



October 10, 2006

BY ELECTRONIC DELIVERY

Mark McClellan, 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-1506-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2007 payment rates, published in the Federal Register on August 23, 2006 (the "Proposed 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.

¹ 71 Fed. Reg. 49506 (August 23, 2006).

Representing an industry that is devoted to discovering new therapies and ensuring patient access to them, BIO is troubled that CMS' proposal to reduce reimbursement for many separately paid drugs and biologicals will harm hospitals' ability to provide these important therapies to Medicare beneficiaries. We are concerned that the proposed rates of average sales price (ASP) plus five percent for drugs and biological products without pass-through status are not sufficient to reimburse hospitals for their acquisition costs, much less their pharmacy service costs. Our analysis of the claims data has found serious flaws in the OPPS rate-setting methodology that indicate that Medicare is not paying appropriately for all of the costs of providing drugs and biologicals.

To ensure that hospitals are reimbursed appropriately for providing advanced drugs and biologicals to Medicare beneficiaries, we recommend the following measures:

- 1) Medicare should set reimbursement under the OPPS for drugs and biological products at no less than ASP plus six percent, the rate applicable in physicians' offices;
- 2) CMS should continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs;
- 3) CMS should eliminate the bundling threshold and pay separately for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting;
- 4) CMS should continue to use the methodology implemented in 2006 for payment of radiopharmaceuticals;
- 5) CMS should not apply an equitable adjustment to any drugs or biologicals;
- 6) CMS should finalize its proposed drug administration ambulatory payment classifications (APCs) to ensure that hospitals are paid appropriately for the second and subsequent hours of infusion services;
- 7) CMS should pay for a second or subsequent intravenous push of the same drug;
- 8) CMS should provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions, regardless of the setting in which they are administered;
- 9) CMS should allow hospitals to separately bill and receive payments for therapeutic infusions and hydration infusions provided in the same encounter; and
- 10) CMS should continue to pay for preadministration-related services for intravenous immune globulin (IVIG).

We discuss these comments in more detail below.

I. CMS must not finalize its proposed reimbursement for drugs, biologicals, and radiopharmaceuticals because these rates are not adequate to reimburse hospitals for all of the costs of providing these therapies. [OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals]

A. Payment for Drugs and Biological Products

1. CMS must reimburse hospitals adequately for their acquisition and pharmacy service costs.

For 2007, CMS proposes to reduce reimbursement for drugs and biological products without pass-through status² to ASP plus five percent from the current rate of ASP plus six percent.³ BIO remains concerned that reimbursement at ASP plus six percent may not be adequate to ensure beneficiary access to appropriate therapies, and we believe that reducing payment to ASP plus five percent will place additional burdens on hospitals that already are straining to provide drugs and biologicals. As the Medicare Payment Advisory Commission (MedPAC) recently testified to the House Ways and Means Subcommittee on Health, in some parts of the country, hospital outpatient departments are taking on larger patient loads as physicians are unable to provide chemotherapy in their offices at Medicare's current reimbursement rates. In particular, patients who do not have supplemental insurance coverage are being sent to hospital outpatient departments for cancer care. If hospitals are not appropriately reimbursed for providing care, these patients will have nowhere to turn for treatment. Reducing Medicare's payments to hospitals also will exacerbate the access problems for IVIG that currently exist under the ASP plus six percent payment methodology.

Not only does CMS propose to reduce reimbursement for drugs and biologicals, but it also asserts that the proposed rates are sufficient to cover hospitals' pharmacy handling costs. We strongly disagree with this assertion. Pharmacy services 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. Complex therapies, such as advanced biologicals, must be stored and prepared under carefully controlled conditions to protect them from changes caused by

² This proposed reduction will also apply to clotting factors.

³ *Id.* at 49585.

variations in temperature and light. In addition to preparing drugs and biologicals for administration, pharmacists and pharmacy technicians consult with physicians about the appropriate selection, dosage, and administration of drugs, perform quality assurance measures to verify that therapies are correctly prepared, and safely dispose of any unused medications. The costs associated with providing these services include salaries and benefits for pharmacists and pharmacy technicians, supplies, equipment, and renovations required to comply with recent changes in pharmacy regulations. Without these quality and safety protections, errors involving these therapies are likely to occur. Medicare payment for all aspects of providing drug and biological therapies, including preparing drugs, performing quality control, and administering drugs, must be adequate to protect hospitals' ability to satisfy patients' needs and continue to provide quality care.

