Submitter : Mr. Kevin Grabowski **Date:** 01/02/2007

Organization : DigitalDerm, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Interim Relative Value Units

Interim Relative Value Units

RE: CPT Code 96904, Whole Body Integumentary Photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi or patients with a personal or familial history of melanoma

CMS-1321-FC-51-Attach-1.DOC

1. CMS-1321-FC-7

Date: January 2, 2007

Submitter: **Kevin M. Grabowski**

Organization: **DigitalDerm, Inc.**

Category: **Service Provider**

Issue Areas/ Comments:

Establishment of Interim PE RVUs for New and Revised Physician's CPT Codes and HCPCS Codes for 2007

January 2, 2007

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 independence Avenue, SW
Washington, DC 20201

Re: CPT Code 96904, Whole Body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi or patients with a personal or familial history of melanoma.

Dear Ms. Norwalk,

On behalf of DigitalDerm, Inc. (DDI), please accept our appreciation for this opportunity to express our views on the referenced subject.

With 14 years of experience in developing and promoting the use of Whole Body Integumentary Photography or Total Body Photography (TBP) for high-risk melanoma patients, DDI is pleased to see TBP acknowledged as a recognized service. During this period, a strong body of professional opinion has concluded that TBP has elevated the standard of care for the high-risk melanoma patient by enhancing the detection of melanomas in earlier stages, decreasing biopsies of non-melanoma lesions and sparing the patient excessive scarring, pain and associated medical expenses. However, as this service is presented and categorized by CMS, a number of unresolved issues remain.

To comprehensively evaluate the TBP process, let us examine the AMA issued coding for TBP:

Rationale: Code 96904 was established with the conversion of Category III codes 0044T and 0045T to Category I status to report whole body integumentary photography for the monitoring of high-risk patients

with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma. This code is intended to report the use of photography as a benchmark for skin cancer identification, and is meant to be used no more than once per year for retention in the patient's record.

Clinical Example: A 29-year-old woman presents with an atypical mole and a family history of melanoma. Her physician evaluates her skin every three months to spot and identify changes in existing moles and pigmented lesions in addition to identifying the appearance of new developments. The physician uses the patient's permanent benchmark set of images for an accurate and precise evaluation of the patient's skin, eliminating guesswork, memorization and unnecessary biopsies.

Description of the Procedure: The patient undergoes whole body integumentary photography under established guidelines and protocols. Images are produced in digital format with an image viewing software program and also produced with an interactive viewing album.

In addition to the parameters stated by the AMA, DDI feels their position fails to include an important component in the early detection of melanoma: empowering the patient during their at-home skin self-examination (SSE). As breast exams have enhanced the fight to detect breast cancer, supplying the patient with a convenient and easy to use image set will benefit them in their efforts in detecting melanoma in its earliest stage. Past literature indicates up to 50% of new melanomas are initially discovered by the patient during SSE. An end-product like the MoleMapCD allows them to visually compare suspected changes with the benchmark set of images and print out a copy of the suspected change for discussion with their physician. A recent study published by Chiu, et al, from Brown University in the August edition of the Journal of the American Academy of Dermatology indicates patients can improve the accuracy of the SSE with these benchmark images. The benefit of supplying the TBP images to the patient is two-fold: first, a suspected change will be brought to the physician's attention at its earliest inception and secondly, it involves the patient in their own healthcare management, a situation we know leads to better patient and treatment outcomes. Although not a major issue, DDI feels CMS can complete and take full advantage of the TBP detection cycle by enhancing patient participation with supplemental images for correlation with their SSE.

The major issue of concern for DDI involves the CMS enacted restrictions placed upon this service, specifically a PC/TC indicator of "5". This will only allow TBP to be performed incident to physician service and under his or her direct supervision. This restriction may be feasible for large franchises such as multi-office practices and medical university based departments who have a sufficient patient base to justify the cost associated with equipment, fixed space for imaging and a qualified photographer. However, small to medium sized dermatology practices will be denied access to TBP because the small cohort of eligible patients under their care will not allow them to recoup these costs. Redesignating this procedure with a PC/TC indicator of "3" will allow for the establishment of neutral, outpatient TBP imaging facilities located within the practitioner's practice area. This neutral imaging site option does not force the practitioner to incur capital equipment costs and also leads to other benefits for CMS and other insurers, as defined below.

To explain the neutral imaging site concept, one must have the developmental history and premises upon which it was conceived. The development of our product and service, the MoleMapCD®, began in 1994 in conjunction with the Duke Comprehensive Cancer Center. Unlike equipment vendors, we focused on providing a consummate TBP service including patient and physician education, an intuitive and innovative end product (MoleMapCD) and patient scheduling, imaging and insurance submission services. Due to the lack of consistent insurance reimbursement, we developed this service to be "cost-free" to the referring physician and affordable for the patient. The final product was designed to be stand-alone and portable, eliminating dependence on any one viewing system or software. In an effort to further streamline the service and provide all end users with added value, DDI paid special attention to the proceedings and lessons learned from the CMS hearings concerning stand-alone radiological imaging facilities. The lack of quality control methods, inadequate technician training, sub-standard equipment and capitalization costs for each imaging site (physician practice) caused undo expense to be borne by all in the health care industry. Taking these lessons to task, the MoleMapCD neutral site imaging service offers CMS, physicians and patients the following benefits that are not available under the proposed rule:

a. Baseline Medical Record – The MoleMapCD consists of 33 high resolution digital images of the patient's skin providing a useful benchmark from which to gauge future changes. It

is completely portable and designed to autorun on any Windows 98SE or higher based computer with a CD-ROM component. All MoleMapCDs include instructional tutorials, digital photo albums of the patient's images, speed optimized viewing and magnification software and are completely self-contained. No images remain resident on the computer, post viewing. The referring physician and the patient receive a copy for use during office skin examinations and at-home SSEs. The MoleMapCD has an average estimated life of five (5) years and can be extended further if significant skin changes do not occur. This minimizes the need for annual imaging.

b. Standardization – All imaging processes are optimized and standardized to include equipment requirements, lighting specifications, image format, sequencing, and acquisition matrices. This insures all MoleMapCDs display the same images, in the same format and order, no matter where they are acquired.

c. Quality Control – All patient images are reviewed at the time of imaging to insure proper lighting, cropping and content. Camera performance characteristics are captured at the beginning of each patient imaging session through the use of gray scale and imaging performance charts. Upon receipt of the patient images at our production facility, images are again reviewed to verify they meet quality control standards. An in-house Quality Assurance Committee, headed by the DDI Medical Director, meets on an as-needed, but no less than a quarterly basis to identify and correct potential or documented imaging, production or product deficiencies. The Medical Director is a board certified dermatologist with professional imaging experience and qualifications.

d. Education – The TBP process begins with education. DDI provides patient and physician education seminars in every city in which we image. A ten (10) step physician TBP practice template was developed to aid the referring physician's integration of the TBP process into the management of their high-risk patients. Patient brochures are made available in physician offices and delivered with each MoleMapCD. They explain the TBP process, issues involved in early melanoma detection, computer instructions pertaining to the MoleMapCD, use of the MoleMapCD during SSE, what to do if a skin change is seen and a log to track SSE frequency. A web site is also available at www.digitalderm.com, providing additional links to melanoma education sites.

e. Photographers – DDI photographer employees are the only TBP photographers with dual credentialing: corporate and national (Bio-Communications Association). The BCA is the national organization representing bio-medical photographers. Initially, prospective photographers must pass an in-house credentialing process involving didactic and practical components. Simultaneously, they must start the national credentialing process by passing the written BCA exam. A demonstration patient imaging disk and oral exam must be completed through the BCA within two years for the applicant to remain a MoleMapCD photographer. Additionally, due to the nature of the images, all MoleMapCD photographers must have a clear background check and are covered by $1,000,000 in liability insurance.

f. Practice Integrity – The viability of a physician's practice is second only in significance to the health and well-being of their patients. The ever increasing financial "efficiencies" currently thrust upon all physicians demands retaining a sufficient patient base. A neutral imaging site by its nature eliminates "patient cannibalism", insures the patient will receive the benefits of TBP and assures the referring practitioner he or she will continue to care for his or her patient. This is an especially significant consideration for small to medium size practices.

g. Insurance Submission and Fraudulent Procedure Claims – Utilizing neutral imaging sites will streamline the insurance billing process for CMS as TBP will be the only service provided. Proof of service can easily be confirmed by the electronic delivery of the patient images along with the claim. This process will insure no unauthorized dermatologic imaging procedure is billed as 96904, thereby further protecting against waste and fraud.

h. Equipment capitalization and obsolescence – DDI has calculated that most major metropolitan areas can be serviced with 2 to 8 neutral imaging sites, depending on population. It is not difficult to see the equipment capitalization and amortization savings associated with equipping these sites versus paying for single "practice based" sites. The institution of equipment changes brought about by product advancement or technique refinement will also be more timely and uniform through the neutral site format.

i. Self-Referral and the Stark Laws – The neutral imaging site scenario eliminates the problem of over-utilization of service as referring physicians will not have a financial stake or interest in any facility within their practice area.

j. Practice Option – Although listed last, this is the item of most concern to the practitioners to whom we supply service. Many dermatologist do not want to image their patients due to the following reasons:

   i. Lack of the imaging expertise
   ii. Present management techniques do not allow sufficient time for TBP imaging.
   iii. Do not have adequate space or space to dedicate to imaging equipment
   iv. Lack of properly trained personnel
   v. Unwilling to invest in equipment/technique with a potentially limited or negative revenue stream.

   In light of the recent events affecting the contraction of the stand-alone radiological imaging community, our practitioners have very little incentive or desire to invest money in a procedure that may be withdrawn at any time and for any reason. They feel it would be discriminatory toward them and their patients if they are denied access to the TBP process because they chose not to accept the equipment purchase option being put forth by this proposed rule.

In regards to the CMS proposed interim PE RVU, DDI concurs with the level designated for photographer's costs. We wish to state additional costs components associated with the TBP process for consideration in developing a fair value RVU for 96904. These components are:

1. Equipment capitalization and amortization costs
2. Viewing software
3. Final product media and delivery
4. Standards/ Protocol/ Quality Control/ Compliance processes
5. Patient/ Physician/ Photographer education, materials and/or training
6. Facilities charges
7. Travel/ set-up fees.

DigitalDerm believes the MoleMapCD service and neutral imaging site concept to be a fiscally responsible option for whole body integumentary photography. Its development was based on providing optimal physician and patient benefit and service and is being successfully utilized in ten (10) neutral and six (6) medical university sites throughout the Southeast. As CMS practices and fee schedules are becoming the basis for all insurance reimbursement policies, your office is mandated to explore all options and provide a fair and balanced offering of services to meet the needs of all your subscribed patients and physicians. As a TBP service provider, we were excluded from the initial developmental process, but now look to CMS for advice in the further development of this option. We stand ready to assist in the creation of a fair value RVU and an appropriate PC/TC indicator for this service.

With Kind Regards,

Kevin M. Grabowski

Director, Corporate Development

DigitalDerm, Inc

Columbia, SC

Submitter : **Date: 01/02/2007**

Organization :

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1321-FC-52-Attach-1.PDF

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January 2, 2007

BY HAND DELIVERY

The Honorable Leslie V. Norwalk, Esq.,
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS–1321–FC: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007

Dear Acting Administrator Norwalk:

On December 1, 2006, the referenced Centers for Medicare & Medicaid Services' ("CMS") final rule with comment period ("Final Rule") was published in the Federal Register, 71 Fed. Reg. 69624. Among other things, the Final Rule addresses the calculation of "average sales price" ("ASP") for Medicare Part B drugs and makes certain corresponding amendments to CMS' ASP regulations, 42 C.F.R. § 414.800 et seq.[1] On behalf of Novation, LLC ("Novation"), University HealthSystem Consortium ("UHC"), and VHA, Inc. ("VHA"), we respectfully submit comments to these amendments.

UHC is a legal cooperative that is owned, governed and controlled by state-owned and private, non-profit academic medical centers and teaching hospitals. VHA is a legal cooperative that is owned, governed and controlled by non-profit, tax-exempt,

[1] All citations are to Title 42 of the Code of Federal Regulations, unless otherwise indicated.

community based hospitals. Both UHC and VHA are idea-generating and information-disseminating enterprises that help their members pool resources, create economies of scale and improve clinical care and operating efficiency. Consistent with their missions, UHC and VHA offer their members (among other things) group purchasing programs. For purposes of these programs, UHC and VHA act both directly and through their jointly-owned agent, Novation.

