Submitter : Kathy Francisco **Date:** 10/09/2006

Organization : The Pinnacle Health Group, Inc.

Category : Health Care Industry

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Breast Brachytherapy - See Attached Letter

CMS-1506-P-376-Attach-1.PDF

#316

THE PINNACLE HEALTH GROUP
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October 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

The Pinnacle Health Group is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

This comment letter specifically addresses the proposed payment for breast brachytherapy including the high dose rate brachytherapy source required to perform breast brachytherapy.

Breast conservation therapy is a treatment alternative for breast cancer patients that allows patients the option to treat breast cancer while preserving the breast. Breast brachytherapy allows patients better access to treatment by reducing treatment time from six weeks to five days. This treatment cannot be performed without the use of high dose rate brachytherapy.

According to the National Institute of Health consensus statement regarding treatment of early-stage breast cancer "Breast Conservation surgery plus radiotherapy is preferable to total mastectomy because it provides survival equivalence while preserving the breast".

The proposed changes in the CMS hospital outpatient payment system will limit patient access to breast conservation therapy and may cause more patients to opt for more costly alternatives such as Mastectomy. The impact of these changes will weigh significantly on hospitals ability to offer breast conservation therapy to Medicare beneficiaries.

BREAST BRACHYTHERAPY (CPT 19296 and 19297)

Breast brachytherapy codes (CPT 19296, 19297 & 19298) were implemented January 1, 2005 and have been assigned to appropriate New Technology APCs. CMS proposes to

reassign two of the three codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment would result in significant decreases in 2007 payment, (see table below) which range from -22% to -37% and -$741 to -1017.31.

HCPCS	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percentage Change 2006-2007
19296	1524	$3,250.00	30	$2,508.17	($741.83)	-22.8%
19297	1523	$2,750.00	29	$1,732.69	($1,017.31)	-37.0%

Another significant issue of concern is the change in status indicator if the proposed change is made effective. Breast brachytherapy CPT codes 19296, 19297 and 19298 require the use of a high cost device that is bundled into the procedure payment thus classifying these procedures as device-dependent. 19297 is ALWAYS performed at the time of lumpectomy. Lumpectomy procedures map to a clinical APC that also has a T status indicator. This procedure would be reduced by 50% each time the procedure is performed as the code descriptor indicates "concurrent with partial mastectomy (list separately in addition to code for primary procedure". The table below outlines the proposed change in status indicators for CPT 19296 and 19297.

HCPCS	2006 APC	2006 Status Indicator	2007 Proposed APC	2007 Proposed Status Indicator
19296	1524	S	30	T
19297	1523	S	29	T

During the review of CMS claims data, it was noted that the reporting of the required catheter code (C1728) was non-existent on a majority of the claims used to calculate the median costs for these procedures. More accurate median costs are reported when using single claims that include the cost of the catheter.

HCPCS	Single Frequency	Median Cost
19296	491	$2,879
19296 + C1728	32	**$3,508**
19297	36	$1,631
19297 + C1728	1	**$3,371**

CMS has proposed to map 19296 and 19297 to clinical APCs in which the current procedures are not similar clinically or in resource utilization. These procedures do not utilize a high cost device, and the median cost of the procedures within these APCs violate the two times rule when the device dependent median cost is utilized (19296 and 19297 + C1728).

APC 30		
CPT	Median Cost	Median Cost 19296+C1728
19240	2,479.58	**$3,508**
19340	1,974.69	
19380	2,002.58	

APC 29		
CPT	Median	Median 19297 +C1728
19180	1,942.76	**$3,371**
19182	1,390.91	
19316	2,116.31	
19328	1,397.57	
19330	1,356.21	
19355	1,169.32	
19366	1,890.47	
19370	1,875.37	
19371	1,837.35	
19396	38.48	

CPT 19296 and 19297 were new codes in 2005 so no claims were available for 2006. The number of hospital outpatient claims for 2005 is low and inadequate for CMS to make assumptions regarding which clinical APC to assign these codes. The proposed clinical APC assignment is based upon only one year of CMS claims data. Further, the volume of procedures in 2005 for CPT codes 19296 and 19297 were low in comparison to other device-dependent procedures

CPT	2004 Claims - 2006 Payment (number of single frequency claims)	2005 Claims – Proposed 2007 Payment (number of single frequency claims)
19296	n/a	491
19297	n/a	36
19298	n/a	49

If CMS finalizes the proposed clinical APC assignment, this will limit the hospitals ability to offer breast brachytherapy as a cancer treatment option to Medicare beneficiaries. The cost of the device itself exceeds the proposed APC assignments for 2007. Hospitals will not be able to purchase the high cost device required to implant into the breast to perform breast conservation therapy. Therefore, the CMS proposed APC assignment will limit patient access to this less invasive breast cancer treatment.

HIGH DOSE RATE BRACHYTHERAPY (HDR)

Breast brachytherapy requires the use of a High Dose Rate brachytherapy source. The HDR source is a unique brachytherapy source that requires allocation of the quarterly source cost by each hospital. The actual cost of the source is based upon the number of treatments or fractions that are administered to patients over the life of the source.

CMS claims data shows a huge variation in cost per unit reported on claims data across hospitals for the source:

APC	Number of Hospitals	Number of Claims	Variation of Cost per Unit
1717	283	4740	$0-4,746

In addition to the large variation of cost per unit across the hospitals and claims in the CMS data, the highest utilization hospital should have the lowest cost for the HDR

source and hospital cost from there should increase in numeric succession. The analysis of the top five volume hospitals, per CMS claims data, indicates significant anomalies in the data. Clearly this information should cause CMS to question the accuracy of the data when considering payment based upon the claims data.

