October 8, 2004

BY HAND 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-1427-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates) – Pass-Through; Drugs, Biologicals, and Radiopharmaceuticals Non-Pass-Throughs; HCPCS Codes; Vaccines; Orphans; Radiopharmaceuticals; and Drug Administration

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on August 16, 2004 (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 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

1 69 Fed. Reg. 50448 (Aug. 16, 2004).

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Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO consistently has expressed concerns that OPPS could create substantial access and quality of care issues for Medicare beneficiaries. After years of meeting with CMS, submitting comments, and testifying before the Advisory Panel on Ambulatory Payment Classification (APC) Groups, we are pleased to see that the agency has made significant progress in addressing many of our concerns in the Proposed Rule. In particular, we support CMS' plan to set the pass-through payment amount for drugs at zero[2] and dedicate some of the funds from the pass-through pool to increasing the conversion factor accordingly. We commend CMS' proposal to treat all new drugs with Healthcare Common Procedure Coding System (HCPCS) codes as pass-through therapies,[3] regardless of whether an application for pass-through status has been filed. BIO also thanks CMS for finally implementing the provision in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requiring immediate reimbursement for drugs and biologicals for which HCPCS codes have not yet been assigned.[4] We support the continued exclusion of certain orphan drugs,[5] CMS' acknowledgment that radiopharmaceuticals are indeed drugs and biologicals,[6] and the agency's decision not to apply an equitable adjustment or functional equivalence.[7] These proposals will help ensure patient access to innovative therapies by more appropriately reimbursing hospitals for their costs, and BIO urges CMS to implement them in the final rule.

We remain concerned, however, that the MMA's significant changes in Medicare payment for drugs and biologicals will have dire consequences for patient access to important, innovative therapies. As we discussed in our comments on the Medicare physician fee schedule proposed rule for 2005,[8] the shift to average sales price (ASP) based reimbursement is causing confusion and uncertainty among health care providers. Because the Medicare statute ties pass-through payments to rates applicable in physician offices, CMS' implementation of the ASP-based payment methodology will have far-reaching

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2 Id. at 50503.
3 Id. at 50514.
4 Id. at 50516.
5 Id. at 50518.
6 Id.
7 Id. at 50513.
8 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS (Sept. 24, 2004).

effects. We urge CMS to monitor patient access and do everything in its power to make this transition as smooth as possible for providers so that they can continue to provide patients with quality care. We appreciate CMS' straightforward implementation of the MMA's payment methods for "specified covered outpatient drugs" (SCODs),[9] including the treatment of all biologicals as sole source products as Congress intended. For the categories of drugs and biologicals for which the MMA does not specify a payment methodology, we urge CMS to replace its deeply flawed process of determining costs from charge data[10] with a fair, consistent methodology based on actual costs. The choices CMS makes now as it implements the MMA will determine whether payment rates will be adequate to ensure that hospitals can continue to provide these therapies to patients in appropriate outpatient settings. We ask CMS to consider carefully our recommendations for the continued improvement of the OPPS.

We focus our comments on several main areas of concern. First, we recommend that CMS provide immediate and clear guidance to manufacturers on their ASP reporting requirements. Second, we urge CMS maintain its packaging threshold at $50 unless a thorough study reveals that raising the threshold will not harm beneficiary access to important therapies. Third, we advise CMS to extend the future rate-setting methodology for SCODs to all separately paid drugs and biologicals. Fourth, we encourage CMS to work with the Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) on their respective hospital acquisition and pharmacy service cost studies to ensure that CMS has the data it will need to set appropriate rates in 2006.

With respect to the radiopharmaceutical therapies Bexxar® and Zevalin®, we are concerned that CMS' proposed payment rates for these cutting-edge therapies and their related preparation and administration costs and associated procedures is not adequate. We ask that the agency to examine this issue thoroughly to ensure that patient access to these lifesaving therapies will

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9 A SCOD is a covered outpatient drug for which separate APC has been established and that is a radiopharmaceutical or a drug or biological for which pass-through payments were made on or before December 31, 2002, but does not include a drug or biological for which pass-though payments were made on or after January 1, 2003, a drug or biological for which a temporary HCPCS code has not been assigned, or an orphan drug designated by the Secretary during 2004 and 2005. Social Security Act (SSA) § 1833(t)(14)(B).