2. CMS' proposed rates are based on flawed assumptions and analyses.

BIO believes that CMS' proposal to set reimbursement for these therapies at ASP plus five percent is based on several flawed assumptions and analyses. First, although MedPAC noted in its June 2005 report that hospital officials believed they set their charges high enough to account for pharmacy handling costs, MedPAC also noted that most hospitals do not set charges for handling costs and lack precise information about the magnitude of these expenses.⁴ In the aggregate for all the drugs and biologicals dispensed by the pharmacy department, both inpatient and outpatient, charges may include overhead costs. Hospital charges are not likely to reflect overhead on a product-by-product basis, however.

Second, because overhead costs are not distributed evenly to all drugs, CMS' use of the claims data for only separately paid drugs and biologicals to calculate that the total cost of pharmacy services, including acquisition and overhead, vastly underestimates total overhead costs. We believe these costs are substantially greater than five percent of ASP.

As we have explained in comments on prior OPSS rules, CMS' application of a constant cost-to-charge ratio (CCR) to pharmacy charges results in inaccurate calculations of costs for specific drugs and biologicals. Hospitals tend to mark up their charges for higher cost items by a smaller percentage than lower

⁴ Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

cost items. When CMS applies a single CCR to these items, the charge of the higher cost item may be reduced below its cost, while the estimated cost of the lower cost item may exceed its actual cost.⁵ As a result, CMS' estimated unit costs and the Medicare payment rates based on those costs bear no relation to the actual costs of drugs and biological products. Our analysis of CMS' methodology for determining average acquisition costs for drugs and biological products found that these average costs, stated as a percentage of ASP, range from ASP minus 100 percent to ASP plus 2395 percent. These wide variations indicate that CMS' methods for calculating average acquisition cost produce inaccurate, unpredictable, and unreasonable results.⁶ CMS itself acknowledged in the final inpatient prospective payment system rule for fiscal year 2007 that charge compression might cause distortions in Medicare's payment systems, and the agency has engaged a contractor to study the phenomenon.⁷

Further, CMS used these mean unit costs for only separately paid drugs and biologicals in the estimate of the total costs for drugs compared to the total costs using ASP. This causes CMS to underestimate the overhead costs associated with those therapies. If all drugs and biological products had HCPCS codes and were included in this calculation, the handling costs included in hospitals' charges would be accounted for in an estimate of total costs, although the share of total handling costs assigned to each therapy might be inaccurate. In the OPPS, however, drugs and biological products whose costs are below the \$55 per day packaging threshold are not separately reimbursed. Additionally, there are many very low cost drugs that do not have HCPCS codes or ASPs, but do have charges reported under general pharmacy department revenue codes. Because CMS excluded these therapies from its analysis of average acquisition costs, it failed to capture the disproportionately large share of pharmacy service costs allocated to packaged drugs. When we included 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 five. The difference between mean unit cost and ASP was double the amount we calculated without these packaged drugs. This finding does not account for overhead charges for many lower cost drugs without

⁵ MJ Braid, KF Forbes, DW Moran. "Pharmaceutical Charge Compression under the Medicare Outpatient Prospective Payment System" *Journal of Health Care Finance* Spring 2004, p. 21-33.

⁶ See also, Government Accountability Office (GAO), Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, September 2004, at 16 ("CMS's methodology does not recognize hospitals' variability in setting charges, and, therefore, the costs of services used to set payment rates may be under or overestimated.").

⁷ 71 Fed. Reg. 47870, 47897, (August 18, 2006).

HCPCS codes, which, if it were possible to include, could result in an even wider disparity between CMS' proposed rate and hospitals' actual costs.

It is possible that if all drugs and biologicals could be included in the calculation of pharmacy overhead costs that CMS would find these costs to be comparable to those found by MedPAC. MedPAC reported that pharmacy department wages, salaries, fringe benefits, and supplies made up 26 to 28 percent of pharmacy department direct costs.⁸ Overhead costs of 28 percent would result in a calculation of hospital acquisition and handling costs of ASP plus 39 percent, assuming that all hospitals could purchase covered drugs and biologicals at ASP.

