September 30, 2005

BY ELECTRONIC DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1502-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006)

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 payment policies under the Medicare physician fee schedule, published in the Federal Register on August 8, 2005 (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.

As we have explained in our comments on prior average sales price (ASP) and physician fee schedule proposed rules, BIO is committed to working with

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1 70 Fed. Reg. 45764 (Aug. 8, 2005).

CMS to ensure Medicare beneficiaries' access to advanced drugs and biologicals. We have been pleased with CMS' efforts to implement the reimbursement changes required by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), but we continue to be concerned that patient access to care will be disrupted by cuts in payment for drugs and biologicals and the services required to administer them. Physicians will be able to provide innovative therapies only if they receive adequate reimbursement. Manufacturers will continue to develop new therapies only if physicians are able to provide them. It is essential, therefore, that rates established under the ASP methodology compensate providers for their acquisition costs, and Medicare's rates for drug administration services adequately reimburse physicians for all of the resources needed to provide drugs and biologicals safely and effectively to patients.

BIO is pleased to offer the following recommendations to ensure continued beneficiary access to innovative drugs and biologicals. First, we urge CMS to not implement its proposed ASP calculation methodology that uses a weighted average of ASPs for direct and indirect sales because we do not believe it will have a significant impact on ASP accuracy and will impose significant administrative burdens on manufacturers. If CMS insists on implementing this proposal, we believe manufacturers should be permitted to elect whether or not they want to use the new methodology. We also urge CMS to clarify its definitions of "direct sales" and "indirect sales," offer manufacturers the opportunity to correct honest mistakes and unintentional errors without liability for misrepresentations, and delay implementation of the new methodology at least until the April 2006 submission deadline. Again, we prefer for CMS not to implement this proposal at all.

Second, we ask CMS to modify its formula for calculating the payment amount for each drug or biological health care common procedural coding system (HCPCS) code to reflect the true weighted average of reported ASPs. We recommend that CMS finalize its proposed changes to the reporting format for ASP data. These changes will help CMS implement our recommended modifications to the formula for calculating the payment rate for each HCPCS code and will inform CMS of the date on which a manufacturer's ASP reporting requirement ceases. We also support CMS' clarification of manufacturers' obligations regarding reports of wholesale acquisition cost (WAC).

Third, BIO urges CMS to implement safeguards, as intended by Congress, regarding the substitution of widely available market price (WAMP) or average

manufacturer price (AMP) for ASP. We are disappointed that neither CMS nor the Office of Inspector General (OIG) has provided any information about the OIG's studies of market prices. We urge CMS to make no substitutions without first explaining the methods used in these studies and offering the public an opportunity to comment on any substitution.

Fourth, to protect beneficiary access to drugs and biologicals furnished through durable medical equipment (DME), BIO asks CMS to publish rates for all of these drugs in the ASP or not otherwise classified files posted on the CMS website. Fifth, we also support the proposal to reimburse separately billed end-stage renal disease (ESRD) drugs furnished in freestanding facilities at ASP plus 6 percent. Sixth, we agree with the predicted increase to the furnishing fee for clotting factor, but urge the agency to not implement its proposed cuts to the supplying fees for oral anticancer and immunosuppressive drugs.

Finally, BIO urges CMS to take whatever action is needed to ensure that physicians are adequately reimbursed for administering drugs and biologicals. We are deeply concerned that the projected 4.3 percent cut in the conversion factor, combined with the end of both the transition adjustments for drug administration services and the potential termination of the Demonstration of Improved Quality of Care for Patients Undergoing Chemotherapy, could harm physicians' ability to provide essential drug and biological treatments for their patients. We urge CMS to monitor this situation carefully and to act now to ensure patients will not be denied access to the drug and biological therapies they need in 2006 and thereafter.

I. ASP Issues

In the Proposed Rule, CMS announces several possible revisions to the calculation and reporting requirements for ASP data that it believes will "ensure more accurate calculation of Medicare payment amounts."[2] BIO supports this critical goal, and we thank CMS for continuing to work with manufacturers to refine the ASP reporting requirements. As we have commented many times in the past, beneficiary access to advanced drugs and biologicals depends upon adequate Medicare reimbursement for these therapies. Because manufacturers ASPs are the basis of Medicare payment rates, it is critical that CMS' instructions for calculating and reporting these figures be as clear as possible. CMS' methodology for

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[2] Id. at 45843.

determining a single payment amount for each HCPCS code also must produce an accurate rate.