10 See U.S. Government Accountability Office, "Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services," No. GAO-04-772 (Sept. 2004), at 16, 18.

not be compromised. Regarding drug administration coding, we ask CMS to adopt G-codes in both the physician office and hospital outpatient settings to reflect the new Current Procedural Terminology (CPT) codes that recently were adopted by the American Medical Association (AMA). Use of the new codes in the hospital outpatient setting will enable CMS to collect the data necessary to set more appropriate reimbursement rates for these critical services as soon as possible.

I. Pass-Through – Transitional Pass-Through Payment for Additional Costs of Drugs and Biologicals

A. Concern About Payment at 106 Percent of ASP

As required by the statute, CMS proposes to pay for drugs and biologicals with transitional pass-through status at 106 percent of ASP, the same rate applicable to physician offices.[11] BIO continues to be concerned that these rates may not adequately compensate hospitals for the costs of providing innovative drug and biological therapies, however. We explained our concerns in our comments on the proposed physician fee schedule for calendar year 2005,[12] and we ask CMS to review these comments[13] with the OPPS in mind as well. Moreover, we ask CMS to clarify that the ASP-based payment rates for therapies with transitional pass-through status will be based on the latest ASP data available and will be updated quarterly as in the physician office setting. To fail to do so could impede patient access. We also remind CMS that, because the statute precludes the use of ASP for radiopharmaceuticals, payment for pass-through radiopharmaceuticals should not be based on 106 percent of ASP. Instead, we recommend that radiopharmaceuticals be paid using the methodology applicable to SCODs or using external data.

Patient access to pass-through therapies is particularly vulnerable because these drugs and biologicals are new, and it will be difficult to shift administration to a different setting should reimbursement at 106 percent of ASP not be adequate. If the ASP-based rate is inadequate, neither physicians nor hospital outpatient departments will be able to provide the therapy. In contrast, because non-pass-through therapies will be paid different amounts in

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11 SSA § 1833(t)(6)(D)(i).
12 69 Fed. Reg. 47488 (Aug. 5, 2004).
13 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS (Sept. 24, 2004).

different settings, providers have more flexibility to ensure patient access by shifting the site of care to where reimbursement is most adequate.

BIO urges CMS to exercise care to ensure that the transitional pass-through works as Congress intended – to protect patient access to innovative drug and biological therapies in appropriate outpatient settings. We ask CMS to monitor patient access closely during the transition to ASP-based payment and to react quickly to any problems. We also urge CMS to update the OPPS payment rates quarterly to reflect 106 percent of the most recently reported ASP.

B. Other Pass-Through Reforms

CMS proposes to set pass-through payments at zero[14] and to apply unused funds from the pass-through pool to increase the conversion factor.[15] By zeroing-out pass-through payments, CMS ensures that pass-through drugs and biologicals receive the full payment possible under the law and eliminates the risk of a pro-rata reduction. BIO believes this logical proposal will help protect patient access to cutting-edge therapies, and we urge CMS to implement it in the final rule.

BIO also supports CMS' proposal (discussed below) to treat all new drugs with HCPCS codes as pass-through therapies, regardless of whether a pass-through application actually is submitted.[16] We recommend that this proposal be implemented, as well.

II. Drugs, Biologicals, and Radiopharmaceuticals Non-Pass-Throughs

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14 69 Fed. Reg. at 50503.
15 Id. at 50527.
16 Id. at 50514.

A. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

As required by the MMA,[17] CMS proposes to continue to pay separately for drugs, biologicals, and radiopharmaceuticals whose median cost per day exceeds $50.[18] The MMA only requires this threshold for 2005 and 2006, however. CMS has expressed a preference for additional packaging in the future and has said that it would continue to study the issue. BIO encourages CMS to examine its packaging thresholds carefully before considering an increased threshold. We urge CMS to maintain the $50 threshold for drugs and biologicals unless CMS can show with a thorough study that patient care will not be affected by increasing it.

CMS proposes to exclude injectible and oral forms of anti-emetic treatments from the $50 packaging threshold.[19] CMS correctly recognized that applying the threshold to these products would result in some therapies receiving separate payment, while others would be packaged. Rather than create an incentive for hospitals to select anti-emetic therapies based on their ability to obtain additional reimbursement, not on the therapy's benefit to each individual patient, CMS proposes to treat all of these products alike. We commend CMS for its efforts to "ensure that [its] payment rules do not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."[20] BIO urges CMS to implement this proposal in the final rule and to consider whether its packaging threshold harms patient access to other drug and biological therapies.

