Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

September 14, 2007

BY ELECTRONIC DELIVERY

Kerry 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-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates)

Dear Acting Administrator Weems:

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 2008 payment rates and proposed changes to the ambulatory surgical center (ASC) payment system, published in the Federal Register on August 2, 2007 (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. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new therapies and ensuring patient access to them, BIO is troubled by CMS' proposals to expand packaging for drugs, biologicals, and radiopharmaceuticals and to reduce reimbursement for many separately paid therapies. In the Proposed Rule, CMS proposes to increase the packaging threshold for drugs and biologicals to $60,

1 72 Fed. Reg. 42628 (August 2, 2007).

package payment for diagnostic radiopharmaceuticals and contrast agents, and consider expanded packaging in the future for more specified covered outpatient drugs. CMS asserts that these proposals will help "create incentives for efficiency and volume control,"[2] yet CMS presents no evidence that growth in this setting is inappropriate or that volume control is necessary. We believe that the innovations of the biotechnology sector, along with other investments in advanced medical technologies, have allowed patients to benefit from increased treatment options in hospital outpatient departments, saving the time and cost of inpatient care. We share CMS' concern that increased packaging could cause higher cost bundled services to be shifted to other ambulatory settings,[3] but we also urge the agency to consider that packaging and bundling could affect demand for more costly inpatient care as well.

After years of working with CMS to help develop accurate payment rates for these critical therapies, we are greatly concerned that CMS' proposals, if implemented, will set back Medicare's progress toward protecting access to care in an appropriate outpatient setting. 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 necessary to deliver care safely to beneficiaries. Although we are pleased that CMS now will make separate payment for drugs and biologicals that are separately reimbursed under the OPPS when they are provided in ambulatory surgical centers (ASC), we believe this change only increases the importance of ensuring that the OPPS rates are correct, so that any errors are not carried over to the ASC setting as well. 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, including clotting factor, at no less than ASP plus six percent, the rate applicable in physicians' offices;

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2 Id. at 42651.
3 Id. at 42652.

2) CMS should not implement its proposal to ask hospitals to report pharmacy overhead charges on an uncoded revenue code line and instead 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, including all radiopharmaceuticals and contrast agents, as it does in the physician office setting;
4) CMS should continue to use the current methodology for payment of radiopharmaceuticals while analyzing potential edits to correct hospital claims data that would ensure accurate payment for both diagnostic and therapeutic radiopharmaceuticals in the future;
5) CMS should not apply an equitable adjustment to any drugs or biologicals;
6) The agency should exercise caution when determining that a drug or biological no longer qualifies for pass-through status;
7) CMS should continue to pay for preadministration-related services for intravenous immune globulin (IVIG) at the current rate and implement an additional payment to ensure beneficiary access to this critical biological therapy;
8) CMS should make separate payment for concurrent drug infusion services; and
9) CMS should ensure that Medicare's payment policies support access to care in ASCs as well as in hospital outpatient departments.

We discuss these comments in more detail below.

I. CMS must not finalize its proposed reimbursement rate for separately paid drugs, biologicals, and radiopharmaceuticals without pass-through status because these rates are not adequate to reimburse hospitals for all of the costs of providing these therapies. [OPPS: Specified Covered Outpatient Drugs]

A. Payment for Drugs and Biologicals Without Pass-Through Status that Are Not Packaged

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

For 2008, CMS proposes to reduce reimbursement for separately paid drugs and biological products without pass-through status[4] to ASP plus five percent from the current rate of ASP plus six percent.[5] 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) testified to the House Ways and Means Subcommittee on Health in 2006, 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 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. Pharmacists cannot bill separately for any of these important services, yet these services are critical to ensuring patient safety.

The costs associated with providing these services include salaries and benefits for pharmacists and pharmacy technicians, supplies, equipment, and

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4 This proposed reduction also would apply to clotting factors. Id. at 42736.
5 Id.