HCPCS	Hospitals	Median	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5
C1717	283	$135	$3	$9	$479	$118	$95

To further validate the variation in cost per unit, a survey of eighty hospitals was conducted by The Pinnacle Health Group to determine the actual cost of the HDR source to the hospital. This survey was originally conducted using 2002 hospital data and was updated using 2005 hospital specific costs and actual source runs. The findings indicated that the variation in cost per unit among these 80 hospitals range from $4-5,775. These findings validate the CMS claims data that indicate variation in cost per unit of ($0-4,746).

Number of Hospitals	Total ACUTAL Source Runs	Average Quarterly Unit Cost	Average Quarterly Source Service Cost	Average Quarterly Source Cost	Variation of Cost per Unit
80	47,050	$17,500	$7,150	$10,000	$4-5,775

In addition to the variation in HDR source cost in the CMS claims data and the actual hospital survey, the GAO had an opportunity to review the HDR source cost as part of the report published by the agency this year. The GAO stated "data from 8 hospitals was determined to be usable to evaluate Ir-192 causing the GAO to recognize there was too much variability in Ir-192 source cost and therefore no recommendations could be made."

The cost of the HDR source is a fixed cost. Hospitals must purchase the source and have it available to treat cancer patients at any time. HDR cost varies from other diagnostic imaging technologies that may also have associated fixed costs. The HDR source must be on hand at all times so the hospital incurs the cost on a daily basis. For imaging services, the cost of the imaging agent is only incurred by the hospital if a study is performed or ordered by the physician. The cost of the source is incurred by the hospital even if patients are not treated.

RECOMMENDATIONS

Due to the low volume of procedures in the CMS claims database, CMS should maintain 19296 and 19297 in New Technology APCs 1524 and 1523 respectively, so that additional claims data may be collected through calendar year 2006. At this time the claims data should be reevaluated for possible reassignment to a more appropriate clinical APC in 2008.

As an alternative, CPT 19296 and 19297 are similar both clinically and with respect to resource costs to procedures included in APC 648 Breast Reconstruction with Prosthesis. The identical medical device is required for both breast brachytherapy procedures (CPT 19296 and 19297) and the cost of the catheter is exactly the same. All of the current procedures in APC 648 involve the placement of an expensive device, as do breast brachytherapy codes 19296 and 19297.

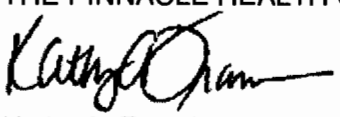
PROPOSED APC 648 – Breast Reconstruction				
HCPCS	Description	APC Value	Single Frequency	Median Cost
19357	Breast reconstruction	$3,002	200	$3,016
19296	**Post-op implant of breast cath**	**$3,002**	**491**	**$2,879**
19342	Delayed breast prosthesis	$3,002	65	$2,775
19325	Enlarge breast with implant	$3,002	6	$2,414
19297	**Implant of breast cath for rad**	**$3,002**	36	**$1,631**

The Pinnacle Health Group recommends that CMS maintain breast brachytherapy codes 19296 and 19297 in their current New Technology APCs (1524 and 1523 respectively) for 2007. Alternatively, CMS could assign CPT codes 19296 and 19297 to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the APC group title from "Breast Reconstruction with Prosthesis" to "Level IV Breast Surgery."

The required brachytherapy that follows the implant of the catheter to perform breast conservation therapy requires the use of the HDR brachytherapy source (C1717). In addition, we agree with the recommendations by the APC panel and PPAC that CMS should continue to reimburse hospitals for the HDR brachytherapy source based upon charges reduced to cost.

We appreciate the opportunity to provide comments during this proposed rule period and thank CMS for the opportunity to meet and discuss these important issues in person.

Sincerely,
THE PINNACLE HEALTH GROUP, INC.



Kathy A. Francisco
Principal
kfrancisco@thepinnaclehealthgroup.com

cc: Carol Bazell, MD, Acting Director, Division of Outpatient Care (via email)

Submitter : Mr. Douglas Myking **Date:** 10/09/2006

Organization : Radiation Medical Group

Category : Other Health Care Professional

Issue Areas/Comments

OPPS

OPPS

See Attached

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 : **Ms. Marla McCandless** **Date: 10/09/2006**

Organization : **Blues Management, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

I am writing to call your attention to an urgent matter. The Center for Medicare and Medicaid Services (CMS) is proposing changes in reimbursement to providers of outpatient services that would have far reaching injurious effects on psychiatric service access. Reimbursement cuts from 2005 and 2006 resulted in the closing of many programs in Community Mental Health Centers. I work in a Mental Health Facility and these cuts are a devastating disaster for the mentally ill. The amount of money that it will cost the government when these patients are always in emergency rooms, inpatient psych. hospitals, nursing homes, and jail will be astronomical. There are so many success stories with the mentally ill who attend Psychiatric Partial Hospital Programs. I ask you to join me in contacting CMS officials to suspend the proposed cut, create a behavioral health task force to establish an effective method of calculating rate changes to preserve the availability of this lower cost benefit. I invite you to come visit the Mental Health Facility I work for in Houston. Thanking you in advance. Marla McCandless

Submitter : Mr. Kevin Lofton **Date:** 10/09/2006

Organization : Catholic Health Initiatives

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments of Catholic Health Initiatives addressing the "Visits" and "Medicare Contracting Reform" sections of proposed rule CMS-1506-P.