A. Price Concessions: Wholesaler Chargebacks; Weighted Average of Direct and Indirect Sales ASPs

CMS proposes to require manufacturers to calculate separate ASPs for direct sales and indirect sales and report a weighted average of the two numbers.[3] Currently, manufacturers can not classify rebates according to whether they are associated with a direct or indirect sale. Although we share CMS' concern for improving the accuracy of reported ASP data, we are concerned that this proposal will have little effect on the accuracy of most reported ASPs and will substantially increase the complexity and administrative burden of manufacturer calculations. As CMS notes, the effect of the new methodology on reported ASPs will depend on the extent to which the ratio of direct and indirect sales in the reporting quarter differs from the ratio of these sales for the 12-month period.[4] In many cases, we anticipate that the proposed methodology will not produce a material change in ASPs because these ratios for the typical manufacturer and product do not vary from quarter to quarter. Moreover, many manufacturers do not have any direct sales at all.

Although the proposed methodology might improve the accuracy of ASPs for those few drugs where this ratio does change materially, it would greatly increase the complexity of the ASP calculation for all drugs and biologicals as a whole. At a minimum, the proposed methodology would require manufacturers to perform each step of the current calculation methodology twice, once for direct sales and again for indirect sales. For example, manufacturers would be required to separate all sales data into two groups, calculate two estimates of lagged price concessions, and two ASPs, before calculating the weighted average of direct and indirect ASPs. To perform these calculations, our members must develop, test, and implement extensive revisions to their computer systems.

We urge CMS not to implement this proposal. If CMS concludes that the proposed methodology's increased complexity is necessary for greater accuracy, we ask that CMS give manufacturers the option of using it. That way, manufacturers whose ASPs do not change materially under the proposed

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3 Id.
4 Id.

methodology will not be forced to undergo the administrative burden and increased complexity that the new calculations would entail.

Should the proposed methodology be finalized, however, we also urge CMS to clarify the proposed definitions of "direct sales" and indirect sales."[5] To employ the proposed methodology, manufacturers must be able to identify which sales are direct and which are indirect, but the proposed definitions do not clearly describe all potential purchasers. For example, a specialty pharmacy could act both as a pharmacy that dispenses drugs and biologicals directly to patients and a distributor that resells drugs and biologicals to hospitals and physicians. The proposed definitions do not clearly state whether sales to such a pharmacy are direct or indirect. Similarly, the proposed definitions do not address drop shipments, in which the manufacturer ships its product to a provider, but bills the wholesaler or distributor. We recommend that these sales be classified according to the entity that is invoiced. If the wholesaler or distributor is billed, the drop shipment should be treated as an indirect sale. BIO asks CMS to clarify the definitions to address these situations. We appreciate the examples of "providers" given in the definition of "direct sales," and we ask CMS to provide similar examples of "suppliers" and "similar entities that sell to others in the distribution chain."

Additionally, BIO urges the agency to ensure that its penalties for errors in ASP submissions are fair. Under the ASP statute, manufacturers may face substantial penalties for misrepresentations, whether knowing or inadvertent, in reported ASPs.[6] CMS also requires manufacturers to certify their ASP reports[7] and to date has issued no guidance regarding its treatment of inadvertent errors. As we explained in our comments on the ASP final rule, manufacturers should be allowed to correct honest mistakes and inadvertent errors without being held liable for misrepresentations.[8] The additional complexity introduced by the proposed methodology serves only to increase the likelihood of such mistakes. For that reason, if CMS implements the proposed methodology, it will be even more important that CMS hold manufacturers liable only for knowing errors. We also ask CMS to allow manufacturers to correct errors in their ASP calculations within 90 days of their submission.

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5 Proposed 42 C.F.R. § 414.802.
6 Social Security Act § 1847A(d)(4)(A).
7 42 C.F.R. § 414.804(a)(5).
8 Letter from Carl B. Feldbaum, President, BIO, to Mark McClellan, Administrator, CMS, June 7, 2004.