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.[6] In the aggregate for all the drugs and biologicals dispensed by the pharmacy department, both inpatient and outpatient, charges may include pharmacy services and overhead costs. Hospital charges are not likely to reflect these costs on a drug-by-drug basis, however.

Second, because pharmacy services and 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 pharmacy cost, including acquisition and overhead, vastly underestimates total pharmacy services and overhead costs. We believe these costs are substantially greater than five percent of ASP. As we have explained in comments on prior OPPS 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 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.[7]

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

7 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.

The recent RTI International study of the effects of charge compression in calculating diagnosis-related group (DRG) relative weights supports this conclusion. The report found evidence of charge compression in the pricing for IV solutions when compared to therapeutic drugs.8 Disaggregating IV solutions from other drugs charged to the patient produced a reduction in the CCR for IV solutions and an increase in the CCR for other drugs.9 The report recommended that CMS disaggregate the CCRs for drugs and IV solutions to produce more accurate estimates of the costs of these therapies.10 In the Proposed Rule, CMS acknowledges the "obvious importance" of this research for the OPPS, but does not propose to implement any of RTI's recommended improvements to the CCRs for drugs and biologicals.11 Instead, CMS proposes to develop a new model for analyzing CCRs that would be used to determine whether disaggregated CCRs should be used in the 2009 OPPS proposed rule.12

As a result, CMS' estimated unit costs and the Medicare payment rates based on those costs substantially underestimate the actual costs of drugs and biological products. Our consultants found that CMS estimated average unit costs, stated as a percentage of ASP, range from ASP minus 98 percent to ASP plus 1074 percent. These wide variations indicate that CMS' methods for calculating the overhead costs associated with separately paid drugs produce inaccurate and unpredictable results on a drug by drug basis and, we would suggest, in aggregate as well.13

Further, it appears that 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 pharmacy services and overhead costs associated with those therapies. If CMS included all drugs and biologicals with HCPCS codes in this calculation, the

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8 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.
9 Id. at 11.
10 Id. at 16.
11 72 Fed. Reg. at 42642.
12 Id.
13 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' 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.").

handling costs included in hospitals' drug charges would be accounted for in the estimate. In the aggregate for all the drugs and biologicals dispensed by the pharmacy department, both inpatient and outpatient, charges may include pharmacy services and overhead costs. Hospital charges are not likely to reflect these costs on a drug-by-drug basis, however. Thus, when CMS proposes to package drugs and biological products whose costs are below $60 per day and does not use the mean unit costs of these packaged drugs in its overall estimate, inappropriately low payment rates are set for separately paid drugs and biologicals. These rates are not sufficient to pay for the pharmacy services and handling that they are supposed to cover.

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 appears to have excluded these therapies from its analysis of average acquisition costs, the agency 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 ASP plus more than 14 percent. This finding does not account for pharmacy services and overhead charges for many lower cost drugs without 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 services and 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.[14] Pharmacy services and 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.

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 2008.

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[14] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

We recommend that CMS recalculate total pharmacy costs, including acquisition and pharmacy services and overhead, using costs for all drugs and biologicals with HCPCS codes, not just the separately paid therapies, to ensure that all pharmacy services and 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 March 2007 and September 2007 meetings.15

If CMS decides to continue to base reimbursement for drugs and biologicals on its estimates of mean unit cost, it should implement an adjustment for charge compression in 2008. If this adjustment cannot be implemented for 2008, CMS should not make any changes to its reimbursement rates until such an adjustment can be made. BIO also urges CMS to issue detailed instructions to hospitals regarding pharmacy services and overhead charges, specifying the types of costs that should be captured – from pharmacist salaries to drug disposal and transportation costs – when setting the overall charge for drugs and biologicals. Future payment rates are more likely to be appropriate if hospitals are told explicitly what precise items and services should be captured by their charges.

4. CMS should not implement its proposal to ask hospitals to report pharmacy overhead charges on an uncoded revenue code line and instead continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs.

