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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, SW
Washington, D.C. 20201

**Re: CMS-1427-FC (Medicare Program; Changes to the Hospital
Outpatient Prospective Payment System and Calendar Year
2005 Payment Rates)**

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment period regarding changes to the hospital outpatient prospective payment system (OPPS) and calendar year 2005 payment rates, published in the Federal Register on November 15, 2004 (the Final 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. 65682 (Nov. 15, 2004).

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO consistently has expressed concerns that OPPTS could create substantial access and quality of care issues for Medicare beneficiaries. As we acknowledged in our comments to the proposed rule,² however, we are pleased to see that the agency has made significant progress in addressing many of our concerns this year. Specifically, we appreciate the agency finalizing the following and believe that these improvements will go a long way to helping ensure beneficiary access to critical drugs and biological therapies in the hospital outpatient setting:

- Setting the pass-through payment amount for drugs and biologicals at zero and using the excess funds from the pass-through pool to increase the conversion factor;³
- Paying separately for all new drugs with Healthcare Common Procedure Coding System (HCPCS) codes using the same methodology as for pass-through therapies, regardless of whether an application for pass-through status has been filed;⁴
- Verifying that payment for pass-through drugs and biologicals will be based on the latest average sales price (ASP) data available and will be updated quarterly;⁵
- Paying separately for all six injectible and oral forms of anti-emetics.⁶
- Implementing the payment methods required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) for “specified covered outpatient drugs” (SCODs) in a straightforward manner and recognizing that all biological products are sole source;⁷
- Treating three expiring pass-through drugs as SCODs;⁸
- Implementing the MMA’s provision requiring immediate reimbursement for drugs and biologicals for which HCPCS codes have not yet been assigned;⁹

² Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS (Oct. 8, 2004) available at <http://www.bio.org/letters/>.

³ 69 Fed. Reg. at 65776.

⁴ *Id.* at 65776, 65798.

⁵ *Id.* at 65777.

⁶ *Id.* at 65781.

⁷ *Id.* at 65781-94, 65803.

⁸ *Id.* at 65795.

⁹ *Id.* at 65807.

- Continuing to reimburse vaccines under the reasonable cost methodology;¹⁰
- Setting payment rates for certain orphan drugs at the higher of 88 percent of their average wholesale price (AWP) or 106 percent of their ASP, updated quarterly;¹¹
- Basing the payment rate for J0256, Alpha 1-Proteinase Inhibitor, on the volume-weighted average of all three brands currently available on the market, updated quarterly;¹² and
- Acknowledging that radiopharmaceuticals are indeed drugs and biologicals and paying for radiopharmaceuticals with transitional pass-through status using the same methodology as for SCODs.¹³

We continue to be concerned, however, that the MMA's significant changes in Medicare payment for drugs and biologicals could have negative consequences for patient access to important, innovative therapies. As you are aware, the Medicare statute ties reimbursement for pass-through therapies in the hospital outpatient setting to the rates applicable in physician offices. Neither the new drug administration G-codes nor the demonstration project on improved quality of care for cancer patients undergoing chemotherapy are applicable in the hospital outpatient setting though. Thus, we believe it is critically important for CMS to monitor patient access to these pass-through therapies closely and to act immediately if access is compromised. Hospital outpatient departments are an extremely important part of the drug and biological delivery infrastructure in this country, particularly for high-risk patients with comorbidities and for patients previously enrolled in clinical trials. CMS needs to do what is necessary to preserve patient access to drug and biological therapies in this critical setting.

Moreover, as we discussed in our comments to the Medicare physician fee schedule final rule for 2005,¹⁴ we are deeply concerned that paying for new drug and biologicals at wholesale acquisition cost (WAC) until a rate based on

¹⁰ Id. at 65807.

¹¹ Id. at 65807-09.

¹² Id. at 65809.

¹³ Id. at 65799, 65810-11.

¹⁴ Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 5-6 (Dec. 27, 2004) available at <http://www.bio.org/letters/>.

ASP can be implemented could jeopardize patients' access to new therapies. Accordingly, we urge the agency to pay for these single source drugs and biologicals at 95 percent of their AWP – as they currently are paid in the hospital outpatient setting until a HCPCS code is assigned – or at a WAC-based rate appropriate to ensure beneficiary access to them.

BIO raises the following concerns stemming from the Final Rule. First, although we appreciate CMS' willingness to permit outlier payments for the compounding costs of the radiopharmaceutical therapies Bexxar® and Zevalin®,¹⁵ we continue to be concerned that the final payment rates for these therapies and their related preparation and administration costs and associated procedures are not adequate. We ask the agency to work with the manufacturers and hospitals involved in this issue to find a way to ensure that patient access to these lifesaving therapies will not be compromised. Second, we do not believe functional equivalence, an "equitable adjustment," or any similar standard should be applied to the payment rate of any product and are disappointed CMS did so in the final rule. Third, we urge CMS to apply its special single-indication orphan drug payment rules to additional deserving therapies used to treat rare diseases and disorders, including Elitek™ (J2783) and Fabrazyme® (C9208).