CMS-1506-P-379-Attach-1.DOC

H 219

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October 10, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1506P

RE: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual payment Update Program – HCAHPS® Survey, SCIP, and Mortality; Proposed Rule

Dear Dr. McClellan:

Catholic Health Initiatives appreciates the opportunity to comment on the proposed rule CMS-1506-P. Catholic Health Initiatives is a faith-based, mission-driven health system that includes 71 hospitals, 42 long-term care, assisted-living and residential units, and two community health service organizations in 19 states.

Our national hospital associations will be providing you with extensive comments on the proposed rule that reflect many common concerns. Catholic Health Initiatives would like to offer input on two issues – Emergency Department Visit Guidelines and Medicare Contracting Reform.

Visits – Emergency Department Visit Guidelines

In the 2007 proposed Outpatient Prospective Payment System (OPPS) regulations, the Centers for Medicare and Medicaid Services (CMS) seeks public input before adopting national guidelines for facility visit levels. All comments below are in response to CMS' request for input on the revised American Hospital Association (AHA) and American Health Information Management Association (AHIMA) guidelines which were published in the proposed regulation.

Catholic Health Initiatives supports a national standard for visit level assignment for outpatient visits. CMS has outlined eight general areas of concern regarding the AHA/AHIMA model. Our comments will follow this sequence and additional comments are added. Our comments are specific to the Emergency Department (ED) Visit Guidelines.

1. **Three versus five level of codes**

   We agree with CMS that there should be five levels of codes for both clinic and ED visits for the purposes of consistency in coding/billing to all payers.

2. **Lack of clarity for some interventions**

   We agree with CMS that there is a lack of clarity in specific intervention descriptions. We piloted the AHA/AHIMA guidelines in several facilities using both nursing and coding staff to interpret the guidance. Our observations are as follows:

   - Lack of specificity in definitions. Additional descriptions and definitions would be beneficial in reducing incorrect interpretations by coders.

   - It would be helpful to provide examples of patient acuity or symptoms as additional explanation for visit levels. A description of a typical patient for the visit level (i.e., chest pain patient w/EKG and no cardiac monitoring) would be helpful. Level 5 should correlate to more severe patient symptoms, acuity level (life threatening).

   - Based on existing guidelines, several ED encounters did not meet any criteria to be assigned a Level I ED visit. For example, patient presenting with chest pain, received an initial nursing assessment, vitals, and low pain scale assessment. Patient received blood chemistry (with separately billed venipuncture), EKG, x-ray, no oral or SL medications. Patient was discharged home with a diagnosis of costochondritis and instructions to take Ibuprofen. It would be inappropriate to disallow payment for a patient who presents to the ED with chest pain and requires clinical evaluation to rule out cardiac risk.

   - Current guidelines do not take trauma level care into consideration for ED level.

   - More clearly define ED visit level criteria. For example:
     - Are triage assessments for EMTALA requirements considered to be a Level I ED visit?
     - Does a primary assessment qualify for Level I ED Intervention "assisting physician with examination"?

- Are scheduled follow-up visits appropriate to be assigned to an ED visit level when no there are no other health provider options?
- Please clarify if application of off-the-shelf splints (not separately billable) are considered first aid?
- Does manual suctioning apply or is it only limited to NT and OT?
- Can interaction with home health, community services, housing authorities, or some other type of assistance be considered contributory factors or do they need to be specific to law enforcement or protective services personnel?

3. Treatment of separately payable services

We agree with CMS that this needs to be re-addressed. Current interventions include items that currently are separately billable (i.e. Cardiac monitoring, fecal disimpaction) and are therefore inconsistent. In general we feel that there needs to be more descriptions on interventions for all levels. Status N procedures should be included as contributory factors for ED visit level assignment. They are separately identifiable procedures but are bundled for payment.

4. Some interventions appear overvalued

We agree with CMS on continuous irrigation of eye (Morgan lens) as being overvalued as a level five intervention. We also feel there are inconsistencies in the interventions reflecting the same degree of complexity within each level.

5. Other observations:

We have overall concerns that existing level assignment does not accurately capture resource consumption in the ED. The facility level should be representative of all resources that are not otherwise captured in payments for other separately payable services. This should include staff involvement with indirect patient care such as counseling and coordination of care in the ED. For example, there is no accommodation for nursing time involved with tasks to support patient care but that are not direct hands on patient care. Examples are as follows: coordinating consultations, dealing with a belligerent or unruly patient, extra time spent with family, and time providing complex discharge instructions.

More specifically, the following interventions have not been identified as contributory factors to ED visit level determinations such as: ace/sling application, pre-fabricated splint application, different levels of dispositioning, seizure precautions, language barrier, drug and/or alcohol influence, triage/primary care assessment, assisting with ADL's, obtaining consents, prepping for surgery, preparing an ED patient for Observation/Inpatient status, oral suction, remaining with the patient during testing procedures, arranging transportation for a departing patient, discharge instructions, burn/abrasion care/wound care (more than simple first aid), working with a patient in restraints,

behavioral health assessments, post mortem care, pediatric 1:1 (no adult), telephone calls to follow-up on potential drug seeker (numerous telephone calls are placed to local clinics and pharmacies to obtain information about the patients' prescription drug use).

Medicare Contracting Reform Mandate

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) PL 108-173 included certain "Medicare contracting reform" for Medicare fee-for service provisions. These reform provisions were intended to improve Medicare's administrative services to beneficiaries and health care providers and to bring standard contracting principles to Medicare, such as competition and performance incentives. The MMA provisions replaced the prior Medicare intermediary and carrier contracting authorities. The MMA requires that the CMS complete the transition to the new contracting program by October 1, 2011.