Finally, we request that any changes to the ASP calculation methodology be made effective no sooner than the April 2006 submission deadline for ASP data for the first quarter of 2006. Manufacturers will need adequate time to develop and test revisions to their information systems and to perform and review calculations under the new methodology. We urge CMS to provide at least a 2 quarter grace period or delay to allow manufactures to implement the necessary systems changes to comply with the proposed methodology and a 4 quarter grace period in estimating the lagged price concessions so that manufactures do not have to reclassify prior sales according to the new reporting requirements. In other words, manufacturers need 2 quarters to make systems changes and 2 quarters of trial reporting. We do not see how manufacturers possibly could make these significant systems and procedural changes between the publication of the final rule and the next data submission deadline.

B. Determining the Payment Amount Based on ASP Data

BIO thanks CMS for publishing the formula it uses to calculate the payment amount for each billing code in the Proposed Rule.[9] After reviewing this formula, we have concluded that it does not produce a true weighted average for most therapies. We believe CMS should modify it accordingly.

As CMS explains, it divides the reported ASP for a national drug code (NDC) by the number of billing units in that NDC. For example, if a NDC represents a 20 mg vial, and the HCPCS code describes a 10 mg vial, CMS would divide the ASP for that NDC by 2 to determine the ASP for 10 mg of that NDC. Next, CMS multiplies the ASP per billing unit for that NDC by the total number of that NDC sold. CMS performs this calculation for each NDC under the billing code, then computes the total of these calculations for all NDCs. Finally, CMS divides this number by the total number of NDC units sold for this HCPCS code. For a HCPCS with three NDCs, this formula can be stated as:

$$\frac{(\text{ASP/HCPCS unit}_A \text{ X NDC units}_A) + (\text{ASP/HCPCS unit}_B \text{ X NDC units}_B) + (\text{ASP/HCPCS unit}_C \text{ X NDC units}_C)}{\text{NDC units}_A + \text{NDC units}_B + \text{NDC units}_C} = \text{ASP}$$

Under CMS' formula, the agency weights the ASP per billing unit by the total number of NDC units sold, not the total volume of the billing units sold. As a result, CMS does not determine a weighted average ASP for each billing code, but

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9 70 Fed. Reg. at 45844.

rather a weighted average ASP per NDC unit. This is not an appropriate number to use for CMS' rate-setting purposes for most therapies.

We urge CMS to revise its methodology to calculate the average ASP per billing unit as follows:

1. Calculate the number of HCPCS units per NDC by dividing the volume of the NDC (e.g., 20 mg) by the volume of the HCPCS code (e.g., 10 mg).
2. Calculate the ASP per HCPCS unit for a NDC by dividing the reported ASP for a NDC by the number of HCPCS units in that NDC to determine the ASP per HCPCS unit for that NDC.
3. Calculate the number of HCPCS units sold for a NDC by multiplying the number of NDC units sold by the number of HCPCS units per NDC.
4. For the numerator:
    a. Multiply the ASP per HCPCS unit by the number of HCPCS units sold for that NDC.
    b. Repeat this calculation for each NDC in the HCPCS code.
    c. Compute the total of all of these calculations.
5. For the denominator: Compute the total number of HCPCS units sold for all NDCs.
6. Divide the results of step 4 by the results of step 5.

The correct formula is:

$$\text{ASP} = \frac{(\text{ASP/HCPCS unit}_A \text{ X \# of HCPCS units sold}_A) + (\text{ASP/HCPCS unit}_B \text{ X \# of HCPCS units sold}_B) + (\text{ASP/HCPCS unit}_C \text{ X \# HCPCS units sold}_C)}{\text{HCPCS units sold}_A + \text{HCPCS units sold}_B + \text{HCPCS units sold}_C}$$

To demonstrate the difference between CMS' proposed methodology and our alternative, assume a HCPCS code describes 10 mg of a biological that is sold under three NDCs. NDC A is a 20 mg vial of a biological with an ASP of $50. NDC B is a 40 mg vial with an ASP of $100. NDC C is a box of four 20 mg vials (80 mg total volume) with an ASP of $160. The ASP per HCPCS unit for each biological is as follows:

	Volume per HCPCS unit	Volume per NDC Unit	# of HCPCS units/NDC	ASP per NDC Unit	ASP per HCPCS unit
NDC A	10 mg	20 mg	2	$50	$25
NDC B	10 mg	40 mg	4	$100	$25

NDC C	10 mg	80 mg	8	$160	$20

In the reporting quarter, the three NDCs have the following sales:

	Total NDC Units Sold (in thousands)	# of HCPCS units/NDC	Total HCPCS Units Sold (in thousands)
NDC A	80	2	160
NDC B	70	4	280
NDC C	20	8	160

Under CMS' methodology, the ASP per HCPCS unit would be multiplied by the number of NDC units sold, as follows:

$$\frac{(\$25 \text{ X } 80) + (\$25 \text{ X } 70) + (\$20 \text{ X } 20)}{80 + 70 + 20} = 24.412$$

The ASP per HCPCS unit of NDC A is weighted four times as much as the ASP per HCPCS unit of NDC C. Due to the differences in package sizes, however, the amount of biological sold under NDC A equals the amount of biological sold under NDC C. If the ASP for the HPCS Code is calculated based on the total number of HCPCS units sold as proposed above the result is as follows:

$$\frac{(\$25 \text{ X } 160) + (\$25 \text{ X } 280) + (\$20 \text{ X } 160)}{160 + 280 + 160} = 23.667$$

This calculation produces the more accurate ASP per HCPCS unit for most therapies. In this case, our recommended methodology produces a lower ASP than CMS' methodology. In other cases, the ASP would be increased under this method. In nearly all cases, however, this methodology accurately reflects the average price of all of the units of the biological sold. Accordingly, BIO urges CMS to use this formula when computing the ASP for a HCPCS code that includes multiple NDCs.

We are aware, however, that for certain biologicals where the unit of measurement is determined by biological activity rather than by weight, there may be differences among therapies described by the same HCPCS code. Under those circumstances, weighting by the NDC packaging may reflect the distribution of

sales more appropriately than weighting by HCPCS unit. Therefore, we recommend that CMS provide for weighting by NDC under an exceptions process to be applied when the units of biological activity vary among therapies in the same HCPCS code.

If CMS determines that manufacturers should report their ASPs at the HCPCS billing level or a smaller unit (e.g., milligram) to facilitate the agency's calculations, we would support such a change in the reporting requirements. To the extent that a revision in the regulatory definition of "unit"[10] is needed as well, we recommend that "unit" be defined as "the quantity of drug or biological represented by a HCPCS billing code" or a smaller unit relevant to a particular drug, such as a milligram or microgram. Overall, we ask that CMS revise its formula to ensure ASPs for HCPCS codes including multiple NDCs reflect the true weighted average as appropriate for rate-setting. Finally, we urge CMS to clarify that since multiple brands of vaccines are delivered in a common HCPCS and CPT code for a given patient indication, and these vaccines are dosed by biological activity not weight, we believe vaccines should be excluded from weight-based measures a priori, and there is no need to follow the exception process.

C. Reporting WAC

BIO supports CMS' proposed clarification of the circumstances under which manufacturers must report WAC. As explained in the Proposed Rule, manufacturers are required to report WAC and ASP each quarter for NDCs assigned to a single source drug or biological billing code.[11] In addition, manufacturers must report WAC during the initial period in which data are not available to compute an ASP. CMS also clarifies that the relevant figure is the WAC in effect on the last day of the reporting period.[12] These clarifications should help to ensure that CMS has the data it needs to set appropriate payment rates for all Part B drugs and biologicals, and we recommend that CMS include them in the final rule.

D. Revised Format for Submitting ASP Data

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10 42 C.F.R. § 414.802.
11 70 Fed. Reg. at 45844.
12 Id.

BIO also supports CMS' proposed revised format for submitting ASP and WAC data. CMS proposes to add to the current requirements the package size (strength of product, volume per item, and number of items per NDC) and expiration date for last lot manufactured.13 Reporting package size data is necessary for CMS to calculate a true weighted average of all reported ASPs, as described in Section I.B. above. We urge CMS to finalize this proposal so it can begin using the modified formula we describe. The proposal to report expiration date of the last lot manufactured also is logical, and we support the proposal, explained in the information collection notice regarding the revised reporting format, to end a manufacturer's ASP reporting obligation for a given drug or biological on this date.14 After this date, the therapy cannot be sold, and thus ASP data would no longer be needed to set payment rates. We recommend that CMS include both of these proposals in the final rule.