For 2008, CMS proposes to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and report the overhead charge on an uncoded revenue code line.16 BIO is opposed to this proposal because it would be extremely difficult for hospitals to implement and would not produce useful or accurate data for CMS to use in setting future rates. If implemented, this instruction would require hospitals to set charges for hundreds of drugs and implement hundreds of changes to their chargemasters before January

15 Advisory Panel on Ambulatory Payment Classification Groups, Recommendations: March 7-8, 2007, at 2, http://www.cms.hhs.gov/FACA/Downloads/Mtg_Rpt_03072007.zip.
16 72 Fed. Reg. at 42735.

1, 2008. These costly programming changes are only part of the burden hospitals would face. They also would have to make substantial investments in performing time and motion studies to determine the appropriate charge for each drug. If hospitals could make these changes, there is no assurance that the data would be of use to CMS because the agency would allow hospitals to decide whether to report a charge per drug or per episode of drug administration services.17 The data CMS would receive therefore would not necessarily identify the overhead charges associated with any particular drug and would not be appropriate to use as the basis for packaging payment for these services into payment for other procedures. The APC Panel also recommended at its September 2007 meeting that CMS work to develop a simplified system to capture pharmacy services and overhead, with fewer implementation burdens for hospitals. We urge CMS not to implement its proposal.

Instead, we urge CMS to continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs. One such method is the three-phase plan that was recommended by the APC Panel at its March 2007 meeting. This plan is similar to one developed by stakeholders and would involve an automatic payment for pharmacy services and overhead costs based on three levels of complexity, in addition to payment for the acquisition cost of the drug or biological at ASP plus 6 percent, in phase one.18 The agency would assign all drugs and biologicals with HCPCS codes to one of the three pharmacy services categories and would pay the pharmacy services amount automatically each time a hospital billed a HCPCS-coded drug or biological. In phase two, CMS would consider Government Accountability Office (GAO) and MedPAC reports estimating pharmacy services and overhead costs and would accept outside survey data from stakeholders to set reimbursement rates for the three pharmacy services categories.19 In phase three, CMS would establish payments for pharmacy services and overhead costs based on claims data as it does for most other items and services in the OPPS.20

An alternative approach would be a two-phase plan that would omit the use of survey data. Phase one would be the same as the first phase described

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17 Id.
18 Advisory Panel on Ambulatory Payment Classification Groups, Recommendations: March 7-8, 2007, at 2, http://www.cms.hhs.gov/FACA/Downloads/Mtg_Rpt_03072007.zip.
19 Id.
20 Id.

above. In phase two, however, hospitals would not receive the pharmacy services payments unless they reported associated charges and costs. Rather than setting unique charges for each individual drug and biological, they only would need to set charges for the three categories. We understand that hospitals would need at least a year to be able to revise their chargemasters and billing systems to implement this change. They would need detailed guidance on the items and services to include when setting charges and would also need guidance on processing crossover claims and complying with uniform charge requirements. We believe that as long as the charge for the drug or biological plus the charge for pharmacy services equals the charge to other payers for the drug with the overhead combined, the uniform charge requirements will be met. CMS needs to address these issues explicitly, however, and to be sensitive that hospital billing systems must meet the needs of private payers and Medicare alike. Regardless of the approach taken, we believe that payment for pharmacy services and overhead costs effectively could be packaged into payment for the drug by automatically linking the pharmacy services and handling code to the HCPCS code for the drug or biological.

We believe these options would be much easier for hospitals to implement than CMS' proposal, would produce valuable data for use in future rate setting, and are consistent with CMS' goals for the OPPS. By requiring reporting on only three categories of drugs instead of hundreds of individual drugs, these proposals would impose far less work for hospitals than CMS' proposal. The data collected would be of better quality than under CMS' proposal because hospitals would report costs consistently for each category of drugs. CMS has rejected the recommendations of the APC Panel and other stakeholders, in part, because the agency views them as unpackaging payment for these services, contrary to CMS' goals of increasing packaging.[21] We believe that these proposals are consistent with CMS' goals because they would allow the payment for pharmacy overhead and handling costs to be packaged, while also ensuring that the amount of payment is sufficient to reimburse hospitals for the costs of providing these important services. CMS also cites a single statement from the June 2005 MedPAC report that hospital officials believed they set their charges high enough to account for pharmacy handling costs, but the agency again disregards the report's other findings that these costs are not uniformly included in charges. As discussed in section I.A.2, above, MedPAC also reported that these costs are far greater than CMS' data analysis suggests.