One provision of the change repealed the ability of providers to nominate their servicing intermediary. In the NPRM, CMS proposes that providers would be assigned to the Medicare administrative contractor (MAC) that is contracted to administer the types of services billed by the provider within the geographic locale in which the provider is physically located or provides health care services. CMS proposes to allow large chain providers that were formerly permitted by CMS to "nominate" an intermediary to request an opportunity for similar consideration under the new contractor program. And, qualified chain providers that were formerly granted single intermediary status would not need to re-request such privileges at this time.

Catholic Health Initiatives makes the following recommendations concerning MACs:

- CMS should allow large health systems comprised of individual providers to request the consolidation of its Medicare billing activities to the MAC with jurisdiction over the geographic locale in which a system's home office or billing office (if located in a different locale) is located.

- CMS should allow large multi-hospital systems that have previously elected to use a single fiscal intermediary (FI) to remain with the same FI (if it is designated as a MAC) until a MAC is designated for the health system's home/billing office in order to avoid unnecessary multiple transitions.

- CMS should extend the opportunity to designate a single MAC to a health care system which timely requested and was acknowledged as meeting the requirements for single designation but which was unable to accomplish a final transition to one intermediary/MAC due to issues solely on the part of Medicare.

(Catholic Health Initiatives moved a portion of its providers to Mutual of Omaha in 2003 with agreement that remaining providers would be moved to this single FI in 2004. However, CMS allowed only a portion of the remaining providers to be moved to Mutual in 2004, citing deficiencies in Mutual. Catholic Health Initiatives applied again in 2005 to have the balance of its providers served by Mutual, but CMS denied the request citing continued Mutual deficiencies and the impending Medicare Contracting Reform.)

Thank you for the opportunity to review and comment on the proposed OPPS rule for 2007. If you have any questions, please feel free to contact Colleen Scanlon, RN, JD, Senior Vice President Advocacy, at 303-383-2693.

Sincerely,

Kevin E. Lofton
President and Chief Executive Officer

Submitter : **Ms. Laurel Sweeney** **Date: 10/09/2006**

Organization : **Philips Medical Systems**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-380-Attach-1.DOC

#280

PHILIPS

LAUREL SWEENEY
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October 9, 2006

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8018

Re: CMS 1506-P; Hospital Outpatient Prospective Payment System (HOPPS) CY 2007 Proposed Policies and Rates

Dear Dr. McClellan:

On behalf of Philips Medical ("Philips"), I am delighted to have this opportunity to provide these comments regarding the proposed revisions of the Hospital Outpatient Prospective Payment System (HOPPS) for CY 2007 published on August 23, 2006 in the Federal Register (the "Proposed Rule"). Philips Medical is one of the largest manufacturers of medical systems in the world. Philips' product line includes technologies in general imaging and cardiac ultrasound, X-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), nuclear medicine (including Positron Emission Tomography (PET), radiation therapy planning, patient monitoring and resuscitation, as well as information technology solutions.

Philips applauds CMS for its implementation of the abdominal aortic aneurism (AAA) screening benefit that is included in the Deficit Reduction Act. We also applaud CMS for its decision to refrain from implementing the multiple procedure reduction for medical imaging services provided on contiguous body parts in the hospital outpatient setting at this time. We believe that, in light of the substantial payment challenges that providers of medical imaging services are facing, application of the multiple procedure reduction to imaging services provided in the hospital outpatient setting at this time would be imprudent.

However, Philips is extremely concerned about several aspects of the Proposed Rule:

- We urge CMS to reconsider its proposal to reclassify PET/CT from New Technology APC 1514 to APC 308--the same APC proposed for stand-alone PET.

- We believe that the proposed reclassification of both single and multiple myocardial PET studies into a single APC (APC 307) is unsupported by the data and that the resulting APC rate is inadequate to support the provision of this service.

- Also with respect to nuclear medicine services, we fully support the comments submitted on behalf of the Society for Nuclear Medicine with respect to Medicare payment for radiopharmaceuticals, and urge CMS to incorporate the recommendations made by SNM into the final APC rates for CY 2007.

- We urge CMS to provide separate payment for ultrasound guidance for vascular access (CPT code 76937).

- We continue to urge CMS to reconsider its decision to classify new CPT codes, such as cardiac CT/CTA, directly into a New Technology APC, and urge the agency to establish a uniform practice of classifying new codes into a New Technology APC until accurate cost data can be collected.

I. PET and PET/CT

a. PET/CT

Philips is extremely concerned about CMS's proposal to reclassify PET/CT (CPT codes 78814, 78815, and 78816) into clinical APC 308. This reclassification is inconsistent with the August 6, 2006 recommendations of the APC Panel (recommendations 7 and 17), and with the recommendations of the Society of Nuclear Medicine, the Academy of Molecular Imaging, the Society of Nuclear Medicine, the National Electrical Manufacturers Association, and the Nuclear Medicine APC Task Force. Consistent with the recommendations of these groups, Philips urges CMS to keep CPT codes 78814, 78815 and 78816 in New Technology APC 1514, at a rate of $1250, for CY 2007.

We do not believe that CMS has adequate claims data from CY 2005 upon which to determine the median cost of performing PET/CT. The new PET/CT technology codes were introduced in January 2005. Therefore, the new APC assignment appears to be based on a full year or less of CMS claims data--a far shorter "track record" than the two year track record generally used before reclassification of a procedure from a New Technology to a permanent APC.

