**Submitter :** **Date: 10/10/2006**

**Organization :** **Susan G. Komen Foundation**

**Category :** **Consumer Group**

**Issue Areas/Comments**

**CY 2007 ASC Impact**

CY 2007 ASC Impact

See attached letter

**OPPS**

OPPS

See attached letter

**OPPS Impact**

OPPS Impact

See attached letter

**Policy and Payment Recommendations**

Policy and Payment Recommendations

See attached letter

**Radiology Procedures**

Radiology Procedures

See attached letter

CMS-1506-P-461-Attach-1.DOC

#461

The Susan G. Komen Breast Cancer Foundation

5005 LBJ Freeway
Suite 250
Dallas, Texas 75244
Tel: 972.855.1600
Fax: 972.855.1605
Helpline: 1.800 I'M AWARE®
www.komen.org

**Headquarters**

October 10, 2006

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

**Re: CMS-1506-P; Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates and CY 2007 Update to the ASC Covered Procedures List**

Dear Acting Administrator Norwalk:

The Susan G. Komen Breast Cancer Foundation is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the proposed CY 2007 Hospital Outpatient Prospective Payment System ("HOPPS") payment rates and CY 2007 update to the Ambulatory Surgery Center ("ASC") covered procedures list. We will provide comment on the CY 2008 ASC payment system and rates under separate cover.

The Komen Foundation is a global leader in the war against breast cancer. Founded in 1982, the Komen Foundation is now comprised of 121 Affiliates nationwide, three international Affiliates and 75,000 volunteers. Komen has invested more than $630 million dollars for breast cancer research, education, screening and treatment programs, and actively addresses the gaps and disparities in the needs of the medically underserved.

## A. Proposed CY 2007 OPPS and ASC Rates

The Foundation appreciates the work CMS has done in the past to help ensure access to quality breast health care and breast cancer care. However, we are seriously concerned about the reductions in the proposed CY2007 payment rates for virtually all breast care services in the hospital outpatient and ambulatory center settings.

We are particularly concerned about the rate reductions for the following procedures critical to the early detection of breast cancer and improving the quality of life for breast cancer survivors:

| HCPCS/CPT | Descriptor |
|---|---|
| **76092** | Mammogram screening |
| **G0240** | Diagnostic mammography |
| **76095** | Stereotactic breast biopsy |
| **19350** | Nipple areola reconstruction |
| **12162** | Partial mastectomy w/ lymph node removal |
| **19357** | Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion |
| **19361** | Breast reconstruction, with latissimus dorsi flap, with or without prosthetic implant |
| **19364** | Breast reconstruction with free flap |
| **19366** | Breast reconstruction with other technique |
| **19367** | Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle |
| **19368** | Breast reconstruction with TRAM, single pedicle, with supercharging |
| **19369** | Breast reconstruction with TRAM, double pedicle |

**B. CY 2007 Update to the ASC Covered Procedures List**

We fully support CMS's efforts to ensure that physicians and patients are able to make decisions about the optimal site of service. Komen extends our appreciation to the agency for adding CPT code 19297 (Placement of radiotherapy after-loading balloon catheter into the breast, including imaging guidance; concurrent with partial mastectomy), to the list of ASC approved procedures.

The Komen Foundation understands that CMS is statutorily bound to freeze CY 2007 ASC payments at CY 2006 levels, and to cap ASC procedure payment at the CY 2007 OPPS rate. However, we are very concerned that these rates are unsustainable and will harm patient access to care. In designing the CY 2008 ASC system, we urge the agency to work with patient and physician groups as well as congressional staff to make sure patient access is maintained.

The Susan G. Komen
Breast Cancer Foundation

The Komen Foundation appreciates the opportunity to comment on the proposed regulations and urges the agency to work with Congress to preserve beneficiary access to care by providing appropriate payment for treatment in all appropriate sites of service. We hope that our letter highlights our sincere interest in continuing to work with CMS to make breast health services cost effective, properly reimbursed and readily accessible. Please do not hesitate to contact me at 972-855-4315 if you have any questions regarding these comments.

Sincerely,

Diane L. Balma

Diane Balma
Public Policy Director

The Power of a Promise
20 YEARS

**Submitter :** Mrs. Sylma Millares **Date:** 10/10/2006

**Organization :** American Therapeutic Corporation

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

CMS-1506-P-462-Attach-1.TXT

#462

10/09/06
Gentlemen,

I am a Registered Nurse with over 20 years in-patient and out-patient experience in mental health care, and have been working for a PHP for the last 2 ½ years.

I am writing to you to ask you to reconsider the projected cuts for the Partial Hospitalization Programs. These cuts will adversely affect the quality of care these patients receive and need, and I believe, in the long run, will end up costing the taxpayers, and medicare, more money. It is my experience that without this more intense level of care, these patients will end up getting admitted to the hospital.

These programs are highly effective in stabilizing patients and keeping them out of the hospital. These are sub-acute level programs, meaning they provide step-down care so that the patients can leave the hospital before they are completely well enough to go to out-patient treatment only. These programs also care for patients who are not responding to out-patient treatment and we catch them before they are so sick that they have to be admitted to the hospital.

That is why the CMS guidelines are so specific and strict. That is also why the projected cuts will mean that the level of care will be directly affected.

It is a sad truth that it takes money to provide this level of care.

It is also true that the Partial Hospitalization Program is still the less costly alternative to in-patient care.

Thank you,

Sylma M. Millares, RN

**Submitter :** **Marcel R. Marc** **Date: 10/10/2006**

**Organization :** **Varian**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1506-P-463-Attach-1.PDF

#1163

VARIAN

Medical Systems, Inc.
3100 Hansen Way, M/S E-175
Palo Alto, CA 94304
*tel* 650 424-5809
*fax* 650 424-5779
www.varian.com

October 6, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

**RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy**

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

**STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.**

**We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:**

| APC | CPT | CY'07 Proposed Payment Rate | CY'06 Payment Rate |
|---|---|---|---|
| 0664 | 77520 and 77522 | $1,136.83 | $947.93 |
| 0667 | 77523 and 77525 | $1,360.10 | $1,134.08 |

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

**STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES**

*For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.*

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

| Comparison of Freestanding Centers' Proton Therapy Rates by State | | | |
|---|---|---|---|
| | Indiana – Current | Florida – Proposed 9/11/06 | Texas – 9/1/06 |
| 77520 | — | $750.63 | $652.75 |
| 77522 | $516.36 | $776.90 | $653.90 |

| | | | |
|---|---|---|---|
| 77523 | $782.43 | $806.93 | $783.79 |
| 77525 | $782.43 | $900.76 | $954.41 |

**As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules.**

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

**We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.**

*It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.*

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

CONCLUSIONS

In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

**We agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.**

**Also, we strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates are made in a consistent manner with those in effect for Hospital Outpatient Departments.**

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

Thank you for your prompt attention to this critical issue.

Sincerely,

Marcel R. Marc

**Submitter :** Mr. William Flynn **Date:** 10/10/2006

**Organization :** Addition Technology, Inc.

**Category :** Device Industry

**Issue Areas/Comments**

**OPPS**

OPPS

See attached file CMS 1506 P (Addition Technology)

CMS-1506-P-464-Attach-1.DOC

#464

Intacs®

**By Electronic Submission**

October 10, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P

Dear Dr. McClellan:

Addition Technology, Inc. ("ATI") would like to thank you for the opportunity to comment on the Proposed Rule CMS-1506-P, "The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule"[1] and the proposed payment of keratoprosthesis procedures performed using the AlphaCor™ prosthetic cornea. As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

At the outset we wish to commend and thank the members of the hospital outpatient PPS team with whom we have been working. Throughout this process we have felt that these individuals have given their time and attention to the problematic circumstances surrounding this procedure.