B. Extending the Future Rate-Setting Methodology for SCODs to All Separately Paid Drugs

In years 2006 and beyond, the MMA requires CMS to develop a payment methodology for SCODs that takes into account a GAO study of hospital acquisition cost data and a MedPAC study of pharmacy service and overhead costs. BIO firmly believes that a rate-setting methodology based on actual hospital acquisition costs for drugs and biologicals is far more appropriate than a rate-setting methodology based on deriving costs from hospital charges based

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17 MMA § 621(a)(2).
18 69 Fed. Reg. at 50505.
19 Id. at 50505.
20 Id.

on claims data. The GAO recently confirmed what BIO has said in our comments on previous OPPS proposed rules: CMS' methodology for deriving costs from charge data may under or overestimate costs and that CMS's application of a constant cost-to-charge ratio may not result in an accurate calculation of hospital costs.21 We support the MMA's acquisition cost-based payment methodology for SCODs after January 1, 2006, and we believe that it should apply to all separately paid drugs and biologicals.

Unless CMS applies the acquisition cost-based payment methodology to all separately paid drugs and biologicals, it risks creating an unfair, unpredictable, and inconsistent payment system that could be even more complex than the current rules. For example, two drugs whose pass-through status expires on the same date could be paid under different methodologies based on the date they first received pass-through payments. One therapy would be paid under the MMA's methodologies for SCODs because it received pass-through payments as of December 31, 2002, while CMS could opt to use a different methodology for the other because it first received pass-through payments one day later. We strongly believe that CMS should not divide drugs and biologicals into arbitrary categories, but rather simplify its payment for these treatments by applying the same methodology to all separately paid therapies.

We applaud CMS for proposing a fair and consistent payment methodology for drugs and biologicals whose pass-through status expires on December 31, 2004. In the Proposed Rule, CMS recognizes that the situation we describe above applies to the thirteen expiring pass-throughs. Although ten of these therapies are SCODs, three are not because they began to receive pass-through payments after December 31, 2002. CMS acknowledges that the MMA does not describe how these three therapies should be paid, and also realizes that paying for them under a different methodology than the SCODs would "penalize those products for receiving pass-through status on or after January 1, 2003."22 We strongly support CMS' common sense proposal to treat these three therapies as SCODs, and we encourage CMS to expand this treatment to all separately paid drugs and biologicals in the future.

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21 U.S. Government Accountability Office, "Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services," No. GAO-04-772 (Sept. 2004), at 16, 18.

22 69 Fed. Reg. at 50513.

C. CMS Cooperation with GAO and MedPAC on Cost Studies

To develop the payment methodology for 2006 and beyond, the MMA requires the GAO, and later CMS, to study the hospital acquisition costs of SCODs. MedPAC also will study pharmacy service and overhead costs for these therapies. These studies are crucial to the development of the new payment methodology. Because future payment rates will be based on the data gathered now, it is critical that these studies collect complete and accurate data on all products that will be subject to the new payment methodology. BIO urges CMS to work with GAO and MedPAC to ensure that these studies provide CMS with the data it needs to set proper payment rates in the future. Specifically, the studies must include all separately paid drugs and biologicals so that CMS can develop the fair and consistent methodology we discuss above. The GAO's first round of surveys, currently being sent to 1000 hospitals, asks for data on SCODs and designated orphan drugs. We recommend that the three expiring pass-through products that CMS proposes to treat as SCODs and any therapies that will roll off pass-through status in 2006 be included in the second round of surveys to be issued next summer, if they cannot be surveyed now.

We also recommend that CMS continue to accept external cost data that may be submitted by knowledgeable stakeholders, such as manufacturers, providers or patients to provide verification of hospital acquisition costs for specific drugs and biologicals.

D. Payment for Specified Covered Outpatient Drugs – Zevalin® and Bexxar®

In the Proposed Rule, CMS acknowledges that section 621(a)(1) of the MMA unambiguously requires that separately paid radiopharmaceuticals be classified as SCODs[23] CMS proposes to pay for radiopharmaceuticals in 2005 using the MMA's methodology for SCODs. We appreciate CMS' attempt to implement the MMA's requirements in a straightforward manner – as well as to finally treat radiopharmaceuticals as the drugs and biologicals they indeed are – but we are concerned that the proposed payments for Zevalin® (In-111 and Y-90 ibritumomab tiuxetan, C1082 and C1083) and Bexxar® (I-131 tositumomab, C1081 and C0182) are inadequate to preserve patient access to these very unique and critical therapies.

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[23] Id. at 50507, 50518.