Moreover, the Proposed Rule would include stand-alone PET and PET/CT for tumor imaging in the same clinical APC. Lumping stand-alone PET and PET/CT into the same APC ignores the most basic principles underlying the APC system. Specifically, we understand that

procedures that are included in the same APC should be comparable both in terms of resource use and in terms of clinical utility. PET/CT uses different and more costly equipment, requires higher maintenance costs, and requires higher ongoing personnel and other operational expenditures than stand alone PET, and grouping stand alone PET and PET/CT in the same APC ignores these resource differences. Even more importantly, grouping PET/CT and stand alone PET in the same APC ignores the substantial clinical advantages of PET/CT over stand alone PET. The PET/CT scanner provides, in a single patient sitting, both the data to be expected from a high-end advanced spiral CT scanner and information recorded by a top of the range PET scanner, capable of depicting the distribution of positron-labeled tracers such as fluorodeoxyglucose (FDG). Routine image fusion is obtained, CT data being merged with PET data to aid in the exact localization of the site of FDG uptake. Several well-designed studies have demonstrated the benefits of PET/CT, and a number of these are summarized in Attachment A.

For these reasons, we request that CMS retain PET/CT (CPT codes 78814, 78815 and 78816) in New Technology APC 1514, at a rate of $1250, for CY 2007.

b. Other PET for Tumor Detection and Staging

CMS is proposing to classify all stand-alone PET services, including PET of the Brain and PET used for other tumor detection and staging, into a single APC. For the reasons set forth in the comments of the Nuclear Medicine APC Task Force, we do not believe that this proposal results in a clinically coherent APC or one that accurately groups procedures with comparable resource use. We urge CMS to adopt the recommendations of the Nuclear Medicine APC Task Force with respect to PET for tumor imaging and to refrain from grouping all of these procedures together.

c. Myocardial PET

Medicare payment for myocardial PET has been extremely unstable over the past two years. Specifically, CMS currently classifies myocardial PET into two APCs, depending on whether single or multiple studies are involved. This year, CMS proposes "lumping" single and multiple scans into a single APC, and reducing the Medicare payment for all myocardial PET scans to approximately $719.

Contrary to CMS's statements in the preamble to the Proposed Rule, it appears that there is insufficient claims data for single scans for CMS to conclude that single and multiple scans are appropriately classified into a single myocardial PET APC. The proposal to group single and multiple studies together is inconsistent with the APC classifications for other nuclear medicine procedures, which generally group such procedures into different levels, depending in part on whether single or multiple scans are provided. For this reason, we urge CMS to maintain two APCs for myocardial PET-- Level I for CPT 78459 and 78491, and Level II for CPT 78492.

We also note that the APC rates for myocardial PET have been extremely unstable over the past several years. In 2005, the APC rate for these procedures was approximately $735; in 2006, CMS (appropriately) established two separate APCs for myocardial PET, with rates of $800 for myocardial PET (single scan); and $2,487 for myocardial PET (multiple scans). Now, CMS is again proposing to substantially modify the APC classification and rates for these procedures. In light of the instability of payment for myocardial PET over the years, CMS should seek external data on the actual costs of providing this important service.

II. Other Comments related to Nuclear Medicine

We note that CMS is proposing to increase the "threshold" for separate payment of radiopharmaceuticals and other drugs from $50 to $55 and to use mean hospital cost data to establish payment allowances for radiopharmaceuticals. It is our understanding that both of these modifications are inconsistent with recommendations of the APC Advisory Panel Recommendation #19 (August, 2006) (recommending elimination of any threshold for separate payment for radiopharmaceuticals and other drugs); Recommendations 18 and 20 (urging CMS to continue current payment methodology for radiopharmaceuticals for CY 2007).

III. "Packaging" of Ultrasound Guidance for Vascular Access

Philips is concerned about the continued "packaging" of the code for ultrasound guidance for vascular access (CPT 76937) for 2007. AHRQ's June 2001 report entitled "Making Health Care Safer: A Critical Analysis of Patient Safety Practices"[1] cites the use of real-time ultrasound guidance of central venous catheter insertion to be one of the top 11 practices needed to improve patient safety. As observed in that report, and as verified by an independent claims analysis conducted by Direct Research and discussed at length in the comments submitted by the National Electrical Manufacturers Association (NEMA), the vast majority of central venous catheter insertions are not performed using ultrasound guidance. For this reason, the continued packaging of this service is clearly inappropriate, and separate payment for this important safety procedure should be allowed.

IV. Process for Classification of New CPT Codes

Last year, we expressed concern about CMS's classification of Level III CPT codes--which are used by the CPT to recognize emerging technologies--into permanent clinical APCs. Level III CPT codes are assigned for technologies that, by definition, require additional data collection; yet, last year, CMS has assigned a number of Level III CPT codes to clinical APCs. This trend has continued this year. We again request that CMS refrain from classifying new CPT codes--especially new Level III CPT codes--into permanent APCs until sufficient resource data

[1] Shojania KG, Duncan BW, McDonald KM, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43. (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

has been collected. In this regard, we are particularly concerned about the impact of premature classification of cardiac CT/CTA into APCs that do not reflect the significant post-processing costs involved in the provision of these services, and request that CMS revisit this issue.

We very much appreciate your consideration of these comments. If you have any questions, please do not hesitate to contact me at (978) 659-2972.