We are deeply concerned that CMS' proposal to reimburse hospitals at a payment rate of $3,116.62 for performing an integrated keratoprosthesis will impair Medicare Beneficiaries access to this last resort treatment. Hospitals will find it financially impossible to continue to offer the procedure at this grossly inadequate payment rate. In fact, we are aware of several hospitals who are no longer performing the procedures because the current Medicare reimbursement is insufficient to cover the costs.

At the August 2006 meeting of the Ambulatory Payment Classification Panel (the "Panel") it was recommended that CMS develop a separate payment methodology that will reimburse hospitals an appropriate amount for the AlphaCor. The Panel also expressed its desire to ensure this treatment is available to Medicare beneficiaries. We urge CMS to accept the recommendation of the Panel and appropriately pay for integrated keratoprosthesis so that access to this critical procedure can be preserved in 2007 and beyond.

Addition Technology, Inc.
A VMG LLC Investment Company

950 N. Lee Street, Suite 210, Des Plaines, IL 60016
Main: (847) 297-8419 - Fax: (847) 297-8678

155 Moffett Park Drive, Suite B-1, Sunnyvale, CA 94089
Main: (408) 541-2700 - Fax: (408) 541-1400

[1] 71 *Fed. Reg.* 49504 (Aug. 23, 2006).

## I. CMS should ensure that Medicare beneficiaries continue to have access to integrated keratoprosthesis

### A. Integrated keratoprosthesis is a last resort treatment option for a limited patient population

AlphaCor was cleared by the FDA in 2002 and designed to replace a scarred or diseased native cornea. It is the only technology available today that is a flexible, bio-integratable, one piece synthetic cornea made of poly-HEMA, with a 7.0 mm diameter. AlphaCor is implanted directly into the corneal pocket dissected by a surgeon and the surgeon sutures the incision. No corneal donor tissue is used. The device bio-integrates over the three to six months following surgery and in some cases, the patient's cornea above the AlphaCor is removed once the AlphaCor device stabilizes.

While the majority of Medicare beneficiaries are successfully treated with a standard corneal transplant procedure, keratoprosthesis implantation using AlphaCor provides a critical treatment option for those patients who are not candidates for a corneal transplant procedure. Keratoprosthesis is a last resort procedure for those patients with corneal opacity not suitable for standard penetrating keratoplasty with donor tissue, who have rejected donor tissue or where adjunctive measures required to prevent graft rejection are medically contraindicated. Left untreated, these Medicare beneficiaries likely will become blind.

In 2005, only 78 procedures using AlphaCor were performed. The number of Medicare beneficiaries who received AlphaCor is a smaller patient sub-set of this total. Because this technology is intended for a very limited patient population, there is no risk of over-utilization.

### B. Unless there is a fair and adequate reimbursement for this innovative treatment, hospitals will not be able to offer this procedure to Medicare beneficiaries

We are deeply concerned that CMS's proposal to reimburse providers at a payment rate of $3,116.62 will impair Medicare Beneficiaries access to this last resort treatment. This reimbursement rate is clearly inadequate when it does not even cover the cost of the device, which is approximately $7,000. In fact, we are aware of several hospitals who are no longer performing the procedure because the current Medicare reimbursement is insufficient. As a result, Medicare beneficiaries and physicians will have no choice but to turn to ASCs for this procedure. Furthermore, some ASCs are currently refusing to perform the procedure because some Carrier Medical Directors' gap-filling methodology results in a payment that is less than invoice cost for the device. Lastly,, access through ASCs will become essentially non-existent in 2008 if the new ASC payment methodology is implemented as proposed and the APC payment for this procedure is not corrected.

## II. CMS should not use its unreliable 2005 claims data to set the payment rate for APC 0293

### A. Coding Confusion

The claims data used to set the payment rate APC 0293 does not accurately reflect the costs of performing keratoprosthesis. ATI engaged The Moran Company to analyze the 2004 and 2005 OPPS data for APC 0293 and simulate the mean for the APC 0293 using only single claims that contained both CPT Codes 65770 and C1818. The following chart provides an overview of the payment history for CPT Code 65770:

| | 2005 | 2006 | 2007 Proposed |
|---|---|---|---|
| APC | 0244 | 0244 | 0293 |
| Payment Rate | $2,262.17 | $2,275.16 | $3,116.62 |
| Median | $2,379.46 | $3,617.49 | $3,127.51 |
| Mean | $2,388.72 | $4,271.67 | $4,331.44 |
| Total Frequency | 94 | 145 | 140 |
| "Singles" Frequency | 22 | 42 | 41 |

Only 41 single procedure claims listing CPT 65770 were used to determine the median cost for APC 0293. Of these 41 claims, only six claims also properly reported C1818. Thus, CMS included 35 claims in its rate-setting for APC 0293 that reported CPT 65770 without any other procedure code or C1818. CPT code 65770 describes a procedure that requires a prosthetic cornea, yet the overwhelming majority of the claims used to calculate payment for this procedure did not contain the code for the prosthetic device (C1818). Every integrated keratoprosthesis procedure using the AlphaCor device should be reported using both CPT Code 65770 (keratoprosthesis) to describe the procedure and C1818 (integrated keratoprosthesis) to report the AlphaCor device. While there is one other artificial cornea used today, it is not described by C1818 because it is not a single piece device, it is not bio-integratable, and it requires human donor tissue to attach to the recipient.

Hospital confusion regarding the appropriate use of C1818 is illustrated further by the fact that the 2005 claims data included claims with C1818 billed with CPT Code 66180 (implant eye shunt), CPT Code 65710 (corneal transplant) and CPT Code 66984 (cataract surgery) but without CPT Code 65770. These claims are clearly erroneous because none of these procedures require an artificial cornea. In other cases, hospitals are reporting CPT Code 65770 with other 6xxxx procedures without C1818. In the 2005 claims data, there are 69 claims that listed CPT Code 65770 but did not list C1818.

**B. Median costs/charges understate the resources expended to perform keratoprosthesis**

The 2005 claims data used to set the median cost for APC 0293 also does not accurately reflect all the costs to furnish keratoprosthesis. The Median cost of $3,127.51 does not cover the cost of the device (approximately $7,000).

The claims data shows that hospitals' billing practices are inconsistent and hospitals are not accurately reporting the cost of performing keratoprosthesis. This is illustrated by the fact that only two of the 17 hospitals known to have purchased AlphaCor in 2005 submitted claims to Medicare containing both C1818 and 65770. One hospital has a charge of $2,129 for the procedure, and the other claim had a charge of $8,182. Clearly the charges cannot be accurate when the device alone costs approximately $7,000 and neither ATI nor the predecessor company that sold AlphaCor has charged a rate for the device that was outside of this range. Given that so few devices are sold, they are not discounted in any way.

**C. A programming error involving the rate setting methodology used to set the proposed payment rate for 2007 incorrectly excluded costs associated with C1818**

An error in the data file used to calculate the median for integrated keratoprosthesis may also have added to the significantly low payment rate for keratoprosthesis with the AlphaCor. CMS's published median for APC 0293 was $3,127.51. Yet, when Moran simulated the median for the

single claims correctly coded with CPT Codes 65770 and C1818, it calculated a much higher median of $10,514.

