BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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***BY ELECTRONIC DELIVERY***

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-1392-FC (Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates)**

Dear Administrator Weems:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) final rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2008 payment rates, published in the Federal Register on November 27, 2007 (the "Final Rule").[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 in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

In the past, BIO has applauded CMS's efforts to improve the OPPS and protect Medicare beneficiaries' access to drugs, biological therapies, and other innovative healthcare technologies. In the Final Rule, however, CMS abandons these efforts by expanding packaging and setting reimbursement for separately paid drugs at average sales price (ASP) plus five percent, with the intention of setting reimbursement at ASP plus three percent in 2009. By implementing these changes to the OPPS, CMS has disregarded the clear language of the Social

[1] 72 Fed. Reg. 66580 (Nov. 27, 2007).

Security Act (SSA) and the reasoned advice of the Advisory Panel on Ambulatory Payment Classification Groups (the APC Panel) and numerous stakeholders. We are deeply concerned that these policies will harm beneficiary access to critical therapies and will discourage future innovation.

As CMS begins to work on the proposed rule for 2009, we urge the agency to reverse course and establish payment for drugs and biologicals at no less than ASP plus six percent, adjust payments to ensure 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. We urge CMS not to expand packaging for drugs and biologicals in 2009 as it suggests in the Final Rule. In addition, we urge the agency to adjust its calculations of the costs of drugs and biologicals to account for charge compression. Before the agency proposes any major changes to the OPPS methodology in the future, we urge it to make available to the public the data necessary to understand the full effect of the proposed changes, in sufficient time that stakeholders are able to perform their own independent analysis of it.

## I. The Final Rule Fails to Comply with the Statutory Requirement to Reimburse Each Drug and Biological Therapy Without Pass-Through Status at the Average Acquisition Cost for the Drug for that Year with an Adjustment for Pharmacy Service Costs.

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.[2] As we explained in our comments on the 2007 and 2008 proposed rules, 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

[2] SSA § 1833(t)(14)(A)(iii)(I).

pharmacy service costs.[3] As we explained in detail in our comment letter on the proposed rule, there are several significant problems with this 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's analysis fails to account for the effects of charge compression by applying for each hospital a single cost-to-charge ratio (CCR) to all pharmacy charges. Hospitals tend to mark up their charges for more costly drugs less than their charges for lower priced drugs. Applying a single CCR to the higher cost, separately paid drugs produces charge compression, or inaccurately low estimates of these drugs costs. In 2004, the Government Accountability Office (GAO) found that CMS's OPPS ratesetting methodology produces rates that "do not uniformly reflect hospitals' costs" because it "does not recognize hospitals' variability in setting charges."[4]

These concerns were reinforced by the RTI International report on charge compression in calculating payments under the inpatient prospective payment system. This report found evidence of charge compression in hospitals' pricing for IV solutions when compared to other drugs,[5] and the report recommended that

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[3] Id. at 66763.
[4] Government Accountability Office, Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, Sept. 2004, at 15-16.
[5] Kathleen Dalton, A Study of Charge Compression in Calculating DRG Relative Weights, Jan. 2007, at 10, http://www.cms.hhs.gov/reports/downloads/Dalton.pdf.

CMS disaggregate the CCRs for drugs and IV solutions to produce more accurate estimates of the costs of these therapies.[6] Although CMS acknowledged the "obvious importance" of the RTI report's findings, it did not implement an adjustment for charge compression in its calculation of payment rates for 2008. As a result, CMS greatly underestimates the true costs of separately paid drugs. Additionally, the agency's estimated costs for all drugs, compared to ASP on a drug-by-drug basis, continue to vary widely. Our own analysis found that CMS's methodology produces estimated average unit costs, stated as a percentage of ASP, that range from ASP minus 97 percent to ASP plus 7179 percent.

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.[7] 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).[8]

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 in our prior comments to CMS, we 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

[6] Id. at 16.
[7] SSA § 1833(t)(14)(A)(iii)(I).
[8] SSA § 1833(t)(14)(A)(iii)(II).

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.

Third, 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.[9] MedPAC noted that most hospitals do not set charges for handling costs and lack precise information about the magnitude of these expenses,[10] 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 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.[11] We see no reason to believe that ASP plus three or five percent is any more

[9] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.
[10] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.
[11] 71 Fed. Reg. 68059, 68091 (Nov. 24, 2006).