Zevalin® and Bexxar® are types of radioimmunotherapies that are used to treat patients with certain forms of non-Hodgkin's lymphoma (NHL). These therapies are administered in two separate steps. First, a diagnostic dose of the therapy is administered to determine radiopharmaceutical biodistribution of radiolabeled antibodies. Second, the patient receives a therapeutic dose of targeted radiolabeled antibodies. These breakthrough therapies offer patients new hope in fighting NHL. That hope can be fulfilled only if patients have access to these therapies, however.

For 2005, CMS proposes to pay for both Zevalin® and Bexxar® at the SCOD floor of 83% of AWP. BIO is concerned that this rate will not support patient access to these therapies, and we remind CMS that 83% of AWP is a floor that CMS has the option to exceed. We encourage CMS to consider carefully our members' specific comments on these therapies.

BIO also is concerned about payment for administration and preparation of these therapies as well as for the associated procedures needed to provide them. Ensuring access to these therapies requires appropriate reimbursement for not just the radiopharmaceutical, but also for the complex administration and preparation tasks associated with each step of the therapeutic regimen. As CMS sets rates for these therapies, we urge the agency to consider all of the costs associated with these therapies and to set reimbursement at levels that will protect beneficiary access to these potentially lifesaving advances.

E. Equitable Adjustments

BIO commends CMS on not applying functional equivalence or an "equitable adjustment" to the payment rate of any product, including darbepoetin alfa (Q0137), in the Proposed Rule. However, CMS specifically solicits comment on whether such an adjustment should apply again.[24] BIO consistently has opposed the application of a "functional equivalence" standard, regardless of how it is phrased, for any product. Moreover, Congress has spoken on this issue by enacting section 622 of the MMA, prohibiting the future application of functional equivalence. This provision prevents the Secretary from publishing regulations that apply a functional equivalence or similar standard, except for purposes of determining pass-through eligibility for drugs

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24 Id. at 50513.

to which the functional equivalence standard already was applied prior to enactment of the MMA.25 Section 622 also prohibits the Secretary from applying a functional equivalence standard for "the purpose of any other payments under this title."26 BIO urges CMS not to apply functional equivalence again. To do so would violate the MMA and would endanger patient access.

F. Proposed CY 2005 Payment for New Drugs and Biologicals with HCPCS Codes and without Pass-Through Application and Reference AWP

BIO supports CMS' proposal to treat new drugs with established HCPCS codes as pass-throughs, regardless of whether a pass-through application has been made.27 CMS correctly recognizes that packaging payment for these new therapies might jeopardize beneficiary access to them, and that separate payment could be delayed if a pass-through application has not been submitted.28 This proposal will allow immediate payment for these therapies at the physician office rate and will help eliminate barriers to beneficiaries' access. BIO requests that CMS implement this proposal in the final rule.

III. HCPCS Codes – Proposed Payment for New Drugs, Biologicals, and Radiopharmaceuticals Before HCPCS Codes Are Assigned

CMS explains in the Proposed Rule how it is implementing the MMA's provision to provide immediate reimbursement for drugs for which HCPCS codes have not yet been assigned.29 BIO is encouraged to see that CMS has developed a plan to meet the MMA's requirements, although we had hoped the agency instead would adopt the APC Panel's recommendations to preload several new codes into CMS' computer system and assign them to new drug and biologicals as the Food and Drug Administration (FDA) approves them,30 rather than to require manual processing of claims using a single miscellaneous code. We do not know yet whether the new procedures will impede patient access to new drugs and biologicals because the billing instructions were issued

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25 MMA § 622; SSA § 1833(t)(6)(F); H.R. Conf. Rep. No. 108-391 at 683 (2003).
26 MMA § 622; SSA § 1833(t)(6)(F)(ii)(II).
27 69 Fed. Reg. at 50514.
28 Id.
29 Id. at 50516.
30 See id.

only in May. We recommend that CMS monitor this issue closely over the next few months and respond quickly if hospitals become concerned that the administrative burden and delays in processing claims will harm their ability to provide new drugs and biologicals to Medicare beneficiaries. If patient access to important new therapies is not improved by CMS' proposed method of reimbursing for new therapies without HCPCS codes, we urge CMS to reconsider this proposal and to explore preloading placeholder codes instead.

IV. Vaccines

BIO strongly supports CMS' proposal to continue to pay for vaccines under the reasonable cost methodology.[31] This policy protects beneficiaries' health and access to important vaccines by ensuring that OPPS rates are adequate to cover hospitals' costs of providing vaccines to Medicare beneficiaries. BIO recommends that CMS implement this proposal in the final rule.

