Statement of the Biotechnology Industry Organization

Before the
Advisory Panel on Ambulatory Payment Classification Groups
February 17-19, 2010

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APC Panel Presentation Checklist
Biotechnology Industry Organization (BIO)
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List the financial relationship of presenter(s), if any, with any company whose product, services, or procedures are under consideration: The presenter is employed by BIO, a trade association that represents more than 1200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO receives membership dues from manufacturers of drug and biological therapies.

Physicians' Current Procedural Terminology (CPT) code(s) involved: Various drug and drug administration codes
APC(s) affected: Multiple drug and biological APCs
Description of the issue(s): BIO's statement will address Hospital Outpatient Prospective Payment System (OPPS) payment for drugs and biologicals and pharmacy services.
Clinical description of the service under discussion *(with comparison to other services within the APC)*: Various drugs and biologicals as well as their administration services. No other services are included in the relevant APCs.
Recommendations and rationale for change:
To improve beneficiary access to and payment accuracy for drug and biological therapies in hospital outpatient departments (HOPDs), BIO recommends that:

1. CMS pay no less than Average Sales Price (ASP) plus six percent for separately payable drugs and biologicals administered in the OPPS;
2. CMS reallocate a larger portion of pharmacy overhead costs from packaged to separately payable drugs than it did in the final rule for 2010;
3. If CMS does not finally reimburse the acquisition cost for drugs at no less than ASP plus six percent and increase the allocation of overhead costs to separately payable drugs, then the agency should remove data from hospitals that participate in the 340B program from CMS's rate-setting calculations for drugs and biologicals; and
4. CMS 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.

Expected outcome of change: Improved Medicare patient access and more appropriate payment to hospitals for all aspects of providing drug and biological

therapies in HOPDs**.**

Potential consequences of not making the change: Inaccurate and inadequate reimbursement to hospitals for providing drug and biological therapies and reduced beneficiary access as a result.

BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Statement to the Advisory Panel on Ambulatory Payment Classification Groups
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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 1200 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 understands that appropriate reimbursement based on an accurate payment methodology is essential to protecting beneficiary access to care and encouraging continued investment in innovation. We appreciate that the Centers for Medicare and Medicaid Services (CMS) has recognized some of the problems with its rate-setting methodology for drugs and biologicals and that the agency has worked to improve its methodology for 2010. We continue to believe that separately payable therapies are under-reimbursed, however, and ask the APC Panel to recommend yet again that they be paid no less than Average Sales Price (ASP) plus six percent.

In the hospital outpatient prospective payment system (OPPS) final rule for 2010, CMS acknowledged that its "standard drug payment methodology has the potential to 'compress' the calculated costs of separately payable drugs and biologicals and inflate the calculated costs of packaged drugs and biologicals to some degree."[1] CMS recognized that "[c]hanges to the packaging threshold and the packaged status of drugs and biologicals may result in changes to the estimated combined acquisition and pharmacy overhead costs of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products."[2] The agency also acknowledged that its calculated estimated acquisition and pharmacy overhead costs of ASP minus three percent for separately payable drugs likely is too low and ASP plus 259 percent for packaged drugs probably is too high.

At its last meeting, the APC Panel recommended that CMS pay for all separately payable drugs and biologicals at ASP plus six percent and that CMS

1 74 Fed. Reg. 60316, 60664 Nov. 20, 2009).
2 Id.

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redistribute costs from packaged drugs to separately payable drugs in order to do so. The Panel asked that CMS analyze the impact of this on different classes of hospitals and on the payment rates for other services. Finally, the APC Panel recommended that CMS and stakeholders refine their drug payment analysis "to assess the infrastructure costs associated with the preparation and handling of these products."[3]

Instead of following the recommendations of the APC Panel and the stakeholders and paying at least ASP plus six percent for separately payable drugs and biologicals, CMS implemented a payment methodology that maintained the payment rate at ASP plus four percent. The agency did this by reallocating a total of $200 million of the pharmacy overhead cost attributed to packaged drugs and biologicals to separately payable ones – $150 million from coded packaged drugs and biologicals with an ASP and $50 million from those that are uncoded and packaged.