Finally, we are concerned about the packaging threshold and payment for SCODs and other separately paid drugs and biologicals in 2006 and beyond. Although we recognize that CMS believes these issues are outside the scope of the Final Rule,¹⁶ we urge the agency to become more actively engaged on them today to ensure that the future rate-setting methodology is appropriate and that the agency will have the information it needs to proceed. Rather than wait until the comment period on next year's proposed rule, we hope CMS will have an open dialogue with us, other stakeholders, and the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) as soon as the Government Accountability Office's (GAO) study on hospital acquisition costs and the Medicare Payment Advisory Commission's (MedPAC) study on pharmacy service costs have been completed. We welcome the opportunity to work with you to create a new rate-setting methodology for 2006 and thereafter

¹⁵ 69 Fed. Reg. at 65787.

¹⁶ Id. at 65801.

that will help ensure beneficiary access to important drug and biological therapies in hospital outpatient departments.

Rather than repeating our extensive comments on the proposed rule, supporting numerous proposals that CMS now has finalized, we instead focus these comments on only those aspects of the Final Rule about which we continue to have concerns.

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

Consistent with the Social Security Act (SSA), CMS will pay for drugs and biologicals with transitional pass-through status at 106 percent of ASP in 2005 – the same rate applicable in physician offices.¹⁷ As discussed in depth in our comments to the proposed rule¹⁸ and to the proposed and final Medicare physician fee schedule rules for 2005,¹⁹ BIO continues to be concerned that these rates may not adequately compensate hospitals for the costs of providing innovative drug and biological therapies, however. This is particularly true because the neither the new drug administration G-codes nor the demonstration project on improved quality of care for cancer patients undergoing chemotherapy are applicable in the hospital outpatient setting.

Hospital outpatient departments are a critical part of the drug delivery infrastructure. Frequently they treat patients who are higher-risk or have complicating comorbidities, such as a history of infusion reactions. Hospitals also tend to be early adopters of new technologies, particularly if they participate in clinical trials. Often patients who previously were enrolled in clinical trials in a hospital setting will want to continue treatment at that setting where staff are familiar with the therapy, the patient's medical history, and any complexities involved in the drug or biological's administration. Because most pass-through therapies are new with recently completed clinical trials, this is

¹⁷ SSA § 1833(t)(6)(D)(i).

¹⁸ Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 4-5 (Oct. 8, 2004) available at <http://www.bio.org/letters/>.

¹⁹ Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS at 4-5 (Sept. 24, 2004); Letter from Michel Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 3-4 (Dec. 27, 2004) available at <http://www.bio.org/letters/>.

another reason why access to them in a hospital outpatient setting is so imperative.

In our previous comments, BIO has urged CMS to monitor patient access to drug and biologicals proactively as the MMA's new payment methodologies are implemented and to act immediately if access is compromised. We appreciate CMS' statements that it is committed to ensuring beneficiary access and request that the agency add a form to its website to facilitate the reporting of access issues. In addition, we firmly believe that CMS should inform patients and providers that the 1-800-Medicare number and website form are available to report any problems. Unless beneficiaries know that these avenues exist to give feedback, CMS will not be able to collect the information it needs to fully evaluate access issues. This is particularly important in the hospital outpatient setting where neither the new drug administration codes nor the demonstration project will be available to cushion the impact of the ASP-based payment rates. As part of each annual rulemaking, we also encourage CMS to state explicitly what measures it proposes to use to assess access and to report its findings from such assessment. The agency should solicit comment on both such methodology as well as its findings.

The Final Rule provides that in the absence of ASP data, the agency will use WAC to establish the initial payment rate.²⁰ The Final Rule continues, "If WAC is also unavailable then we will calculate payment at 95 percent of the May 1, 2003 AWP or the first reported AWP for the product."²¹ Although the statute authorizes payment *based on* WAC or the methodology in effect on November 1, 2003 – 95 percent of AWP,²² we are deeply concerned that payment *at* WAC – as appears to be the case with the physician office payment rates recently released by CMS – will jeopardize patients' access to new therapies, particularly in hospital outpatient departments. As articulated in our comments to the Medicare physician fee schedule final rule,²³ we urge CMS to pay for these single source therapies at 95 percent of AWP or at a WAC-based rate appropriate to ensure beneficiary access to them. Because pass-through

²⁰ 69 Fed. Reg. 65798.