During the course of Moran's analysis, they noticed a significant methodology problem in rate setting APC 0293. When Moran first attempted to run their simulation for the subset of correctly coded single claims including both CPT Codes 65770 and C1818, their replication program produced zero claims with both codes.

Upon investigation, Moran discovered because the C1818 had a status indicator of "H" in 2005, it was not counted in the packaged costs of the single claims using the 2007 single claim methodology which based selection of packaged items on status indicator "N". During the process of developing the Moran replication program for 2007 OPPS rates, Moran asked CMS staff which file of status indicators was used to identify single claims and packaged items. In response to this inquiry, CMS responded that the Moran should use a particular 2005 file—the file in which C1818 had status indicator "H". Accordingly, we believe that the costs associated with C1818 may have been excluded from the packaging. This error may be the cause, at least in part, for the extremely low median for APC 0293. We urge CMS to review their payment methodology for APC 0293 and the impact this potential error may have had on the proposed payment rate for this procedure.

**III. CMS should accept the August 2006 APC Panel's recommendation to develop a payment methodology that would provide for an appropriate payment rate for keratoprosthesis**

CMS has previously recognized that coding and billing errors can lead to significant variability in median calculations for low-incidence procedures. When this has occurred, CMS has created alternative methodologies to determine a fair payment for certain low-volume procedures. For example, CMS created a low-volume adjustment methodology for blood products because the claims data may have not captured the complete costs of the products due to coding and billing errors. This is precisely what has occurred for integrated keratoprosthesis. We urge CMS to make similar accommodations for keratoprosthesis. When the erroneous claims are excluded, the single claims that accurately report CPT Codes 65770 and C1818 have a median cost of $10,514. This simulated median more accurately captures the costs of keratoprosthesis procedure and the device.

Given the extensive coding errors associated with this procedure, the inconsistent cost and charge data, and the additional confusion created by the possible billing of an incorrect device under the C1818, there is a significant need to implement a process to ensure CMS is receiving accurate data about keratoprosthesis with the AlphaCor. Assuming the error identified by Moran is accurate, CMS could, in the short-term (i.e., for 2007), set the median based on the few claims with the procedure correctly coded and that seem to have reported realistic costs and charges. This median would be assigned to APC 0293. The problem with this methodology, however, is that it does not address the long-term coding problems created by the inappropriate use of C1818 by devices that are not described by the code.

Alternatively, CMS could take a longer-term approach aimed at collecting clean data about integrated keratoprosthesis procedures with the AlphaCor (and the devices similar to AlphaCor that are expected to marketed in the near future) as well as data regarding the procedures involving the other technology. The collection of meaningful data would require CMS to develop two G codes. One G code would describe the procedure when performed with an integrated cornea that does not require human tissue. The other G code would be reserved for

the other technology. We recommend that CMS consider creating the following two G Code descriptors:

- **G code #1 = Keratoprosthesis with implantation of integrated artificial cornea, no donor cornea tissue required**

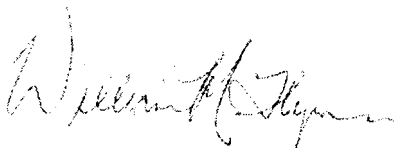
- **G code #2 = Keratoprosthesis with insertion of artificial cornea requiring use of donor cornea tissue**

Next, CMS would have to include an edit that required that C1818 always appear with G code #1. This code should be assigned to New Technology APC 1574 for 2007. G code #2 could be assigned to the newly created APC 0293. An edit could be created that did not accept claims containing this G code and C1818. Assuming that hospitals are educated regarding the coding differences, which ATI has agreed to do, then over the next 2 to 3 years CMS should have reliable data from which to set payment rates.

ATI would a gain like to thank CMS for the opportunity to submit formal comments on the Proposed Rule. We urge CMS to adopt the recommendation of the APC Panel to develop a payment methodology that will ensure that hospitals are adequately reimbursed for providing keratoprosthesis with the AlphaCor that Medicare beneficiaries continue to have access to this innovative, last resort treatment option.

Thank you for your careful consideration to this matter.

Sincerely,



William Flynn
President & CEO

**Submitter :** Mr. EDWARD QUINLAN **Date:** 10/10/2006

**Organization :** Hospital Association of RI

**Category :** Health Care Provider/Association

**Issue Areas/Comments**

**OPPS**

OPPS

Ref: [CMS-1506-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

CMS-1506-P-465-Attach-1.DOC

#4165

HARI
The Hospital Association of Rhode Island
100 Midway Road – Suite 21
Cranston, Rhode Island 02920
(401) 946-7887

Edward J. Quinlan
President

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., Rm 445-G
Washington, DC 20201

***Ref: [CMS-1506-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates***

Dear Dr. McClellan:

On behalf of our member hospitals, the Hospital Association of Rhode Island (HARI) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (PPS) for calendar year (CY) 2007. The rule also includes proposals on inpatient quality reporting for fiscal year (FY) 2008, ambulatory surgical center (ASC) payments for 2007 and 2008 and Medicare Administrative Contractors.

The proposed changes in many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2007 than in 2006. These changes make it extremely difficult for hospitals to plan and budget from year to year. We request that an effort be made by CMS to stabilize the payment rates and associated payment-to-cost ratios.

In addition to this instability, the entire outpatient PPS is underfunded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues including severe workforce shortages; increasing liability premiums; the rising cost of drugs, fuel, and technologies, aging facilities; and expensive regulatory mandates and more. HARI will continue to work with Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.

**LINKING INPATIENT QUALITY DATA REPORTING TO OUTPATIENT PPS UPDATE**

HARI member hospitals are committed to public transparency of hospital quality information. As a matter of fact, HARI hospitals were among the first in the nation to post such data.

For CY 2007, CMS has proposed reducing the outpatient PPS update for those hospitals that are required to report quality data under the hospital inpatient PPS, but failed to do so. Specifically, CMS proposes that hospitals that failed to submit the required quality data for a full market basket update for inpatient PPS for FY 2007 would have their outpatient update also reduced by 2 percentage points.

We find this troubling for many reasons. First, it simply makes no sense to link outpatient payments to inpatient measures of quality. Second, linking a reduction in the conversion factor to the submission of inpatient PPS data that have already been reported and made public does nothing to further CMS' stated goals of encouraging hospital accountability and quality improvement. Third, linking payment to data submission that predates the outpatient PPS rule is unfair and basically retroactive rulemaking. Lastly, in linking outpatient payments to the reporting of quality data, we question if CMS has exceeded its statutory authority.

We urge CMS to rescind its proposal to link inpatient quality reporting to the outpatient payment update and rely on the efforts of the Hospital Quality Alliance (HQA)and Ambulatory Quality Alliance (AQA) to develop outpatient quality measures.

**FY 2008 INPATIENT QUALITY MEASURES**

In the proposed rule, CMS announces the measures that hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to receive the full inpatient payment in FY 2008. We appreciate CMS' adding to its requirements for a full inpatient payment in FY 2008 measures that have been adopted by the HQA. These well-designed measures represent aspects of care that are important to patients and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care.

We also appreciate CMS' proposing in August the measures that hospitals will be required to report to receive their full FY 2008 inpatient payments. This early notice allows hospitals sufficient time to establish the proper data collection processes. While unsure if the OP PPS proposed rule is the most appropriate vehicle for this notice, we urge CMS to continue with this timely rulemaking as a mechanism to notify hospitals several months in advance of the inpatient PPS quality reporting requirements for the upcoming fiscal year.

