Submitter : **Dr. Joel Sherman** **Date: 12/22/2005**

Organization : **Consultants In Urology, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Submitter : **Mr. James Greenwood** **Date: 12/23/2005**

Organization : **Biotechnology Industry Organization (BIO)**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachement

Interim Relative Value Units

Interim Relative Value Units

see attachement

CMS-1502-FC-47-Attach-1.DOC

December 23, 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-FC and CMS-1325-F (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B)

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 regarding revisions to payment policies under the Medicare physician fee schedule and certain provisions related to the Competitive Acquisition Program (CAP), published in the Federal Register on November 21,

2005 (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.

BIO is pleased that CMS has implemented several of the measures recommended by BIO to protect beneficiary access to drugs and biologicals. Through provisions such as setting reimbursement for all separately billable end-stage renal disease (ESRD) drugs at average sales price (ASP) plus 6 percent, providing an additional payment to physicians for locating and acquiring intravenous immune globulin (IVIG), and increasing the furnishing fee for clotting factor, the Final Rule will ensure that physicians and other providers are reimbursed appropriately for drugs and biologicals administered to Medicare beneficiaries.

BIO also thanks CMS for not implementing several provisions from the proposed rule. We support CMS' decision not to reduce supplying fees for anti-cancer and immunosuppressive drugs, as initially proposed. Rather than cutting the supplying fee for additional prescriptions to $8, the Final Rule sets the fee at a more appropriate $16. We commend the agency for not implementing the proposed ASP calculation methodology that uses a weighted average of ASPs for direct and indirect sales that would not have had a significant impact on reported ASP and would have imposed great burdens on manufacturers. Finally, we appreciate CMS' willingness to allow vendors offer additional national drug codes (NDCs) as well as the agency's clarification regarding payment under the CAP for unused portions of single use vials.

We remain concerned that CMS has not implemented several significant recommendations. First, CMS did not correct its formula for calculating the payment amount for each drug or biological Health Care Common Procedural Coding System (HCPCS) code. As we explained in our comments on the proposed rule, CMS' current formula fails to reflect the true weighted average of reported ASPs. Second, BIO is concerned that CMS' regulatory text does not express the Secretary's discretion in determining whether to substitute widely available market price (WAMP) or average manufacturer price (AMP) for ASP. BIO also believes it is imperative that CMS give the public notice and an opportunity to comment

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1 70 Fed. Reg. 70116 (Nov. 21, 2005).

before any such substitution occurs. Finally, CMS decided to permit, but not require, CAP vendors to provide single indication orphan drugs and newly approved drugs. We urge CMS to reconsider these decisions and implement the changes in a revised rule.

I. ASP Issues

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

BIO applauds CMS' decision not to implement its proposed requirement for manufacturers to calculate separate ASPs for direct sales and indirect sales and report a weighted average of the two numbers.[2] CMS correctly recognized that its proposed methodology would have little effect on the accuracy of reported ASP data and would substantially increase the complexity of manufacturers' calculations. CMS plans to continue working with manufacturers to "better understand the circumstances in which the proposed methodology may benefit the program and the potential for appropriate use of that methodology for certain or all [National Drug Codes]."[3] We appreciate CMS' ongoing efforts to work with manufacturers to refine its instructions for calculating and reporting ASP data. CMS' instructions must be clear and complete for the agency to receive the data it needs to calculate accurate ASPs. Because beneficiary access to critical drugs and biologicals depends on whether Medicare's reimbursement is adequate, BIO remains committed to ensuring that manufacturers have the information they need to file accurate ASP data and that payment rates are calculated accurately from these data.

B. Determining the Payment Amount Based on ASP Data

In our comments on the proposed rule, BIO explained why CMS' formula for calculating the payment amount for each billing code is incorrect.[4] 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 rather a weighted average ASP per NDC unit. Because this is not an appropriate number to

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2 Id. at 70217.
3 Id.
4 Letter from James C. Greenwood, President and CEO, BIO, to Mark McClellan, Administrator, CMS, Sept. 30, 2005.

use for CMS' rate-setting purposes for most therapies, we recommended that CMS revise its formula 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:

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

In the Final Rule, CMS acknowledged that several stakeholders urged CMS to change its formula, but declined to implement this change.[5] We reiterate our recommendation that CMS make this necessary change so that the agency will calculate more accurate ASPs for most therapies. 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.