²¹ *Id.*

²² SSA § 1847A(c)(4)

²³ Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 5-6 (Dec. 27, 2004) available at <http://www.bio.org/letters/>.

therapies for which a unique HCPCS code has not been assigned are paid at 95 percent of AWP in the hospital outpatient setting,²⁴ we believe that continued payment at 95 percent of AWP makes the most sense in this situation particularly given the limited period of time until ASP data are available. We urge CMS to make this change immediately. Unless payment rates are adequate, patients will not have access to cutting-edge therapies that may provide their best hope for treatment.

II. Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

A. Ensuring Patient Access to Bexxar® and Zevalin®

In our comments to the proposed rule,²⁵ we expressed concern that the 2005 payment rates for the radiopharmaceutical therapies Bexxar® and Zevalin® and their related preparation and administration costs and associated procedures may not be adequate to ensure patient access to them. In the Final Rule, CMS acknowledged that it shares our concerns but that these radiopharmaceuticals meet the definition of sole source SCODs and must be paid in accordance with the MMA.²⁶ The Final Rule also states that outlier payments are permitted for the substantial compounding costs of these radiopharmaceutical therapies, however.²⁷

Although BIO appreciates CMS' willingness to permit outlier payments for the compounding costs of these radiopharmaceutical therapies, we continue to be concerned that the final payment rates for Bexxar® and Zevalin® and their related preparation and administration costs and associated procedures are not adequate. We request that the agency work with the manufacturers and hospitals involved in this issue to find a way to ensure that patient access to these lifesaving therapies will not be compromised.

²⁴ 69 Fed. Reg. at 65807.

²⁵ Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 8-9 (Oct. 8, 2004) available at <http://www.bio.org/letters/>.

²⁶ 69 Fed. Reg. at 65786-87.

²⁷ *Id.* at 65787.

B. Equitable Adjustments to Payment Rates

In the proposed rule, CMS solicited comment on whether the agency should again apply an equitable adjustment to the payment rate of darbepoetin alfa (Q0137).²⁸ BIO commented – as we repeatedly have done in the past – that we do not believe functional equivalence, and equitable adjustment, or any similar standard should be applied to the payment rate of any product.²⁹ We are disappointed that CMS now has applied such an adjustment in the Final Rule³⁰ and ask the agency to reconsider its decision.

III. Changes in Payment for Single Indication Orphan Drugs

BIO applauds CMS for recognizing the unique concerns for patients with rare disorders and for continuing to making separate payments for orphan drugs based on their currently assigned ambulatory payment classifications (APCs).³¹ We firmly believe that CMS' setting payment rates for certain orphan drugs at the higher of 88 percent of their AWP or 106 percent of their ASP, updated quarterly,³² will help ensure that patients with certain rare disorders have access to the life-saving therapies they so desperately need. We are concerned, however, that CMS' criteria for determining which orphans will be eligible for this special treatment is overly narrow. First, we urge CMS to include drugs and biologicals that also are eligible for transitional pass-through status. Second, we ask that the agency expand its special payment rules to all drugs and biologicals designated as orphan therapies by the Food and Drug Administration (FDA) and used for orphan indications.

In the Final Rule, CMS declined to extend single-indication orphan status to Elitek™ (J2783) because it has an off-label, non-orphan use as indicated by the 2004 United States Pharmacopoeia Drug Information (USPDI).³³ We have attached the USPDI's listing for Elitek™, however, and only the orphan use is reported. We ask CMS to make this correction.

²⁸ 69 Fed. Reg. 50448, 50513 (Aug. 16, 2004).

²⁹ Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 9-10 (Oct. 8, 2004) available at <http://www.bio.org/letters/>.

³⁰ 69 Fed. Reg. at 65796.

³¹ *Id.* at 65807-09.

³² *Id.* at 65809.

³³ *Id.* at 65808.

Elitek™ also is a current pass-through therapy. In the Final Rule, CMS determined that Fabrazyme® (C9208), another single-indication orphan drug that also is a pass-through, should be paid at 106 percent of ASP.³⁴ Given the unique concerns CMS has articulated about orphan drugs used solely for orphan conditions and the need to ensure patient access to these critical therapies, we ask the agency to expand its special payment rules to include single-indication orphan drugs that also have been granted pass-through status. This would mean that single-indication pass-through drugs and biologicals such as Elitek™ and Fabrazyme® would be paid the higher of 88 percent of their AWP or 106 percent of their ASP, updated quarterly. We believe such treatment is consistent with CMS' objective to ensure that patients suffering from rare diseases continue to have access to the treatments they need.

Even more broadly, we sincerely hope CMS will consider expanding the number of orphan therapies that qualify for special payment. As addressed in depth in our comments to the proposed rule,³⁵ we ask CMS to extend its special payment rules to all drugs and biologicals designated as orphan therapies by the FDA and used for orphan indications. We believe such treatment supports the goals of the Orphan Drug Act – creating incentives for the research, development, production, and distribution of therapies to treat patients with rare disorders – and will help ensure that patients suffering with rare disorders have access to the life-saving treatments they need.