## HOSPITAL CLINIC AND ED VISIT CODING

HARI member hospitals find it unwise that CMS proposes to establish new G codes to describe hospital clinic visits, ED visits and critical care services in the absence of national guidelines. The creation of temporary G codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – G codes for Medicare and current procedural terminology (CPT) codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. This additional burden adds more costs to the care provided to Medicare beneficiaries. We suggest that CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized. This would provide for stability for hospitals in terms of coding and payment policy, eliminate the additional administrative costs, and allow CMS and stakeholders to focus on

developing comprehensive national hospital visit guidelines that could be applied to a new set of hospital visit codes in the future.

HARI appreciates the opportunity to comment and supports the detailed comments expanding on the points raised above and also on several other important proposals in the rule being submitted to you by the American Hospital Association. If you have questions, please feel free to contact Pat Moran, Vice President – Finance, at (401) 946-7887 x 103.

Sincerely,

Edward J. Quinlan

Edward J. Quinlan
President

**Submitter :** Jacob S. Philip **Date:** 10/10/2006

**Organization :** IMPAC Medical Systems, Inc.

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1506-P-466-Attach-1.PDF

#166

IMPAC

IMPAC Medical Systems, Inc.
www.impac.com

Corporate Headquarters:
100 West Evelyn Avenue
Mountain View, CA 94041-1464
T 650.623.8800
F 650.428.0721

October 4, 2006

Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8018

**RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy**

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

**STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.**

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

| APC | CPT | CY'07 Proposed Payment Rate | CY'06 Payment Rate |
|---|---|---|---|
| 0664 | 77520 and 77522 | $1,136.83 | $947.93 |
| 0667 | 77523 and 77525 | $1,360.10 | $1,134.08 |

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

**STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES**

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

| Comparison of Freestanding Centers' Proton Therapy Rates by State |
|---|

| | Indiana – Current | Florida – Proposed 9/11/06 | Texas – 9/1/06 |
|---|---|---|---|
| 77520 | — | $750.63 | $652.75 |
| 77522 | $516.36 | $776.90 | $653.90 |
| 77523 | $782.43 | $806.93 | $783.79 |
| 77525 | $782.43 | $900.76 | $954.41 |

**As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules.**

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

**We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.**

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit from the RUC for proton beam therapy. Due to the limited availability of this technology in the freestanding setting and the established coverage and payment policy established by CMS for hospital outpatient departments, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

CONCLUSIONS

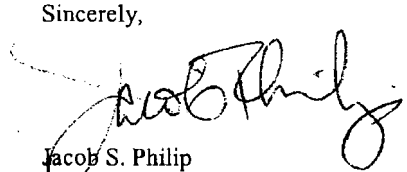
In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

**We agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.**

**Also, we strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates are made in a consistent manner with those in effect for Hospital Outpatient Departments.**

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

Sincerely,



Jacob S. Philip
Director, Radiation Oncology Business Unit
IMPAC Medical Systems, Inc.
An Elekta Company

**Submitter :** Theresa Wiegmann **Date:** 10/10/2006

**Organization :** AABB

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**Blood and Blood Products**

Blood and Blood Products

See Attachment.

CMS-1506-P-467-Attach-1.DOC

#467

Advancing Transfusion and
Cellular Therapies Worldwide

October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard, C4-26-05
Baltimore, MD 21244-1850

Subject: CMS-1506-P Medicare Program; The Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Notice

Dear Dr. McClellan:

AABB appreciates the opportunity to offer these comments on the proposed APC rates for blood and blood products in the Centers for Medicare and Medicaid Services (CMS) Proposed Notice on the revisions to Medicare payment policies under the Hospital Outpatient Prospective Payment System for calendar year 2007, published in the August 22 *Federal Register*.

AABB (formerly known as the American Association of Blood Banks) is the professional association representing approximately 8,000 individuals and 1,800 institutions – including hospital-based blood banks, laboratories and transfusion services as well as blood and bone marrow collection facilities – involved in blood banking, transfusion medicine and bone marrow and peripheral blood stem cell collection, processing and infusion.

Blood and Blood Products

As we have noted to CMS on a number of occasions in the past few years, payment for blood and blood products present some unique challenges. Briefly, these include:

- There are substantial differences in the market environment and processes for acquiring blood and blood products, which are collected by nonprofit blood centers, as compared with obtaining drugs and other products.
- There is a critical and ongoing need for continued vigilance to maintain the safety of the nation's blood supply which contributes to the escalation of the costs of

| APC | HCPC Code and Descriptor | 2007 Proposed Medicare APC Rate | Average Hospital Payment in 2004[1] | Difference Between 2007 Medicare Payment Rate and 2004 Average Hospital Payment |
|---|---|---|---|---|
| 0954 | P9016, RBC Leukocytes reduced | $176.89 | $201.07 | - $24.18 (-13.67%) |
| 9508 | P9017, Plasma 1 donor frz w/in 8 hr | $71.87 | $56.29 | + $15.58 (+21.68%) |
| 0957 | P9019, Platelets | $60.28 | $63.67 | - $3.39 (- 5.62%) |
| 9501 | P9035, Platelet pheresis leukoreduced | $488.80 | $510.05 | -$21.25 (-4.35%) |

[1] Source: 2005 Nationwide Blood Collection and Utilization Survey Report.

AABB believes it is reasonable to estimate that the average amount hospitals will pay for these products in 2007 will have increased by a minimum of 10 percent. (This rate of inflation is less than the amount the hospital market basket will have increased over this time period.) Thus it is clear that the proposed APC rates will not cover the cost of blood products, particularly the most commonly transfused product, leukoreduced red blood cells. **AABB therefore would recommend that CMS base the APC rate for these products on the 2004 survey data inflated by 10 percent.** The proposed APC rates for these products follow.

| APC | AABB Recommended APC Rate |
|---|---|
| 0954 | $221.18 |
| 9508 | $61.91 |
| 0957 | $70.03 |
| 9501 | $561.05 |

It should be noted that these rates are extremely conservative; they only reflect the cost of acquiring the blood products and do not include any allowance for the cost incurred by hospitals for overhead, storage, handling and wastage due to shelf life limitations. In addition, this proposal is consistent with recent recommendations by the Advisory Panel on APC Groups that urged CMS to use external data in setting rates for blood and blood products. They recommended the following at the August 2006 meeting:

> "The Panel recommends that CMS reconsider its methodology to develop payment rates for blood and blood products to more accurately reflect the true costs of blood and blood products to hospitals, including using external data."

AABB is committed to working with CMS to provide any support needed to implement our proposal to help ensure that patients have access to the best possible blood products. AABB is now working with HHS on the latest Nationwide Blood Collection and Utilization Survey. We would welcome the opportunity to work with CMS, along with

HHS, in determining how to capture the most useful blood cost data as part of this survey.

APC 0112

For the past several years, AABB has expressed concern about the inadequate payment for certain apheresis procedures and specifically those procedures assigned to APC 0112, Apheresis, Photopheresis and Plasmapheresis. These procedures are very time consuming and involve the use of very costly disposable supplies. We were, therefore, pleased to learn that the 2007 rate is proposed to be increased and appreciate CMS' efforts in this regards. However, while this represents some improvement, AABB believes that the proposed payment rate will still fall far short of covering the costs of providing these important services.

Thank you for the opportunity to offer these comments. If you have any questions or require additional information, please do not hesitate to contact me at 301-215-0514 or Theresa_l@aabb.org.