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[21] 72 Fed. Reg. at 42735.

We urge CMS to reconsider the advice of the APC Panel, work with stakeholders to refine these proposals, and include an appropriate payment for pharmacy overhead and handling costs in the payments for drugs and biological products in 2008. At a minimum, until CMS develops an appropriate method of reimbursing hospitals for pharmacy services and overhead costs, we recommend that CMS not make any reductions to payment for drugs and biologicals.

5. CMS should pay separately for all drugs and biological products with HCPCS codes. [OPPS: Packaging Drugs and Biologicals]

BIO continues to believe that CMS 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. Although we recognize this is inconsistent with the agency's desire to increase packaging across the board as well as its proposal to increase the packaging threshold for drugs and biologicals from $55 per day to $60,[22] we believe paying separately for HCPCS-coded drugs and biologicals would help ensure appropriate reimbursement to hospitals while the agency is working on more permanent fixes for charge compression and adequate payment for pharmacy services and overhead. In addition, paying separately for all drugs and biologicals with HCPCS will remove the incentives currently built into the OPPS that discourage hospitals from using packaged therapies that might be the most appropriate clinically. It also would help to improve transparency for beneficiaries attempting to compare the costs of treatment in different settings and would eliminate site-of-service reimbursement differentials that could inappropriately drive where care is delivered.

Separately reimbursing all drugs and biologicals with HCPCS codes would not increase hospitals' administrative burdens because hospitals are strongly encouraged to code for these drugs currently.[23] Our analysis of claims data indicates that hospitals indeed are 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. As

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22 Id. at 42732.
23 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.

discussed in section IV below, paying separately for all drugs and biologicals with HCPCS also would improve the accuracy of payment rates for hospitals administering concurrent infusions for packaged drugs, assuming that CMS maintains its current policy with respect to concurrent infusions.

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. These differences also are counter to the transparency initiative and make it difficult for beneficiaries to compare costs for care administered in different settings.

BIO also is concerned that packaging low cost drugs has a disproportionate effect on rural hospitals. We believe these hospitals tend to provide a greater proportion of lower cost drugs compared to other hospitals. As discussed above, hospitals tend to mark up their charges for higher cost items by a smaller percentage than lower cost items. Thus, CMS' proposal to reduce payment for separately paid drugs and biologicals to ASP plus five percent, discussed above, combined with increasing the packaging threshold, is likely to have a disproportionate impact on rural hospitals. If CMS continues to package lower cost drugs and biologicals in 2008, we ask that the agency analyze how rural hospitals are affected by this policy.

BIO supports the proposal to continue to make separate payment for all oral and injectable forms of 5HT3 anti-emetics.[24] We agree that CMS should "continue to ensure that Medicare's payment rules do not impede a beneficiary's access to particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."[25] We also believe this desire should influence Medicare's payment policy for all therapies, and CMS should eliminate the packaging threshold for all drug and biological products accordingly.

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[24] 72 Fed. Reg. at 42733.
[25] Id.

We discuss the proposals to package diagnostic radiopharmaceuticals and contrast agents below.