Although BIO commends the agency's willingness to make the reallocation as well as its recognition that a portion of overhead from uncoded packaged drugs and biologicals also should be included, we are concerned that the reallocation is not sufficient. We believe that as long as CMS lacks data on hospitals' average acquisition cost, it must reimburse the acquisition cost of separately payable drugs and biologicals at ASP plus six percent, the rate applicable in physician's offices, plus an adjustment for pharmacy overhead. We also are concerned that CMS does not exclude data from hospitals that participate in the 340B program from its rate-setting calculations for drugs and biologicals.

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 separately payable drugs and biologicals administered in the OPPS;
- Reallocate a larger portion of pharmacy overhead costs from packaged to separately payable drugs than it did in the final rule for 2010;
- If CMS does not finally reimburse the acquisition cost for drugs at no less than ASP plus six percent and increase the allocation of overhead costs to separately payable drugs, then the agency should remove data from hospitals

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3 APC Panel Recommendations, August 5-6, 2009, available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.

that participate in the 340B program from CMS's rate-setting calculations for drugs and biologicals; 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. The APC Panel Should Recommend that CMS Pay No Less Than ASP Plus Six Percent for Separately Payable Drugs and Biologicals Administered in the OPPS.

For calendar year 2010, CMS continues to reimburse the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status at ASP plus four percent.[4] Although we commend CMS for reallocating some of the pharmacy overhead costs associated with packaged drugs to separately payable drugs – increasing the proposed payment rate from ASP minus three percent, as calculated using CMS's current methodology, to the proposed ASP plus four percent – we remain concerned that CMS does not have the data necessary to ensure that its proposed reimbursement rates equal hospitals' average acquisition cost. In the absence of this information, we urge the APC Panel to recommend that CMS pay no less than ASP plus six percent for separately payable drugs and biologicals, as Congress intended in the Social Security Act (SSA).[5]

Reimbursement at no less than ASP plus six percent for separately payable drugs and biologicals administered in the OPPS would ensure that hospitals are reimbursed appropriately for the acquisition costs of drugs and biologicals. Payment at ASP plus six percent is supported by our prior analysis of mean unit costs for non-340B hospitals yet is less than estimated cost for all drugs with HCPCS codes and ASP information of ASP plus 11 percent as calculated by CMS.[6] Moreover, unlike CMS's current methodology, reimbursement for acquisition cost at ASP plus six percent is consistent with the Medicare statute. 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

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4 74 Fed. Reg. at 60512.
5 SSA § 1833(t)(14)(A)(iii)(I).
6 74 Fed. Reg. at 60512.
7 SSA § 1833(t)(14)(A)(iii)(I).

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 Government Accountability Office (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 appreciate 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 CMS's current 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. Accordingly, we urge the APC Panel to recommend that CMS pay at least ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.

II. The APC Panel Should Recommend that CMS Reallocate a Larger Portion of the Pharmacy Overhead Costs Associated with Packaged Drugs to the Separately Payable Drugs.

CMS reallocated a total of $200 million of the pharmacy overhead cost attributed to packaged drugs and biologicals to separately payable ones – $150 million from coded packaged drugs and biologicals with an ASP and $50 million from those that are uncoded and packaged. BIO appreciates the agency's willingness to make the reallocation as well as its recognition that a portion of overhead from uncoded packaged drugs and biologicals also should be included; however, we are concerned that the amount of the reallocation is not sufficient.

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[8] SSA § 1833(t)(14)(A)(iii)(II).