Sincerely,

Theresa L. Wiegmann, JD
Director, Public Policy

**Submitter :** Dr. Myron Gerson **Date:** 10/10/2006

**Organization :** American Society of Nuclear Cardiology

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-1506-P-468-Attach-1.DOC

#1168

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

4550 Montgomery Avenue
Suite 780 North
Bethesda, Maryland 20814
Telephone: 301-215-7575

Website: www.asnc.org
Email: admin@asnc.org
Fax: 301-215-7113

Submitted Electronically: http://www.cms.hhs.gov/regulations/ecomments

October 10, 2006

Administrator Leslie Norwalk
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

**ATTN: FILE CODE CMS-1506-P**

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear Administrator Norwalk:

We are writing in response to the proposed 2007 Hospital Outpatient Prospective Payment System (HOPPS) Rule, 71 Fed. Reg. 163, August 23, 2006. **The American Society of Nuclear Cardiology (ASNC)** appreciates the opportunity to provide comments to assist the Centers for Medicare & Medicaid Services (CMS) in further refining the HOPPS. We look forward to working with the agency collaboratively as you respond to our concerns and recommendations.

As you know, ASNC is a nearly 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology, develops standards and guidelines for training and practice, promotes accreditation and certification in this sub-specialty field, and is the principal advocacy voice for nuclear cardiology.

**Our comments on the proposed rule address two areas of concern:**

**A. Changes In Myocardial PET APC's Based on Obviously Flawed Data Potentially Causing Acute Access Issues To Medicare Beneficiaries**

**B. Appropriate Radiopharmaceutical Cost Capture**

**A. Myocardial PET CPT Codes 78491, 78492 and 78459:**

For Calendar Year (CY) 2007, CMS is recommending to move all myocardial PET studies into a single APC (0307). This proposal includes lumping single and multiple studies based on CMS' statement that

> *"our data do not support a resource differential that would necessitate the placement of these single and multiple scan procedures into two separate APCs. As myocardial PET scans are being provided more frequently at a greater number of hospitals than in the past, it is possible that most hospitals performing multiple PET scans are particularly efficient in their delivery of higher volumes of these services and, therefore, incur hospital costs that are similar to those of single scans, which are provided less commonly."*

**ASNC strongly disagrees with this conclusion**. First, for other nuclear cardiology studies, CMS recognizes, and its claims data supports, separating those that require multiple imaging sessions (CPT 78460-1, 78464-5, 78472-3, 78481-3). Second, by stating that "it is possible that" hospitals performing multiple studies are more efficient (and thus less costly), CMS is assuming that single studies are done primarily in hospitals that do not perform multiple studies. However, ASNC has not seen any data to confirm this, nor are we aware of data that would diminish the doubling of time and effort and resources to acquire multiple studies over single studies.

The CMS data has considerably low single frequency claims data for single and multiple studies -- signifying that the cost conclusions are not indicative of real costs and only statistical in nature. With so few single claims used for cost setting in the universe of a relatively small absolute number of total studies performed, data likely represents statistical noise at best.

Further, ASNC disagrees with the proposal to lump both the single and multiple PET myocardial studies into one APC due to clinical and resource inheterogeneity and recommends that there be Level I and Level II Cardiac PET APCs (Level I for CPT 78459 and 78491 and Level II for CPT 78492). The proposed cut for 78492 is larger than any cut in APC history and therefore we believe that CMS must consider some kind of dampening options.

**ASNC joins with the member organizations of the Nuclear Medicine APC Task Force in recommending that reimbursement for CPT 78492 should be based on a dampening formula that determines payment solely for 2007 based on a blend of the 2006 APC rate for 78492 and the mean of CMS FY2005 hospital data for 78492, G0031, -35, -37, -45, -47.**

The CMS proposition that a rest and stress myocardial perfusion PET study can be equated in cost to a single rest study lacks both face-validity, and an understanding of the respective procedures. The second scan requires more than a doubling of the time a scanner is dedicated to a patient, patient repositioning, a repeat positioning scan, a repeat transmission scan, repeat preparation and infusion of radionuclide, a repeat emission scan, reconstruction of all of the data (independent of the initial scan data), quality control of the second set of data, and technical preparation for interpretation of the second set of data. This reality is analogous to other similar procedures where CMS claims data supports, and CMS has recognized, the correctness of a differential for single and multiple imaging studies.

**Recommendations:**

1. **Create Level I and Level II Cardiac PET APC's as described above based on clinical homogeneity, resource homogeneity, and the two times rule.**
2. **In all fairness and consistency within the HOPPS system, CMS must "DAMPEN" the created Cardiac PET APC's until true data can be acquired. A 67 % cut in an APC service creates fluctuating unstable access to care, has never been tolerated before in the history of the APC system, and cannot be tolerated now.**

**B. Reimbursement for Radiopharmaceuticals:**

**Threshold for drugs and radiopharmaceuticals changed from $50 to $55**

During Calendar Years 2005 and 2006, CMS set the threshold for establishing separate APCs for drugs and biologicals at $50 per administration. Because this packaging threshold will expire at the end of CY 2006, CMS evaluated four options for packaging levels so that they could determine what the appropriate packaging threshold proposal for drugs, biologicals, and radiopharmaceuticals would be for the CY 2007 HOPPS update.

For CY 2007, CMS is proposing to update the packaging threshold using an inflation adjustment factor based on the Producer Price Index (PPI) for prescription preparations. For each year beginning with 2007, CMS would update the packaging threshold by the PPI for prescription drugs and then round that adjusted dollar amount to the nearest five dollar increment. For example, the adjusted amount for CY 2007 has been calculated to be $55.99, which was then rounded down to $55.

At the recent August 2006 APC Advisory Panel meeting, the panel recommended (No. 19) that CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes. ASNC supports this August

panel recommendation and strongly recommends that CMS eliminate the $55 threshold for all drugs and radiopharmaceuticals. The panel also recommended (No. 28) and reaffirmed their prior request for CMS to provide claims analyses of the contributions of packaged costs (considering packaged drugs and other packaging) into the median cost of each drug administration service.

**Recommendation: Eliminate drug packaging threshold for radiopharmaceuticals and continue to recognize this category as separately payable.**

**Radiopharmaceutical payment methodology change from CCR to mean hospital data**

For CY 2007, CMS is proposing to establish prospective payment rates for separately payable radiopharmaceuticals using mean costs derived from the CY 2005 claims data, where the costs are determined using CMS' standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges (defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable).

ASNC is concerned that the current method that CMS has chosen to set payments is **inconsistent** with CMS's 2006 clarification to hospitals when the agency was very clear that hospitals would be paid based on the *hospital overall CCR* times the *hospital charge in 2006*. Therefore, hospitals in 2006 began to develop charge description master rates for radiopharmaceuticals consistent with setting their charges high enough to be adjusted by the overall *hospital* CCR and NOT the *department* CCR. Historically, a nuclear medicine department CCR is lower than an overall hospital CCR. Consequently CMS' decision to use the same methodology for drugs to set mean and median radiopharmaceutical costs is flawed and not likely to capture hospital actual costs appropriately.

HCPCS Level II descriptors changed significantly for many radiopharmaceuticals effective January 1, 2006. Therefore, these data are not yet available in CMS 2005 claims data. Hospitals are traditionally slow in adopting changes, and we believe it is quite evident that all the necessary adjustments have not been made.

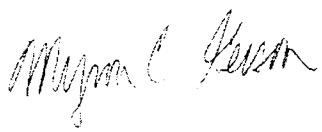
ASNC agrees with the APC Panel (recommendations Nos. 18 and 20) that CMS is premature in moving to a new payment methodology for radiopharmaceuticals for FY2007.

