological therapies. The statute requires CMS to use either an accurate methodology to determine average acquisition cost for each drug or the rates established under sections 1842(o), 1847A, or 1847B.

---

3 SSA § 1833(t)(14)(A)(iii)(I).
4 SSA § 1833(t)(14)(A)(iii)(II).

Accordingly, we urge the APC Panel to recommend that CMS pay at least ASP plus six percent for drugs and biologicals administered in the OPPS.

II. The APC Panel Should Recommend that CMS Adjust Payments to Ensure that Pharmacy Service Costs are Adequately Reimbursed.

Another reason that CMS's methodology is flawed is that in addition to underestimating the acquisition costs for these drugs, CMS fails to adjust payments to ensure that the costs of essential pharmacy services are adequately reimbursed. To provide drugs safely and prevent medication errors, hospitals incur the significant costs of complex and resource-intensive pharmacy services. In 2005, the Medicare Payment Advisory Commission (MedPAC) reported that pharmacy department wages, salaries, fringe benefits, and supplies made up 26 to 28 percent of pharmacy department direct costs.[5] MedPAC noted that most hospitals do not set charges for handling costs and lack precise information about the magnitude of these expenses,[6] therefore, to the extent that these costs are included in hospitals' charges for drugs, it is unlikely that the charges for any individual drug reflect the costs of the pharmacy services associated with providing that drug. Instead, these costs may be included in hospitals' charges for all drugs in the aggregate. Thus, any estimate of these costs also must consider all drugs dispensed by hospital pharmacies, not just the drugs that are separately reimbursed under the OPPS.

When CMS's methodology is applied to all drugs with HCPCS codes, including the drugs that are packaged under the OPPS, the mean unit cost, on average, is ASP plus 12.6 percent. This rate is more likely to represent hospitals' pharmacy service costs plus drug acquisition costs in the aggregate than CMS's significantly lower estimate of ASP plus three percent or the 2008 payment rate of ASP plus five percent.

By failing to account for hospitals' significant costs of safely preparing and handling drugs and biological products, CMS disregards Congressional intent, the findings of the MedPAC, the APC Panel's recommendations, and the advice of numerous stakeholders. We believe that the reasons CMS gave in the final rule for 2007 for not setting payment at rates determined by its estimation methodology remain valid in 2008. Specifically, CMS noted that its methodology produced a

---

5 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

6 MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

payment rate for both drug acquisition and pharmacy service costs (ASP plus four percent) that was comparable to the GAO's survey data for acquisition cost only.[7] We see no reason to believe that ASP plus three or five percent is any more appropriate in 2008 than ASP plus four percent was in 2007. CMS also explained in the final rule for 2007 that it needed "a better understanding of the full nature and magnitude" of hospitals' overhead and pharmacy service costs and that "maintaining stability in the payment levels for drugs and biologicals should be considered in light of the inherent complexity in determining how to best account for pharmacy overhead costs."[8] These considerations are equally valid today.

For these reasons, we urge the APC Panel to recommend that CMS set payment for all drugs without pass-through status at no less than ASP plus six percent in 2009, as required by the statute, and to make an adjustment for pharmacy service costs to ensure they are reimbursed adequately. To create a pool of available funds that best represents the cost of critical pharmacy services in the complex hospital environment, we propose that CMS set the payment for all drugs and biologicals at no less than ASP plus six percent. Separately paid drugs would be reimbursed at no less than ASP plus six percent, and for packaged drugs, the cost of the drug attributed to the cost of the associated procedure would be at least ASP plus six percent for the drug. CMS could then set aside in a separate pool the difference between estimated mean unit cost as calculated for all drugs with HCPCS codes (ASP plus 12.6 percent) and payment for acquisition cost (ASP plus six percent).

We have identified several methods CMS could use to allocate these costs among drugs and biological products, and urge the agency to meet with us and other stakeholders to discuss the options. One approach would be to divide the pool evenly among all separately paid drugs and biological products and automatically make a flat payment for pharmacy services each time a hospital bills for one of these therapies. In effect, the pharmacy payment would be bundled into payment for the drug or biological product. CMS also could make payments based on a percentage of ASP. Alternatively, CMS could set different payments for each of three tiers of pharmacy services representing low, medium, and high complexity. CMS would assign all separately paid drugs and biological products to one of these pharmacy service categories and would make a payment for pharmacy services automatically each time a hospital bills one of these therapies.

---

7 71 Fed. Reg. 68059, 68091 (Nov. 24, 2006).
8 Id.

This would be similar to the plan recommended by the APC Panel in the past.[9] A third option would be for CMS to use the pool to reimburse specific pharmacy services. CMS could reimburse these services through composite APCs that would require hospitals to bill for both a drug and a corresponding service to receive the full payment. We the APC Panel to recommend that CMS consider these options and work with hospitals, pharmacists, and other stakeholders to develop a fair and easy to implement payment methodology.

III. The APC Panel Should Recommend that CMS Make Separate Payment for All Drugs and Biologicals with HCPCS Codes or Alternatively, Not Increase the Packaging Threshold for These Therapies.

In the Final Rule, CMS indicates that it intends to extend packaging for drugs and biological products in future years.[10] To the contrary, BIO believes that CMS should make separate payment for all drugs and biologicals with HCPCS codes in the OPPS just as it does for these therapies when they are administered in a physician office. That said, for 2008, CMS packages payment for all diagnostic radiopharmaceuticals and contrast agents. CMS explains that these therapies can be treated differently from other SCODs because the statutory packaging threshold has expired and the agency believes that these drugs "function effectively as supplies that enable the provision of an independent service, rather than serving themselves as the therapeutic modality."[11] Moreover, CMS notes that these drugs could be considered to not be SCODs because CMS has not established a separate APC for them.[12] These assertions ignore the clear language of the statute and Congressional intent. The statute defines a SCOD as a "covered outpatient drug for which a separate ambulatory payment classification group (APC) has been established" and that is a radiopharmaceutical or a drug or biological for which pass-through payments were made on or before December 31, 2002.[13]

We note first that the statute does not distinguish between drugs and biologicals that serve as a therapeutic modality and those that are used with other services.[14] CMS has no authority to reclassify a drug or biological as a supply simply to avoid payment as a SCOD. Second, Congress did not intend for CMS to

---

9 APC Panel on Ambulatory Payment Classification Groups, Recommendations: March 7-8, 2007, at 2, http://www.cms.hhs.gov/FACA/Downloads/Mtg_Rpt_0372007.zip.
10 72 Fed. Reg. at 66757.
11 Id. at 66767.
12 Id.
13 SSA § 1833(t)(14)(B).
14 Id.

circumvent the statutory payment provisions for SCODS by establishing high packaging thresholds or packaging whole classes of therapies. To do so would render the statute's explicit payment instructions meaningless. When Congress enacted this definition, it established a packaging threshold of $50 per administration for drugs administered in 2005 and 2006[15] because it objected to the $150 packaging threshold that was in effect in 2003. Congress intended for CMS to establish a low packaging threshold for all drugs and biological products, and the absence of a statutory requirement regarding the packaging threshold after 2006 should not be interpreted as support for widespread packaging.

We ask the APC Panel to urge CMS to comply with the language and intent of the statute. Although BIO believes that separate payment should be made for every drug or biological with a HCPCS code just as it is made in the physician office, at a minimum, packaging should not be expanded beyond current levels. We ask the APC Panel to make this recommendation to CMS.

* * *

Thank you for the opportunity to present this statement on behalf of BIO. I would be pleased to answer any questions.

---

[15] SSA § 1833(t)(16)(B).