IV. Payment Methodology for Drugs and Biologicals in 2006 and Beyond

In years 2006 and thereafter, 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 on claims data. The GAO recently confirmed what BIO

³⁴ Id. at 65809.

³⁵ Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 11-13 (Oct. 8, 2004) available at <http://www.bio.org/letters/>.

has said in our comments on previous OPPTS 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.³⁶ Accordingly, we hope that CMS will apply the MMA’s acquisition cost-based payment methodology to all separately paid drugs and biologicals. Moreover, we encourage the agency not to increase the \$50 packaging threshold in 2007 and beyond unless it can show with a thorough study that patient care will not be affected by such a change. Both of these issues are discussed in depth in our comments to the proposed rule.³⁷

In the Final Rule, CMS acknowledges the comments on the MMA-mandated surveys and on the future payment methodology for drugs and biologicals, but explains that these issues fall outside the scope of the Final Rule.³⁸ Similarly, the agency states that it will take all the commenters’ recommendations regarding the packaging threshold as the agency works on its proposal for 2007.³⁹ Although we understand the agency’s hesitance to discuss these issue in the 2005 Final Rule, we urge the agency to consider them carefully today to ensure that the future rate-setting methodology is appropriate and that the agency will have the information it needs to proceed.

Specifically, should CMS decide to extend the MMA’s acquisition cost-based payment methodology to all separately paid drugs and biologicals – as we urge the agency to do – these therapies will need to be included in the acquisition cost survey GAO now is administering. If the agency waits until next fall to request this information from GAO, we are concerned that it will be too late to collect the reliable data necessary. Moreover, we encourage CMS to work with GAO and MedPAC today to ensure that their studies provide CMS with the data the agency needs in the format it needs to set appropriate payment rates in the future.

³⁶ U.S. GAO, "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.

³⁷ Letter from Michael Werner, Chief of Policy, BIO, to Mark McClellan, Administrator, CMS at 6-8 (Oct. 8, 2004) available at <http://www.bio.org/letters/>.

³⁸ 69 Fed. Reg. at 65801.

³⁹ *Id.* at 65779-80.

Rather than waiting until the comment period on next year's proposed rule, BIO hopes CMS will have an open dialogue with us, other stakeholders, and the APC Panel as soon as the GAO and MedPAC studies have been completed. We encourage the agency to use the sub-regulatory process – similar to what it has done to seek input on the Medicare Part D prescription drug benefit – to seek comment, schedule working group meetings, and provide other opportunities for transparency and public input regarding the payment methodology for drugs and biologicals in 2006 and beyond. 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. We are hopeful that the future rate-setting methodology will help ensure beneficiary access to important drug and biological therapies in hospital outpatient departments. We welcome the opportunity to work with you to make this occur.

V. Conclusion

In conclusion, BIO commends CMS for making important improvements to the OPDS, and we urge the agency to continue to make patient access to quality care its primary focus as it implements the MMA. 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;
- Add a form to the CMS website to facilitate the reporting of access issues and inform Medicare beneficiaries and providers that the form and the 1-800-Medicare number are available to give feedback;
- Pay for new single source drugs and biologicals at 95 percent of their AWP or at a WAC-based rate appropriate to ensure beneficiary access to them;
- Ensure that the final payment rates for Bexxar® and Zevalin® and their related preparation and administration costs and associated procedures are adequate to ensure beneficiary access;

Administrator Mark McClellan

January 14, 2005

Page 12 of 12

- Reconsider the application of an equitable adjustment to the payment rate for darbepoetin alfa and never apply it or a similar standard again;
- Apply the agency's special single-indication orphan drug payment rules to additional deserving therapies used to treat rare diseases and disorders, such as Elitek™, Fabrazyme®, and other drugs and biologicals designated as orphan drugs by the FDA and used for orphan indications;
- Expand the future rate-setting methodology for SCODs to include all separately-paid drugs;
- Do not increase the \$50 packaging threshold in 2007 and beyond unless a thorough study shows that patient care will not be affected;
- Work with GAO and MedPAC now to ensure that their studies of the acquisition costs and pharmacy service and overhead costs include all the data the agency needs in the format it needs to set appropriate payment rates in the future; and
- Begin an open dialogue with BIO and other stakeholders as soon as the GAO and MedPAC studies have been completed and work with them to create a payment methodology for 2006 and thereafter that will help ensure beneficiary access to important drug and biological therapies in hospital outpatient departments.

BIO appreciates this opportunity to comment on the Final Rule, and we look forward to working with CMS to protect Medicare beneficiaries' access to life-improving drug therapies both now and in the future. Please contact Jayson Slotnik 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/

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Chief of Policy