**Recommendation : ASNC urges the agency to continue with the current invoice CCR payment methodology ( hospital overall CCR) for one more year (CY 2007) in order to establish good data and give appropriate time to explore alternative methods for capturing hospital costs for the complex situation of radiopharmaceuticals.**

ASNC agrees with CMS that it is critical to come forth with an equitable solution for radiopharmaceuticals based on acquisition and handling costs. Our Society's representatives look forward to discussing possible alternatives for payments of radiopharmaceuticals when CMS meets with the Nuclear Medicine APC Task Force on September 28, 2006.

Thank you for your attention and consideration of these recommendations and comments. We look forward to continue working with CMS as we refine the nuclear cardiology procedure and radiopharmaceutical APCs. If you need additional information, please contact Christopher Gallagher, ASNC Director of Health Policy, at 301-215-7575 or via email at Gallagher@asnc.org.

Sincerely,



Myron Gerson, MD
President

cc: Herb Kuhn, CMS
Kenneth Simon, MD, CMS
Edith Hambrick, MD, CMS
James Hart, CMS
Carol Bazell, MD, CMS
Joan Sanow, CMS

**Submitter :** **Ms. Saira Sultan** **Date: 10/10/2006**

**Organization :** **Sanofi Aventis**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-1506-P-469-Attach-1.DOC

Hugh M. O'NEILL
Vice President

October 10, 2006

***BY ELECTRONIC MAIL***

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

**Re: CMS-1506-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule)**

Dear Administrator McClellan:

Sanofi-aventis appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on August 23, 2006 (the Proposed Rule). 1/ As a pharmaceutical company backed by world class research and development, we are developing innovative therapies to help Medicare beneficiaries lead longer, healthier, and more productive lives. We are pursuing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

Sanofi-aventis is committed to the fight against disease throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of

1/ 71 Fed. Reg. 49506 (Aug. 23, 2006).

medical science and launching pharmaceutical products all over the world that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

As a company dedicated to bringing advanced therapies to patients, our comments focus on our concerns about protecting patients' access to therapies and necessary services. Specifically, we are strongly opposed to CMS' proposal to increase the packaging threshold for drugs 2/ under the OPPS to $55. Packaging therapies in the hospital outpatient setting creates a disincentive for hospitals to use drugs under the threshold, even if they are the most clinically appropriate. Further, we are concerned about CMS' proposal to reduce reimbursement for many separately paid drugs. If hospitals cannot receive adequate reimbursement, they will be unable to provide critical therapies to their Medicare patients. We also believe that CMS is not adequately recognizing hospitals' related pharmacy service costs. To ensure that Medicare beneficiaries can continue to access life-saving and important drugs when in a hospital outpatient setting, we urge CMS to:

- Eliminate the threshold for packaging therapies into the ambulatory payment classifications (APCs) and pay separately for all therapies with Healthcare Common Procedure Coding System (HCPCS) codes;

- Reimburse drugs under the OPPS at a minimum of ASP plus six percent, the same as the current reimbursement rate and the rate applicable in a physician office setting; and

- Ensure appropriate reimbursement for hospital pharmacy service and handling costs.

These recommendations are consistent with those made by the Advisory Panel on APC Groups (APC Panel). 3/ We discuss these comments in more detail below.

In addition, as we have discussed with CMS, we recommend that the HCPCS Workgroup adopt a unique code for each sodium hyaluronate product

---

2/ We use the term "drugs" to refer to both drugs and biologicals.

3/ Advisory Panel on APC Groups, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip (Aug. 23-24, 2006).



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6000 · www.sanofi-aventis.com

and that CMS assign each product to a distinct APC with payment determined based upon the ASP for the individual product.

Finally, we applaud CMS' efforts to improve the quality of care in the hospital setting and support the goals of developing and implementing performance measurement and reporting by hospitals. If CMS moves forward with its proposals to establish a quality reporting program in the outpatient setting, and to expand the quality measures in the inpatient quality reporting program, sanofi-aventis urges CMS to update and revise its quality measures to reflect current standards of practice to ensure that Medicare patients receive the most up-to-date care.

We discuss these comments in more detail below.

## I. CMS Should Eliminate the Packaging Threshold for All Therapies with HCPCS Codes. [OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals]

Sanofi-aventis is very concerned that CMS is proposing to increase the packaging threshold for drugs from $50 to $55. We urge CMS to implement the recommendation of the APC Panel and eliminate the packaging threshold for all drugs with HCPCS codes to ensure appropriate payment for therapies in the outpatient setting. Packaging payments for certain drugs into the APCs gives hospitals a disincentive to use these drugs, even though a lower cost drug under the packaging threshold may be more clinically appropriate for the patient. Further, if CMS pays separately for all drugs with HCPCS codes, hospitals will be more likely to code and set appropriate charges for them, improving CMS' ability to pay appropriately for items and services provided under the OPPS.

Paying separately for drugs in the outpatient setting also is consistent with Medicare payment for drugs dispensed in physician offices. Sanofi-aventis is concerned that the differential in payment for packaged therapies will result in the migration of patient care from hospital outpatient departments to physician offices. We believe the setting for patient care should be driven by clinical appropriateness, not by differences in reimbursement. Yet CMS' packaging policy creates just the opposite incentive. In the physician office, CMS proposes to pay for all drugs with HCPCS codes at ASP plus six percent. In contrast, in hospital outpatient departments, payment for drugs below the $55 threshold will be bundled in with the APC payment, and drugs paid separately only will be reimbursed at ASP plus five percent. We believe that CMS' proposals will drive care away from hospital outpatient departments and to the physician office setting.



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel. (908) 243-6000 · www.sanofi-aventis.com

This does not ensure that Medicare beneficiaries receive the best possible care in the setting most appropriate for their medical needs.

Moreover, we do not believe that paying separately for drugs with HCPCS codes would add to hospitals' administrative burden. Hospitals already are encouraged to code separately for these drugs, even though they are packaged into the underlying APCs. In our review of claims data, hospitals are coding for some therapies that are below the packaging threshold. Since the advent of packaging under the OPPS, however, our review has found an aggregate decline in reported claim lines for packaged therapies. We believe that if CMS pays separately for these therapies, hospitals not only will have an incentive to focus solely on the clinical merits of a particular therapy, but they will also have an incentive to code and capture charge and cost data more accurately. Such increased accuracy in coding will improve the data set upon which CMS will set future payments.

## II. CMS Should Pay at Least ASP Plus Six Percent for Drugs Administered in the Hospital Outpatient Department Setting. [OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals]

CMS' Proposed Rule would set reimbursement for drugs without pass-through status at ASP plus five percent. 4/ This cut will be difficult for hospitals to absorb, particularly at a time when they are asked to take on more and more patients with complex medical problems as a result of reimbursement shortfalls in the physician office setting.

Hospital outpatient departments incur greater costs than physician offices, both because of the patient population they serve as well as the level of service they are required to provide. Sanofi-aventis is concerned that if hospitals are not adequately reimbursed for providing drugs, they will be unable to provide necessary therapies to Medicare beneficiaries, leaving these beneficiaries with no where else to turn.

We believe that CMS' proposal to reduce payment for these drugs to ASP plus five percent does not take several factors into account. First, CMS assumes that the claims data include charges for pharmacy services, but Medicare Payment Advisory Commission's (MedPAC) June 2005 report noted that most hospitals do not set charges for drug handling costs and do not have detailed information about the scope of these costs. 5/

---

4/ Id. at 49585.

5/ MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Jun. 2005, at 139-140.