B. CMS should continue to use the current payment methodology for therapy-related radiopharmaceuticals. [OPPS: Payment for Therapeutic Radiopharmaceuticals; OPPS: Payment for Diagnostic Radiopharmaceuticals]

We have significant concerns regarding CMS' proposed approach to setting the prospective payment rate for therapy-related radiopharmaceuticals. We use this term to include both the diagnostic and therapeutic products which are approved by the Food and Drug Administration (FDA) as an integral part of the therapeutic regimen. For 2008, CMS proposes to package payment for all diagnostic radiopharmaceuticals and to set a prospective payment rate for therapeutic radiopharmaceuticals (that currently include nine HCPCS codes) based on mean costs.[26] The payment rate is calculated using CY 2006 hospital claims data that are adjusted to costs using the department-specific CCRs or the hospital-wide CCR if the department-specific CCR is not available. This approach is nearly identical to that which was proposed by CMS for 2007 using CY 2005 hospital claims data, but that was ultimately not implemented. The proposed CY 2008 payment rates are virtually the same—and some are lower—as the rates in last year's proposal and are equally invalid reflections of acquisition cost of the therapy, let alone the pharmacy services and overhead costs (e.g., radiopharmacy compounding fee).

BIO believes the proposed rates reflect flaws in the claims data, in the application of CCRs, or both. CMS expects that the CY 2006 claims data being used to set the CY 2008 rates reflect both the radiopharmaceutical charge and the associated pharmacy services and overhead costs.[27] As evidence that this expectation is justified, CMS notes that "a greater proportion of radiopharmaceuticals experienced an increase in their median costs from CY 2005 to CY 2006 than experienced a decrease."[28] We believe this evidence demonstrates that CMS' expectations have not been fulfilled. If the CY 2006 claims data had included handling and preparation costs, all radiopharmaceuticals should have experienced an increase in median costs. Although CMS first clarified

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26 Id. at 42738.
27 Id. at 42739.
28 Id.

in 2005 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 of these products,"29 it is likely that many hospitals were not able to update their charges for 2006 and did not begin to include these costs in their charges until 2007. In addition, the level of mark-up that would be necessary to adequately capture acquisition cost under this methodology would be inconsistent with many hospitals' current price transparency initiatives. Therefore, it is critical that CMS not assume that reported charges include all preparation and handling costs and instead develop an alternative payment methodology for therapy-related radiopharmaceuticals.

We also note if the CY 2006 data did include pharmacy services and overhead costs, the fact that the proposed 2008 payment rates are virtually identical to the rates proposed last year that were based on data that did not include these costs indicates that CMS has applied an incorrect CCR to charges for radiopharmaceuticals. If hospitals did, in fact, increase their charges to include pharmacy services and overhead as well as acquisition costs, but CMS applied a CCR that assumes that a larger markup was actually used, the estimated costs would be less than hospitals' actual costs. This is a classic example of the effect of charge compression on the estimated costs of higher-priced therapies. Although CMS acknowledges stakeholders' concerns that charge compression can result in an underestimation of costs for high-cost radiopharmaceuticals (and hence an inadequate payment rate), the agency suggests that it will not address the issue until next year.30 This delay is inappropriate because the payment rates calculated in the meantime are likely to be less than acquisition cost, even though the statute requires that payment be based on hospitals' average acquisition costs.31 If the Medicare payment rate for therapy-related radiopharmaceuticals is below acquisition cost, hospitals will need to subsidize the cost of the therapy. If hospitals cannot afford to do this, Medicare beneficiaries will not be able to access these important therapeutic regimens.

We also are concerned that these errors will affect payment for the diagnostic radiopharmaceuticals that CMS proposes to package in 2008. We have identified numerous examples of the failure of the packaging proposal to reflect average acquisition cost according to CMS' own calculations. For example, CMS

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29 70 Fed. Reg. at 68653.
30 72 Fed. Reg. at 42740.
31 SSA § 1833(t)(14)(A)(iii).

proposes to bundle A9565 Indidum In-111 pentetrotide. The typical dose of this radiopharmaceutical is 5 millicuries, and CMS has calculated the per millicurie cost at $224.85, producing a per dose cost of about $1,124. CMS proposes to package A9565 into the following APCs:

- APC 406 (Level I tumor/infection imaging): Payment = $287; shortfall of $837
- APC 414 (Level II tumor/infection imaging): Payment = $478; shortfall of $646
- APC 408 (Level III tumor/infection imaging): Payment = $1,023; shortfall of $101.