V. Orphan Drugs – Proposed Changes in Payment for Single Indication Orphan Drugs

BIO applauds CMS for proposing to "continue making separate payments for orphan drugs based on their currently assigned APCs."[32] CMS correctly recognized that paying for these therapies as SCODs would result in "lower payments which could impede beneficiary access to these unique drugs dedicated to the treatment of rare diseases."[33] CMS appropriately chose to exercise its authority to set payment rates for certain orphan drugs.[34] For 2005, CMS proposes to pay for the 12 selected orphan drugs at the higher of 88 percent of AWP or 106 percent of ASP capped at 95 percent of AWP.[35] BIO believes that the 95 percent of AWP cap is inappropriate and should be removed. At a minimum, payment rates should be updated quarterly and should be based on the latest ASP and AWP data available. To lock in the rates for a year based on outdated information could impede patient access to vital therapies, counter to CMS' stated objective.

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31 Id. at 50517.
32 Id. at 50517.
33 Id. at 50518.
34 MMA § 621(a)(1).
35 69 Fed. Reg. at 50518.

BIO also would like to highlight concern regarding the proposed payment rate for J0256, Alpha 1-Proteinase Inhibitor. The proposed rate is 29 percent lower than the current rate. In the interest of patient access, BIO asks CMS to freeze the current payment rate for 2005 so patients with Alpha-1 Antitrypsin Deficiency may continue to have unimpeded access to this critical therapy.

Moreover, BIO continues to be troubled that CMS' criteria for determining which orphans will be eligible for special treatment is overly narrow. We urge CMS to expand the number of therapies that qualify as orphan by the agency to other deserving orphan therapies in order to ensure patient access to them. Congress passed the Orphan Drug Act (ODA) in 1983 to create incentives for the research, development, production, and distribution of therapies to treat patients with rare disorders. The ODA has been a tremendous success, and since its enactment more than 250 new orphan drugs have been developed, approved, and marketed in the United States and more than 1000 additional drugs are in the research pipeline.

Unfortunately, rather than build on the FDA's success, CMS has created a roadblock between these exciting discoveries and the patients who need them. By their very nature, orphan drugs are not clinically comparable to any other therapy. In addition, orphan therapies are used by small populations, and their use is highly variable from one hospital outpatient center to another. Most important, access to orphan therapies is critical for patients who typically have no other treatment option. This is precisely why BIO has advocated special treatment for all drugs and biologicals designated as orphan therapies by the FDA and used for orphan indications. Specifically, we believe that the following therapies should be designated by CMS as orphan under section 1833(t)(14)(B)(ii)(III) of the Social Security Act (SSA): (1) orphan drugs designated under section 526 of the Federal Food, Drug and Cosmetic Act; or (2) a drug or biological which is described under the same HCPCS product code (or product code under a successor coding system designated in regulations promulgated under section 1173(c)), has the same non-proprietary name, or is the "same drug" as that term is defined by the FDA under regulations promulgated under section 527 of the Federal, Food, Drug and Cosmetic Act. We firmly believe such special treatment is necessary to ensure that patients suffering from rare diseases continue to have access to the treatments they need. Accordingly, we urge CMS to expand its special payment rules to all drugs and

biologicals designated as orphan therapies by the FDA and used for orphan indications.

VI. Radiopharmaceuticals – Proposal to Change Payment Policy for Radiopharmaceuticals

In the Proposed Rule, CMS concludes, "We believe it is reasonable to include radiopharmaceuticals in the general category of drugs" in light of their inclusion as SCODs in the MMA.[36] BIO commends CMS for finally treating radiopharmaceuticals as the drugs and biologicals that they are. We urge the agency to finalize this proposal, making radiopharmaceuticals eligible for the MMA's safeguards to assure patient access as Congress intended. As we recommend with regard to other SCODs, we urge CMS to work with GAO and MedPAC now to ensure that the acquisition cost and pharmacy services and overhead data collected will enable CMS to set appropriate payment rates for radiopharmaceuticals in 2006 and beyond.

VII. Drug Administration – Proposed Coding and Payment for Drug Administration

BIO appreciates CMS' efforts to improve the accuracy of coding and payment for drug administration services. At BIO, we strongly believe that reimbursement and coding need to distinguish between uncomplicated administrations of simple products, such as saline, and complex administrations of advanced biologicals. Biological products are not only more costly than saline, but they require administration by specially-trained nurses, precise reconstitution, and careful monitoring to control the risk to the patient and to achieve their full effectiveness. Patient access to advanced drugs and biologicals requires appropriate reimbursement for all of the resources associated with administering these therapies.