In a separate analysis we found that while approximately half of the packaged drug and biological costs (HCPCS coded and revenue coded) were included on 'single' bills and used for rate-setting, the vast majority of these were on claims for procedures other than pharmacy administration services. Only 5 percent of packaged drug costs were included in drug administration code median cost calculations. Both the product and handling costs for packaged drugs are spread throughout the APC system and are not being reimbursed as separate drug payments or under the drug administration codes.

3. CMS should include all drugs and biologicals with HCPCS codes in its calculations of pharmacy costs and should reimburse separately payable drugs at no less than ASP plus six percent in 2007.

We look forward to the results of the study of the effects of charge compression on the inpatient PPS and we hope any lessons learned from it can be applied to the OPSS. Until the charge compression study is completed, we recommend that CMS recalculate the total costs of pharmacy services, including acquisition and overhead, using costs for all drugs and biologicals with HCPCS codes, not just the separately paid therapies, to ensure that all pharmacy overhead costs are included in the agency's calculation. In no event should CMS set payment for drugs and biological products at less than ASP plus six percent, the rate applicable in physician's offices. This is consistent with what the Advisory Panel on APC Groups ("APC Panel") recommended at its August meeting.

⁸ Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

4. CMS should continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs.

In the longer term, we urge CMS to continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs. We recommend that CMS not make any reductions to payment for drugs and biologicals until it develops such a method. As we explain above, we believe that the claims and cost report data are inadequate to calculate accurate payments for the acquisition and handling costs for each drug or biological. To improve the accuracy of these data, CMS should provide hospitals with clear guidance on how to report their pharmacy costs and set charges for all pharmacy services. CMS also should consider mechanisms to provide more accurate reimbursement for pharmacy service costs, such as payment for medication therapy management codes or the use of codes for pharmacy handling services similar to those proposed for use in the OPSS in 2006.⁹

5. CMS should pay separately for all drugs and biological products with HCPCS codes.

CMS also should pay separately for all drugs and biological products with HCPCS codes to ensure that hospitals are reimbursed appropriately for all of the therapies they provide. CMS proposes to increase the packaging threshold from \$50 per day to \$55.¹⁰ BIO opposes this proposal. Instead, we support the APC Panel's recommendation to eliminate the packaging threshold for all drugs and biologicals with HCPCS codes.¹¹ Paying separately for these therapies will remove the incentives currently built into the OPSS that discourage hospitals from using packaged therapies that might be the most appropriate clinically. It also would help to ensure that all services provided in hospital outpatient departments are appropriately reimbursed. Our analysis found that most of the costs of packaged drugs are not included in drug administration payments. Only four percent of packaged drug lines and five percent of packaged drug costs are on drug administration single claims. However, 43 percent of packaged drug lines and 44 percent of costs were on single claims for other procedures, while the remaining 53 percent of lines and 51 percent of costs were not used in CMS' analysis. Therefore,

⁹ 70 Fed. Reg. 42674, 42730 (July 25, 2005).

¹⁰ 71 Fed. Reg. at 49582.

¹¹ Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

although packaged drug costs are included in the OPSS, they are not included in charges for drug administration services. Unpackaging payment for these drugs and biologicals would improve the accuracy of OPSS rates for all services in which drugs and biologicals are used.

Separately reimbursing all drugs and biologicals with HCPCS codes also would not increase hospitals' administrative burdens because hospitals are strongly encouraged to code for these drugs currently.¹² Our analysis of claims data indicates that hospitals are indeed coding for many of these therapies. 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. Moreover, such treatment is consistent with payment in the physician office setting and would be more equitable for hospitals. 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 at ASP plus six percent in the physician office but only certain drugs are paid separately in the hospital outpatient department, and the reimbursement rate for those drugs is one percent of ASP less.

B. CMS should continue to use the methodology implemented in 2006 for the payment of radiopharmaceuticals.

For 2007, CMS proposes to establish prospective payment rates for radiopharmaceuticals in 2007 using mean costs derived from calendar year 2005 claims data through the application of hospital-specific departmental cost-to-charge ratios.¹³ BIO believes that this methodology is deeply flawed and will deny beneficiaries access to therapeutic and diagnostic radiopharmaceuticals by setting reimbursement rates that are below acquisition cost and impairing CMS' ability to set more appropriate rates in the future. We urge CMS to continue to use the methodology it implemented in 2006 to protect against "rapid reductions [that] could adversely affect beneficiary access to services utilizing radiopharmaceuticals"¹⁴ and to allow the agency to continue to collect data that reflect all of the costs of providing these potentially lifesaving therapies.