C. Limitations on WAMP

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5 70 Fed. Reg. at 70218.

The Medicare statute allows the Secretary to substitute WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.[6] When Congress enacted this provision, it also intended that the Secretary provide "a number of procedural and substantive safeguards to ensure the reliability and validity of the data" in making determinations to use WAMP instead of ASP.[7] In the Final Rule, CMS stated that the methodology used in the Office of Inspector General's (OIG) review of drug prices will be available to the public upon completion of the study.[8] In response to comments urging CMS to provide the public the opportunity to evaluate the validity of the processes used and the data obtained by OIG, CMS said that it does not believe rulemaking is appropriate at this time.[9] The final regulation text states, "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2006, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price."[10]

BIO is concerned that the regulatory text does not express the Secretary's discretion in determining whether to substitute WAMP or AMP for ASP. This language is inconsistent with section 1847A(d)(3)(A) of the Social Security Act that states, "The Secretary *may* disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage" (emphasis added). It also is inconsistent with Congress' intent as expressed by the conference report both that the Secretary "make determinations" whether to substitute WAMP or AMP for ASP and that the Secretary use procedural and substantive safeguards in this process.

To the extent that there is a statutory tension between these provisions and another statutory provision that appears to require the Secretary to make such substitution when ASP exceeds the WAMP or AMP by the specified percentage,[11] the Secretary possesses the authority to resolve that tension. We urge the Secretary to do so in a manner that fulfills the policy goals of additional public input and

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6 Social Security Act (SSA) § 1847A(d)(3)(A).

7 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").

8 70 Fed. Reg. at 70222.

9 Id.

10 42 CFR § 414.904(d)(3).

11 SSA § 1847A(d)(3)(C).

ensuring beneficiary access to care. That is, we submit that the Secretary should clarify in the regulation text that he has discretion regarding substituting WAMP or AMP for ASP. We firmly believe that this is what Congress intended. Because OIG has broad authority in studying WAMP and many drugs and biologicals have unique market dynamics that could skew these studies depending on how they are conducted, it is essential that CMS obtain public input before deciding whether to substitute WAMP or AMP for ASP. Without this information, CMS could reduce payment rates inappropriately, potentially denying patient access to important drug and biological therapies.

BIO requests that CMS change its regulatory text accordingly. Specifically, CMS should modify 42 CFR § 414.904(d)(3) to read, "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2006, the Secretary may, after notice and an opportunity for public comment, revise the payment limit in the quarter following the transmittal of this information to the Secretary to the lesser of the widely available market price or 103 percent of the average manufacturer price." In order to obtain meaningful public input, we urge CMS to provide a thorough description of the sources of information used in the OIG's study, the methodology and criteria for selecting these sources, a description of any surveys and how they were conducted, and the agency's plans to use the data. Again, we believe it is imperative that CMS give the public an opportunity to comment on any such substitution before the agency considers substituting WAMP or AMP for ASP.

II. Payment for IVIG

In the Final Rule, CMS announces its decision to provide an additional payment to physicians in 2006 to reflect the "substantial additional resources that are associated with locating and acquiring IVIG and preparing for an office infusion of IVIG."[12] The OIG also is studying the availability and pricing of IVIG as part of its monitoring of market prices under section 1847A(d)(2)(A) of the Social Security Act.[13] BIO commends CMS for taking action to protect beneficiary access to IVIG during this time of market instability. We are concerned, however, that the additional payment will not be sufficient to protect beneficiary access to IVIG. We urge CMS to work with manufacturers and other

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12 70 Fed. Reg. at 70220.
13 Id.

stakeholders to identify the costs associated with acquiring IVIG and preparing for its administration.