I Final Rule

The Final Rule provides that subject to certain exclusions and exceptions, the ASP of a particular drug is equal to (1) the total dollar value of all units of the drug sold by its manufacturer to all "purchasers" during the quarter at issue, divided by (2) the total number of units covered by these sales.[2] The Final Rule further provides that, in calculating a drug's sales price, the manufacturer must deduct "price concessions" and, more specifically, "volume discounts," "prompt pay discounts," "cash discounts," "free goods that are contingent on any purchase requirement," and "chargebacks and rebates (other than rebates under the Medicaid program)."[3]

Over time, questions have arisen as to whether certain "fees" paid by manufacturers to purchasers or others constitute "price concessions" for purposes of calculating ASP.[4] The Final Rule addresses these questions (at least in part), providing that "bona fide services fees" are not "price concessions" for purposes of calculating ASP.[5] The Final Rule defines "bona fide services fees" as:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.[6]

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[2] 42 C.F.R. § 414.804(a)(1).

[3] 42 C.F.R. § 414.804(a)(2)(i).

[4] 71 Fed. Reg. 48982, 49001 (Aug. 22, 2006).

[5] 42 C.F.R. § 414.804(a)(2)(ii).

[6] 42 C.F.R. § 414.802.

II Comments

A. CMS Should Clarify That Payments Not Meeting the Definition of "Bona Fide Services Fees" are Not Necessarily Price Concessions

The Final Rule provides that if a drug manufacturer pays a "bona fide services fee," that payment does not constitute a "price concession" for ASP purposes. Given the importance of this issue, and in light of certain potentially ambiguous statements in the Preamble,[7] we would urge CMS to clarify that the converse is not true. That is, just because a drug manufacturer's payment does not meet the definition of a "bona fide services fee" does not mean that the payment is, necessarily, a "price concession."

This clarification would be consistent both with (1) the structure and plain terms of the Final Rule and (2) common sense. As to the former, the Final Rule identifies, in § 414.804(a)(2)(i), the categories of "price concessions" (including certain "discounts" and "rebates") to be included in the calculation of ASP; it then provides, in § 414.804(a)(2)(ii), that "bona fide services fees" are not "price concessions." The regulations, however, do not provide that if a payment does not meet the definition of a "bona fide services fee" then the payment, necessarily, constitutes a "price concession."

Indeed, were this CMS' intention, it could simply have amended existing § 414.804(a)(2) to provide that "[i]n calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items": (1) "volume discounts," (2) "prompt pay discounts," (3) "cash discounts," (4) "free goods that are contingent on any purchase requirement," (5) "chargebacks and rebates (other than rebates under the Medicaid drug rebate program)," and (6) *"fees paid by the manufacturer to an entity that are not 'bona fide services fees' under 42 C.F.R. § 414.802."*

This is not how CMS amended the ASP regulations, however. Presumably, CMS did not take this approach because, if it did, any payment made by a drug manufacturer to any "entity" could be deemed a "price concession," even if the payment plainly does not fall into that category. For example, drug manufacturers use electricity and, as such, make payments to utility companies (i.e., "entities"). Such payments may not qualify as a "bona fide services fee" (for example, the amount paid by the manufacturer to the utility might be more or less than fair market value). Plainly, however, the fact

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[7] See, e.g., 71 Fed. Reg. at 69668 ("In codifying the definition of bona fide service fees, we seek to clarify a framework for differentiating between those price concessions that must be included in the calculation of ASP and bona fide service fees, which are not included in the calculation of ASP.")

that the manufacturer's payment to the utility does not qualify as a "bona fide service fee" does not mean that the payment constitutes a "price concession" for ASP purposes.

In order to avoid any confusion or misinterpretation of the Final Rule, we believe that it is important for CMS to clarify that while payments that qualify as "bona fide services fees" are "safe harbored" — that is, such payments do not, as a matter of law, constitute "price concessions" for ASP purposes — payments that do not qualify as "bona fide services fees" may or may not constitute "price concessions" for ASP purposes.

B. CMS Should Clarify That Pending the Issuance of Further Guidance, Fees Paid to GPOs and PBMs Do Not Have To Be Included In the Calculation of ASP

In the Preamble to the Final Rule, after discussing the new "bona fide services fee" provision, CMS notes "many commenters asserted that all fees and other payments" to group purchasing organizations ("GPOs") and pharmacy benefit managers ("PBMs") "should be excluded from ASP."[8] In response, CMS states that it is "continuing to develop [its] understanding of the variety of agreements made with entities such as PBMs and GPOs and the possible effects of these arrangements on the calculation of ASP and provider acquisition costs."[9]

> For this reason, at this time we believe it is premature for us to provide specific guidance with respect to treatment of fees paid by manufacturers to PBMs and GPOs in the ASP calculation . . . Instead, we will continue to consider the comments received and to study the matter further . . . In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices. These assumptions should be submitted along with the ASP data.[10]

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[8] 71 Fed. Reg. at 69669.

[9] 71 Fed. Reg. at 69669.

[10] 71 Fed. Reg. at 69669.

We believe that the most reasonable interpretation of this statement is that until CMS provides specific guidance with respect to the treatment of GPO and PBM fees, if a manufacturer's customary business practice is (for example) to exclude such fees from the calculation of ASP — on the assumption that fees paid to a third party do not constitute "price concessions" offered to a "purchaser" — the manufacturer may continue this practice.

Although we believe that this is the most reasonable interpretation of CMS' statements in the Preamble relating to GPO and PBM fees, in order to avoid uncertainty and confusion among manufacturers, PBMs, GPOs and other third parties, and in an effort to ensure uniformity in ASP reporting to the greatest extent possible, we would urge CMS to make the aforementioned clarification.

C. CMS Should Create a Separate Safe Harbor for Payments Made by a Third Party to a Purchaser That Are Not Controlled by the Manufacturer; Alternatively, CMS Should Amend the "Bona Fide Services Fee" Definition to Achieve the Same Result

Under the current ASP regulations, any "fee" that is paid by a manufacturer to any "entity" will not qualify as a "bona fide services fee" — and, therefore, could potentially constitute a "price concession" for ASP purposes — if the fee is "passed on" by the "entity" to one if its "clients" or "customers". For the reasons set forth below, we believe that there are certain payments that plainly are not "price concessions" but — depending on the meaning of "passed on" — could potentially fall into the non-"bona fide services fee" category. A hypothetical helps demonstrate the point. Assume the following:

- On January 1, 2007, Manufacturer enters into a personal services agreement with Entity. Pursuant to this agreement, Entity furnishes services to Manufacturer on January 1, and Manufacturer pays Entity a $1,000 fee for these services on January 15.

- On February 1, Entity enters into a personal services agreement with Provider (one of Entity's customers). Pursuant to this agreement, Provider furnishes services to Entity on February 1, and Entity makes a $1,000 payment to Provider on February 15.

- Manufacturer was not involved in the negotiation of, and is not a party to, the Entity-Provider agreement.

- On March 1, in discussions with Entity, Manufacturer learns of Entity's agreement with (and $1,000 payment to) Provider.

- During the first quarter of 2007, Manufacturer sells 20 units of Drug A for $100 per unit. 10 of these units are sold by Manufacturer to Provider.

Under these circumstances, it might be contended that the $1,000 fee paid by Manufacturer to Entity (on January 15) does not qualify as a "bona fide services fee" on the ground that it was "passed on" by Entity to Provider (on February 15). (Although we do not believe that this would be a fair or reasonable interpretation of "passed on," the term is not defined in the Final Rule, and this issue is not discussed in the Preamble.) Even were CMS to concur with this interpretation, however — and, as such, conclude that the fee does not qualify as a "bona fide service fee" — CMS presumably would not take the position that the $1,000 fee constitutes a "price concession" by Manufacturer to Provider for ASP purposes.

It is true that the funds for the payment from Entity to Provider came from Manufacturer — at least in the macro sense that $1,000 flowed from Manufacturer to Entity on January 15, $1,000 flowed from Entity to Provider on February 15, and money is fungible. It also is true that Manufacturer had knowledge of this payment. These two facts, however, are not sufficient to establish that Manufacturer made a $1,000 "price concession" to Provider.

The reason for this is straightforward: although (1) the funds originated (again, in a macro sense) with Manufacturer, and (2) Manufacturer had knowledge of the payment by Entity to Provider, Manufacturer did not control this payment. That is, the payment by Entity to Provider was not made pursuant to a contractual (or other legal) obligation that Entity owed to Manufacturer. Rather it was made pursuant to a separate, independent agreement between Entity and Provider, an agreement that Manufacturer did not negotiate and was not a party to. Under these circumstances, we do not believe that it can be said that the $1,000 payment by Entity to Provider is a "price concession" by Manufacturer to Provider.

Indeed, were the case otherwise, third parties would be permitted effectively — and unilaterally — to deflate or inflate a manufacturer's ASP. In the above hypothetical, for example, if Manufacturer is not required to take the $1,000 payment by Entity to Provider into account, then the ASP of Drug A would be $100.[11] If Manufacturer is required to take the $1,000 payment into account — notwithstanding the fact that

[11] That is, $2,000 (the total amount received by Manufacturer from purchasers), divided by 20 units (the total number of units sold to purchasers).

Manufacturer had no control over the payment, which was not made pursuant to any obligation that Entity owed to Manufacturer — then the ASP of Drug A would be reduced by 50 percent, to $50.[12]

In order to ensure that manufacturers (and others) can be confident that payments under circumstances such as these will not be deemed "price concessions" for ASP purposes, we urge CMS to consider amending the ASP regulations by adding the following "safe harbor" as (new) § 414.804(a)(2)(iii):

> *For the purposes of paragraph (a)(2)(i), where an entity (other than the manufacturer) makes a payment to one of its clients or customers, this payment will not constitute a price concession by the manufacturer if the payment was not made pursuant to a contractual or other legal obligation owed by the entity to the manufacturer.*

It should be emphasized that this safe harbor would not protect payments that are, in effect, rebates or other price concessions offered by a manufacturer, but that simply flow through a third party. For example, assume the following:

- Effective January 1, 2007, Manufacturer and Entity enter into an agreement, pursuant to which (1) Manufacturer agrees to sell Drug A to Provider for $100 per unit, (2) Manufacturer agrees to pay Entity a fee equal to two percent of Provider's purchases of Drug A, and (3) Entity agrees that for each $2 in fees that it receives from Manufacturer, it will pass $1 of this $2 back to Provider.

- On January 1, Provider purchases one unit of Drug A from Manufacturer for $100. Pursuant to the Entity-Manufacturer agreement, Manufacturer pays Entity $2 on January 15, and Entity passes $1 of this $2 back to Provider on February 1.

Under these circumstances, the $1 payment by Entity to Provider could — quite reasonably — be considered a "price concession" by Manufacturer to Provider (and would not be protected by the safe harbor proposed above). Although the payment at issue was made by Entity to Provider, it was made pursuant to a preexisting contractual obligation owed by Entity to Manufacturer. Indeed, as a practical matter, the Manufacturer-Entity agreement effectively provided (1) for Manufacturer to pay a one

[12] That is, $1,000 (or the total amount received by Manufacturer from purchasers, $2,000, minus the $1,000 payment by Manufacturer to Entity), divided by 20 units (the total number of units sold to purchasers).

percent fee to Entity and (2) for Manufacturer to pay a one percent rebate to Provider, which rebate simply was administered by Entity.

* * *

As an alternative to developing a new safe harbor, CMS could amend the "bona fide services fee" definition. As revised, the definition of this term would be:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. *For purposes of this definition, a payment by an entity to one of its clients or customers will not be considered "passed on" if the payment is not made pursuant to a contractual or other legal obligation owed by the entity to the manufacturer.*

D. CMS Should Create a Safe Harbor for Payments That are Made by a Manufacturer to an Entity Other Than a Purchaser and Not Passed on to a Purchaser; Alternatively, CMS Should Amend the "Bona Fide Services Fee" Definition to Achieve the Same Result

Under the current ASP regulations, any "fee" that is paid by a manufacturer to any "entity" will not qualify as a "bona fide services fee" — and, therefore, could potentially constitute a "price concession" for ASP purposes — if the fee does not represent "fair market value," even if the fee is not "passed on," in whole or in part, to a purchaser. For the reasons set forth below, we believe that there are certain payments that could potentially fall into this (non-"bona fide services fee") category but plainly should not be considered "price concessions" offered by a manufacturer to a purchaser. Again, a hypothetical helps demonstrate the point. Assume the following:

- Manufacturer has a personal services agreement with Entity. Pursuant to this agreement, Entity furnishes services to Manufacturer on January 1, 2007, and Manufacturer pays Entity a $2,000 fee for these services on January 15.

- The "fair market value" of the services furnished by Entity to Manufacturer is $1,800.

- During the first quarter of 2007, Manufacturer sells 20 units of Drug A for $100 per unit.

- Entity does not make any payments to any of the purchasers of Drug A.

Under these circumstances, the $2,000 payment from Manufacturer to Entity would not qualify as a "bona fide services fee" because it is greater than "fair market value." By the same token, we assume that CMS would not deem the payment a "price concession" by Manufacturer to a purchaser because no portion of the $2,000 paid by Manufacturer to Entity was ever paid, passed on or otherwise transferred to any purchaser.

