The Biotechnology Industry Organization's Testimony
Before 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 (the 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 appreciates the Centers for Medicare and Medicaid Services' (CMS') efforts to address stakeholders' concerns about access to quality care under the OPPS, and we look forward to working with the agency to continue to refine the hospital outpatient prospective payment system (OPPS) proposed rule for 2008. We support CMS' decisions to pay separately for the second and subsequent hours of infusion services and to continue to reimburse separately paid drugs at average sales price (ASP) plus six percent in 2007 instead of reducing payment for drugs without pass-through status to ASP plus five percent.

In 2008 and beyond, we recommend the following measures to ensure that hospitals are reimbursed appropriately for providing advanced drugs and biologicals to Medicare beneficiaries: 1) CMS should eliminate the bundling threshold and pay separately for all drugs and biologicals paid separately under the OPPS in the past, and 2) hospitals should receive adequate payments for all aspects of providing drugs and biological therapies, including pharmacy service and handling costs. We ask the APC Panel to make recommendations to CMS on both of these points.

I. CMS should eliminate the bundling threshold and pay separately for all drugs and biologicals paid separately under the OPPS in the past.

BIO's longstanding position is that CMS should pay separately for all drugs and biological products with a healthcare common procedure coding system (HCPCS) code that were separately paid in the past, including all therapies that ever had pass-through status. Paying separately for all drugs and biological products would help to ensure that patients have access to the therapies they need by removing incentives for hospitals to select therapies based on reimbursement rather than clinical characteristics.

It also would establish a more equitable and transparent payment policy for hospitals that is consistent with payment in the physician office setting. In the past, CMS has expressed concern that differences in reimbursement methodologies should not drive patient care from one setting to another. Yet this is precisely what will occur if all drugs and biological products with HCPCS codes are reimbursed in the physician office but only certain drugs are paid separately in the hospital outpatient department. In addition, by using two different definitions for the unit of service (drugs bundled in and out) in hospital and physician office settings, beneficiaries cannot make any valid comparisons about the cost of treatment across settings.

We also note that paying separately for all drugs and biological products with a HCPCS code would not increase hospitals' administrative burden. Hospitals are strongly encouraged to code for these drugs currently,[1] so there should be little increased administrative burden if these therapies are separately paid. In fact, paying separately for these therapies should only further encourage hospitals to code correctly, improving the data upon which future rates will be set.

II. Hospitals should receive adequate payments for all aspects of providing drugs and biological therapies, including pharmacy service and handling costs.

Second, BIO asks the APC Panel to recommend that CMS ensure that OPPS payments are adequate for all services associated with providing pharmaceutical and biological therapies in hospital outpatient departments, including the drug or biological product itself, the service to administer it, and related pharmacy services and handling costs. Currently, CMS reimburses separately paid drugs and biological products administered in hospital outpatient departments at their ASP plus six percent. CMS set this payment rate after comparing its estimated costs for drugs and biological products to ASP-based rates. BIO remains concerned that reimbursement at ASP plus six percent may not be adequate to ensure beneficiary access to appropriate therapies.

Medicare payment for all aspects of providing drug and biological therapies, including preparing drugs, performing quality control, and

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[1] January 2006 Update of the OPPS: Summary of Payment Policy Changes, OPPS PRICER Logic Changes, and Instructions for Updating the Outpatient Provider Specific File (OPSF), Transmittal 804, Change Request 4250, Jan. 3, 2006, at 12.

administering drugs, must be adequate to protect hospitals' ability to satisfy these patients' needs and continue to provide quality care. Pharmacy service and handling costs can be complex and are labor and resource intensive. They range from basic mixings and reconstitutions to more advanced compounding requiring a clean room, trained and certified personnel, and ancillary supplies. For example, most intrathecal drugs, including those used for pain management, must be compounded by specially trained pharmacists using a laminar flow hood to ensure that the specific conditions for safe product preparation are met. For 2006, CMS failed to finalize its proposal to pay an additional two percent of ASP to reimburse hospitals for the significant costs they incur for the pharmacy service and handling costs of separately paid drugs. For 2007, the agency again concluded that ASP plus six percent would be adequate payment for both acquisition and pharmacy service costs.