Sincerely yours,

Laurel Sweeney /BZ

Laurel Sweeney
Sr. Director, Reimbursement & Legislative Affairs

ATTACHMENT A

COMPARISON OF PET/CT WITH OTHER DIAGNOSTIC MODALITIES FOR TUMOR IMAGING: A SUMMARY OF THE CLINICAL LITERATURE

For the past 5 years, combined positron emission tomography (PET) and computed tomography (CT), or PET/CT, has grown because the PET portion provides information that is very different from that obtainable with other imaging modalities. However, the paucity of anatomic landmarks on PET images makes a consistent "hardware fusion" to anatomic cross-sectional data extremely useful. Clinical experience indicates a single direction: **Addition of CT to PET improves specificity foremost, but also sensitivity, and the addition of PET to CT adds sensitivity and specificity in tumor imaging. Thus, PET/CT is a more accurate test than either of its individual components** and is probably also better than side-by-side viewing of images from both modalities (Ref 1.). Fluorodeoxyglucose (FDG) PET/CT appears to provide relevant information in the staging and therapy monitoring of many tumors, including lung carcinoma, mesothelioma, colorectal cancer, lymphoma, melanoma, and many others, with the notable exception of prostatic cancer. For prostatic cancer, choline derivatives may become useful radiopharmaceuticals. The published literature on the applications of FDG PET/CT in oncology is still limited, but several well-designed studies have demonstrated the benefits of PET/CT. The following is a short list of some of the key papers:

When comparing the accuracy of tumor staging in solid tumors, **PET/CT proved significantly more accurate in assessing tumor-node-metastasis system stage compared with CT alone, PET alone, and side-by-side PET + CT** ($P < .0001$). Of 260 patients, 218 (84%; 95% CI, 79% to 88%) were correctly staged with PET/CT, 197 (76%; 95% CI, 70% to 81%) with side-by-side PET + CT, 163 (63%; 95% CI, 57% to 69%) with CT alone, and 166 (64%; 95% CI, 58% to 70%) with PET alone. Combined PET/CT had an impact on the treatment plan in 16, 39, and 43 patients when compared with PET + CT, CT alone, and PET alone, respectively (Ref 2.)

PET/CT imaging also increases the accuracy and certainty of locating lesions in **colorectal cancer. More definitely normal and definitely abnormal lesions (and fewer probable and equivocal lesions) were identified with PET/CT than with PET alone**. Staging and restaging accuracy improved from 78% to 89% in a study conducted by researchers at the Johns Hopkins Hospital (Ref 3.)

In staging of **non–small-cell lung cancer, integrated PET–CT provided additional information in 20 of 49 patients (41 percent), beyond that provided by conventional visual correlation of PET and CT** (Ref 4). Integrated PET–CT had better diagnostic accuracy than the other imaging methods. Tumor staging was significantly more accurate with integrated PET–CT than with CT alone (P=0.001), PET alone (P<0.001), or visual correlation of PET and CT (P=0.013); node staging was also significantly more accurate with integrated PET–CT than with PET alone (P=0.013). In metastasis staging, integrated PET–CT increased the diagnostic certainty in two of eight patients.

Diagnostic accuracy and impact on patient management with integrated PET/CT in **differentiated thyroid cancer** was studied in 40 patients (Ref 5). Diagnostic accuracy was 93% and 78% for PET/CT and PET, respectively (P = 0.049, per-patient analysis). In 17 (74%) of 23 patients with suspicious (18)F-FDG foci, **integrated PET/CT added relevant information to the side-by-side interpretation of PET and CT images by precisely localizing the lesion(s)**. In tumor-positive PET patients, PET/CT fusion by co-registration led to a change of therapy in 10 (48%) patients. Futile surgery was prevented in an additional 3 patients. Integrated PET/CT is able to improve diagnostic accuracy in a therapeutically

relevant way in patients with iodine-negative DTC. The authors concluded that by precisely localizing tumor tissue, **image fusion by integrated PET/CT is clearly superior to side-by-side interpretation of PET and CT images**.

The additional value of PET/CT over PET in FDG imaging of **oesophageal cancer** has been also demonstrated (Ref 6). PET/CT provided better specificity and accuracy than PET for detecting sites of oesophageal cancer (81% and 90% vs 59% and 83% respectively, $p < 0.01$). Fusion was of special value for interpretation of cervical and abdomino-pelvic sites, for disease assessment in loco-regional lymph nodes before surgery and in regions of postoperative anatomical distortion. PET/CT had an impact on the further management of four patients (10%), by detecting nodal metastases that warranted disease upstaging ($n = 2$) and by excluding disease in sites of benign uptake after surgery ($n = 2$). Authors concluded that **PET/CT improves the accuracy of FDG imaging in oesophageal cancer and provides data of diagnostic and therapeutic significance for further patient management**.

Combined PET/CT has been shown to be more accurate than PET or CT alone for the depiction of malignancy in the head and neck (Ref 7.). ROC analyses demonstrated that PET/CT is significantly superior to PET or CT alone for depiction of malignancy in the head and neck ($P < .05$). In this study, PET/CT had a sensitivity of 98%, a specificity of 92%, and an accuracy of 94%. Radiologist confidence was substantially higher with the combined modality.

References:

1. Integrated PET/CT: Current Applications and Future Directions. Gustav K. von Schulthess, MD, PhD, Department of Nuclear Medicine, University Hospital of Zurich, Radiology. 2006; 238(2):405-22

2. Accuracy of Whole-Body Dual-Modality Fluorine-18–2-Fluoro-2-Deoxy-D-Glucose Positron Emission Tomography and Computed Tomography (FDG-PET/CT) for Tumor Staging in Solid Tumors: Comparison With CT and PET. Gerald Antoch, Department of Diagnostic and Interventional Radiology, and Department of Nuclear Medicine, University Hospital Essen, Essen, Germany. J Clin Oncol. 2004; 22(21):4357-68

3. Direct Comparison of 18F-FDG PET and PET/CT in Patients with Colorectal Carcinoma Christian Cohade, MD, Medhat Osman, MD, PhD, Jeffrey Leal, BA and Richard L. Wahl, MD Division of Nuclear Medicine, Russell H. Morgan Department of Radiology and Radiological Sciences, Johns Hopkins Hospital, Baltimore, Maryland. Journal of Nuclear Medicine 2003 Vol. 44 No. 11 1797-1803

