December 27, 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-1429-FC (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005)

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 revisions to payment policies under the Medicare physician fee schedule, 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.

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1 69 Fed. Reg. 66236 (Nov. 15, 2004).

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO continues to be concerned that the major reimbursement changes mandated by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) will have serious ramifications for patients. That being said, we are pleased by CMS' statements in the Final Rule that the agency will continue to monitor patient access through the 1-800-Medicare line, the regional office staff, claims analysis, and other environmental scanning activities. We commend the agency for agreeing to work with Congress should any access issues occur.[2] Moreover, we believe that CMS' adoption of the new drug administration codes and the initiation of a demonstration project on improved quality of care for cancer patients undergoing chemotherapy will go a long way to help ensure that Medicare patients continue to have access to the critical and potentially life-saving therapies they need. This goal is more likely to be realized if CMS waives the beneficiary coinsurance for the demonstration project.

Other policies adopted by CMS in the Final Rule also will help ensure beneficiary access to care. Reimbursing for the ten top separately billable end stage renal disease (ESRD) drugs and biologicals at the weighted average of the actual acquisition costs of both large and small dialysis providers as determined by the Office of Inspector General (IG) and updated by the Producer Price Index (PPI) is appropriate and properly implements the statute. Similarly, the increase in the furnishing fee for blood clotting factor from $0.05 per unit to $0.14 per unit will much more adequately reimburse providers and ensure patient access to this life-saving therapy. Finally, we applaud CMS for increasing the per prescription supplying fee from the proposed $10 per prescription to $24 and implementing the proposed common sense reforms to the billing requirements and shipping time frames.

Although we appreciate CMS' clarification in the Final Rule regarding payment rates for new drugs and biologicals until a rate based on average sales price (ASP) can be implemented, we are deeply concerned that payment at wholesale acquisition cost (WAC) could jeopardize patients' access to new therapies. Accordingly, we urge the agency to pay for these single source drugs and biologicals at 95% of their average wholesale price (AWP) or at a rate

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2 Id. at 66300.

appropriate to ensure beneficiary access to them. We also urge the agency to give manufacturers the guidance they need to submit accurate ASP data to the agency. Until all questions are answered thoroughly, payment rates will not be accurate. We particularly ask that CMS detail the process manufacturers should use to correct erroneous filings. This has been particularly important in light of the recent clarification the agency issued with respect to bona fide service fees.[3] In addition, we reiterate our requests for the agency to release ASP-based rates promptly each quarter and to have all calculations confirmed by an outside auditor. The list of the national drug codes (NDCs) considered in setting the rate for each health care common procedural coding system (HCPCS) code has been very helpful. These issues are discussed in detail below.

I. ASP Payment Methodology

A. Patient Access

As we discussed in depth in our comments to the proposed rule,[4] patients' access to biological therapies is dependent both on adequate reimbursement for the therapies themselves as well as adequate reimbursement for the unique costs of handling, administering, and preparing them. In implementing the payment reforms required by section 303 of the MMA, we urged CMS to put beneficiaries first. We also asked the agency to monitor patient access issues proactively and to establish simple mechanisms by which beneficiaries and providers could easily report access issues. We are particularly concerned about beneficiary access for patients with rare diseases and conditions.

BIO is pleased that CMS addressed this issue in the Final Rule and that the agency is committed to monitoring access issues through the 1-800-Medicare line, the regional office staff, claims analysis, and other environmental scanning activities.[5] We also appreciate that the agency is willing to work with Congress should any access issues occur. We hope CMS will use its website as an additional mechanism to collect data regarding

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3 Letter from Herb B. Kuhn, Director, Center for Medicare Management, CMS, to John Gray, President and CEO, Healthcare Distribution Management Association, and Steve Collis, President, Specialty Biotech and Distributors Association, dated December 9, 2004.

4 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, dated September 24, 2004.

5 69 Fed. Reg. at 66300.

problems with patient access. Moreover, we urge the agency to educate beneficiaries about the availability of the 1-800-Medicare number and website form to register concerns and complaints about access issues. 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.