E. Limitations on WAMP

In the Proposed Rule, CMS announces its threshold for determining when the Secretary may substitute WAMP or AMP for ASP.15 CMS also notes that the OIG is conducting is first review of drug prices, but the agency does not provide any information about that review. In November 2004, CMS believed it was "premature to address the implementation issues prior to the OIG establishing its methodology and conducting its first review."16 Now that the methodology has been developed and is being used, we are disappointed that CMS has provided no information about it. Before CMS considers substituting WAMP or AMP for ASP, we urge the agency to provide a thorough description of the sources of information used in the OIG's study, the methodology and criteria for selecting these sources, and the agency's plans to use the data, and to offer the public an opportunity to comment on any such substitution. This explanation and opportunity for comment are necessary to satisfy Congress' clear intent that the Secretary provide "a number of procedural and substantive safeguards to ensure the reliability and validity of the data" used to make determinations to use WAMP instead of ASP.17

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13 Id. at 45844-45.
14 70 Fed. Reg. 48770-71 (Aug. 19, 2005).
15 Id. at 45845.
16 70 Fed. Reg. 66235, 66301 (Nov. 15, 2004).
17 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H. R. Rep. No. 108-391, at 592 (noting that the safeguards include "notice and comment rulemaking, identification of the specific sources of information used to make [a determination to use WAMP instead of ASP], and explanations of the methodology and criteria for selecting such sources").

F. Publication of Prices for all Infusion Drugs and Biologicals Furnished Through an Item of DME

Finally, BIO recommends that CMS publish payment rates for all infusion drugs and biologicals furnished through an item of DME in the ASP or not otherwise classified (NOC) file. As of January 1, 2004, these therapies are reimbursed at 95 percent of their October 1, 2003 average wholesale price (AWP). Although the pricing files contain rates for DME infusion drugs and biologicals that had their own HCPCS codes and pricing as of October 2003, we understand that newer products are not included in these files. We have learned that some carriers have not been manually pricing these drugs and biologicals at 95 percent of AWP, as instructed by CMS, but instead are treating these therapies as if they are compounded. As a result, these drugs and biologicals are reimbursed at WAC or have their payment delayed until the carrier determines the appropriate payment methodology. To simplify timely and appropriate payment for these therapies, we recommend that CMS include the correct rates for DME infusion drugs and biologicals with or without product-specific HCPCS codes in the ASP or NOC files.

II. Payment for ESRD Drugs

The Medicare statute gives the Secretary authority to establish payment amounts for separately billed ESRD drugs beginning in 2006 based on one of two methodologies: (1) acquisition costs as determined by the OIG, or (2) payment amounts specified under Section 1847A (i.e., ASP plus 6 percent).[18] CMS discusses both of these methodologies in the Proposed Rule and concludes that ASP plus 6 percent "is a more reliable indicator of the market transaction prices for these drugs" than updating the OIG's 2003 acquisition cost data to 2006 levels by the producer price index.[19] We agree with this conclusion, and we recommend that CMS finalize its proposal to reimburse all ESRD drugs and biologicals when separately billed by freestanding ESRD facilities, as well as EPO when furnished in hospital-based facilities, at ASP plus 6 percent.[20] ASP-based reimbursement the best option available under the statute. An ASP-based methodology not only

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18 SSA § 1881(b)(13)(A)(iii).
19 70 Fed. Reg. at 45846.
20 Id. at 45845.

reflects provider's costs more accurately than updating a prior year's acquisition cost data, it also is easier for CMS to administer because the agency already collects and updates ASP data on a quarterly basis. We strongly recommend that CMS finalize its proposal to reimburse separately billed ESRD drugs at ASP plus 6 percent. If CMS decides not to implement its proposal, however, we remind the agency that the only acceptable alternative under the statute is acquisition cost as determined by the OIG, updated to 2006 levels.

III. Clotting Factor

In the Proposed Rule, CMS explains that it will increase the clotting factor furnishing fee by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending June 2005.[21] This proposal is consistent with the statute[22] and should help to protect beneficiary access to these life-saving treatments. BIO asks CMS to publish the updated furnishing fee in the final rule.