4. Staging of Non–Small-Cell Lung Cancer with Integrated Positron-Emission Tomography and Computed Tomography. Didier Lardinois, M.D. N Engl J Med. 2003; 348(25):2500-7

5. Integrated PET/CT in differentiated thyroid cancer: diagnostic accuracy and impact on patient management. Palmedo H, Department of Nuclear Medicine, University Hospital of Bonn. J Nucl Med. 2006; 47(4):616-24

6. The additional value of PET/CT over PET in FDG imaging of oesophageal cancer. Bar-Shalom R; Department of Nuclear Medicine, Rambam Medical Center, Haifa, Israel. Eur J Nucl Med Mol Imaging. 2005; 32(8):918-24

7. Head and neck malignancy: is PET/CT more accurate than PET or CT alone? Branstetter BF Departments of Radiology, University of Pittsburgh School of Medicine, Pittsburgh, USA. Radiology. 2005; 235(2):580-6

Submitter : **Date: 10/09/2006**

Organization :

Category : **Congressional**

Issue Areas/Comments

Medicare Contracting Reform
Impact

Medicare Contracting Reform Impact

I am a LMHC working in the field for over 6 years. Presently working in a PHP program faciliating groups on coping skills, relapse prevention, insight, goals, and stress to improve overall quaitly of life and wellbeing and I have seen the postive impact these services have on many patients. If funding continues to be cut many patients who are mentally ill and have limited income will continue to suffer and be in danger to themselves and their communities. With less money used for mental health services more money will be spent on incarceration and hospitlization due to relapse and lack of reliable support and services.

Submitter : **Date: 10/09/2006**

Organization :

Category : **Nurse**

Issue Areas/Comments

Medication Therapy Management Services

Medication Therapy Management Services

AS A NURSE IN AN OUTPATIENT CHF CLINIC, I WORK CLOSELY WITH A PHARM.D. AFTER ASSESSING THE PATIENT, ORDERS ARE OBTAINED FROM THE PHARM. D. PER THEIR CONSULTING AGREEMENT WITH THE REFERRING PHYSICIAN. THIS PHARM. D. ALSO RUNS THE COUMADIN CLINIC, ALONG WITH OTHER HOSPITAL PROJECTS. THE ROLE OF THE PHARM. D. IS EXTENSIVE IN THE MEDICATION MANAGEMENT OF THE CHF PATIENT. CONSEQUENTLY, OUR CHF READMISSION RATE IS EXTREMELY LOW. THEREFORE, I SUPPORT CONSIDERATION OF NEW APCs AND THEIR ASSOCIATED PAYMENT RATES.

Submitter : **Heide Bajnrauh** **Date: 10/09/2006**

Organization : **Arnold and Porter LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

Arnold and Porter LLP is submitting comments on behalf of the National Electrical Manufacturers Association (NEMA). For full description of comments, please see attachment.

CMS-1506-P-383-Attach-1.PDF

Setting Standards for Excellence

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Vice President, Medical Products

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October 6, 2006

Mark McClellan, M.D., Ph.D.
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RE: [CMS-1506-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Administrator McClellan:

The National Electrical Manufacturers Association (NEMA) is pleased to submit comments regarding proposed rule *Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates.*[1] As the leading trade association representing companies whose sales comprise over 90 percent of the global market for medical imaging, we appreciate the opportunity to provide our perspectives on the proposed rule to the Centers for Medicare and Medicaid Services (CMS).

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, nuclear medical imaging including positron emission tomography (PET) and magnetic resonance imaging (MRI). Imaging is used both to diagnose and treat patients with disease and offers physicians the ability to view soft tissue and organs, often reducing the need for costly and invasive medical and surgical procedures. With advanced medical imaging, physicians are able to perform a range of less-invasive, highly targeted medical therapies that translate into better and more comfortable care for patients.[2,3] This leads to convenience and easier access for patients increasing the likelihood they will get the tests, treatments and follow-up they need.[4]

Imaging has become a standard of modern care for virtually all major medical conditions and diseases, including cancer, stroke, heart disease, trauma, and abdominal and neurological conditions. That role is reflected in the reliance of physicians upon imaging in everyday practice and its prominence in physician-developed practice guidelines across a broad range of medical conditions. Because of its dependence by practicing physicians today as well as its substantiation for increasing health outcomes and

[1] 71 Fed. Reg. 49506 (August 23, 2006)

[2] Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., New England Journal of Medicine, Vol 352, No 17; pp1760-1768, April 28, 2005.

[3] "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." Jelinek, JS et al. *Radiology*. 223 (2002): 731 - 737.

[4] "Travel Distance to Radiation Therapy and Receipt of Radiotherapy Following Breast-Conserving Surgery", Athas WF, et. Al., *Journal of the National Cancer Institute*, Vol. 92, No. 3, February 2, 2000, pp. 269-271.

prolonging lives of beneficiaries, it is important for CMS to understand the detrimental effects being inflicted on imaging today.

NEMA's comments on the proposed rule are organized below under the headings that CMS asked commenters to use.

I. APC Relative Weights

a. Proposed Use of Single versus Multiple Procedure Claims

NEMA appreciates the Agency's efforts to increase the accuracy of the APC relative payment weights by including multiple procedure claims data. However, we have concerns about an aspect of the methodology used to provide the single claims needed for analysis. In particular, we are concerned that the increasing prevalence of imaging codes on the bypass list will undervalue the APC's to which those codes are assigned.