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6000 · www.sanofi-aventis.com

Second, we are concerned that the application of a constant cost-to-charge ratio (CCR) to pharmacy charges used by CMS does not generate accurate estimates of costs for certain therapies. In addition, we believe that CMS' failure to include the costs of drugs that are packaged into its rate-setting methodology for separately paid drugs results in an underestimation of hospitals' overhead costs. CMS ignored both the acquisition cost and overhead charges for packaged drugs. If CMS included all drugs used in the outpatient setting in its calculations, the estimate of total costs would better account for the full amount of handling costs in hospitals' charges.

We believe that if CMS included all drugs with HCPCS codes in its rate-setting for separately paid therapies that CMS would generate more accurate results, similar to those found by MedPAC in its report to Congress in June 2005. 6/ MedPAC found that pharmacy department wages, salaries, fringe benefits, and supplies were 26 to 28 percent of direct costs. 7/ Assuming all hospitals are able to purchase drugs at ASP, under the MedPAC calculation hospital acquisition and handling costs for therapies would be ASP plus 39 percent. While this may not be true for some hospitals, CMS should not reduce reimbursement to less than the physician office payment rates until it can refine its rate-setting methodology.

## III. CMS Should Adequately Reimburse Hospitals For Pharmacy Services and Overhead. [OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals]

As described in depth above, sanofi-aventis is concerned that CMS is not adequately recognizing pharmacy service and handling costs. Hospital pharmacy services are resource and labor intensive. They require a high degree of training and can involve very complex compounding of products, requiring appropriate equipment, personnel, and supplies. Biological therapies and other highly complex drugs may require very expensive storage solutions to shield them from variations in temperature and light. Further, pharmacy department personnel must be in regular communication with physicians to ensure that each patient receives the appropriate therapy, at the right dose, and through the correct route of administration. These pharmacy personnel must continually apply quality assurance measures to ensure correct preparation and environmentally safe disposal of materials. These quality and safety measures are costly, but absolutely essential to protecting patients' health and lives. CMS should continue to study mechanisms to reimburse hospitals appropriately for these

---

6/ MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Jun. 2005.

7/ Id. at 140.



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6000 • www.sanofi-aventis.com

considerable pharmacy service and handling costs and should pay hospitals no less than ASP plus six percent for separately paid drugs until this issue can be resolved.

## IV. Coding and Payment for Sodium Hyaluronate Products (Hyaluronans/Hylans)

In our submissions, we have recommended that the HCPCS Workgroup adopt unique codes for each of the sodium hyaluronate products given the unique features of each product. Consistent with this recommendation, we would also request that each product be assigned to a distinct APC and that payments be assigned based upon the ASP for each product.

Sodium hyaluronate products are single source products administered by intra-articular injection for the treatment of pain in patients with osteoarthritis of the knee. Currently, there are 5 sodium hyaluronate products approved for commercial use in the US: (1) Hyalgan (sanofi-aventis), (2) Euflexxa (Ferring), (3) Orthovisc (Johnson & Johnson), (4) Supartz (Smith & Nephew) and (5) Synvisc (Genzyme). These products differ in terms of molecular weights, biological activity, the scope and extent of published clinical evidence, dose-per treatment, number of treatments-per course 8/ and labeling for repeated treatment courses.

Although there are 5 distinct sodium hyaluronate products, the Proposed Rule identifies only 3 codes and payment amounts across these products. The chart below demonstrates the payment disparities that result from CMS' current coding policy on hyaluronans:

8/ According to package labeling, Hyalgan is given as 3 or 5 injections per course, Orthovisc as 3 or 4 injections per course, Supartz as 3 or 5 injections per course and Synvisc as 3 injections per course.



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6000 - www.sanofi-aventis.com

| Product | Mol Wt | Code | APC | Status | Payment Amount Identified in NPRM |
|---|---|---|---|---|---|
| Euflexxa 9/ | 2.4-3.6 MDa | J7317 | 7316 | K | $112.04 |
| Hyalgan | 0.50-0.73 MDa | | | | |
| Supartz | 0.62-1.17 MDa | | | | |
| Orthovisc | 1.0-2.9 MDa | C9220 | 9220 | K | $197.62 |
| Synvisc | >6 MDa | J7320 | 1611 | K | $196.99 |

As we have indicated in written comments to CMS, in meetings with CMS staff and at the HCPCS Workgroup public meeting in May 2006, the current coding structure for the sodium hyaluronate products is not supportable on scientific or clinical grounds and creates financial incentives that distort clinical decision making and appropriate market forces. We believe the most appropriate and scientifically defensible approach for this class of products is to adopt a unique code for each sodium hyaluronate and to assign discrete APC payment amounts for each product using product-specific ASP amounts. There is no scientific justification for maintaining the status quo, or any other version of the status quo, where some products are assigned to product-specific codes while others are lumped together in a shared code.

## V. CMS Should Ensure that any Hospital Quality Data Reporting Requirements in the Hospital Outpatient Department Setting are Consistent with Current Standards of Care [Hospital Quality Data]

Sanofi-aventis applauds CMS for its efforts to improve the quality of care in the hospital outpatient department setting. While we do not comment on whether CMS' proposal to adapt the Inpatient Prospective Payment System (IPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program to the OPPS is consistent with its authority under section 1833(t)(2)(E) of the Social Security Act, we support CMS' goals to develop and implement performance measurement and reporting by hospitals to improve the quality of health care delivery.

---

9/ Euflexxa has been assigned to code J7317 under the Part B ASP drug listings: See file Oct06_ASPNDC-HCPCSCrosswalk_20Sep06.xls at http://www.cms.hhs.gov/apps/ama/license.asp?file=/McrPartBDrugAvgSalesPrice/downloads/oct06_asp_cross.zip.



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6000 - www.sanofi-aventis.com

We believe that the starter set of 10 quality measures established for the IPPS RHQDAPU as of November 1, 2003 represent critical barometers of care for patients in a hospital setting. However, if this starter set of quality measures is adapted to the OPPS, we believe the Heart Attack (Acute Myocardial Infarction/AMI) measures should be expanded to reflect current standards of care. For example, guidelines promulgated by the American College of Cardiology (ACC) and the American Heart Association (AHA) suggest that patients with Acute Coronary Syndrome (ACS) receive both aspirin and clopidogrel bisulfate when they are discharged from the hospital. 10/ The existing starter set provides for only aspirin at discharge, 11/ but providing patients with ACS with both aspirin and clopidogrel bisulfate at discharge reduces risk of another heart attack, and enhances quality of care.

In addition, we urge CMS to include two key measurements from the Surgical Care Improvement Project (SCIP) to any quality measures applied to the hospital outpatient department setting: venous thromboembolism (VTE) prophylaxis ordered for a surgery patient (SCIP-VTE 1) and VTE prophylaxis within 24 hours pre/post surgery (SCIP-VTE 2). These are measures CMS is proposing to add to the IPPS RHQDAPU for 2008 12/, and we believe they would be appropriate under the OPPS as well. VTE occurs after approximately 25 percent of all major surgical procedures performed without prophylaxis. More than 50 percent of major orthopedic procedures are complicated by VTE if prophylactic treatment is not administered. However, in spite of the well-researched and established efficacy of preventive measures, studies show that VTE prophylaxis is often underused or used inappropriately. Incorporating the SCIP-VTE 1 and SCIP-VTE 2 into a OPPS RHQDAPU program will help ensure that Medicare beneficiaries who undergo surgery on an outpatient basis receive appropriate quality care.