In order to ensure that manufacturers (and others) can be confident that payments under circumstances such as these will not be deemed "price concessions," we urge CMS to consider amending the ASP regulations to add the following "safe harbor" as (new) § 414.804(a)(2)(iv):

> *For the purposes of paragraph (a)(2)(i), where a manufacturer makes a payment to an entity other than a purchaser, and this payment is not passed on in whole or in part by the entity to a purchaser, this payment will not constitute a price concession by the manufacturer.*

Once again, as an alternative to developing a new safe harbor, CMS could simply amend the "bona fide services fee" definition as follows:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. *Where a manufacturer makes a payment to an entity other than a purchaser, and this payment is not passed on in whole or in part by the entity to a purchaser, this payment need not represent fair market value in order to qualify as a bona fide services fee.*

E. CMS Should Create a "Fair Market Value" Deeming Provision for Fees That Result From Arm's Length, Bona Fide Bargaining Between a Manufacturer and a GPO

As noted above, one of the elements of the "bona fide services fees" definition is that the fee represent "fair market value." CMS correctly notes in the Preamble that the "appropriate method or methods for determining whether a fee represents fair market value may depend upon the specifics of the contracting terms," and that "manufacturers are well-equipped to determine the most appropriate, industry-accepted method" for determining fair market value.[13] "Therefore," CMS concludes, "we are not mandating the specific method manufacturers must use to determine whether a fee represents fair market value for purposes of excluding bona fide service fees from the calculation of ASP."[14]

While we wholeheartedly agree that CMS should not mandate the specific method manufacturers must use to determine whether a fee represents fair market value, we would urge CMS to consider developing one or more "deeming" provisions that would enable manufacturers to rely upon the protections of the "bona fide service fee" safe harbor (or any other safe harbors that include a "fair market value" element) without having to engage in potentially costly and time consuming valuations.

Toward that end, we respectfully submit that it would be appropriate to develop and implement such a deeming provision with respect to fees (1) paid by manufacturers to a "group purchasing organization," as that term is defined at 42 C.F.R. § 1001.952(j)(2), (2) pursuant to arm's length, bona fide negotiations between the manufacturer and the GPO. Such fees have long been recognized by Congress and the U.S. Department of Health & Human Services as an integral part of the hospital supply chain and, indeed, have been afforded statutory and regulatory exemption from the prohibitions of the federal health care program anti-kickback law.

Accordingly, we urge CMS to consider amending the ASP regulations to further clarify — by adding a new definition to the ASP regulations, amending the definition of "bona fide services fee," or otherwise — that a fee paid by a manufacturer to a group purchasing organization, as that term is defined in 42 C.F.R. § 1001.952(j), represents "fair market value" if the fee results from arm's length, bona fide bargaining between the manufacturer and the GPO.

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[13] 71 Fed. Reg. at 69669.

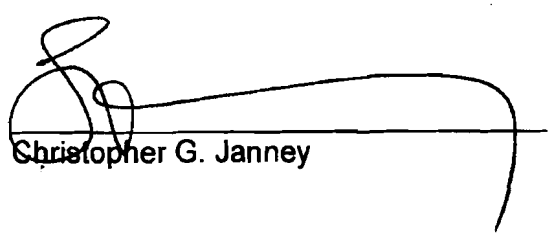
[14] 71 Fed. Reg. at 69669.

* * *

In closing, we would like to thank CMS for providing us with this opportunity to comment on, and make recommendations concerning, the Final Rule. Please do not hesitate to contact us if you have any questions concerning these comments or require further information.

Respectfully,

SONNENSCHEIN NATH & ROSENTHAL LLP

By: 
Christopher G. Janney

Submitter : **Dr. Samuel Masket** **Date: 01/02/2007**

Organization : **ASCRS/OOSS**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-FC-53-Attach-1.PDF

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

January 2, 2007

Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B

Dear Ms. Norwalk:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing more than 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures done annually in the United States.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association of more than 1,000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical procedures performed in cost-effective outpatient environments, including ambulatory surgical centers (ASCs).

First and foremost, ASCRS and OOSS appreciate the opportunity to submit comments on the final rule for the 2007 Medicare physician fee schedule. Second, we encourage CMS to work with us as provisions related to the Administration's and Congress' quality initiatives, outlined in the recently enacted Tax Relief and Health Care Act of 2006, are implemented. We understand that the Secretary of Health and Human Services has been granted authority to carry out many provisions related to quality initiatives, and we continue to believe our input is essential.

Sustainable Growth Rate (SGR)

With the passage of the Tax Relief and Health Care Act of 2006, physicians were able to avert the 5% cut in their 2007 Medicare physician fees due to the flawed SGR formula. However, the legislation did not include any fix to the SGR formula and, due to the funding of the 2007 "freeze," a cut of approximately 10% is predicted for 2008. In addition, the flawed SGR formula is slated to produce steep negative

updates, totaling almost 40% by 2015.

Furthermore, it is imperative that CMS take action on the following issues, particularly since many specialties, such as ophthalmology, are facing additional cuts in their Medicare payments as a result of CMS' newly implemented practice expense methodology, including the use of updated practice cost data for some specialties and outdated data for others and changes resulting from the recent 5-year review.

We understand the Centers for Medicare and Medicaid Services (CMS) agrees with the medical community that the SGR formula is unsustainable, yet the agency has failed to appropriately address problem areas over which it has control. Year after year, we express concern with the flawed SGR formula and offer realistic solutions for addressing these concerns. Yet, once again, the agency failed to take action or, at a minimum, to address our comments in the 2007 Medicare physician fee schedule final rule.

Removal of Physician-Administered Medicare-Covered Drugs Retroactively

We continue to be disappointed that CMS does not use its administrative authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress will permanently repeal the SGR.

It is clear that physicians do not have control over the cost of drugs and biologics. In addition, part B drugs are not procedures, diagnostic tests, or services; part B drugs are only used in conjunction with certain procedures, diagnostic tests, and/or services. Therefore, they have no place in the physician payment pool.

For the past several years, ASCRS and OOSS, as well as numerous other medical and specialty societies, members of the Medicare Payment Advisory Commission (MedPAC) and the Practicing Physicians Advisory Committee (PPAC), the Government Accountability Office (GAO), congressional committees with jurisdiction over the Medicare program, and the majority of Congress, have identified the cost of physician-administered drugs as a primary factor that drives physician spending above the expenditure target. Collectively and independently, these groups have consistently recommended CMS use its administrative authority to remove drugs from the definition of physician services back to the base year, 1996.

We are still unclear why the agency continues to believe it does not have the authority to make the necessary adjustments that would drastically reduce the cost of replacing the flawed SGR formula with a stable payment system. There is overwhelming support in favor of making this necessary change, and we continue to maintain that the agency has the authority to assist Congress in fulfilling its goal of replacing the flawed SGR formula. The final rule did not include any discussion of our concern, and we are unsure why the agency neglected to address our issue in the comment and response area.

Accurately Accounting for Changes in Law and Regulation

We are disappointed that CMS has, once again, failed to show how it accurately accounts for changes in law and regulation when calculating the physician payment update. Specifically, we had asked the agency to ensure that national and local coverage decisions and screening benefits (including the services they generate) that have been added to the Medicare program be included in the expenditure target. To date, CMS has not addressed this issue in its response to comments. We

are frustrated with CMS' non-response and urge the agency to formally consider our comments and respond accordingly.

In comments on the proposed rule, we explained how new coverage decisions—national and local—have had an impact on utilization. Most notable are coverage decisions that require certain diagnostic tests be performed in conjunction with the procedure(s) being addressed by the coverage decision.

We understand that only coverage decisions added to the program by legislation—not by regulation—have been accounted for in the expenditure target previously. However, we continue to believe that CMS should include all coverage decisions—whether added to the program by statute or by the agency—when calculating the expenditure target.

CMS is directly responsible for volume increases related to certain services and procedures. We are very disappointed that the agency has failed to adjust the SGR target accordingly.

Practice Expense Methodology and Use of Supplemental Survey Data

As noted previously, we are opposed to CMS' acceptance and use of supplemental survey data. The result for ophthalmology is a reduction of 6% over the next 4 years, which does not include the SGR-related cuts predicted for the next 8 years. We do not believe it is fair to base practice expense payments for some specialties on updated supplemental data while basing the practice expense payments of other specialties on outdated survey data. Second, the use of current practice expense data for some specialties and outdated practice expense data for others distorts the relativity of payments. This concern has been raised in the past, most recently by the Medicare Payment Advisory Commission (MedPAC) in its June 2006 *Report to the Congress: Increasing the Value of Medicare*. Specifically, MedPAC states the following with regard to the use of updated supplemental survey data:

> *Relying on more current practice cost data submitted by some (but not all) specialties raises several issues. Supplemental submissions do not provide a recurring source of information for all specialties. Although the [Balanced Budget Refinement Act of 1998 (BBRA)] gave providers the option to submit more current information, they are not mandated to do so. Since the BBRA, few groups (16 out of more than 60 specialties) have submitted newer data. Groups informed the commission that collecting PE information is costly and time consuming, and that they do so only when it is likely to increase their payment rates.*
>
> *Using more current information from some but not all specialties could cause significant distortions in relative PE payments across services. When CMS uses supplemental submissions, a redistribution of PE RVUs occurs because it generally implements the change in a budget neutral manner...As a result, once CMS uses specialties' supplemental data, PE payment for services primarily furnished by them could increase while payments for services furnished by other specialties could decrease.*

As you are aware, the medical community is working with the American Medical Association on a new practice expense survey effort. This new multispecialty survey will provide all medical specialty societies an opportunity to participate and will assist in collecting updated, reliable, and consistent practice expense data that can be used in the PE RVUs for all services. The data from this survey are expected to be available for use by CMS beginning in 2009.

Again, we are opposed to CMS' acceptance and use of supplemental survey data as we do not believe it is fair to base practice expense payments for some specialties on updated supplemental data while basing the practice expense payments of other specialties on outdated survey data.

Budget Neutrality

We are very disappointed that CMS chose to make budget neutrality adjustments to the work RVUs rather than to the 2007 conversion factor.

ASCRS and OOSS, as well as many others in the medical community, submitted comments on the 5-year review of work relative value units (RVUs) proposed rule. CMS had proposed to meet its budget-neutrality requirement by reducing all work RVUs by an estimated 10% in its proposal, and we urged CMS to apply its budget-neutrality adjustments to the physician fee schedule conversion factor, rather than the to work RVUs. In the final rule, CMS ignored the recommendation of the majority of medical specialties and made its statutory budget-neutrality adjustment to the work RVUs. The application of a budget-neutrality adjuster to the work RVUs goes against CMS' long-standing policy that adjustments to RVUs to maintain budget-neutrality are ineffective and cause confusion. It is for this reason CMS had, in the past, applied budget-neutrality adjustments due to changes in work RVUs to the physician fee schedule conversion factor.

As you know, the vast majority of private payers use the Medicare-published RVUs to negotiate contracts with physicians. Should private payers use budget-neutrality-adjusted work RVUs, physicians could be unfairly affected. To maintain two separate work RVUs lists, one adjusted for budget neutrality and one not adjusted for budget neutrality, has great potential to generate needless confusion and administrative hassle.

We note CMS' rationale for proposing to reverse its long-held policy of applying budget neutrality adjustment to the work RVUs; however, we are confused about why the agency would pursue this option when the agency has admitted that it causes problems and confusion.

Furthermore, CMS explained in the proposed rule that it planned to implement the work adjuster instead of applying budget-neutrality adjustments to the conversion factor because it believes it is more equitable to make the reduction to the portion of the physician payment formula that was directly involved in the 5-year review. This rationale is not plausible because it assumes all work RVUs were involved in the 5-year review. As you know, only 422 of the more than 7,500 physician codes were involved in this past five year review. However, many codes will be penalized simply because they have work RVUs.

We maintain that CMS' decision to apply budget-neutrality adjustments to the work RVUs rather than to the conversion factor is unfair.

Pay for Performance and Health Information Technology

Based on the agency's actions to date, it appears CMS has chosen to ignore the aforementioned concerns and instead highlight its commitment to moving the Medicare program toward becoming a value-based purchaser of health care services, alluding to the fact that linking quality to payment is a way to solve the SGR conundrum. Because CMS continues to view pay-for-performance as a panacea to the SGR problem, we would like to remind the agency that under the current flawed SGR payment system, pay-

for-performance will not be successful and has the strong potential to increase the volume and intensity of physician services.

Under the current flawed payment system, it is difficult, if not impossible, for physicians to adopt and maintain health information technology (HIT) systems or participate in pay-for-performance programs. It is unreasonable for the agency to expect physicians to invest in HIT and participate in pay-for-performance programs when they have not received a full inflation update in 5 years, and prior to that took a 5.4% cut. And the future looks even grimmer, with cuts of approximately 40% by 2015 and additional reductions in practice expense payments due to CMS' new practice expense methodology.