B. Need for Additional ASP Guidance

For ASP-based payment rates to be appropriate, manufacturers must obtain the guidance they need to submit accurate data. We raised numerous questions in our comments to the proposed rule[6] as well as to the Interim Final Rule on ASP data submissions[7] that the agency has not yet answered. We urge CMS to give these issues the immediate attention that they deserve, particularly now that payment rates are being set based on these ASP data. We do appreciate the agency's recent clarification regarding bona fide service fees.[8]

Some of our members would like to correct their filings based on this new information or for other reasons. We urge CMS to provide prompt guidance on the process manufacturers should use to correct erroneous filings. Specifically, we seek detailed answers to the following questions:

1) Where should manufacturers send corrections?
2) How will the receipt of corrected information be confirmed?
3) How quickly will corrections be reflected through revised payment rates?
4) Will reimbursements that occurred prior to the correction be modified?
5) Does CMS intend to hold providers harmless for any overpayments made prior to the correction?

We urge the agency to answer these questions – as well as the others we have posed in prior comments – without delay.

C. Calculation and Release of ASP-Based Payment Rates

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6 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, dated September 24, 2004.

7 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, dated June 7, 2004.

8 Letter from Herb B. Kuhn, Director, Center for Medicare Management, CMS, to John Gray, President and CEO, Healthcare Distribution Management Association, and Steve Collis, President, Specialty Biotech and Distributors Association, dated December 9, 2004.

BIO commends the agency for recognizing the need "to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the effective date of those rates."[9] We are deeply concerned, however, that the actual release of the rates on December 17 – a mere two weeks before they actually become effective – does not meet this goal. As we discussed in our comments to the proposed rule, these calculations are complicated and errors inevitably will occur. Releasing the payment rates promptly will allow manufacturers and other interested parties to have a few weeks before the rates become effective to identify errors and will give CMS ample time to correct them before they actually go into effect. This is particularly important because, as noted above, there is no clear process for working with the agency to resolve errors in released ASP figures before the rates go into effect.

We urge CMS to release future payment rates at least a month before they become effective and to establish a process for correcting rates before their effective date. Part of this process should be the establishment of a task force or other mechanism to which a manufacturer or other interested party could go for a quick resolution regarding a potential error. We also would appreciate some assurance from the agency that it is using an external auditor or some other mechanism to verify rates are properly calculated. BIO appreciates CMS' release of the list of NDCs associated with each HCPCS code. This information has been helpful in attempting to better understand the agency's calculation of ASP-based rates.

D. Payment Methodology in Cases Where the ASP During the First Quarter of Sales in Unavailable

Section 1847A(c)(4) of the Social Security Act (SSA) states, "In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on – (A) the wholesale acquisition cost; or (B) the methodology in effect under this part on November

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9 69 Fed. Reg. at 66300.

1, 2003, to determine the payment amounts for drugs or biologicals." The Final Rule clarifies that CMS will pay on this basis for a limited period of time, starting "on the date that sales of the drug begin and end[ing] at the beginning of the quarter after [the agency] receives data from the manufacturer regarding ASP for the first full quarter of sales."[10] We appreciate CMS' acknowledgement in the Final Rule that this period may last during the product's second full quarter of sales when the manufacturer's ASP has been reported but is not yet in use.

After seeing the recently released payment rates for these products whose ASPs are unavailable, it appears that CMS has set payment rates *at* WAC rather than *based on* WAC or the methodology in effect on November 1, 2003 (i.e. 95% of AWP). BIO is deeply troubled that reimbursement at WAC may deny beneficiaries access to new therapies. Section 1847A(c)(6)(B) defines WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, . . . as reported in wholesale price guides or other publications of drug or biological pricing data." We believe that the price at which wholesalers purchase a drug or biological from manufacturers is not an appropriate reimbursement rate for physicians because they are unlikely to be able to purchase drugs and biologicals from wholesalers for this amount. This is why the statute specifies that payment for existing drugs and biologicals is at the lesser of 106% of ASP or 106% of WAC.[11] We believe that the later reference to payment for new drugs should be read to mean 106% of WAC.

BIO requests that CMS exercise its clear statutory authority to set reimbursement rates for single source products whose ASPs are unavailable at 95% of AWP or at a rate appropriate to ensure beneficiary access to them. New drugs without unique HCPCS codes are paid at 95% of AWP in the hospital outpatient prospective payment system, and payment at this amount would equalize payment across settings and not create economic incentives to treat patients needing new drugs in the hospital outpatient department setting instead. We urge CMS to act within its statutory discretion and ensure adequate reimbursement for these therapies. Unless payment rates are adequate, patients will not have access to cutting-edge therapies that may provide their best hope for treatment.

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10 69 Fed. Reg. at 66302.
11 SSA § 1847A(b)(1)(B).