Further, we urge CMS to take a leadership role with stakeholders to develop consensus recommendations regarding the addition of new quality

---

10/ E. Braunwald et al., American College of Cardiology (ACC), American Heart Association (AHA), Committee on the Management of Patients with Unstable Angina. *ACC/AHA 2002 guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction – summary article: a report of the American College of Cardiology/American Heart Association task force on practice guidelines* (Committee on the Management of Patients with Unstable Angina). J Am Coll Cardiol 2002;40:1266-74; E. Antman et al., *ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction – executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines* (Writing Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Circulation 2004; 110(5):588-636.

11/ 71 Fed. Reg. at 49666.

12/ 71 Fed. Reg. at 49672.



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6000 · www.sanofi-aventis.com

measures under the RHQDAPU program. For example, there is increasing evidence that for patients with unstable angina, non-ST-segment elevation myocardial infarction, and acute ST-segment elevation myocardial infarction with or without percutaneous coronary intervention (PCI), the pretreatment administration of both aspirin and clopidogrel in the acute setting followed by longer-term therapy will reduce major cardiovascular events. 13/ As a leading Federal agency in the development of quality measures for hospitals, CMS has a responsibility to keep abreast of changes in the standard of care, bring together the relevant stakeholders to build consensus, and to act quickly and appropriately to update the quality measures for the RHQDAPU program.

Sanofi-aventis also believes that certain quality measures developed as part of the 16 measure core starter set in the Physician Voluntary Reporting Program (PVRP) should be included in the OPPS RHQDAPU program. While we understand that the starter set developed for the PVRP is specifically designed for reporting by individual physician providers, to the extent that services overlap with hospital outpatient services, CMS's quality measures should be consistent across provider settings. For example, we support the use of thromboembolism prophylaxis in surgical patients as a reportable measure in both the PVRP starter set and the OPPS RHQDAPU. Sanofi-aventis also encourages CMS to consider adding to the PVRP core starter set antiplatelet therapy for patients with coronary artery disease, as endorsed by the National Quality Forum (NQF). 14/

CMS should also consider updating the Hemoglobin A1c control standard for patients with Type I or Type II diabetes mellitus to be consistent with clinical guidelines established by the American Diabetes Association (ADA). These guidelines, supported by a broad collection of public health experts and medical societies, provide a quality of care measure of A1c less than 7 percent for people with diabetes. 15/ CMS' Core Starter Set Specifications only require documentation of A1C less than 9 percent. 16/

---

13/ E. Braunwald, et al., *ACC/AHA 2002 guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction – summary article: a report of the American College of Cardiology/American Heart Association task force on practice guidelines*; E. Antman et al, *ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction – executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.*

14/ National Quality Forum (NQF), National Voluntary Consensus Standards for Ambulatory Care: An Initial Physician-Focused Performance Measure Set at 10, http://www.qualityforum.org/ (May 2006).

15/ American Diabetes Association (ADA), *Standards of Medical Care in Diabetes 2006*, S10, Diabetes Care, 29:1 (Jan. 2006).

16/ CMS, PVRP 16 Measure Core Starter Set G-Code Specifications and Instructions at 2, http://www.cms.hhs.gov/pvrp/ (effective Date Jul. 1, 2006).



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6000 · www.sanofi-aventis.com

The ADA recommends lowering A1c to less than 7 percent to reduce the microvascular and neuropathic complications of diabetes. 17/

Lastly, sanofi-aventis encourages CMS to revise the PVRP measure for the assessment of elderly patient falls to require an assessment of patients 65 years or older. Currently, CMS' core starter set would measure these assessments only for patients aged 75 or older. 18/ But studies validated by a World Health Organization working group on osteoporosis have shown that hip fracture risk increases 4-fold between the ages of 50 and 80. 19/ CMS should ensure that all Medicare beneficiaries at risk for osteoporosis are assessed for falls, not just those aged 75 or older.

## VI. CMS Should Consider Additional Quality Measures to Improve Patient Care in the Hospital Inpatient Setting [FY 2008 IPPS RHQDAPU]

Sanofi-aventis applauds CMS' proposal to add SCIP-VTE 1 and SCIP-VTE 2 to the IPPS RHQDAPU Program. The addition of these measures for hospitals reporting quality data under this program will help to improve quality of care for Medicare beneficiaries, and reduce the risk of post-operative complications associated with VTE. As we noted above, VTE is an all-too-common risk for patients after surgery, but the risk can be mitigated through the administration of prophylactic treatment.

We are concerned, however, that CMS' Medicare Quality Improvement Community (MedQIC) has delineated inappropriate cost effectiveness factors for the SCIP target areas. Specifically, MedQIC's SCIP target area of "Deep vein thrombosis" includes a discussion of the cost of low-dose unfractionated heparin (LDUH) verses the cost of low-molecular-weight heparin (LMWH). 20/ We believe that the development of quality measures and treatment decisions should be driven by clinical outcomes and patient care, not cost.

Sanofi-aventis also urges CMS to take the lead in developing a new VTE measure for prophylaxis of medical patients at risk for VTE. This is consistent with NQF-endorsed safe practices, which include:

---

17/ ADA, *Standards of Medical Care in Diabetes 2006* at S11.
18/ CMS, PVRP 16 Measure Core Starter Set G-Code Specifications and Instructions at 7.
19/ J. Kanis et al., *Assessment of Fracture Risk*, Osteoporosis Int (2005) 16: 581-589.
20/ MedQIC, SCIP Target Areas, www.medqic.org (last visited Oct. 5, 2006).



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel (908) 243-6000 - www.sanofi-aventis.com

- The evaluation of each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Utilize clinically appropriate methods to prevent DVT/VTE.
- The use of dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management. 21/

For patients admitted to the hospital who are at risk of developing VTE, evaluation and appropriate prophylactic treatment can reduce the risk of this life-threatening and often fatal condition. The IPPS RHQDAPU Program currently only includes measures for VTE prophylaxis in surgery patients. Sanofi-aventis believes CMS should expand the measures to include a measure for prophylactic treatment of medical patients at risk for VTE.

Sanofi-aventis appreciates CMS' call for comments from stakeholders regarding the expansion of quality measures beyond those proposed in the IPPS proposed rule. 22/ As we noted in our comments on hospital quality data reporting in the outpatient setting, we believe the Heart Attack (Acute Myocardial Infarction/AMI) measures should be expanded to reflect ACC and AHA guidelines suggesting patients receive both aspirin and clopidogrel bisulfate acutely in the hospital and when they are discharged from the hospital. 23/ Dispensing aspirin and clopidogrel bisulfate to ACS patients at discharge reduces risk of a heart attack and enhances quality of care.

## V. Conclusion

We thank you for your consideration of these comments on the Proposed Rule and hope we can continue to work with CMS to advance Medicare beneficiaries' access to innovative and life-saving therapies. Please contact me or Saira Sultan, Director of Federal Government Affairs, at 202-

---

21/ NQF, Safe Practices for Better Healthcare: A Consensus Report at VII, http://www.qualityforum.org/ (last visited Oct. 5, 2006).

22/ 71 Fed. Reg. at 49673.

23/ E. Braunwald et al., *ACC/AHA 2002 guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction – summary article: a report of the American College of Cardiology/American Heart Association task force on practice guidelines*; E. Antman et al, *ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction – executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.*



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6800 · www.sanofi-aventis.com

360-9985 if you have any questions or if we can be of further assistance on these comments. Thank you for your attention.

Sincerely,

Hugh O'Neill
Vice President
Market Access and Business Development



300 Somerset Corporate Boulevard, PO Box 6997, Bridgewater, NJ 08807-0977
Tel: (908) 243-6900 · www.sanofi-aventis.com