For each of these APCs, the proposed payment level fails to cover the costs that CMS has calculated for the radiopharmaceutical alone. If hospitals' costs are actually greater than CMS has calculated, the shortfalls would be even larger.

If CMS decides to pursue expanded packaging in the OPPS, it is essential that the agency have accurate data and appropriate methodologies for calculating costs of all items and services provided in the OPPS. Any errors in determining the costs of packaged diagnostic radiopharmaceuticals could produce inadequate payments for the associated procedure. Moreover, once CMS begins to package payment for these radiopharmaceuticals, hospitals may lose interest in taking the time to ensure that they report their charges for these products. CMS must take care to ensure that its rates are correct in 2008 and that it will continue to collect data to calculate accurate payments for future years. If CMS decides to package payment for diagnostic radiopharmaceuticals, we urge the agency to provide hospitals with clear instructions to report all charges for these products to provide CMS will the data it needs to set appropriate rates in the future.

We consider CMS' proposed payment approach for radiopharmaceuticals to be inconsistent with statutory requirements that all radiopharmaceuticals qualify as specified covered outpatient drugs and that payments should reflect average acquisition cost and be subject to any adjustment for pharmacy services and overhead costs. Instead of using a flawed rate-setting methodology and data that do not reflect the actual acquisition cost of radiopharmaceuticals, we recommend that CMS continue to apply the current payment method for therapy-related radiopharmaceuticals for 2008. This is consistent with the APC Panel's recent recommendation that CMS continue to apply the current payment method for all therapy-related radiopharmacueticals and diagnostic radiopharmaceuticals over $200 in 2008. Although BIO supports payment under the current methodology in

2008, we firmly believe that all drugs and biologicals with HCPCS codes, including radiopharmaceuticals and contrast agents, should be paid separately, and, at a minimum, that the packaging threshold should not be increased.

In addition, we ask CMS to continue its work with stakeholders to develop a new payment methodology for therapy-related radiopharmaceuticals that could be implemented in CY 2009, along with appropriate adjustments for charge compression. As recommended by the APC Advisory Panel, CMS also should consider edits that correct data for radiopharmaceuticals to ensure appropriate payment that is consistent with the statutory requirements.

C. CMS should continue to make separate payment for contrast agents.

CMS proposes to package payment for all contrast agents into payment for the associated diagnostic or therapeutic procedure.[32] We are opposed to this proposal for the same reasons that we opposed expanded packaging of other drugs, biological products, or radiopharmaceuticals. Namely, because CMS does not use an accurate methodology for determining the acquisition cost of drugs, it likely is not accounting for the full costs of these products in its proposals. Additionally, if CMS begins to package payment for contrast agents or other drugs, it is likely to discourage accurate coding and will lose the ability to set appropriate rates in the future.

Contrast agents also present additional concerns because there are some procedures in which they are rarely used, but can add significantly to the costs of those procedures when they are used. For example, contrast imaging agents are used relatively infrequently in echocardiography procedures. Unlike other contrast-enhanced imaging procedures, there are no echocardiography procedure codes that describe the use of contrast imaging drugs. If this proposal is finalized, hospitals using contrast imaging drugs with echocardiography, when medically necessary, will incur costs for the contrast imaging drugs and their administration without receiving any incremental payment beyond the payment for an unenhanced echocardiography procedure. BIO believes that all drugs, radiopharmaceuticals, and biological with HCPCS codes – including contrast agents – should be paid separately under the OPPS.

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[32] 72 Fed. Reg. at 42672.