IV. Supplying Fee

CMS proposes to reduce the supplying fee paid for the second and subsequent prescriptions provided by a supplier to a beneficiary each month.[23] Currently, the supplying fee is set at $24 for each prescription of oral anticancer chemotherapeutic drugs and oral anti-emetic drugs, and $50 for the initial oral immunosuppressive prescription supplied in the first month after a transplant.[24] CMS set the fee at this level after reviewing estimates of pharmacy costs that ranged from $13 to $27 per prescription, including average dispensing costs of $7.50-$8, added costs of $8 due to Medicare's lack of an online claims adjudication system for these bills, and personnel costs of $9.[25] CMS proposes to cut the supplying fee for the second and subsequent prescriptions each month to $8, based on an assumption "that there are likely to be substantial economies of scale and that the burden associated with our lack of online claims adjudication would be relatively similar whether one prescription or multiple prescriptions were supplied during the same month."[26]

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21 Id. at 45846-47.
22 SSA § 1842(o)(5)(C).
23 70 Fed. Reg. at 45849.
24 Id.
25 69 Fed. Reg. 66235, 66312 (Nov. 15, 2004).
26 70 Fed. Reg. at 45849.

We are greatly concerned that CMS has underestimated the costs of dispensing prescriptions to these Medicare beneficiaries. The burden of filing claims without an online adjudication system often is not reduced when more than one prescription is supplied in a month. If a patient fills prescriptions on multiple days or the claims for prescriptions filled on the same day encounter different adjudication problems, the costs associated with billing for each drug would remain constant. As CMS acknowledged last year, these costs are estimated to add $8 on top of the $7.50 to $8 cost of dispensing a prescription to a non-Medicare beneficiary. Additionally, cancer patients and organ transplant recipients have complicated medical histories and often receive multiple drugs. Each time a drug is dispensed, the pharmacist must check the drug against all other drugs the patient receives, determine whether there have been any changes in the patient's medical history, and update the pharmacy's records accordingly. For these reasons, the second prescription each month often requires just as much pharmacist time to dispense as the first. We urge CMS to protect beneficiary access to vital anticancer therapies and immunosuppressive drugs by continuing the supplying fees at their current levels.

V. Practice Expense RVUs and SGR

BIO remains deeply concerned that Medicare payments for drug administration services may not be adequate to reimburse physicians for all of the costs associated with providing advanced drugs and biologicals. Due to the expected 4.3 percent cut in the conversion factor, the expiration of the MMA's transitional adjustment payments, and the proposed termination of the Demonstration of Improved Quality of Care for Patients Undergoing Chemotherapy, payment for each drug administration service likely will be significantly less in 2006 than in 2005. In addition, although CMS has introduced the new, more detailed drug administration Current Procedural Terminology (CPT®) codes in the physician office setting, it does not yet have accurate utilization data necessary to revise the RVUs for these services, as it proposes to do for other services.[27] We urge CMS to take whatever steps are necessary to ensure that physicians are adequately reimbursed for drugs and biologicals and their related administration services. We recommend that CMS work with physician specialty groups to determine what measures, such as recalculating the sustainable

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[27] Id. at 45777.

growth rate (SGR) and extending or revising the demonstration project, would be most appropriate.

VI. Conclusion

BIO appreciates the opportunity to comment on the important issues raised in the Proposed Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. Toward this end, we urge CMS to:

- Not require manufacturers to report a weighted average of their direct and indirect sales ASPs, but instead allow manufacturers the option of using this methodology, and clarify the definitions of "direct sales" and "indirect sales" to help manufacturers identify the appropriate category for their sales if they choose to use the weighted average methodology;
- Allow manufacturers to correct honest mistakes and inadvertent errors within 90 days of making an ASP submission without being held liable for misrepresentations and hold manufacturers liable for knowing errors only;
- Correct the formula for calculating a payment amount for each HCPCS code so that it produces a true weighted average of reported ASPs;
- Implement the requirement for manufacturers to report WAC and ASP each quarter for NDCs assigned to a single source drug or biological billing code and to report WAC during the initial period in which data are not available to calculate an ASP;
- Finalize the proposed revisions regarding the revised format for submitting ASP data;
- Ensure that appropriate safeguards are in place before substituting WAMP or AMP for ASP;
- Publish prices for all infusion drugs furnished through DME in the ASP or NOC file to ensure that carriers provide appropriate and timely reimbursement these drugs;
- Finalize the proposal to reimburse all separately billed ESRD drugs at ASP plus 6 percent;
- Publish the clotting factor furnishing fee, updated as required by statute, in the final rule;

- Not implement the proposed reduction in supplying fees for oral anticancer, anti-emetic, and immunosuppressive drugs; and
- Work with physician groups and take whatever action is necessary to ensure adequate reimbursement for drug and biologicals and their administration services.

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) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President and CEO
Biotechnology Industry Organization