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."[12] These considerations are equally valid today.

For these reasons, we urge CMS to 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 we would like to meet with the agency 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. This would be similar to the plan recommended by the APC Panel.[13] 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

[12] Id.
[13] 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.

drug and a corresponding service to receive the full payment. We urge CMS to consider these options and work with hospitals, pharmacists, and other stakeholders to develop a fair payment methodology.

## II. CMS's Intent to Expand Packaging Is Contrary to the Statute and Congressional Intent.

In the Final Rule, CMS indicates that it intends to extend packaging for drugs and biological products in future years.[14] 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."[15] Moreover, CMS notes that these drugs could be considered to not be SCODs because CMS has not established a separate APC for them.[16] 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.[17]

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.[18] 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 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[19] 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

[14] 72 Fed. Reg. at 66757.
[15] Id. at 66767.
[16] Id.
[17] SSA § 1833(t)(14)(B).
[18] Id.
[19] SSA § 1833(t)(16)(B).

the absence of a statutory requirement regarding the packaging threshold after 2006 should not be interpreted as support for widespread packaging. We urge CMS to comply with the language and intent of the statute and not expand packaging beyond current levels.

## III. CMS Should Adjust Its Calculations to Account for Charge Compression and Make Data Regarding the Impact of Future Proposals Available to the Public.

We urge CMS to adjust its calculations of the costs of drugs and biologicals to account for charge compression. CMS believes that "packaged payment provides payment at average acquisition cost,"[20] but as we described above, CMS's methodology of determining acquisition cost from claims data is deeply flawed and produces wildly inaccurate estimates. To ensure that the costs of drugs, biological products, and other therapies are accurately reflected in payments for associated procedures, CMS must adjust its calculations to account for charge compression.

Moreover, before the agency proposes any major changes to the OPPS methodology in the future, we urge it to make available to the public the data necessary to understand the full effect of the proposed changes in sufficient time that stakeholders are able to perform their own independent analysis of it. Although the agency has made available for purchase the claims file that it uses to set payment rates, it is not practical for many small firms to use this file. Acquiring the file requires going through a process to obtain a data use agreement and the resources required to use this file for meaningful analysis are beyond the means of small companies. Firms exist which do analysis for small firms, however, the cost of these analyses is not insignificant. The agency should provide more analytic tables, such as the tables of medians that are currently available on the CMS web site, that would allow more interested parties to understand the effects of the complicated methodology and meaningfully comment on the proposed changes. For example, the agency should provide tables that show a model of the effects of future packaging or a charge compression adjustment. Such tables could show rates before the policy change and after the policy change for every HCPCS code and APC. CMS also should release the background data in a timely manner, preferably before a formal proposal is made. The same transparency should apply to any significant change proposed for the OPPS. It is

[20] 72 Fed. Reg. at 66639.

impossible to analyze and comment on such complex issues during the limited comment period in the full and thoughtful manner that these issues deserve. We thank CMS for meeting with stakeholders to explain its methodology in 2007, but we believe the development of the final rule for 2008 would be greatly simplified if CMS provided this data to the public in advance of the comment period. We ask CMS to provide this information as soon as possible – well before the proposed rule is released – to allow stakeholders sufficient time to analyze it.

In conclusion, BIO urges CMS to consider carefully its approach to payment for separately paid drugs and biological products without pass-through status and its intentions to expand packaging. The Medicare statute establishes clear requirements for payment for these therapies, and CMS should not ignore these provisions. BIO urges CMS to continue to work with stakeholders to ensure that Medicare's payments for drug and biological therapies are appropriate to protect beneficiary access to care. At a minimum, these therapies should be reimbursed at ASP plus six percent, the rate applicable in physicians' offices, with an additional adjustment for pharmacy service costs. CMS should not expand packaging further. It is critical that CMS account for the costs that hospitals must undertake to provide safe access to drugs and biologicals and reduce medication errors in the complex environment of the delivery of hospital services. In addition, we urge CMS to adjust for charge compression in 2009. Before this and other major changes to the OPPS are proposed, we ask the agency to make available to the public the data necessary to understand the full effect of the proposed changes in sufficient time that stakeholders are able to perform their own independent analysis of it.

Thank you for your consideration of these comments. Please contact me at 202-312-9281 if you have any questions or if we can be of further assistance.

Respectfully submitted,

/s/

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