D. CMS should continue to reimburse clotting factors at ASP plus six percent. [OPPS: Blood Clotting Factors]

CMS proposes to reduce the payment for blood clotting factors from ASP plus six percent to ASP plus five percent.[33] CMS does not explain why it believes the reduced rate is appropriate, however. We believe this reduction is inappropriate for the same reasons that reducing payment for other drugs and biologicals is inappropriate, as discussed above. We urge CMS not to reduce the payment rate for these important therapies until it can confirm that the new rate accurately reflects acquisition cost and will not harm beneficiary access to clotting factor.

E. 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 2008. Continuation of a policy of market-based reimbursement via the ASP-based methodology for all therapies is consistent with Congress' intent in the Medicare Prescription Drug, Improvement, 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 urge CMS not to apply an equitable adjustment to any drug or biological products in the final rule. We encourage the agency to clarify that it will not change its position on the use of equitable adjustment for any drug or biological without giving stakeholders adequate notice and opportunity to comment through rulemaking in the Federal Register.

II. CMS should exercise caution when determining that a drug or biological no longer qualifies for pass-through status. [OPPS: Pass-Through Drugs]

As CMS explains in the Proposed Rule, the statute specifies that pass-through payments for drugs and biologicals may be made for no less than two

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33 Id. at 42736.

years and no longer than three years.[34] CMS proposes to terminate the pass-through status of seven drugs or biologicals based on these criteria. BIO urges CMS to exercise caution when determining that a drug or biological's pass-through status has expired. In some cases, unique circumstances may have prevented a drug from being marketed, and therefore from receiving pass-through payments, during the time in which CMS has granted it pass-through status.

For example, natalizumab, one of the biologicals whose pass-through status is proposed to expire this year, initially was granted pass-through status in April 2005. One month earlier, the biological voluntarily was withdrawn from the market and did not resume sales until July 2006. Because no patients received natalizumab during the 17.5 months the biological product was not being sold, that time should not count toward its two to three years of pass-through eligibility. We ask CMS to continue to designate natalizumab as having pass-through status in 2008 and to exercise caution in determining that a drug or biological product's pass-through status has expired.

III. CMS should continue to make payments for preadministration-related services for IVIG at the current rate and implement an additional payment to ensure beneficiary access to this critical biological therapy. [IVIG Preadministration-Related Services]

BIO applauds CMS for proposing to continue to make payment for preadministration-related services for IVIG, but we are concerned by the significant reduction in payment for these services. Currently, CMS reimburses hospitals for these services through new technology APC 1502, with a payment rate of $75. For 2008, CMS proposes to transition payment for these services to new clinical APC 430, with a payment rate of $39.[35] We remain concerned about access to IVIG, and we believe that reducing the payment for preadministration-related services now would create further uncertainty about hospitals' ability to provide this therapy.

The Office of Inspector General report found that 44 percent of sales to hospitals by the three largest distributors were at prices above ASP plus six

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34 Id. at 42730 (citing Social Security Act § 1833(t)(6)(C)(i)).
35 Id. at 42705.

percent.[36] If CMS reduces the payment for preadministration-related services to $39, combined with a reduction in payment to ASP plus five percent, many more hospitals may not be able to provide IVIG to their Medicare patients. We also are concerned that the reported charges for these services may not be accurate because many hospitals may have established erroneous charges for them. We ask CMS to collect charge data for at least one more year before transitioning these payments to a clinical APC.

Moreover, BIO believes that CMS should establish an additional payment in order to ensure providers are able to purchase IVIG. One model that has worked in the past is the add-on payment for blood clotting factor. This model is based on a January 2003 GAO report that recommended that CMS establish a separate payment for the cost of delivering clotting factor to Medicare beneficiaries.[37] Then Congress granted such authority to the Secretary in order to preserve patient access to blood clotting factor. BIO believes that the IVIG payment also is insufficient and requires a permanent additional payment to help deliver the therapy. The HHS Office of the Inspector General (OIG) in its April 2007 study of the IVIG market demonstrates that only 56 percent of IVIG sales to hospitals by the three largest distributors occurred at prices below the Medicare payment amounts at the time of the study.[38] One would expect this percentage to further decline when taking into account smaller distributors.