If CMS wishes to see a true pay-for-performance system succeed, it must do everything within its statutory authority to enable Congress to repeal the SGR and replace it with a payment system that accurately reflects the cost of providing high-quality care to Medicare beneficiaries, such as the Medicare Economic Index (MEI).

* * * * *

Again, we urge the agency to take immediate action on the following recommendations:

- **Use its authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress will permanently repeal the SGR.**

- **Accurately account for changes in law and regulation when calculating the physician payment update. Specifically, we urge the agency to ensure that national and local coverage decisions and screening benefits (including the services they generate) that have been added to the Medicare program be included in the expenditure target.**

ASCRS and OOSS look forward to working with CMS throughout 2007 on these and other issues related to the Medicare physician fee schedule. We also look forward to working with the agency as it implements several provisions outlined in the Tax Relief and Health Care Act of 2007. Should you have questions or comments, please contact Emily L. Graham, RHIT, CCS-P, CPC, ASCRS Manager of Regulatory Affairs, at 703-591-2220 or egraham@ascrs.org, or Michael A. Romansky, OOSS Legal Counsel, at MRomansky@OOSS.org.

Sincerely,

Samuel Masket, MD
President, ASCRS

William Fishkind, MD
President, OOSS

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
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OUTPATIENT OPHTHALMIC SURGERY SOCIETY
6564 Umber Circle •Arvada, CO 80007 • 866-892-1001• Facsimile 303-940-7780

Submitter : **Ms. Emily Graham** **Date: 01/02/2007**

Organization : **Alliance of Specialty Medicine**

Category : **Health Care Professional or Association**

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

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. Michael Repka** **Date: 01/02/2007**

Organization : **American Academy of Ophthalmology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1321-FC-55-Attach-1.PDF

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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Federal Affairs Department

January 2, 2007

Via Electronic Submission:
Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B.

Dear Ms. Norwalk,

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the proposed Medicare Program Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) final 2007 physician fee schedule rule.

Five Year Review - 2005

The Academy appreciates CMS' validation of the efforts of ophthalmology during the recent Five Year Review (5YR). We are disappointed in the lack of response to the Academy and the majority of medicine's request that the resulting budget neutrality adjustment not be applied to the conversion factor. This departure from the consistent past practice of CMS and instead applying it to the work values that have been fairly and relatively valued by their respective specialties is not appropriate. Such a decision has a disproportiate negative effect for the practicing physician who provides pivotal care to Medicare patients across the country.

Practice Expense – New methodology

- *Specialty weighting of PCI*

The Proposed Notice states that the Secretary has determined that PE RVUs should reflect the resources required to perform a service for a "typical" patient. Therefore, we suggest that the approach of basing the specialty adjusted weight on a weighted average of all specialties providing a service is flawed. Rather, we suggest that the weight should be based on the weight of the specialty or specialties that represent 95 percent of the total utilization of the appropriate

CPT code and modifier. Otherwise, the practice expense (PE) related payment is impacted by the practice costs of specialties who do not represent the "typical" patient.

We believe that this adjustment will be important for codes that are billed by a wide range of specialties that typically are not performing the entirety of the service. For example, CPT code 66894 which describes cataract surgery is billed by 19 specialties, even though almost all of the procedures are actually performed by ophthalmologists.

The specialty-based weights impact the PE RVU calculation because the indirect costs are determined based on the direct cost estimate at the procedure level and the ratio of direct and indirect costs at the practice level. The Academy has analyzed the proposed PE RVUs and determined that the alternative approach described below would correct some of the anomalies that result from the inclusion of specialties that are not typically related to providing a service.

In addition, we believe that the utilization data used in calculating the weighted values for CPT 66984 are incorrect and do not reflect the clinical reality of the non-surgical role of optometrists in the service. The surgical procedure is performed only by ophthalmologists. The utilization data contained on the CMS website indicates that 85.4 percent of the utilization of CPT 66984 is associated with an ophthalmologist while another 14.2 percent is associated with an optometrist and 0.4 percent is associated with some 17 other specialties. The Academy believes that many of these claims must be due to coding error because this belies the clinical reality that the surgery is exclusively provided by ophthalmologists.

Optometrists are involved only during the post-procedure period for a limited number of post-operative visits and not involved in the pre-service, intra-service, and day of service discharge portions of the procedure. CMS limits this co-management fee to 20% of the full procedure payment. This clinical reality could be confirmed if the utilization data at the CPT code level also included modifiers since most optometrists will bill for CPT code 66984 with the "54" modifier to indicate their role during the post- operative period.

With the adjustment in the role for optometry and other specialties listed as providers of 66984, the RVU should be 4.1 percent higher. The proposed RVU deflates the practice costs associated with this procedure by 14 percent because the final value is a blend of the practice costs of both ophthalmology and optometry. The 14 percent utilization estimate is based on inaccurate data that does not distinguish between the various modifiers used in conjunction with CPT 66984. When billed correctly, optometrists should use a --54 modifier to indicate the service is for post-operative management only, when one physician performs the post-operative management and another physician performs the surgical procedure.

If CMS were to base the practice expense calculation to reflect the clinical reality where the optometrist role is limited to post-operative care, the PE RVU would be 6.84, or 3.3 percent higher than the proposed RVU for cataract surgery. The two alternatives that AAO proposes does not increase the PE RVU by a significant percentage change and the budget impact may not seem significant in the context of the budget impact of the change to a bottom-up methodology. Nonetheless, the change can have a dramatic impact at the individual practice level and will ensure that the PE RVU reflects the costs that ophthalmologists incur as they provide services related to cataract surgery.

AAO requests that the PE RVU for CPT 66984 be based solely on ophthalmology utilization, or if a weighting of the optometry practice costs is necessary, then the weight assigned reflect the clinical reality of the provision of a portion of the postoperative service.

The result will be a PE RVU which better approximates the resources needed to perform this service.

- *CPT Code 92015*

We note that as a result of the changes to the PE methodology that the PE RVU's for refraction, CPT Code 92015, are reduced to nearly zero. We are concerned that there may be an error in the methodology for this code and would like to request that CMS review their data for the non-facility service to ensure that the proposed values are reflected accurately. Such a steep reduction does not seem appropriate given the relatively low value of PE RVU's for this service. Although this is not a Medicare covered service, the Academy wants to ensure that the relative payment for this is reflected accurately for payments by non-Medicare payers.

New and Revised Process: CPT 2007

The Centers for Medicare and Medicaid Services (CMS) announced that the agency had reviewed all of the RUC recommendations and accepted 98 percent of the RUC recommended values. The Academy strongly supports the RUC process and believes the RUC committee works extremely hard to fairly and appropriately value medical services. The groups that present go to great lengths to survey following the rigorous standards imposed by the RUC and to also provide the correct data and inputs for practice expense. Your level of acceptance shows that there is continued confidence in this process and that is appreciated.

For CPT code 92025 (*Computerized corneal topography, unilateral or bilateral with interpretation and report*) we disagree with the assessment of CMS that equipment indicated in the practice expense for this new code is not typical. In fact, it is the only equipment that will provide the services for this procedure and it is the reason why a new code was developed. Previously existing keratometry equipment provides far less information and simple measurements of the cornea shape which are not separately reportable. Trying to cobble together a pricing for the new procedure made up of components that do not truly represent this piece of equipment is unfair to the physicians utilizing this technology to improve care of their Medicare patients. The work on this code was done jointly with two other specialty groups and the invoices received were verified as accurate. **The pricing of this equipment needs to be updated to reflect the real cost of this new procedure.**

CMS Requests

The Academy appreciates CMS recognition its *Final Rule* published November 1, 2006 that it is willing to reexamine the linkage between the General Ophthalmologic Services codes and the Evaluation and Management codes. We are in conjunction with American Optometric Association and the American Society of Cataract and Refractive Surgeons are surveying these services and will be presenting our findings at the February 2007

RUC meeting. We believe that the previously adopted links that were indicated by CMS in rulemaking to be permanent will be shown to still be appropriate. The same issues that led to reevaluation of the E/M codes affected these as well. If CMS does not agree with the upcoming RUC determination, then the issue of revaluing the eye visit codes to replace work values that were decreased in the first 5 Year Review will need to be addressed. We look forward to working with CMS and the RUC on this important issue.

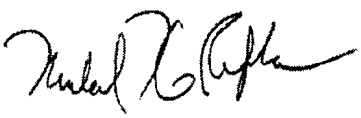
Conclusion

The Academy urges CMS to give serious consideration to the comments raised in this letter. We continue to urge CMS to make appropriate adjustments to the PE methodology that would correctly weigh the practice cost index for provision of cataract surgery (66984) to reflect the co-

management of post surgical care. Ophthalmologists are being unfairly penalized in their practice expense payments for this surgical procedure by the inclusion of optometry practice cost index in calculation of the PCI. The Academy also encourages CMS to accept the equipment pricing information as provided to the RUC and CMS on computer corneal topography and to incorporate this data into the PE database. Lastly, we look forward to upcoming discussion on the issue of the linkage between the evaluation and management codes provided by ophthalmologists and those utilized by other specialties.

The Academy appreciates the opportunity to comment on the final rule. If there are additional questions and/or comments regarding the cost of ophthalmology code inputs we encourage CMS to contact us.

Sincerely,



Michael X. Repka, M.D.
Secretary of Federal Affairs

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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Federal Affairs Department

January 2, 2007

Via Electronic Submission:
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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B.

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We believe that this adjustment will be important for codes that are billed by a wide range of specialties that typically are not performing the entirety of the service. For example, CPT code 66894 which describes cataract surgery is billed by 19 specialties, even though almost all of the procedures are actually performed by ophthalmologists.

The specialty-based weights impact the PE RVU calculation because the indirect costs are determined based on the direct cost estimate at the procedure level and the ratio of direct and indirect costs at the practice level. The Academy has analyzed the proposed PE RVUs and determined that the alternative approach described below would correct some of the anomalies that result from the inclusion of specialties that are not typically related to providing a service.

In addition, we believe that the utilization data used in calculating the weighted values for CPT 66984 are incorrect and do not reflect the clinical reality of the non-surgical role of optometrists in the service. The surgical procedure is performed only by ophthalmologists. The utilization data contained on the CMS website indicates that 85.4 percent of the utilization of CPT 66984 is associated with an ophthalmologist while another 14.2 percent is associated with an optometrist and 0.4 percent is associated with some 17 other specialties. The Academy believes that many of these claims must be due to coding error because this belies the clinical reality that the surgery is exclusively provided by ophthalmologists.

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AAO requests that the PE RVU for CPT 66984 be based solely on ophthalmology utilization, or if a weighting of the optometry practice costs is necessary, then the weight assigned reflect the clinical reality of the provision of a portion of the postoperative service.

The result will be a PE RVU which better approximates the resources needed to perform this service.

- *CPT Code 92015*

We note that as a result of the changes to the PE methodology that the PE RVU's for refraction, CPT Code 92015, are reduced to nearly zero. We are concerned that there may be an error in the methodology for this code and would like to request that CMS review their data for the non-facility service to ensure that the proposed values are reflected accurately. Such a steep reduction does not seem appropriate given the relatively low value of PE RVU's for this service. Although this is not a Medicare covered service, the Academy wants to ensure that the relative payment for this is reflected accurately for payments by non-Medicare payers.

New and Revised Process: CPT 2007

The Centers for Medicare and Medicaid Services (CMS) announced that the agency had reviewed all of the RUC recommendations and accepted 98 percent of the RUC recommended values. The Academy strongly supports the RUC process and believes the RUC committee works extremely hard to fairly and appropriately value medical services. The groups that present go to great lengths to survey following the rigorous standards imposed by the RUC and to also provide the correct data and inputs for practice expense. Your level of acceptance shows that there is continued confidence in this process and that is appreciated.

For CPT code 92025 (*Computerized corneal topography, unilateral or bilateral with interpretation and report*) we disagree with the assessment of CMS that equipment indicated in the practice expense for this new code is not typical. In fact, it is the only equipment that will provide the services for this procedure and it is the reason why a new code was developed. Previously existing keratometry equipment provides far less information and simple measurements of the cornea shape which are not separately reportable. Trying to cobble together a pricing for the new procedure made up of components that do not truly represent this piece of equipment is unfair to the physicians utilizing this technology to improve care of their Medicare patients. The work on this code was done jointly with two other specialty groups and the invoices received were verified as accurate. **The pricing of this equipment needs to be updated to reflect the real cost of this new procedure.**

CMS Requests

The Academy appreciates CMS recognition its *Final Rule* published November 1, 2006 that it is willing to reexamine the linkage between the General Ophthalmologic Services codes and the Evaluation and Management codes. We are in conjunction with American Optometric Association and the American Society of Cataract and Refractive Surgeons are surveying these services and will be presenting our findings at the February 2007

RUC meeting. We believe that the previously adopted links that were indicated by CMS in rulemaking to be permanent will be shown to still be appropriate. The same issues that led to reevaluation of the E/M codes affected these as well. If CMS does not agree with the upcoming RUC determination, then the issue of revaluing the eye visit codes to replace work values that were decreased in the first 5 Year Review will need to be addressed. We look forward to working with CMS and the RUC on this important issue.