E. Payment for Drugs Furnished During 2005 if Separately Billed by Renal Dialysis Facilities

The Final Rule determines that separately billable ESRD drugs will be paid based "on the actual dollar value of the acquisition costs as determined by the IG rather than the acquisition costs relative to ASP,"12 updated by the PPI for prescription preparations. Payment amounts will be based on a weighted average of acquisition costs of the for largest providers and the other facilities. For drugs and biologicals not studied by the IG, payment will be ASP plus 6%.13 BIO applauds this decision because it properly implements the statute and will help ensure beneficiary access to critical ESRD therapies.

II. Drug Administration Payment Policy and Coding Effective in 2005

Section 1848(c)(2)(J)(i) of the SSA requires the Secretary to "promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption." The statute also specifies that the Secretary use existing processes for considering these coding changes and establishing relative values for them.14 In the Final Rule, CMS adopted the drug administration coding changes made by the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel, using G-codes so that the changes will be effective in 2005.15 The agency also adopted the practice expense resource inputs and work relative values as recommended by the AMA's Relative Value Update Committee (RUC).16 BIO applauds CMS' willingness to adopt these coding changes as recommended by the AMA. We believe these changes will go a long way to help ensure beneficiary access to critical drug and biological therapies by reimbursing physicians more appropriately for the important services they perform as well as for the practice expenses they incur. We particularly appreciate the acknowledgment that the administration of certain biologicals is as complex and resource consuming as the administration of chemotherapy agents.

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12 Id.
13 Id.
14 SSA § 1848(c)(2)(J)(ii).
15 69 Fed. Reg. at 66303.
16 Id.

BIO also appreciates CMS' prompt guidance to contractors regarding the 2005 drug administration coding revisions.17 As the December 10, 2004 transmittal on this topic states, "For services furnished on or after January 1, 2005, chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs and also to anti-neoplastic agents provided for the treatment of noncancer diagnoses . . . or to substances such as monoclonal antibody agents and other biologic response modifiers." Although we appreciate that CMS has listed some therapies "commonly considered to fall under the category of monoclonal antibodies" and that always should be assigned to the new chemotherapy code, we encourage the agency and its contractors not to create any single exhaustive list. Indeed, by including the language "such as" in the description, the AMA did not limit the list of therapies eligible for inclusion under the chemotherapy administration codes to monoclonal antibodies and biologic response modifiers or any other particular type of drug. Instead, payers should be encouraged to examine the complexity and resources required to administer each individual drug or biological to determine the appropriate administration code. The test should be whether the physician work and practice expense to administer the therapy is consistent with the new code. It is with this understanding that we hope carriers "provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare."18

In addition to the changes for drug administration services, BIO believes the demonstration of improved quality of care for cancer patients undergoing chemotherapy will help ensure beneficiary access to appropriate care. In the final rule, CMS announced a demonstration project to "identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population."19 The demonstration project, created pursuant to the Secretary's authority under sections 402(a)(1)(B) and 402(a)(2) of the SSA Amendments of 1967,20 will pay participating providers $130 per encounter to collect data on the patient's levels of pain, nausea or vomiting, and fatigue. CMS plans to use the data to "determine ways to

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17 CMS Program Transmittal 129 (Change Request 3631), One-Time Notification, "2005 Drug Administration Coding Revisions" (Dec. 10, 2004).
18 Id.
19 69 Fed. Reg. at 66308.
20 Pub. L. No. 90-248, codified at 42 U.S.C. § 1395b-1.

improve the quality of care and quality of life" for beneficiaries with cancer.[21] This demonstration project could help ensure Medicare beneficiaries' access to critical therapies today and improved quality of care in the future.

BIO is concerned, though, that the demonstration's coinsurance burden will discourage many beneficiaries from participating. CMS has said that the usual Part B deductible and coinsurance apply to the demonstration project,[22] meaning that beneficiaries will be liable for $26 in coinsurance for each chemotherapy administration encounter, in addition to the coinsurance for the drugs and other services provided. For beneficiaries who receive several rounds of chemotherapy, participating in the demonstration could increase their out-of-pocket costs by hundreds of dollars. Many beneficiaries may choose not to participate rather than pay the additional coinsurance, defeating the purpose of the demonstration project by denying CMS the opportunity to collect important data. The coinsurance burden also places providers in the difficult position of asking their patients to pay for CMS' data collection efforts, even though the patients will not receive additional services.