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

¹³ 71 Fed. Reg. at 49587.

¹⁴ 70 Fed. Reg. 68515, 68653 (November 10, 2005).

The proposed payment methodology will cause drastic cuts in reimbursement for therapeutic radiopharmaceuticals, such as Zevalin® and Bexxar®. The proposed 2007 rate for Y-90 Zevalin® is \$12,130.20, a 42 percent reduction from the 2005 level of \$20,948.25, and 38 percent less than the average purchase price reported by the Government Accountability Office in 2005.¹⁵ Bexxar®’s payment would fall by 39 percent, from \$19,422 in 2005 to \$11,868.78 in 2007. In addition, CMS proposes substantial cuts to reimbursement for the administration codes for these therapies as they are moved from new technology APCs to clinical APCs.¹⁶ The combined effect of these cuts will make it difficult for hospitals to continue to offer these therapies to patients.

CMS states that its proposed methodology for radiopharmaceuticals “is consistent with how payment rates for other services are determined under the OPPS” and that the rates it establishes “serve as appropriate proxies for the average acquisition costs of radiopharmaceuticals along with their handling costs.”¹⁷ We agree that this methodology offers consistency across the OPPS, but it also would create inaccurate payments for radiopharmaceuticals just as it does for drugs and biologicals. As we describe above, basing payments on mean charges reduced to cost can lead to inaccurate rates that do not include all of the costs of providing a therapy. Additionally, because hospitals did not report their overhead costs accurately or uniformly in the past, as indicated in comments on the 2006 OPPS proposed rule¹⁸ and the June 2005 MedPAC report,¹⁹ using data from prior years will not capture the full costs of providing therapeutic radiopharmaceuticals.

In 2006, CMS attempted to set appropriate and stable rates for radiopharmaceuticals by basing payment on each hospital’s charge reduced to cost.²⁰ To ensure that “payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients,” CMS also clarified that “it is appropriate for hospitals to set charges for these agents in 2006 based on all costs associated with the acquisition, preparation, and handling

¹⁵ GAO, Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting, GAO-05-733R, July 14, 2005, at 6.

¹⁶ 71 Fed. Reg. at 49556. Payment for 79403 (hematopoietic nuclear therapy) would be reduced by 43 percent and payment for G3001 (administration and supply of tositumomab) would be reduced by 32 percent.

¹⁷ *Id.* at 49587.

¹⁸ 70 Fed. Reg. at 68654.

¹⁹ Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

²⁰ 70 Fed. Reg. at 68653.

of these products.”²¹ This is particularly important for therapeutic radiopharmaceuticals, such as Bexxar® and Zevalin®, and certain diagnostic radiopharmaceuticals that require the most resources of all drugs to prepare due to additional safety and quality assurance requirements.²² These costs include the resources needed to shield patients and staff from radiation exposure and comply with regulations regarding the safe administration, transport, and disposal of radioactive isotopes. If hospitals followed CMS’ guidance to implement new charges for 2006, CMS could have appropriate data for use in setting rates in 2008. In the likely event that many hospitals were not able to update their charges for 2006, CMS will need to wait even longer to be sure that it has sufficient accurate data to set rates for these therapies.

Instead of using a flawed ratesetting methodology and data that do not reflect all of the costs of providing therapeutic and diagnostic radiopharmaceuticals, we recommend that CMS continue to use the payment methodology it implemented for radiopharmaceuticals in 2006. When CMS implemented this methodology, it noted that it is “the best available proxy for average acquisition costs of the radiopharmaceuticals along with their handling costs.”²³ The agency acknowledges again in the Proposed Rule that it is an acceptable proxy for these costs,²⁴ and the APC Panel recommends that CMS continue to use this methodology.²⁵ Continuing to use this methodology will protect beneficiary access to these therapies while creating the stability necessary to allow CMS to continue to collect more accurate data for use in setting future rates. We urge CMS to use the 2006 methodology for at least one more year and evaluate the quality of the data next year to decide how to set rates for 2008.