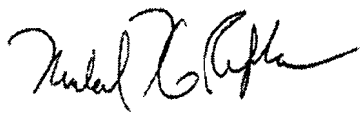
Conclusion

The Academy urges CMS to give serious consideration to the comments raised in this letter. We continue to urge CMS to make appropriate adjustments to the PE methodology that would correctly weigh the practice cost index for provision of cataract surgery (66984) to reflect the co-

management of post surgical care. Ophthalmologists are being unfairly penalized in their practice expense payments for this surgical procedure by the inclusion of optometry practice cost index in calculation of the PCI. The Academy also encourages CMS to accept the equipment pricing information as provided to the RUC and CMS on computer corneal topography and to incorporate this data into the PE database. Lastly, we look forward to upcoming discussion on the issue of the linkage between the evaluation and management codes provided by ophthalmologists and those utilized by other specialties.

The Academy appreciates the opportunity to comment on the final rule. If there are additional questions and/or comments regarding the cost of ophthalmology code inputs we encourage CMS to contact us.

Sincerely,



Michael X. Repka, M.D.
Secretary of Federal Affairs

Submitter : **Ms. Cathleen Dooley** **Date: 01/02/2007**

Organization : **Johnson & Johnson**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attached document

CMS-1321-FC-56-Attach-1.DOC

January 2, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-FC
445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B

Dear Ms. Norwalk:

On behalf of Ortho Biotech Products, L.P., a Johnson & Johnson Company, I am pleased to submit comments on the "Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B" published in the *Federal Register* at Volume 71, No. 231, p. 69624 as a final rule with comment period on December 1, 2006. Of the many provisions on which CMS has solicited further comment, we confine our remarks to one issue related to the calculation of the average sales price or ASP for reimbursement of drugs and biologics under Part B. Specifically, we convey newly available information that demonstrates the pressing need for a rule governing the allocation of incentives paid on dominant drugs bundled with competitive drugs.

During the comment period for the proposed rule, Ortho Biotech and its competitor Amgen Inc. submitted conflicting views regarding the propriety of an allocation rule for bundles containing dominant drugs. The parties agreed that Amgen pays oncology clinics large rebates on its dominant white blood cell growth factor (WBCGF) drugs (Neupogen and Neulasta) contingent on the clinics' purchase of large volumes of Amgen's competitive red blood cell growth factor (RBCGF) drug (Aranesp) in lieu of Ortho Biotech's competitive RBCGF drug (Procrit). They also agreed that Amgen does not allocate to Aranesp for its ASP calculation the incentives Amgen pays on its dominant drugs to drive Aranesp sales. Where the parties differed was with

respect to the effect of Amgen's bundling practices on the drugs' ASPs and the public healthcare system.

The supplemental information conveyed below reveals that Amgen's own data demonstrate what it has consistently denied, i.e., Amgen's bundling practices have caused and are causing significant harm to Medicare and its beneficiaries. Unless addressed, the use of dominant drugs (such as Amgen's WBCGF drugs Neupogen and Neulasta) to drive the purchase of competitive drugs (such as Amgen's RBCGF drug Aranesp) will continue to distort the reported ASPs and harm the public healthcare system. For these reasons, we renew our recommendation that CMS adopt a rule that requires manufacturers to allocate the incentives paid on their dominant drugs that are calculated based on the sales or market share of their competitive drugs to such competitive drugs for the purposes of their ASP calculations.

Consistent with Ortho Biotech's position, the Medicare Payment Advisory Commission (MedPAC) unanimously recommends – in its recent report to Congress titled "Impact of Changes in Medicare Payment for Part B Drugs" (January 2007) – that CMS issue regulatory guidance clarifying the appropriate methodology for the allocation of discounts afforded on bundled products. In the report (summarized below) MedPAC recognizes that bundles involving dominant drugs can lead to distortions in ASP reimbursement rates in the event the bundled discounts are not allocated so as to accurately reflect the drugs' transaction prices. To maintain the integrity of the ASP system, MedPAC proposes that CMS clarify ASP reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. This recommendation is designed to ensure that discounts paid on bundled drugs that are contingent on the purchase of competitive drugs are allocated to the competitive drugs that derive the benefit of the incentives. As the MedPAC report reflects, the issue before CMS is not whether Amgen's bundle is illegal or whether bundling is appropriate, but whether the existing payment methodology is accurate, fair, and minimizes costs to Medicare and beneficiaries. CMS has the authority to implement rules to ensure a fair and accurate ASP reimbursement system for Part B drugs, and we respectfully agree with MedPAC that CMS should act quickly to achieve these goals.

I. BACKGROUND

On August 22, 2006, CMS issue a proposed rule that solicited comments on the methodologies manufacturers should use to apportion price concessions across Part B drugs sold under bundling arrangements for purposes of calculating the drugs' ASPs. CMS explained that the goal of the contemplated guidance is to ensure a drug's ASP "is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives." CMS recognized that any proposed apportionment methodology must account for bundles that include "drugs that may not have clinical alternatives," which we term "dominant drugs" for ease of reference.

Without appropriate regulatory guidance, bundles with dominant drugs can undermine the integrity of the ASP reimbursement system, may impair competition and impose undue costs on the public healthcare system. These adverse consequences result where a manufacturer pays large incentives on a dominant drug to drive sales of a competitive drug but does not allocate the

incentives to the competitive drug for the ASP calculations. In such circumstances, the ASP of the competitive drug is insulated from price competition and does not reflect the incentives paid to drive its sales.

A. Ortho Biotech's Comments: In its September 28, 2006 comments on the proposed rule Ortho Biotech proposed methodologies for the allocation of incentives on bundled drugs. Consistent with CMS's stated goal that the published ASPs reflect drugs' true market prices, Ortho Biotech recommended that the incentives paid on a dominant drug to drive sales of a competitive drug be allocated to the competitive drug for the ASP calculations. Moreover, to illustrate the inequity and the distortion of ASP payment rates resulting from a manufacturer's failure to appropriately allocate incentives on dominant drugs, Ortho Biotech itemized the harm to competition and Medicare program as a result of Amgen's bundled offering to oncologists known as the Amgen Portfolio Contract ("APC").

To review, the APC encompasses Amgen's WBCGF drugs (Neupogen and Neulasta) and Amgen's RBCGF drug (Aranesp). Neupogen and Neulasta are dominant drugs, together accounting for approximately 98% of the sales of WBCGF drugs to oncology clinics. Amgen's drug Aranesp, in contrast, competes with Ortho Biotech's drug Procrit in the oncology clinic RBCGF drug market. Under its APC, Amgen pays large incentives on Neupogen and Neulasta (its dominant drugs) contingent on the oncology clinics' purchase of large amounts of Aranesp (Amgen's competitive drug) in lieu of Ortho Biotech's drug Procrit. That is, oncologists are denied lucrative rebates on Amgen's life saving WBCGF drugs unless they purchase large amounts of Aranesp. Without those rebates, moreover, the oncology clinics actually lose money on the WBCGF drugs administered to Medicare patients. Thus, the APC undermines the integrity of the market-based ASP reimbursement system by pitting the margin on Amgen's three drugs against the margin on Ortho Biotech's one drug, thereby rendering futile any effort to price compete against the bundle.

Ortho Biotech identified in its comments the significant immediate and long-term savings for patients and Medicare that will result from the adoption of Ortho Biotech's proposal to require the allocation to Aranesp of the incentives paid on Amgen's dominant drugs:

- First, the allocation of incentives from Amgen's WBCGF drugs to Aranesp will decrease the Aranesp ASP and increase the WBCGF drugs' ASPs. The realignment of ASPs will generate immediate savings because a much larger percentage of Medicare's payments for the drugs included in the APC are for Aranesp than for Amgen's WBCGF drugs.
- Second, by requiring the Aranesp ASP to reflect the incentives paid to drive its sales, the proposed allocation will level the competitive playing field and afford oncologists the option to purchase Procrit as their drug of choice. The use of Procrit in lieu of Aranesp will generate significant costs savings for the ultimate payors (i.e., patients, private insurers and Medicare) by eliminating the significant Aranesp "dose premium" currently incurred. That is, the volume of Aranesp administered during a course of therapy, in absolute terms and relative to Procrit doses administered, has increased dramatically since Aranesp was introduced in 2002. As the data Ortho Biotech submitted showed, at the doses actually administered in oncology clinics, Aranesp is by far the more costly drug to payors.

- Third, by leveling the competitive playing field for Aranesp and Procrit and thereby fostering price competition, the proposed rule will reduce the drugs' acquisition costs and ASPs.[1] Thus, the proposed bundle apportionment policy ensures the drugs' ASPs do in fact represent the drugs' market prices and allows the competitive marketplace to operate, to the benefit of Medicare and its beneficiaries.

B. Amgen's Comments: Amgen submitted comments to the proposed rule on October 10, 2006. Amgen did not dispute that its APC offers oncology clinics large rebates on its dominant WBCGF drugs contingent on the clinics' purchase of large volumes of Aranesp. Nevertheless, Amgen opposed any rule calling for the allocation of incentives paid on its dominant WBCGF drugs to Aranesp as "unnecessary". Amgen made a series of specious assertions in support of that proposition that are summarily addressed in Appendix A.

More relevant to these supplemental comments, Amgen also asserted that adopting an allocation rule for bundles with dominant drugs "could" increase Medicare costs. Amgen correctly noted that allocating to Aranesp the incentives on its WBCGF drugs likely would shift market share from Aranesp to Procrit (because the allocation will mitigate the coercive nature of the APC). (p. 10). But Amgen argued that the resultant increase in Procrit share could increase Medicare reimbursement because the per unit ASP for Procrit is higher than the per unit ASP for Aranesp. (pp.10-11). What Amgen ignored is that total reimbursement is a function of the per unit cost and the actual doses administered. It is worth noting that Amgen's comments did not address at all the total relative costs of the drugs at the doses actually administered in oncology practices.

C. CMS's Final Rule: CMS published its final rule on December 1, 2006 (71 FR 69624). With respect to the treatment of bundled incentives for the ASP calculation, CMS began by reiterating that "our goal is to ensure that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives" (71 FR at 69673). CMS noted, however, that conflicting comments had been submitted by the parties (Id. at 69764). Without a clear consensus, CMS elected to defer the implementation of allocation rules until it obtains more information (Id. at 69765). CMS advised that it would "continue to monitor this issue" and encouraged constituents to submit "additional information or concerns to us on this issue as they may arise." Moreover, CMS provided explicit notice that it "may provide more specific guidance in the future through rulemaking or through program instruction or other guidance . . . if we determine it is warranted" (Id.). Finally, CMS noted that "MedPAC has indicated it will be studying this issue in the upcoming year, and we look forward to its work in this area" (Id.).

D. The Antos and King Paper: In an effort to influence the debate, Amgen funded and submitted to CMS and other parties a paper prepared by Joseph R. Antos, Ph.D. and Roland (Guy) King, F.S.A., M.A.A.A. titled "Competition and Bundled Pricing in Medicare's Part B Drug Market", dated December 1, 2006 (the "Antos and King paper"). While largely a

[1] Moreover, the actual price of the WBCGF drugs Neulasta and Neupogen should not increase as a consequence of the allocation of incentives under the proposed rule. The WBCGF drugs are dominant products that can be priced without much regard for competitive drugs. Thus, the WBCGF drugs likely are priced at the level the market will bear and a Medicare allocation rule directing Amgen to accurately report Aranesp ASPs should not affect the net prices of the WBCGF drugs.

reiteration of Amgen's talking points, the paper supplemented Amgen's earlier submission with two findings concerning the effect of the allocation of the WBCGF drug incentives to Aranesp. First, the paper states that "shifting back to Aranesp discounts offered on the white cell agents would encourage physicians to purchase J&J's competing anemia product Procrit" (p.1). That finding is significant. The recognition that market share will shift to Procrit if an allocation rule is implemented affirms that the incentives on Amgen's dominant WBCGF drugs are driving Aranesp share. The finding also confirms that any model assessing the cost of the proposed rule must assume, as Ortho Biotech has, that Aranesp share will shift to Procrit. Second, the paper concludes that the allocation rule "would increase spending in Part B and would substantially raise the cost of administering the program without improving patient care." Thus, in contrast to Amgen's initial submission which focused solely on per unit ASPs, the paper analyzes the cost of the program by comparing the total relative costs of the parties' drugs.