We also recommend that CMS create a unique HCPCS code for each brand name IVIG product. Currently, there are only two HCPCS codes for IVIG, even though the products are not interchangeable. As a result, the ASP calculation methodology reflects the prices of all brands of IVIG, not the specific brand that is best suited for a particular beneficiary. We believe that Medicare reimbursement for one brand of IVIG should not be based on another brand that is used for different indications and may be inappropriate for the patient. Creating unique HCPCS codes for each brand would help to protect beneficiary access by ensuring that Medicare's reimbursement is appropriate for each brand. This step also would help CMS better track the supply of each brand in the marketplace.

Finally, we recommend that CMS clarify that the new Current Procedural Terminology (CPT) code for chemotherapy administration by intravenous infusion, 96413, should be used to bill for administration of IVIG. The CPT coding guidelines instruct physicians to use the chemotherapy administration codes for non-radionuclide anti-neoplastic agents, substances such as monoclonal antibodies, and "other biologic response modifiers."[14] IVIG is a biologic response modifier, and thus its administration should be billed using 96413, not 90765, the code for non-chemotherapy intravenous infusion for therapy or diagnosis.

III. Payment for ESRD Drugs

BIO supports CMS' decision to reimburse all end-stage renal disease (ESRD) drugs at ASP plus 6 percent when separately billed by freestanding or hospital-based ESRD facilities.[15] This rate 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 purchasing price index.[16] BIO also supports the agency's decision to increase the drug add-on adjustment to the composite rate from 8.7 percent to 14.7 percent.[17]

IV. Furnishing Fee for Clotting Factor

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14 CPT 2006 Current Procedural Terminology, Professional Edition, at 400.
15 70 Fed. Reg. at 70162.
16 Id. at 70223.
17 Id. at 70167.

CMS implemented its proposal to 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.[18] This increase is consistent with the statute[19] and should help to protect beneficiary access to these life-saving treatments.

V. Supplying Fees for Oral Anticancer, Anti-Emetic, and Immunosuppressive Drugs

For 2006, CMS set the supplying fee for oral anticancer and anti-emetic drugs at $24 for the first prescription and $16 for each additional prescription within a 30-day period.[20] This is a decrease from the current rate of $24 per prescription, but is more than the proposed rate of $8 for each additional prescription. CMS kept the supplying fee for the first immunosuppressive prescription after a transplant at $50, but reduced the fee for subsequent prescriptions to $16. BIO thanks CMS for carefully considering the comments it received regarding the costs of supplying these therapies and the effect cuts in reimbursement would have on beneficiary access. We recommend that CMS monitor beneficiary access to these therapies and increase the supplying fee if it finds that access is impaired.

VI. Ensuring Appropriate Payment for Drug Administration Services

BIO continues to be concerned that the deep cut in the conversion factor will harm beneficiary access to care. This cut, on top of the expiration of the transitional adjustment payments, has reduced Medicare payment for most drug administration services by 25 to 70 percent from 2004 to 2006. We appreciate the agency's efforts to promote quality care in spite of these cuts, including its continuation of a modified oncology demonstration project, but we urge the agency to take whatever steps are necessary to ensure that physicians are adequately reimbursed for administering critical drug and biological therapies, as well as for office visits and other critical services.

VII. Clarifications Regarding the CAP

A. Process for Adding NDCs within a HCPCS Code in an Approved CAP Vendor's Drug List

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18 Id. at 70225.
19 Social Security Act § 1842(o)(5)(C).
20 70 Fed. Reg. at 70234.

BIO is pleased that CMS amended the CAP regulations to allow vendors to request permission to expand their CAP drug lists by offering additional NDCs.[21] This change will improve beneficiary and physician choice of treatment options so the treatment regimen ordered can be the most appropriate regimen for the patient and to minimize discard of excess supplies. We also agree with CMS' clarification that the addition of new NDCs to an approved drug list will not affect the CAP payment amount for that HCPCS that was set during the initial bidding process.