Currently, the OPPS uses three Q-codes (Q0081, Q0083, and Q0084) to pay for chemotherapy administration and infusion of other drugs and biologicals. These three codes do not reflect the variety of resources needed to administer a wide range of drug and biological therapies. These codes' descriptions are too broad to distinguish among therapies, and as long as they are used, CMS will not be able to collect the cost data needed to produce more

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36 Id.

appropriate reimbursement. We thank CMS for acknowledging this problem in the Proposed Rule. To begin collecting more accurate data that will help create more appropriate payment rates in the future, CMS proposes to use the 2004 CPT codes for drug administration in 2005 instead of the current Q-codes.[37] We agree with the need to use more precise coding now to help CMS set more appropriate payment rates in 2007. We are concerned, though, that using the 2004 CPT codes will not capture the data CMS needs as completely as using the new 2005 CPT codes for drug administration services as adopted by the AMA's CPT Panel. We believe that a better method of achieving this important goal would be to use G-codes to adopt the new 2006 CPT codes that will be published later this year.

The CPT Editorial Panel recently approved 12 new and 14 revised codes that will better reflect the varying levels of complexity and resource consumption associated with each drug administration service.[38] In the physician office setting, CMS plans to use G-codes to adopt these new drug administration codes in 2005.[39] The G-codes will allow CMS to make more appropriate payments and collect more accurate data using the revised CPT codes for 2005, even though the new codes will be finalized after the 2005 CPT book has been published. BIO strongly supports this proposal,[40] and we recommend that CMS adopt G-codes in the OPPS as well.

VIII. Conclusion

In conclusion, BIO commends CMS for making important improvements to the OPPS, and we urge the agency to continue to make patient access to quality care its primary focus as it implements the MMA's reforms. To ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies in appropriate hospital outpatient settings, we urge CMS to:

- monitor patient access closely for pass-through drugs and biologicals during the transition to ASP-based payment and to react quickly to any access problems;

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37 Id. at 50519.
38 AMA, CPT Editorial Panel, August 2004 Meeting, Changes to Drug Administration Codes, available at http://www.ama-assn.org/ama1/pub/upload/mm/362/panelactionsdruginf2.doc.
39 69 Fed. Reg. at 47522.
40 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS (Sept. 24, 2004).

- update ASP-based payment rates quarterly, using the latest information available;
- implement the proposal to set pass-through payments at zero and increase the conversion factor accordingly;
- maintain the $50 packaging threshold for drugs in the future and finalize the agency's proposal to exclude anti-emetic therapies from this policy;
- expand the future rate-setting methodology for SCODs to include all separately-paid drugs;
- work with GAO and MedPAC now to ensure that their studies of the acquisition costs and pharmacy service and overhead costs include all separately paid drugs;
- accept and consider cost information from manufacturers, hospitals and other knowledgeable sources to establish accurate cost information;
- evaluate its payment rates for Bexxar® and Zevalin® to ensure that these unique radiopharmaceutical therapies and their related preparation and administration costs and associated procedures are appropriately reimbursed;
- never apply functional equivalence or a similar standard again;
- finalize the proposal to treat all new drugs with HCPCS codes as pass-throughs, regardless of whether a pass-through application was filed;
- monitor implementation of the agency's proposed method of providing immediate reimbursement for drugs for which HCPCS codes have not been assigned and modify it if necessary to ensure patients have access to cutting-edge drugs;
- continue to reimburse vaccines at reasonable cost;
- implement the proposal to reimburse designated orphan drugs at the higher of 88 percent of AWP or 106 percent of ASP, using the latest information available and updated quarterly, and reconsider the restrictive criteria used to designate orphan drugs and biologicals for this payment policy;
- treat radiopharmaceuticals as the drugs and biologicals that they are; and
- adopt G-codes for drug administration services to reflect the new CPT codes that will be effective in 2006 and begin collecting the data necessary to set more appropriate rates for these important services in the future.

BIO appreciates this opportunity to comment on our concerns about the Proposed Rule, and we look forward to working with CMS to protect Medicare beneficiaries' access to life-improving drug therapies. We hope our suggestions will help CMS address these important issues in the final rule. Please contact Michael Werner at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Michael Werner
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