In the Antos and King paper, however, no analysis whatsoever was presented of the relative costs of the parties' drugs as actually administered in oncology clinics. Rather, the paper merely adopted the "dose conversion ratio" of 330:1 adopted by CMS in 2004 for reimbursement under the functional equivalence standard of the Outpatient Prospective Payment System (OPPS) (pp.7, 9). That dose conversion ratio was set as a prospective conversion rate based, in large part, on Amgen's representations to CMS that a dose ratio of 400:1 accurately reflected the relative doses of Procrit and Aranesp actually administered in oncology clinics. (Ortho Biotech took the position that a dose ratio of 260:1 more accurately reflected the actual dosing at that time.) In proffering the larger ratio, Amgen did not submit to CMS the data from its own files – disclosed for the first time below – that demonstrates Amgen knew full well that its 400:1 ratio did not accurately account for the doses of Aranesp actually administered in oncology clinics. Amgen apparently also failed to provide that data to the authors of the Antos and King paper, since they were equally silent with regard to that newly available information.

One final omission from the Antos and King paper is worthy of note. The paper asserts that Aranesp and Procrit's ASPs have decreased since 2005 in the "broad oncology market," implying that the APC has fostered price competition in the oncology clinic market[2] (p.8). What the paper does not disclose or address, however, is the pricing pattern of the parties' drugs in oncology clinics before the implementation of the explicit minimum Aranesp purchase requirements on January 1, 2005, which would demonstrate that the APC effectively ended price competition in the oncology clinic setting.

E. The MedPAC Recommendation: The Medicare Modernization Act (MMA) of 2003 instructs MedPAC to evaluate the impact of the new ASP reimbursement system for Part B drugs on providers and patients and submit its findings in two reports to Congress. MedPAC submitted its second report to Congress on December 29, 2006. The recent report makes

[2] Amgen's APC was and is offered only to oncology clinics. The published ASPs incorporate incentives paid to other markets, such as hospitals. It is misleading therefore to reference changes in the published ASPs for Procrit and Aranesp as a basis for conclusions regarding the impact of the APC on competition.

findings and recommendations that are consistent with those set forth in this comment letter,[3] including the following:

- ASPs Should Reflect Drugs' Actual Transaction Prices: MedPAC recommends that, in establishing guidance, the "goal should be to ensure that ASP reflects the average transaction price for drugs." This goal seeks to ensure that, through transparency and the alignment of reimbursement and costs, Medicare derives the benefit of price competition under its ASP reimbursement system. The goal is thwarted, however, to the extent a drug's published ASP does not reflect the incentives paid to drive its sales.

- Discounts on Bundled Dominant Drugs Distort ASPs Absent Appropriate Allocation: MedPAC correctly recognizes that "[i]t is very unusual to get a large discount on a drug that has no competition." That is, a manufacturer need not provide discounts on dominant drugs to drive their sales. But a manufacturer may provide large discounts on a dominant drug contingent on the purchase of a competitive drug in order to drive the purchase of the competitive drug. MedPAC correctly finds that, without a rule requiring the allocation of the incentives of the dominant drug to the competitive drug, the drugs' ASPs will not reflect their transaction prices: "Without guidelines for the allocation of bundled discounts, the bundling methodology undercuts the ASP payment method."

- Amgen's Coercive APC Restricts Clinical Choice: MedPAC recounts that "many interviewees" described a bundling issue that "posed a problem for them." MedPAC describes this specific bundling issue as follows: "Currently, there are two drugs, we call Drug A and Drug B, similar products that compete for market share. Although the shift to ASP has resulted in lower payment rates for both products, volume and expenditures continued to increase in 2005. In this instance, the manufacturer of Drug A also makes Drug C, a lifesaving drug with no effective competition. It is very unusual to get a large discount on a drug that has no competition, but, in this case, the manufacturer provides a significant discount on Drug C to purchasers who buy Drug A instead of Drug B." Thus, without naming the drugs or parties, MedPAC describes a dominant drug bundle that has the same characteristics as Amgen's bundled contract. Specifically, Drug A corresponds to Amgen's Aranesp, Drug B corresponds to Ortho Biotech's Procrit and Drug C corresponds to Aranesp's dominant WBCGF drugs. The Amgen arrangement is a problem because, as MedPAC finds, physicians "lose money" on the drugs administered to Medicare patients unless they secure the large discounts on the bundled dominant Drug C by purchasing the competitive Drug A. MedPAC states that physicians indicated this economic coercion compromises their "ability to choose a product based on clinical factors." And MedPAC properly identifies the magnitude of the problem, concluding that without guidance, "[o]ther manufacturers of single source drugs might also use this method to increase their sales on products with competition."

[3] The report makes one finding that is not consistent with Ortho Biotech's view of the impact of Amgen's APC. The report states that "[i]n the short term, the bundling arrangement results in lower Medicare payment rates for all three drugs." As explained in Appendix A, Amgen's APC has curtailed price competition in the oncology clinic market, causing Aranesp and Procrit ASPs to be higher than they would have been if the APC had not been implemented.

- CMS Should Issue Regulatory Guidance to Close the Loophole: MedPAC correctly finds that CMS "could support the accuracy of the ASP methodology by clarifying rules about the way bundled discounts should be allocated under manufacturer reporting requirements." Thus, MedPAC recommends that "The Secretary should clarify average sales price (ASP) reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug." Moreover, MedPAC properly emphasizes that, while CMS's policy may need to change over time to reflect changing market practices, this "should not slow down action in this area." MedPAC further highlights the importance of the issue by making the appropriate allocation of discounts for bundled products the only policy recommendation in the entire 56-page report to Congress.

- The Guidance Should Require Allocation of Contingent Discounts to Dominant Drugs: MedPAC proposes two allocation methodologies for bundled discounts. One "option is to allocate bundled discounts in proportion to the sales of each drug sold under the bundled arrangement." According to MedPAC, "[t]his option would parallel bundling requirements under Medicaid and be simpler to administer. However, this method might not capture contingent discounts." That is, the Medicaid allocation methodology is appropriate as a general rule, but a particular rule is required to ensure discounts on dominant drugs that are contingent on the purchase of competitive drugs are properly allocated to the competitive drugs for ASP calculations. To address the contingencies in the contractual arrangement described, MedPAC also proposes an "option reflecting the contingencies in the contract." Consistent with Ortho Biotech's proposed approach, MedPAC's second option calls for a manufacturer to allocate discounts contingent on the purchase of another drug "to the sales of the drug that the discount is meant to increase. This would result in an ASP that more accurately reflects the transaction price of the drugs."

Thus, even without the benefit of the newly available information disclosed below, MedPAC recognized the need to close the loophole that enabled the manipulation and distortion of the published ASPs. The MedPAC report, in addition to the newly available information summarized below reinforces the need for CMS to clarify ASP reporting requirements for bundled products to ensure that ASP calculations reflect actual transaction prices and thus maintain the integrity of the reimbursement system.

II. NEWLY AVAILABLE INFORMATION REGARDING THE RELATIVE COSTS

Following Ortho Biotech's submission of its initial comments on the proposed rule, additional information has become available that confirms Ortho Biotech's representations – and squarely refutes Amgen's representations – concerning the relative costs of Aranesp and Procrit to patients, Medicare and private insurers. This information is derived from the recently unsealed testimony and exhibits presented during the June 2006 hearing in the pending antitrust litigation between Ortho Biotech and Amgen. The evidence submitted under oath in that hearing establishes the significant incremental costs imposed on the public healthcare system by Amgen's payment of incentives on its dominant drugs to drive the purchase of Aranesp in lieu of Procrit. That proof is further corroborated by studies and data concerning the relative dosing and costs of the parties' drugs obtained after the hearing, as well as recent developments in private

insurer reimbursement for Aranesp and Procrit. Indeed, current data pertaining to the adoption of a new Aranesp dosing regimen shows that, without immediate action, the excess costs to Medicare and patients already documented will escalate dramatically.

A. Recently Unsealed Testimony and Exhibits: Starting on June 6, 2006, the United States District Court for the District of New Jersey held a week-long hearing to address Ortho Biotech's request that the Court issue a preliminary injunction to stop Amgen from using its APC until the case is tried to the jury. The issue before the Court (i.e., whether Amgen's APC violates the antitrust laws) is distinct from, and involves a different standard than, the issue before CMS (i.e., whether existing guidelines effectuate a payment methodology that is accurate, fair, and minimizes costs to Medicare and beneficiaries). The Court ultimately concluded that the harm Ortho Biotech incurs as a consequence of Amgen's conduct could be remedied by money damages and, therefore, the parties could proceed to trial on the merits without an injunction. Of relevance here, during the course of the hearing evidence was submitted and testimony was heard regarding the relative costs of the parties' drugs to patients, Medicare and private payors.

All the testimony and documents admitted at the hearing concerning oncology clinics' actual administration of the parties' drugs – including both parties' internal analyses – proved that Aranesp was far more costly than Procrit to the ultimate payors. That is, regardless of the time period examined or the information reviewed, the evidence uniformly showed that the relatively large doses of Aranesp administered in oncology clinics render the drug more costly to payors under both AWP-based and ASP-based reimbursement regimens. Thus, the evidence belies Amgen's assertions that the relative costs of the parties' drugs should be assessed at a dose conversion ratio of 330:1 (at which Procrit would be more costly). Rather, as Amgen was well aware, the data of actual doses administered yield a range of significantly lower dose ratios, all of which reveal a large Aranesp cost premium.

The Court unsealed that evidence by order dated December 12, 2006, thereby enabling Ortho Biotech to make this submission to CMS. To that end, following is a summary of the categories of evidence admitted at the hearing concerning the actual dosing and costs of the parties' drugs, with citation to the pages of the annexed transcripts and trial exhibits:

- Ortho Biotech's expert analyses: Ortho Biotech's expert Dr. Pierre Cremieux of the Analysis Group analyzed two large databases of private insurer reimbursement claims data[4] to determine the average weekly doses of Aranesp and Procrit actually administered in oncology clinics (Tr. 478-575, at 482-488; PD 64-65).[5] At the doses actually administered, Aranesp was 32% to 51% more costly than Procrit under an AWP-based

[4] Reimbursement claims data are insurers' records of the "claims" submitted by oncologists for the reimbursement of drugs actually administered in their offices. Health insurers and other industry participants rely on claims data to conduct analysis of drugs' relative costs (Tr. 427).

[5] References to "Tr. ___" are to the page number of the hearing transcript attached as Appendix B. References to "PD___" are to the numbers of the cited plaintiffs' demonstratives attached as Appendix C. References to "PX __" are to the numbers of the cited plaintiffs' exhibits attached as Appendix D.

reimbursement regime, and from 19% to 33% more costly under an ASP-based reimbursement regime[6] (Id.).

- Ortho Biotech's internal dosing data analyses: In the regular course of business Ortho Biotech tracks the average weekly doses of Aranesp and Procrit actually administered in oncology clinics (Tr. 491-92; PD 66). The data obtained from Ortho Biotech's files showed that, for 2005, Aranesp was 47% more costly than Procrit under an AWP-based reimbursement regime and 33% more under an ASP-based reimbursement regime (Tr. 492).

- Ortho Biotech's internal cost analyses: Ortho Biotech also calculates in the regular course of its business the relative costs of Aranesp and Procrit based on doses of the drugs actually administered in oncology clinics (Tr. 493-495; PX 528 at 291634-35). Ortho Biotech calculated that the Aranesp cost premium grew from 36% in 2004 to 45% in 2005 (Tr. 493-94).

- Amgen's internal dosing data analyses: Like Ortho Biotech, Amgen tracks the average weekly doses of Aranesp and Procrit in the regular course of its business (Tr. 496- 499; PX 350; PD 67). At the doses specified in Amgen's internal reports, Aranesp was from 25% to 34% more costly than Procrit under an AWP-based reimbursement regime, and from 13% to 21% more costly under an ASP-based reimbursement regime (Id.).

- Amgen's internal cost analyses: Amgen also calculated the relative costs of Aranesp and Procrit in the regular course of its business (Tr. 500-02; PX 434 at 92451-52). In 2004, for example, Amgen concluded from its own data that the Aranesp cost premium was 28% (Tr. 500; PX 434 at 92452).

- Amgen's expert analyses: Amgen did not offer an independent expert to testify regarding the relative costs of the parties' products. Instead, Amgen had its own Vice President Dr. Joshua Ofman offer an opinion on that issue. Amgen submitted through Dr. Ofman analyses of reimbursement data conducted by two third party vendors (Tr. 893-.897). As Dr. Ofman conceded at the hearing, both vendors' initial analyses of the relative costs of the parties' drugs demonstrated that Aranesp was more costly than Procrit (Id.). And as was explicitly stated in one vendor's report, Amgen thereafter directed the vendors to alter their analysis in an effort to show the drugs were at cost parity (Tr. 897; 516-517).