Therefore, BIO asks that CMS treat IVIG similar to another blood-plasma derived therapy – blood clotting factor – and provide an additional payment to address this continued therapy reimbursement shortfall. This measure combined with the positive steps that CMS has undertaken – and maintaining the current payment rate – is an important first step toward rectifying the patient access difficulties surrounding IVIG.

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36 OIG, Intravenous Immune Globulin: Medicare Payment and Availability, OEI-03-05-00404, April 2007, at ii.
37 General Accounting Office, Medicare: Payments for Blood Clotting Factor Exceeds Providers' Acquisition Cost, January, 2003, GAO-03-184.
38 OIG, Intravenous Immune Globulin: Medicare Payment and Availability, at ii.

IV. CMS should make separate payment for concurrent infusion of drugs and biologicals. [OPPS: Drug Administration]

For 2008, the APC Panel recommended that CMS pay separately for concurrent infusions of drugs and biologicals, designated by Current Procedural Terminology (CPT) code 90768, at the same rate as additional sequential infusions, designated by CPT code 90767. CMS currently packages payment for this service into payment for other drug administration services and proposes to continue to do so in 2008.[39] CMS explains that it will not make separate payment because it has determined that the costs of concurrent infusions already are represented in the claims data although these codes first were used in the OPPS in 2007 and the agency does not have claims data for use in ratesetting. We are skeptical that the costs of these services have been accounted for in the rates for other drug administration services. We also are concerned that if the drug being administered during the concurrent infusion is packaged, the hospital would be reimbursed for neither the drug nor the administration service. In the absence of clear data establishing that these services are appropriately reimbursed in hospital outpatient departments, we ask CMS to protect access to these services by providing separate payment under the OPPS. We also note that this recommendation would create parity with the physician office setting, where all drug administration services are separately reimbursed.

V. CMS should ensure that any changes it makes to improve access to drugs and biological products in hospitals outpatient departments also apply to ASCs. [ASC Impact]

BIO is pleased that CMS will begin to pay ASCs separately for drugs and biologicals that have pass-through status under the OPPS when the drug or biological is integral to a covered surgical procedure.[40] We believe the decision to reimburse these therapies in ASCs at the rates determined under the OPPS will help to ensure that patients have a choice of settings for surgical procedures. At the same time, however, we are concerned that equal payment in these settings could harm beneficiary access to care if the rates and packaging policies applied in ASCs and hospital outpatient departments are equally flawed. Now that payment in ASCs is linked to the OPPS rates and policies, it is especially important that CMS set appropriate payment rates and packaging thresholds for these therapies.

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39 72 Fed. Reg. at 42751.
40 Id. at 42831.

We urge CMS to consider the impact on access to care in ASCs as it evaluates our comments on payment for drugs under the OPPS. CMS must ensure that Medicare's payment policies support access to care in both of these important settings.

VI. 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, including clotting factor, at no less than ASP plus six percent in 2008;
- Not implement its proposal to ask hospitals to report pharmacy overhead charges on an uncoded revenue code line and instead continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs;
- Eliminate the bundling threshold and pay separately for all drugs and biologicals with HCPCS codes, including contrast agents and radiopharmaceuticals;
- Continue to pay separately for all radiopharmaceuticals using the current payment methodology of charges reduced to cost while analyzing potential edits to correct hospital claims data that would ensure accurate payment for both diagnostic and therapeutic radiopharmaceuticals in the future;
- Not apply an equitable adjustment to any drug or biological;
- Exercise caution when determining that a drug or biological no longer qualifies for pass-through status;
- Continue to make payments for preadministration-related services for IVIG at the current rate and implement an additional payment to ensure beneficiary access to this critical biological therapy;
- Make separate payment for concurrent drug infusion services; and
- Ensure that Medicare's payment policies support access to care in ASCs as well as in hospital outpatient departments.

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 John Siracusa at 202-312-9281 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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