C. CMS should not apply an equitable adjustment to any drugs or biologicals.

BIO supports CMS’ decision not to propose to apply an “equitable adjustment” to any drug or biological for 2007. Continuation of a policy of market-based reimbursement via the ASP-based methodology for all therapies is consistent with Congress’s intent in the Medicare Prescription Drug, Improvement,

²¹ *Id.*

²² Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 145-146.

²³ 70 Fed. Reg. at 68653.

²⁴ 71 Fed. Reg. at 49587.

²⁵ Advisory Panel on Ambulatory Payment Classification (APC) Groups, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

and Modernization Act of 2003 (MMA). By not including any language or discussion proposing to adjust payment for one drug or biological based on another drug or biological, CMS can continue to allow the market to determine the appropriate payment for therapies, not arbitrary government price-setting. We applaud CMS on this point and recommend that CMS not apply an equitable adjustment to any drug or biological products in the final rule.

II. CMS should clarify the payment rates that will apply to drugs and biologicals with pass-through status that are covered under the Competitive Acquisition Program. [Pass-Through Drugs]

CMS proposes to continue to reimburse pass-through drugs and biological products at ASP plus six percent, except that drugs that also are included in the Competitive Acquisition Program (CAP) will be reimbursed at the CAP rate.²⁶ CMS states that two drugs and biologicals with pass-through status are covered under the CAP and will be reimbursed at the “amounts determined under the competitive acquisition program.”²⁷ We ask CMS to clarify that it will base payment for these therapies on their individual payment rates under the CAP, as required by the statute, and not the aggregate payment for all drugs covered under the CAP.

III. CMS should finalize its proposed new APCs for drug administration, implement the APC Panel’s recommendations regarding drug administration services, and continue to make payments for preadministration-related services for IVIG. [OPPS Drug Administration]

BIO is pleased that CMS proposes to create six new APCs for drug administration services and to make separate payment for additional hours of drug administration services. BIO has long urged CMS to adopt such policies. We are hopeful that these changes, combined with the new rates CMS has proposed based on more precise coding, will help to improve the adequacy of Medicare’s payments for administration of advanced drugs and biologicals. We thank CMS for its hard work on these proposals and urge the agency to implement them in the final rule.

We are concerned about the significant reduction in payment for the first hour of administration services, however, and we ask the agency to verify that

²⁶ 71 Fed. Reg. at 49580.

²⁷ *Id.* at 49581.

its calculations are correct. In reviewing these codes, CMS should bear in mind that very few claims for packaged drugs are submitted with a claim for a drug administration service. Therefore, even though CMS intends for payment for drug administration services to include the costs of packaged drugs, its claims data do not include these costs. Unless CMS implements our recommendation to pay separately for all drugs with HCPCS codes, its proposed drug administration codes may be too low to include both the costs of the administration service and the drug.

In addition, we support the APC Panel's recommendation to make payment for a second or subsequent intravenous push of the same drug by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in CY 2007.²⁸ Under the current coding guidance and the proposed new drug administration APCs, CMS will make payment for a second or subsequent intravenous push only if it is used to administer a different drug. This policy fails to recognize that the second push requires the same amount of work and resources as the first push. Furthermore, if payment for the drug is packaged, the hospital is reimbursed for neither the second push nor the additional dose of the drug. When combined with the recommendation to make separate payment for all drugs and biological products with HCPCS codes, implementing the APC Panel's recommendation also will help to ensure that hospitals are appropriately reimbursed for all drugs and biologicals and their administration services.

In addition, the APC Panel recommended that CMS provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions, regardless of the setting. We agree with this recommendation and ask CMS to implement it. As we explained above, most single claims for packaged drugs are made with a service other than drug administration. This could be explained by the Current Procedural Terminology's²⁹ (CPT's) instructions for use of drug administration codes. The CPT instructs providers not to report injection or infusion codes with codes for which an IV push or infusion is an inherent part of the procedure, such as administration of contrast material for an imaging study. There may be situations, however, when it is appropriate to bill a drug administration code, yet hospitals are not doing so.

²⁸ Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

²⁹ Current Procedural Terminology, or CPT, is a trademark of the American Medical Association.