- Independent third party payor analyses: Wellpoint is the nation's largest private health insurer. Wellpoint Vice President Dr. Randy Axelrod testified that the insurer determined that Aranesp was far more costly than Procrit based on analyses of its own claims data conducted in the regular course of its business (Tr. 411-477, at 464-68). Dr. Axelrod explained that, based on those analyses, Wellpoint attempted to encourage oncologists to administer Procrit by offering more favorable reimbursement for Procrit. That is, Wellpoint revised its fee schedule to afford reimbursement for Procrit at ASP plus 35% and Aranesp at ASP plus 6% (Tr. 464-65, 468). Wellpoint reasoned that, due to the large Aranesp dose premium, it could reimburse Procrit at a significant premium to Aranesp and still save money if oncologists switched from the higher cost Aranesp (Id.).

[6] The dosing disclosed in the two databases Dr. Cremieux analyzed yielded dose ratios of 248:1 and 276:1.

The evidence also proved that, while asserting to CMS that Aranesp was less costly, Amgen at the same time deliberately withheld from CMS the analyses Amgen conducted that showed Aranesp to be the more costly drug.

- Amgen Vice President Dr. Joshua Ofman admitted that Amgen has represented to CMS, since the introduction of Aranesp in 2002, that CMS should evaluate the relative cost of Aranesp and Procrit based on an assumed Aranesp weekly dose of 100 micrograms (or 200 micrograms every other week).[7] Dr. Ofman also conceded that in 2002, before oncologists had much clinical experience with Aranesp, Amgen submitted to CMS analyses of reimbursement claims data that purportedly showed that Aranesp actually was administered at an average weekly dose of 100 micrograms (Tr. 871-872).
- Amgen's internal records revealed that, following its initial submission in 2002, Amgen learned from its own claims data analyses that oncologists were administering increasingly larger doses of Aranesp relative to Procrit (PX 434 at 92452; Tr. 873). Dr. Ofman agreed that steep Aranesp "dose escalation" resulted in increased Aranesp costs relative to Procrit from 2003 forward (Tr. 874). Amgen's internal recognition of Aranesp's dose escalation was consistent with disclosures oncologists made to Amgen in 2004 (Tr. 877-880; PX 50; PD 607).
- Dr. Ofman admitted that Amgen did not disclose to CMS its post-2002 internal analyses of reimbursement claims data that disclosed the dose escalation (and therefore escalating costs) of Aranesp (Tr. 875). Rather, Amgen has withheld from CMS the reimbursement claims data analyses Amgen has conducted each year since 2002.
- In fact, Amgen affirmatively instructed its employees not to provide Amgen's internal analyses to CMS after determining the extent of the Aranesp dose escalation. Specifically, in the cover e-mail to its September 2004 monthly claims data report, Amgen determined that the average weekly dose of Aranesp administered was increasing at a far more rapid rate than for Procrit (PX139; Tr. 874-875). Dr. Ofman admitted that Amgen did not disclose that finding to CMS (Tr. 875). Instead, Amgen added to the cover of the October 2004 claims data report a large warning that instructed its employees that the information contained therein was not to be included in Amgen's CMS submissions (PX 156; Tr. 876-77). Consistent with that direction, Amgen has not disclosed to CMS any of its subsequent claims data analyses, including is detailed survey of average weekly doses in October 2005 discussed above (Tr. 496- 499; PX 350; PD 67).
- Further still, at the same time it has been advising CMS that it should evaluate the relative costs of Aranesp and Procrit based on an assumed average weekly dose for Aranesp of 100 micrograms every week (or 200 every other week), Amgen admittedly has been recommending to oncologists in the United States and throughout the world that they should be administering twice that amount[8] (Tr. 573; 859-866; PD 602). Dr. Ofman

[7] This purported 100 microgram per week Aranesp dosing regimen is the premise of the 400:1 ratio Amgen consistently proffered to CMS as the appropriate dose conversion ratio for reimbursement under the hospital Outpatient Prospective Payment system.

[8] That is, while Amgen has consistently represented to CMS that the appropriate dose conversion ratio is 400:1 (at which Aranesp is the less costly alternative), Amgen has represented to oncologists throughout

conceded that, at the doses Amgen has been recommending to oncologists, Aranesp is more costly than Procrit. (Tr. 863).

Finally, the evidence demonstrates that Aranesp dose premium likely will increase significantly with the adoption of Aranesp's new dosing regime. In March 2006, Amgen secured approval for the administration of Aranesp at an initial dose of 500 micrograms once every three weeks. While noting that the data pertaining to the new regimen was not available before the hearing, Ortho Biotech's expert Dr. Cremieux anticipated that the new regime likely would increase the dosing and costs of Aranesp relative to Procrit. (Tr. 507). The data now available validates Dr. Cremieux's predictions.

B. Recent Dose and Cost Studies: The revelations in the unsealed hearing evidence are corroborated by recent studies and analyses of the relative doses and costs of Aranesp and Procrit administered by oncologists in actual practice. Regardless of the data sets used, the studies demonstrate a significant Aranesp premium, which is growing even more rapidly since March 2006, when Amgen secured approval for its new 500 microgram dosing regimen.

- Lefebvre Study: On July 18, 2006 the peer-reviewed journal Current Medical Research and Opinions published an analysis of private insurer reimbursement data similar to, and effectively endorsing, that presented at the hearing by Ortho Biotech's expert Dr. Cremieux. See Lefebvre, Patrick, et al., "*Dosing patterns, treatment costs and frequency of physician visits in adults with cancer receiving erythropoietic agents in managed care organizations*," Current Medical Research and Opinions, 22(9): pp. 1623-1631 (July 18, 2006), annexed as Appendix E. The Lefebvre study examined the actual doses of the drugs administered in oncology clinics reported in the database, which contained "the complete medical history for over 30 million managed care lives from over 35 health care plans, covering all the census regions of the United States" (Id. at 1684). The study found that the average cumulative doses of the drugs actually administered yielded a dose ratio of 236:1, i.e., 236 International Units of Procrit were administered for every microgram of Aranesp. At that relative dosing, and using the drugs' wholesale acquisition costs as a proxy for the private insurer reimbursement,[9] the study concluded that Aranesp was 52% more costly to payors than Procrit. Using the drugs' most current published ASPs (1st quarter 2007), the Aranesp dose premium at the 236:1 dose ratio is 41%. The actual cost premium to Medicare likely is larger under Aranesp's new dosing regimen given that the dosing of Aranesp has increased since the study was conducted.
- Harley Study: Another recent study of private insurer claims data reaching similar conclusions was presented at the December 2006 meeting of the American Society of Health-System Pharmacists. See Harley, C. et al., *Comparison of Utilization Patterns, Resource Use and Treatment Costs Among Cancer Patients Treated with Epoetin alfa or*

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the world that the appropriate dose conversion ratio is 200:1 (at which Aranesp is by far the more costly drug).

[9] The use of wholesale acquisition cost ("WAC") as a proxy for private insurer is based on the assumption that the insurers reimbursed oncologists at the same percentage of the drugs' published Average Wholesale Prices or AWPs, which are set at fixed markups over the WAC. The assumption is conservative in that the AWP for Aranesp generally has been set at 25% above its WAC while the AWP for Procrit is set at 20% above its WAC. Thus, the actual Aranesp cost premium likely is greater.

Darbepoetin alfa, Poster presented at the 41st American Society of Health-System Pharmacy (ASHP) Midyear Clinical Meeting and Exhibition December 3-7, 2006; Orange County, California, annexed as Appendix F. The study "was conducted using medical claims data from a large United States health plan from January 1, 2002 through May 31, 2005" (Id. at p.1). Based on the doses actually administered in oncology clinics and reimbursed by the health plan, the study found a mean cumulative treatment dose of Procrit and Aranesp were 308,791 International Units and 1134 micrograms, respectively, for a dose ratio of 272:1. Based on the actual reimbursement allowed by the health plan, moreover, the study found Aranesp to be reimbursed at a 32% premium over Procrit (Id.). Using the published ASPs for the most recent quarter to determine the relative costs to Medicare, the Aranesp dose premium at the 272:1 dose ratio is 22%.

While demonstrating the significant dose premium associated with Aranesp administration, the data analyzed in the Lefebvre and Harley studies did not encompass doses administered in oncology clinics since March 2006, when Amgen secured approval for its new 500 microgram dosing regimen. To assess the incremental impact of the new Aranesp dosing regime, Ortho Biotech sponsored an independent consultant to manage a registry of Aranesp and Procrit doses administered by oncology clinics in 2006. The findings from the limited data available to date are alarming. That is, the data shows that the new Aranesp regimen drives Aranesp doses – and therefore its costs – to new heights.

- D.O.S.E. Registry: The research and consulting firm Abt Associates manages a registry of Aranesp and Procrit doses administered by oncology clinics in 2006 referred to as the "Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies" or "D.O.S.E." registry. The D.O.S.E. registry tracks real-world practice patterns of more than 1,500 patients from 61 oncology practices. As of December 22, 2006, the treatment of 168 patients (145 Procrit, 23 Aranesp) initiated at approved fixed doses during 2006 has been monitored longitudinally through the course of their treatment. Only those Aransesp patients whose treatment was initiated with the new dosing regimen were included in the analysis. The mean cumulative doses of Procrit and Aranesp administered to the patients were 305,241 IUs and 1,665 mcgs, respectively, which equates to a dose ratio of 183:1. At that dose ratio and the most current published ASPs, the Aranesp dose premium is 81%. This data indicates that the large starting doses called for by the new Aranesp dosing regimen are not being reduced over the course of the patient's therapy, resulting in large incremental costs for Medicare and patients.

In summary, the recent data concerning the doses and costs of Aranesp and Procrit actually administered in oncology clinics corroborates the conclusions derived from the recently unsealed evidence. That is, at the doses actually administered, Aranesp is far more costly than Procrit and that cost premium is increasing rapidly under Aranesp's new dosing regimen.

C. Recent Private Insurer Restrictions on Aranesp Reimbursement: The evidence elicited at the hearing also is corroborated by recent developments in private insurer reimbursement. As noted above, Dr. Axelrod testified at the hearing that the large health insurer Wellpoint implemented in 2006 a differential reimbursement schedule to encourage the administration of Procrit in lieu of Aranesp to address the large Aranesp cost premium. Wellpoint's implementation of a differential reimbursement schedule for drugs administered in oncology

clinics and reimbursed under the medical benefit was virtually unprecedented. For a variety of reasons, insurers historically have been reluctant to impose formulary or utilization controls for physician-administered drugs (in contrast to self-administered drugs reimbursed under the pharmacy benefit, which are routinely subject to formulary management). The dramatic cost premium of Aranesp over Procrit, however, has forced insurers such as Wellpoint to reconsider their options.

Another plan that has elected to implement a different reimbursement schedule is CareFirst Blue Cross Blue Shield, the largest health insurer in the mid-Atlantic region. Effective January 1, 2007, CareFirst will implement a fee schedule that provides reimbursement for Procrit at significant premium over the reimbursement afforded for Aranesp. CareFirst implemented the differential reimbursement after determining, based on the analysis of its own claims data, that it could provide a large reimbursement premium for Procrit and still reduce reimbursement costs if oncologists switched from Aranesp. The same economic rationale militates that CMS adopt a bundle allocation rule that will eliminate that artificial impediment to competition afforded by the current reimbursement that provides the incentive for oncology clinics to purchase the more expensive drug Aranesp in lieu of Procrit.

III. PAYMENT IMPLICATIONS

The supplemental data and disclosures set forth in the preceding sections substantiate Ortho Biotech's positions in its initial comments concerning the costs savings to Medicare resulting from the adoption of the proposed allocation rule. As noted above, Ortho Biotech identified three components of savings resulting from application of an allocation rule that requires Amgen to accurately state the ASPs on its drugs. The largest short-term savings arise from the second component, i.e., the savings from a shift in market share from Aranesp to Procrit. To illustrate the magnitude of those savings, Ortho Biotech calculated that, under the proposed rule, Medicare would have reduced RBCGF drug reimbursement for 2005 alone in the amount of $177 million, assuming a dose ratio of 266:1. The supplemental submissions demonstrate that the assumptions of Ortho Biotech's model are accurate for the prior-year analysis, and conservative for the purpose of estimating the annual costs to Medicare going forward without the proposed guidelines.

The two fundamental assumptions of Ortho Biotech's cost model are that (i) the new rule will result in a shift in share from Aranesp to Procrit, and (ii) the shift in share properly is measured by a dose ratio of 266:1. As discussed, Amgen and its consultants readily concede the first assumption, but challenge the second, asserting without analysis that the 330:1 dose conversion ratio adopted in 2004 for the OPPs program should govern. The supplemental submissions demonstrate that (i) the 330:1 ratio was set without the benefit of full disclosure by Amgen and, more conclusive, (ii) all the data concerning the doses of the parties' drugs actually administered in oncology clinics offices is consistent with a dose ratio of 266:1. That is, the studies cited above show that, prior to 2006, the dose ratios ranged (depending on the data set) from 236:1 (the Lefebvre study) to 248:1 or 276:1 (Dr. Cremieux's analysis for trial). Consequently, Ortho Biotech's adoption of a dose ratio of 266:1 to determine the potential savings for 2005 is eminently reasonable and conservative.