As we explained in our comments on the OPPS proposed rule for calendar year 2007, CMS' conclusion that ASP plus six percent is adequate payment for both drug acquisition and pharmacy costs is based on flawed assumptions and analyses. First, although the Medicare Payment Advisory Commission (MedPAC) noted in its June 2005 report that hospital officials believed that they set their charges high enough to account for pharmacy handling costs, MedPAC also noted that most hospitals do not set charges for these services and lack precise information about the magnitude of these expenses.[2] Therefore, although hospitals' aggregate charges for all of the drugs and biological products dispensed by their pharmacy departments may include overhead costs, it is unlikely that hospital charges for individual drugs reflect the exact overhead cost associated with each drug.

Second, CMS' calculations assume that overhead costs are distributed evenly to all drugs and biological products, ignoring the effects of charge compression on estimated costs for specific therapies. Because CMS applies a constant cost-to-charge ratio (CCR) to pharmacy charges, it tends to overestimate the cost of lower-priced therapies and underestimate the cost of higher-cost items; a tendency otherwise known as "charge compression." In fact, CMS has recognized this concept and has commissioned RTI International to conduct an analysis of charge compression and make recommendations to address this issue for the Hospital Acute Inpatient Prospective Payment System.

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[2] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

Similarly, our analysis found that CMS' estimated unit costs bore no relation to the actual costs of drugs and biological products.

Third, CMS used mean unit costs for only separately paid drugs and biological products in its estimate of total costs compared to total costs using ASP-based rates. Under hospitals' common charge setting methodologies, however, a disproportionately large share of overhead costs are allocated to lower cost drugs that are packaged under the OPPS. Because it excluded packaged drugs from its analysis, CMS underestimated hospitals' total overhead costs and the handling costs of the separately paid therapies. When we included the HCPCS-coded packaged drugs with reported ASPs in our calculations, we found that the mean unit cost, on average, is far higher than ASP plus six percent. We have attached a summary of this analysis, conducted by the Moran Company, for your review.

We ask the APC Panel to recommend that CMS revise its methodology for calculating payment rates for the acquisition and handling costs for drugs and biological products. CMS should include all drugs and biological products with HCPCS codes in its calculations, and reimbursement should continue to be set at no less than ASP plus six percent.

We also ask the APC Panel to recommend that hospitals' substantial costs for pharmacy handling and overhead be reimbursed adequately. We support the proposal by the Association of Community Cancer Centers and other stakeholders to implement a three-phase process for establishing payments for pharmacy handling services. First, in 2008, CMS would make a flat overhead payment for each separately billed drug. CMS would establish categories of drugs based on the complexity of preparing and maintaining each drug and would assign a code and a payment rate, based on claims data and surveys of pharmacy costs, to each category. When a hospital bills for a drug, the billing software automatically would add the code for the handling services to the claim. Second, CMS would survey providers to collect timely and accurate data on pharmacy service costs. This data likely would be collected over several years and would be used to calculate or validate future payment rates. Third, after CMS completes the survey, it would establish payments for pharmacy handling services based on that survey, cost reports, charges, and claims level data from hospitals. If necessary to collect accurate data, CMS could issue guidance to hospitals about billing and charge setting, similar to the

guidance it issued in 2005 and 2006 regarding charges for radiopharmaceuticals.[3]

III. Conclusion

BIO appreciates the opportunity to present these comments to the APC Panel. We ask the APC Panel to make the following recommendations:

1. CMS should continue to pay separately for all drugs and biologicals paid separately in the past, including all therapies that ever had pass-through status.

2. CMS should ensure that OPPS payments are adequate for all services associated with providing pharmaceutical and biological therapies in hospital outpatient departments, including the drug or biological product itself, the service to administer it, and related pharmacy services and handling costs. The agency should work with stakeholders to implement a three phase process for establishing appropriate payments for pharmacy handling services.

Thank you for this opportunity to testify. I would be happy to answer any questions you might have.

Attachment

[3] 71 Fed. Reg. 67960, 68096 (Nov. 24, 2006) ("As we stated for CY 2006, and reiterate here for CY 2007, it is appropriate for hospitals to set charges for radiopharmaceuticals based on all costs associated with the acquisition, preparation, and handling of these products so that their payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients.")