B. Process for Expediting the Addition of Newly Approved Drugs to the CAP

BIO appreciates CMS' recognition that "the earlier addition of newly approved or newly marketed drugs to the CAP is desirable."[22] Instead of requiring CAP vendors to provide new drugs and biologicals as soon as they become available, however, CMS created a process, effective in 2007, for vendors to request permission to add the therapies to their lists. CMS also will consider new therapies for inclusion only if CMS is able to identify a single ASP payment amount for the drug.[23] We are concerned that this process will not ensure timely access to new therapies. Under this system, access to a new drug will be delayed by several months after it is approved for marketing, until the manufacturer reports an ASP, the CAP vendor requests permission to add the drug to its list, and CMS reviews and approves the request. Furthermore, because the process will not be implemented next year, any new therapy first marketed in 2006 or any existing drug for which an ASP had not yet been determined at the time the bidding began may not be available under the CAP until at least 2007. We urge CMS to reconsider this decision and mandate that vendors make available to CAP-participating physicians new drugs upon FDA approval. CMS should reimburse vendors at 106 percent of ASP or WAC plus 6 percent until ASP data are gathered and reported.

C. Inclusion of Single Indication Orphan Drugs in the CAP Category

We are disappointed that CMS decided not to include single indication orphan drugs in the CAP's single drug category.[24] Although CMS acknowledged comments explaining that including single indication orphan drugs in the CAP

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21 70 Fed. Reg. at 70239-40.
22 70 Fed. Reg. at 70240.
23 70 Fed. Reg. at 70241.
24 Id.

would minimize the burden on physicians who administer them and would improve beneficiary access to these therapies, CMS disagreed with requests to require CAP vendors to provide these drugs and biologicals. Instead, CMS created a process to allow vendors to request approval from CMS to supply single indication orphan drugs. We are concerned that this process will do little to improve beneficiary access to these therapies. By making inclusion of single indication orphans optional, CMS returns the burden to the physician to urge the vendor to provide these drugs and gives beneficiaries and physicians no assurance that they will be provided. We strongly recommend that CMS reconsider this decision and require CAP vendors to provide these drugs.

We recommend that one orphan therapy, alpha 1-proteinase inhibitor (J0256), continue to be excluded from the CAP. Alpha 1-proteinase inhibitor is a plasma-derived and recombinant analog therapy. Several brand name versions of this therapy are included in code J0256, but the brands are not therapeutically equivalent. Each brand has a unique effect on the patient, and response to each brand can vary from patient to patient, making it critical that each patient receives the specific brand that is best suited for his or her condition. As long as CAP vendors are required to offer only one NDC for this HCPCS code, it is highly unlikely that a CAP vendor would provide each patient's specific brand. We expect that physicians would have to use the "furnish as written" option frequently for patients who need alpha 1-proteinase inhibitor. It makes more sense, therefore, to exclude alpha 1-proteinase inhibitor from the CAP than to require physicians to routinely use the "furnish as written" option. Each patient's access to alpha 1-proteinase inhibitor would be protected best by excluding these products from the CAP.

D. Clarification Regarding Payment for Unused Drugs under the CAP

We thank CMS for clarifying its policy regarding payment under the CAP for unused portions of single-use vials of drugs and biologicals. CMS explains that it will consider the unused portion of a drug remaining in a single-use vial to have been administered for purposes of the CAP if the "participating CAP physician has made good faith efforts to minimize the unused portion of the CAP drug in how he or she scheduled patients, and how he or she ordered, accepted, stored, and used the drug."[25] In addition, the CAP vendor must make "good faith efforts to

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25 Id. at 70248.

minimize the unused portion of the drug in how it supplied the drug."[26] This is consistent with CMS' policy for drugs reimbursed under the ASP system and will help simplify administration of the CAP.

VIII. Conclusion

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 regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President & CEO
Biotechnology Industry Organization

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26 Id.

CMS-1502-FC-48 **Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006**

Submitter : **Dr. Gary Dillehay** **Date & Time:** **12/27/2005**

Organization : **Society of Nuclear Medicine**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

Interim Relative Value Units

Interim Relative Value Units

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CMS-1502-FC-48-Attach-1.PDF

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