CMS originally had proposed to reallocate $150 million of the $395 million in pharmacy overhead costs attributed to coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals because it represented "a middle ground between the one-third to one-half of the total pharmacy overhead cost associated with this set of packaged drugs and biologicals."9 In the final rule, however, the agency acknowledged that it "did not include uncoded drug and biological costs reported under pharmacy revenue code lines in [its] proposed rule estimate of the pharmacy overhead costs of packaged drugs and biologicals" and that "costs on uncoded pharmacy revenue code lines represent OPPS drug and biological cost."10

An analysis conducted by Chris Hogan, of Direct Research, LLC, found that packaged drugs and biologicals billed without HCPCS codes are subject to the same markup as packaged ones with HCPCS codes. Although CMS reasonably could have assumed that these drugs and biologicals have the same ratio of estimated cost to ASP as the packaged drugs and biologicals billed without HCPCS codes and have included them in the overhead pool, the agency declined to do so. Specifically, CMS explained in the 2010 final rule, "[W]e cannot be certain that we know what portion of the uncoded drug and biological cost is acquisition cost versus pharmacy overhead cost. Therefore, we are not willing to make even broader assumptions about the magnitude of ASP for uncoded drug and biological cost in claims or layer other assumptions on the proposed methodology that would further significantly redistribute costs as reported to us by hospitals within the framework of the OPPS ratesetting methodology."11 CMS acknowledged that there must be some pharmacy overhead cost associated with these uncoded packaged drugs and biologicals, however, and decided that it would adopt a transitional payment rate of ASP plus four percent while it further examined the issue and while hospitals examined administrative changes that would result in the submission of more accurate data.

CMS's analysis indicates that the additional overhead pool is substantial – approximately $656 million.12 We believe it is critical for CMS to continue to analyze this issue and to reallocate a more appropriate amount of overhead from uncoded, packaged drugs and biologicals to separately payable drugs and biologicals in 2011 and beyond.

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9 74 Fed. Reg. at 60510.
10 Id.
11 Id. at 60511.
12 Id. at 60358.

III. The APC Panel Should Recommend that CMS Remove Data from Hospitals that Participate in the 340B Program from Its Rate-Setting Calculations for Drugs and Biologicals If CMS Does Not Finally Reimburse the Acquisition Cost for Drugs at No Less than ASP Plus Six Percent and Does Not Increase the Allocation of Overhead Costs to Separately Payable Drugs.

A year ago, the APC Panel recommended that CMS exclude data from hospitals that participate in the 340B program from its rate-setting calculations if it did not implement the stakeholder proposal,13 and CMS rejected this recommendation. As we have explained in our testimony to you at prior meetings, CMS's cost estimates do not reflect the actual costs of acquiring and preparing drugs and biologicals at most hospitals because CMS calculates mean unit costs using data from all hospitals, including hospitals that purchase drugs and biologicals under the 340B program. Sales under the 340B program are excluded from the ASP calculation, however. Thus, CMS is mixing apples with oranges in its rate-setting calculations for these therapies.

Approximately one-third of all billed drugs and biologicals (by cost) under the OPPS are provided by 340B hospitals. Although the discounts are designed to help the 340B hospitals better serve their patients, including drugs purchased at 340B prices in the OPPS payment rate calculations could harm access to care at non-340B hospitals by significantly reducing the estimated mean unit cost of separately payable drugs. If these hospitals are excluded from the data, we calculate that the mean unit cost would increase about five percent of ASP.

Including sales at 340B prices significantly reduces CMS's estimated mean unit cost of separately payable drugs. The distorting effects of including data from 340B hospitals would be even greater if pending legislative proposals to allow significantly more hospitals to participate in the 340B program are implemented. Because the 340B program was not intended to harm access to care for patients of other hospitals, we believe that these hospitals should be excluded from CMS's rate-setting calculations for drugs and biologicals.