There also may be procedures for which the associated drug administration costs are not included in the claims data. For example, Medicare makes separate payment for echocardiographic imaging drugs that are used to enhance images, but does not pay separately for their intravenous administration. The echocardiography procedure codes do not mention use of contrast agents, and the resources supporting payment for these procedures do not include the contrast agents or their administration. CMS should remove any edits from the Outpatient Code Editor and the hospital version of the Correct Coding Initiative that package intravenous injection codes into codes for echocardiography procedures. Clarifying the coding guidance and allowing payment for drug administration services in all settings will help to ensure that hospitals code appropriately for all services and will help to set more accurate payment rates in the future.

We also support the APC Panel's recommendation to allow hospitals to separately bill and receive payments for therapeutic infusions and hydration infusions provided in the same encounter.³⁰ For payment under the OPSS, CMS currently has a single code assigned to the first hour of a therapeutic or diagnostic infusion. Under guidance issued in 2006, CMS allows hospitals to report a first hour for each different type of infusion provided when the infusions can be reported using different codes, and they meet the requirements for billing an hour of each type of infusion.³¹ Under the Proposed Rule, if a hospital provides an hour of therapeutic, non-chemotherapy infusion and an hour of hydration infusions, the first hour would be paid using code C8950, assigned to APC 440, and the second hour would be paid using code C8951, assigned to APC 437. To ensure that hospitals are reimbursed appropriately for these services, we ask CMS to implement the APC Panel's recommendation to allow hospitals to be paid using first hour codes when both a hydration infusion and a non-chemotherapy infusion are provided in the same visit.

In addition, we ask CMS to make a clarification to its guidance on coding and payment for drug administration services under the OPSS. Consistent with the CPT's guidance for the chemotherapy codes used in physician offices, the guidance explains that "hospitals are to report chemotherapy drug administration

³⁰ Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

³¹ January 2006 Update of Hospital Outpatient Prospective Payment System Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, Dec. 16, 2005 (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

HCPCS codes when providing non-radionuclide anti-neoplastic drugs to treat cancer and when administering non-radionuclide anti-neoplastic drugs, anti-neoplastic agents, monoclonal antibody agents, and biologic response modifiers for treatment of noncancer diagnoses.”³² We appreciate this instruction and recommend that CMS clarify that it also applies to IVIG, hyperimmune IVIG, and DNA-or RNA-based therapies, which are all biological response modifiers, whose administration should be billed using chemotherapy administration codes.

Finally, we urge CMS to continue to make payment for preadministration-related services for IVIG. As you know, BIO has been very concerned about Medicare beneficiary access to IVIG over the past few years as a result of the changes to Medicare’s payment methodologies for drugs and biologicals. BIO was pleased that CMS recognized the unique aspects of this therapy, as well as its importance to Medicare beneficiaries, through the establishment of a \$75 payment for preadministration-related services for IVIG in last year’s OPPTS final rule. Unfortunately, CMS proposes to eliminate this payment for 2007.³³

BIO is very disturbed by the proposed policy determination, especially coincident with a proposal to reduce the payment for IVIG by one percent. As noted above, we believe that CMS made positive strides in ensuring access to IVIG through the preadministration-related services payment. The elimination of the payment would be a significant step backward. All of the costs that CMS identified last year that hospitals incur related to IVIG will continue to be incurred next year, and CMS offers no evidence that these costs would not continue to be incurred. As such, the cost should continue to be reimbursed.

IV. Conclusion

In conclusion, BIO recommends that CMS take the following steps to protect Medicare beneficiaries’ continued access to appropriate drug and biological therapies in hospital outpatient departments:

- Include all drugs and biologicals with HCPCS codes in its calculations of pharmacy costs and reimburse separately payable drugs at no less than ASP plus six percent in 2007;
- Continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs;

³² Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2.2).

³³ 71 Fed. Reg. at 49604.

- Pay separately for all drugs and biologicals with HCPCS codes;
- Continue to use the methodology implemented in 2006 for the payment of radiopharmaceuticals;
- Not apply an equitable adjustment to any drug or biological;
- Clarify the payment rates that will be apply to drugs and biologicals with pass-through status that are covered under the CAP; and
- Finalize the proposed new APCs for drug administration, implement the APC Panel's recommendations regarding drug administration services, and continue to make payments for preadmission-related services for IVIG.

BIO appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at 202-312-9273 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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Economic Policy
Biotechnology Industry Organization (BIO)