The supplemental submissions also demonstrate that going forward, as the oncology clinics adopt the new Aranesp dosing regimen, the excess costs of maintaining the status quo will increase dramatically. That is, if the same cost model is run at the dose ratio generated by the D.O.S.E. registry (183:1), the costs savings are $621 million. Recognizing that the available data currently is limited, the D.O.S.E. registry findings are directional and demonstrate that, absent new guidelines, Medicare's and patients' costs will increase dramatically.

IV. PROPOSED RULE GOVERNING THE ALLOCATION OF INCENTIVES IN BUNDLES CONTAINING DOMINANT DRUGS

The supplemental information presented above confirms that the absence of an explicit rule governing the allocation of incentives in bundles containing dominant drugs is imposing significant excess costs on Medicare and patients. CMS should implement such a rule to (i) curtail those excess costs, (ii) achieve CMS's stated goal of ensuring drugs' ASPs reflect the incentives afforded to drive their sales, and (iii) allow for an equitable payment system that does not foster anti-competitive conduct. The requisite rule is relatively straightforward, involving a process for identifying "dominant drugs" and a simple allocation methodology. In truth, merely stating the rule likely will inspire the appropriate practices.

A. Defining Dominant Drugs: In its proposed rule, CMS correctly noted that there is a class of "drugs that may not have clinical alternatives" that, when bundled, may drive the sales of the other bundled drugs. The Secretary may readily identify such drugs without having to go so far as to render economic or clinical findings regarding the dominant or functional status of the drugs. For payment purposes, the Secretary may weigh a number of factors to determine whether a drug may reasonably be viewed as dominant in its therapeutic class. As we noted in our original comments, these factors include, but are not limited to:

- the approved indications and risk profile relative to other approved drugs and therapies;
- whether the drug is a single source product;
- whether the drug is patent protected;
- the drug's market share;
- the incentives provided on the drug after, relative to before, it was introduced into a bundle; (a dominant drug historically has a minimal discount; if/when a dominant drug is bundled with a drug that has competition and a significant discount is placed on the dominant drug, there is a strong inference that such incentive is used to drive sales of another product in the bundle);
- the effect of the introduction of the drug into the bundle on the sales volume of the other bundled products; (a significant increase in the sales of the competitive drugs following the introduction of the dominant drug into the bundle is indicative of the power of, and lack of alternatives for, the dominant drug); and
- the relative Medicare expenditures on the drug (e.g., large Medicare expenditures for the dominant drug relative to any purported alternatives is evidence the dominant drug is the only viable alternative).

We maintain that it will be fairly self-evident in virtually every instance that a dominant drug exists and the manufacturer would be expected to report the incentive discounts based on its good faith interpretation of whether these guidelines apply. Consequently, the protocol for assessing dominant drugs should impose minimal incremental administrative demands on CMS.

B. Allocation Rule for Dominant Drugs: The appropriate allocation rule for bundles that contain dominant drugs is simple to state and implement. Under the rule, the incentives granted on dominant drugs that are conditioned in whole or in part on purchases of a competitive drug should be allocated to the competitive drug (or drugs, based on the relative sales of the competitive drugs). This allocation ensures the drugs' published ASPs appropriately account for the price incentives offered in bundled arrangements involving dominant drugs.

Ortho Biotech respectfully submits that guidance should be issued immediately through program instruction or other means (consistent with the authority under section 1847A(c)(5)(C)of the Act) regarding the methodology manufacturers must use for allocating price concessions across Part B drugs sold under bundling arrangements. Amgen's WBCGF drugs should be identified as dominant drugs in a bundle.

Thank you for your consideration of our supplemental comments and recommendations. If you have any questions concerning this submission, please contact me at 202-589-1008 or by e-mail at cdooley@obius.jnj.com.

Respectfully submitted,

Cathleen M. Dooley
Executive Director, Federal Affairs
Johnson & Johnson

APPENDIX A

Response to Amgen's Assertions that an Allocation Rule is "Unnecessary"

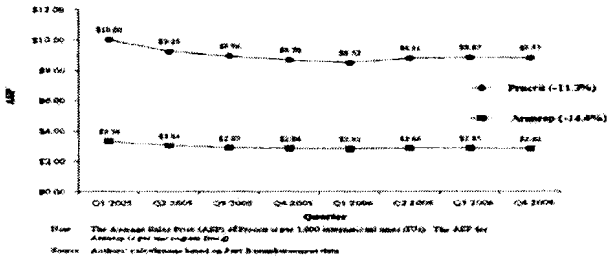
In its October 10, 2006 comments to CMS's proposed rule, Amgen made a series of assertions as to why an allocation rule for bundles containing dominant drugs is unnecessary. Following are Amgen's assertions and succinct responses thereto.

Assertion 1: Amgen asserts that incentives already "are properly disclosed in the quarterly ASP submissions (pp.5-6).

Response: The fact that the published ASPs for Amgen's WBCGF drugs incorporate the large incentives Amgen pays on those drugs to drive Aranesp purchases is undisputed and irrelevant to whether an allocation rule should be established. That is, Amgen's pricing program need not be secret to be coercive.

Assertion 2: Amgen claims that Ortho Biotech's challenge to its bundled arrangement is an attempt to avoid price competition. (p.6.)

Response: To the contrary, Ortho Biotech's proposed allocation rule will level the playing field – and facilitate competition – by ensuring the published ASPs reflect the incentives paid to drive their sales. Amgen and its consultants argue that the Aranesp and Procrit ASPs, which are depicted in the following chart from the Antos and King paper, evidence a downward trend in ASPs consistent with vigorous price competition under the APC. Of note, the ASPs in the chart are not the CMS published ASPs but rather the "authors' calculations based on Part B reimbursement data."



The more objectively reasonable interpretation of this chart is that the ASPs for the two drugs have been relatively flat in 2005 and 2006. Also, the more appropriate economic analysis of the impact of the Amgen bundle is to compare the trend in pricing of the competitive drugs before and after Amgen first implemented the APC in March 2004 and before and after the imposition of the explicit minimum purchase requirements effective January 1, 2005. Amgen has not come forward with data concerning its ASPs – or more squarely net prices in the oncology clinics – from 2002 to 2005. That data likely tells an entirely different story

Assertion 3: Amgen argues CMS should not implement a bundle allocation rule because the judiciary may determine the legality of Amgen's APC (pp. 6-7).

Response: The issue before CMS is not whether Amgen's APC is illegal but whether the existing payment methodology is accurate, fair, and minimizes costs to Medicare and beneficiaries. CMS has the authority to implement rules to ensure the fair and accurate reimbursement under Medicare Part B, which is what the proposed allocation rule accomplishes.

Assertion 4: Amgen claims the incentives paid on its dominant WBCGF drugs contingent on large purchases of Aranesp are not intended to drive Aranesp sales, but instead to offer the best deal to the best customers (p.7).

Response: The Amgen APC does not offer the best deal to the best customers of its WBCGF drugs and, in any event, whether it does is irrelevant. Amgen offers the largest incentives on its WBCGF drugs to those customers that purchase large amounts of Aranesp, and penalizes those that do not. There is no economic rationale for Amgen to pay incentives on its dominant drugs – and in particular, back-end rebates conditioned on the purchase of Aranesp – other than to drive Aranesp sales.

Assertion 5: Amgen contends clinics can choose to disregard its APC and purchase Procrit (p.8).

Response: Amgen's contract presents clinics with an economically untenable choice: The clinics can participate in the contract (i.e., purchase Aranesp in lieu of Procrit) and make large margins on Amgen's WBCGF drugs, or alternatively, the oncology clinics can elect to lose money on Neulasta administered to Medicare patients. That is no choice at all.

Assertion 6: Amgen argues that clinics do not have to participate in its APC because they can purchase Neupogen or Berlex's drug Leukine instead. (p. 8.)

Response: Neupogen is encompassed by the APC and Leukine accounts for just 2% of clinic purchases (and is not indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs, which is the primary indication of Amgen's dominant WBCGF drugs). Again, oncology clinics have no viable alternative.

Assertion 7: Amgen claims it provides "some" incentives on its WBCGF drugs independent of Aranesp purchases (p.8).

Response: Amgen claims that oncology clinics that do not accede to its demands to buy Aranesp can earn "some" incentives merely highlights that the incentives the clinic can secure absent the purchase of Aranesp are *de minimis* and insufficient to breakeven on Neulasta administered to Medicare patients, who comprise the large percentage of Medicare patients treated by the oncology clinics. Indeed, as the Court in the antitrust action recently stated in its decision, "the Medicare reimbursement rate for these drugs is an important factor in health care providers' decision to use one RBCGF drug over another" (Decision, p.3).

Assertion 8: Amgen asserts that oncologists can participate in the Competitive Acquisition Program rather than purchasing its drugs under the APC (p.9.)

Response: Amgen seeks to obfuscate the fact that its APC encourages oncologists to purchase Amgen's drugs rather than participate in CAP by affording large reimbursement to the detriment of Medicare and beneficiaries.

APPENDIX B

Unsealed Transcripts from Ortho Biotech v. Amgen Antitrust Action

APPENDIX C

Plaintiffs' Demonstratives or "PDs" from Ortho Biotech v. Amgen Antitrust Action

APPENDIX D

Plaintiffs' Exhibits or "PXs" from Ortho Biotech v. Amgen Antitrust Action

APPENDIX E

The Lefebvre Study

APPENDIX F

The Harley Study

Submitter : **Ms. Emily Graham** **Date: 01/02/2007**

Organization : **Alliance of Specialty Medicine**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1321-FC-57-Attach-1.PDF

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Sound Policy. Quality Care.

200,000 Physicians Strong

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January 2, 2007

Leslie Norwalk, Esq.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B

Dear Ms. Norwalk:

On behalf of the undersigned members of the Alliance of Specialty Medicine, a coalition of 11 medical societies representing more than 200,000 specialty physicians in the United States, we would like to comment on the 2007 Medicare physician fee scheduled final rule published in the *Federal Register* on December 1, 2006.

The Alliance was founded in 2001 to serve as a strong voice for specialty medicine. Its mission is to improve access to quality medical care for all Americans through the unified voice of specialty physicians promoting sound federal policy. A fee schedule that adequately and fairly accounts for the costs of furnishing medical services to Medicare beneficiaries indisputably affects access to and the quality of care for our nation's elderly citizens, and thus, is of paramount concern to us.

The Alliance continues to be concerned that physicians of every specialty have experienced five years of payments that have not begun to keep up with inflation as measured by the Medicare Economic Index (MEI). While Congress gave physicians a 0.0 percent update for 2007 with the passage of the Tax Relief and Health Care Act of 2006, they did not address the underlying problem - the sustainable growth rate formula (SGR). As you know, the 5.0 percent reduction originally scheduled for 2007 is one of several years of additional cuts projected by the Medicare actuaries. Costs of staff, liability premiums, equipment, etc. continue to increase at rates above general inflation. While physicians may not completely drop out of the Medicare program, they will explore other means to limit their exposure to continuing losses, which in turn may have a negative effect on beneficiary access.

Budget Neutrality Adjustment

We are disappointed that CMS made its statutory budget neutrality adjustments through the work values rather than through an adjustment to the conversion factor. There is a long-established CMS precedent for applying budget neutrality adjustments to the conversion factor. As the agency is aware, tampering with the work relative values is detrimental for a variety of reasons. We are joined by the majority of physician specialties in our disappointment in CMS' decision.

Practice Expense Issues

The Alliance strongly urges CMS to declare its intention to work with the physician community to provide support to the design and implementation of a new, multi-specialty practice expense survey. A well-designed survey conducted every few years will ensure that all specialties are reporting common data elements in a timely and equitable manner.

The Alliance of Specialty Medicine appreciates the opportunity to comment on these important issues affecting Medicare beneficiaries and the physician community. The undersigned organizations thank CMS for considering our views on the final rule. **In addition, we encourage CMS to work with us as provisions within the Tax Relief and Health Care Act of 2006 are implemented by the agency.** Please do not hesitate to contact Emily L. Graham, ASCRS Manager of Regulatory Affairs, at egraham@ascrs.org or at 703-591-2220, or Robin Hudson, AUA Manager of Regulatory Affairs, at rhudson@auanet.org or at 410-689-3762 if you have any questions regarding our comments and recommendations.

Sincerely,

American Academy of Dermatology Association
American Association of Orthopaedic Surgeons
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American Gastroenterological Association
American Society of Cataract & Refractive Surgery
American Urological Association
Congress of Neurological Surgeons
National Association of Spine Specialists