To ensure that Medicare beneficiaries receive optimal care today and in the future, we recommend that CMS waive the coinsurance requirement for this demonstration. CMS has the authority to waive this requirement under section 402(b) of the SSA Amendments of 1967,[23] allowing the Secretary to waive Medicare's usual payment requirements in demonstration programs. Relieving beneficiaries of the coinsurance burden would facilitate greater participation by cancer patients and would allow CMS to collect data from all Medicare beneficiaries undergoing cancer treatment.

III. Blood Clotting Factor

For blood clotting factor supplied on or after January 1, 2005, CMS had proposed to establish a separate payment of $0.05 per unit to hemophilia treatment centers, homecare companies, and other suppliers for the items and services associated with the furnishing of blood clotting factor. BIO was deeply concerned that this amount would not be adequate to protect beneficiary access

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21 69 Fed. Reg. at 66309.
22 CMS Manual System, Pub. 100-19 Demonstrations, Change Request 3634, Chemotherapy Demonstration Project, Dec. 10, 2004, available at http://www.cms.hhs.gov/manuals/pm_trans/R12DEMO.pdf.
23 42 U.S.C. § 1395(b).

to these critical therapies, especially in light of payment cuts for clotting factor therapies. The Final Rule increases this amount to $0.14 per unit of clotting factor in 2005.[24] For years after 2005, the MMA specifies that the furnishing fee be updated by the percentage increase in the consumer price index for medical care for the 12-month period ending with June the previous year. BIO appreciates CMS' willingness to increase the furnishing fee to a reasonable amount and believes this will go a long way to help ensure that Medicare patients with hemophilia are able to access the care they need.

IV. Supplying Fee, Billing Requirements, and Shipping Time Frame

Similarly, the Final Rule increases the supplying fee to pharmacies for immunosuppressive drugs and oral anticancer drugs and anti-emetics from the proposed $10 per prescription to $24.[25] CMS also establishes a higher supplying fee of $50 for the initial oral immunosuppressive prescription in the first month after a beneficiary has a transplant "because the costs of supplying immunosuppressives are likely to be higher immediately following a transplant, when the practitioner is adjusting the dose of immunosuppressive drugs."[26] BIO applauds CMS for increasing the supplying fee and believes such an increase was imperative to ensure beneficiary access to these critical therapies. We also appreciate the common sense reforms the agency has made to the billing requirements and shipping time frames.[27] These reforms will eliminate some of the paperwork and delays associated with obtaining payment for these therapies and will help reduce pharmacies' administrative expenses.

V. Conclusion

In sum, BIO continues to be concerned that the major reimbursement changes created by section 303 of the MMA will have serious ramifications for patients and urges CMS to make patient access the agency's primary focus as it implements this section. In light of this goal, we are pleased by the substantial improvements CMS has made in the Final Rule. Specifically, we appreciate the agency's recognition of the importance of actively monitoring patient access as the reforms are implemented and believe that the adoption of the new drug

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24 69 Fed Reg. at 66311.
25 Id. at 66313.
26 Id.
27 Id. at 66314

administration codes and the demonstration of improved quality of care for cancer patients undergoing chemotherapy will help improve beneficiaries' access to care. Reimbursing for the top ten separately billable ESRD drugs and biologicals at the weighted average of the actual acquisition costs of both large and small dialysis providers as determined by the IG and updated by the PPI, increasing the furnishing fee for blood clotting factor from $0.05 per unit to $0.14 per unit, and increasing the per prescription supplying fee from the proposed $10 per prescription to $24 also will help ensure that Medicare beneficiaries will have access to the care they need.

There are some shortcomings in the Final Rule, however, and we urge CMS to make the following improvements:

- use the website as an additional mechanism to collect data regarding patient access problems and educate beneficiaries about the availability of the 1-800-Medicare number and website form to register concerns and complaints about access issues;

- provide manufacturers with detailed guidance immediately so they can submit accurate ASP data and promptly correct any erroneous filings;

- release future ASP-based rates at least a month before they are effective to give the public an opportunity to identify errors and give the agency an ample opportunity to correct them before they go into effect;

- use an external auditor or some other mechanism to verify that ASP-based rates are calculated properly;

- exercise CMS' clear statutory authority to set reimbursement rates for single source products whose ASPs are unavailable at 95% of AWP or at a rate appropriate to ensure beneficiary access to them; and

- waive the coinsurance requirement for the demonstration of improved quality of care for cancer patients undergoing chemotherapy to encourage widespread participation.

BIO appreciates the opportunity to comment on the important issues raised in the Final Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Jayson Slotnik at (202) 312-9273 if you have any questions. Thank you for your attention to this very important matter.

Respectfully submitted,

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Michael Werner,
Chief of Policy