If CMS excludes data from the 340B hospitals, BIO strongly believes that CMS should continue to establish a single payment rate for all hospitals, including

13 APC Panel Recommendations, February 18-19, 2009, available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.

340B hospitals. As detailed in the attachment, the 340B program aims to improve access to care for poor and uninsured by allowing certain hospitals and other entities that serve those patients to purchase drugs at deep discounts. Congress intended for the savings from these discounts "to enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."14 The Health Resources and Services Administration (HRSA) that administers the 340B program has said that participating entities may use the savings achieved from participation in the program to "invest in more services for patients."15

Establishing a separate, lower reimbursement rate for these hospitals would be contrary to Congressional intent for participating hospitals to use savings under the 340B program to support their mission. These hospitals play a critical role in ensuring that all Americans have access to health care. Medicare should not impede these hospitals' efforts by reducing their reimbursement. Instead, CMS should focus its efforts on correcting the significant flaws in its rate-setting methodology for drugs and biologicals once and for all by paying no less than ASP plus six percent for therapies administered in the OPPS and increasing the allocation of overhead costs from packaged to separately payable drugs to ensure that pharmacy service costs are reimbursed adequately.

IV. 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.

For 2010, CMS increased the packaging threshold to $6516 and continued to package payment for all diagnostic radiopharmaceuticals and contrast agents.17 CMS also subjected 5-HT3 anti-emetics to this threshold, reversing a policy that has been in place since 2005.18 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. CMS continues to assert that that diagnostic radiopharmaceuticals and contrast agents can be treated differently from other SCODs because the statutory packaging threshold has expired and the agency believes that these drugs "function effectively

14 H.R. Rep. No. 102-384, pt. 2, at 12 (1992).
15 Elizabeth M. Duke, HRSA Administrator, Remarks to the Primary Health Care All-Grantee Meeting, June 22, 2005, http://newsroom.hrsa.gov/speeches/2005/BPHC-June.htm.
16 74 Fed. Reg. at 60487.
17 Id at 60496.
18 Id. at 60488.

as supplies that enable the provision of an independent service."[19] 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.[20]

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.[21] 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 entire 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[22] 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.

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. To the extent that drugs and biologicals continue to be packaged, CMS should reiterate its guidance that hospitals continue to bill for them using HCPCS codes and revenue code 636. This way, better data will be available for future rate-setting, helping to preserve patient access to critical therapies. Moreover, we believe that all 5-HT3 anti-emetics should be separately payable in order to preserve beneficiary access to them. We ask the APC Panel to make these recommendations to CMS.

* * *

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

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19 Id. at 60496.
20 SSA § 1833(t)(14)(B).
21 SSA § 1833(t)(14)(B).
22 SSA § 1833(t)(16)(B).

Background on the 340B Program

- The 340B program is a program administered by the Health Resources and Services Administration (HRSA) that allows certain health care providers to obtain access to Medicaid-level drug discounts.

- Eligible covered entities include:

    - Certain public and non-profit disproportionate share hospitals
    - Federally Qualified Health Centers (FQHCs)
    - Urban Indian Health Centers
    - Family planning clinics
    - Certain federal grantees
- There are more than 800 hospitals (and 1600 individual sites) receiving 340B pricing, and they account for 35% of Medicare's Hospital Outpatient Prospective Payment System's drug cost volume.

- The 340B price is a "ceiling price." Covered entities may negotiate prices with manufacturers below this level. 340B prices are proprietary and therefore not published publicly. On average, 340B drugs and biologicals cost 20 to 40 percent below Average Wholesale Price.

    - The 340B price is calculated as either average manufacturer price (AMP) minus 15.1% or AMP minus best price.

    - Manufacturers are required to participate in the 340B program as a condition of participating in the Medicaid program.

    - 340B pricing applies to drugs and biologicals in the outpatient setting only.

- 340B participating entities may not dispense drugs and biologicals at 340B prices if the state Medicaid program will be requesting a rebate ("double dipping" prohibition). Participating entities are also prohibited from reselling or otherwise transferring drugs and biologicals purchased at the 340B prices to individuals who are not patients of the participating entity.

- Reasons for non-enrollment:
    - Lack of awareness of the 340B program
    - Regulatory, operational, and compliance requirements such as maintaining two inventories of 340B and non-340B drugs and biologicals and additional record keeping
    - Cost-benefit analysis and expected cost savings
    - Insufficient personnel to efficiently operate the program