Underpayment has occurred historically for a number of device-related APCs due, in part, to under-estimation of costs deriving from CMS's single and "pseudo" single procedure claims rate-setting methodology. This concern has been particularly acute for procedures routinely performed in combination with other procedures, such as the case with some imaging studies, whose costs are often reported on multiple procedure claims, and thus not reflected under the single claims methodology. As CMS recognizes, this undermines calculation of the aggregate utilization rate of such technologies, as well as the estimation of associated costs, leading to chronic underpayment for selected procedures. NEMA encourages CMS to continue refining its methodologies for setting these payment rates in order to maximize accuracy in capturing utilization and costs associated with multiple procedure claims for payment purposes. Specifically, NEMA urges CMS to validate its current methodology, which relies on single procedure claims, to make sure that the costs of imaging are not systematically understated. We urge that CMS consider reviewing costs in benchmark hospitals as one means to make this validation.

II. Packaged Services

NEMA offers the following specific comment regarding the continuance of packaged services of CPT[5] code +76937 for 2007. This code is used to report the use of ultrasound guidance for vascular access. AHRQ's June 2001 report entitled "Making Health Care Safer: A Critical Analysis of Patient Safety Practices"[6] cites the use of real-time ultrasound guidance of central venous catheter insertion to be one of the top 11 practices needed to improve patient safety. Yet the report also indicates that "The majority of central venous catheter (CVC) insertions are placed using the landmark method" - meaning that no ultrasound guidance is used - resulting in unsuccessful insertion in up to 20 percent of cases. These so-called "blind insertions" have significantly higher rates of serious complications such as arterial puncture, hematoma, pneumothorax, and infection. Additionally, inaccurate needle-sticks ultimately lead to longer hospital stays which in turn increase hospital costs and endanger patients' lives.[7]

In support of the contention that ultrasound guidance is not frequently used with the placement of central venous catheters, we would like to report on an analysis done by Christopher Hogan, Ph.D. of

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[5] CPT® codes and descriptions are copyright 2005 American Medical Association

[6] "Making Health Care Safer: A Critical Analysis of Patient Safety Practices." Shojania KG, Duncan BW, McDonald KM, et al., eds. Evidence Report/Technology Assessment No. 43. (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

[7] "Ultrasonic Locating Devices for Central Venous Cannulation: Meta-Analysis," Daniel Hind, et al, *The British Medical Journal*, Volume 327, 16 August 2003

Direct Research LLC. In September of 2005, Dr. Hogan analyzed the claims file that CMS released with the 2006 OPPS proposed rule to determine the level of utilization of +76937 under OPPS in 2004.

The results of this data analysis showed for those vascular access procedures that +76937 can be used with, CPT codes 36555 to 36585, CPT code +76937 was reported an average of 14 percent of the time with the greatest utilization rate no more than 25 percent. The data confirms that it is currently not the "typical" practice to use ultrasound to guide vascular access procedures.

HCPCS	Label	APC for this HCPCS	Count of claims lines for this HCPCS	Percent of vasc. access claims with +76937	Number of claims with +76937	
36555	Insert non-tunnel cv cath	0621	234	**6%**	14	
36556	Insert non-tunnel cv cath	0621	19,589	**15%**	2,954	
36557	Insert tunneled cv cath	0622	216	**18%**	39	
36558	Insert tunneled cv cath	0622	26,230	**23%**	6,111	
36560	Insert tunneled cv cath	0623	93	**17%**	16	
36561	Insert tunneled cv cath	0623	48,814	**10%**	4,747	
36563	Insert tunneled cv cath	0623	558	**4%**	24	
36565	Insert tunneled cv cath	0623	3,205	**6%**	190	
36566	Insert tunneled cv cath	1564	606	**7%**	40	
36568	Insert tunneled cv cath	0621	246	**18%**	44	
36569	Insert tunneled cv cath	0621	30,561	**25%**	7,516	
36570	Insert tunneled cv cath	0622	37	**8%**	3	
36571	Insert tunneled cv cath	0622	14,395	**6%**	836	
36575	Repair tunneled cv cath	0621	1,218	**0%**	3	
36576	Repair tunneled cv cath	0621	563	**0%**	2	
36578	Replace tunneled cv cath	0622	924	**1%**	9	
36580	Replace tunneled cv cath	0621	2,265	**2%**	49	
36581	Replace tunneled cv cath	0622	9,075	**2%**	200	
36582	Replace tunneled cv cath	0623	1,265	**2%**	27	
36583	Replace tunneled cv cath	0623	122	**1%**	1	
36584	Replace tunneled cv cath	0621	2,065	**4%**	80	
36585	Replace tunneled cv cath	0622	341	**2%**	8	
		Total	**162,622**		**22,913**	**14%**

In light of this information, in order to help encourage the use of this important safety practice, NEMA requests that CMS assign a status indicator of "S" to CPT code +76937 and assign it to APC 0268 - Ultrasound Guidance Procedures.

III. New Technology APCs

a. Proposed Movement of Procedures From New Technology APCs to Clinical APCs

In the November 30, 2001 Final Rule[8], CMS finalized the time period for which a service was eligible for payment under a New Technology APC. Based on this decision, new technologies were to remain in this category until sufficient claims were gathered to determine assignment of an appropriate

[8] 66 Fed. Reg. 59903 (November 20, 2001)

Clinical APC category. This prospective payment system was created based on the principles that services and procedures should be grouped based on an important degree of homogeneity in both clinical terms and in associated input costs and resource use.

NEMA believes that certain technologies should be assigned to New Technology APCs and remain in that category until CMS has collected sufficient data to make accurate determinations of those technologies costs. Only after those determinations can be made should those technologies be moved to a clinical APC designation. Generally, the assignment of a technology to a New Technology APC should be for more than one year, given the lack of consistency in the manner by which hospitals report costs.

Because APCs are updated quarterly, it can be difficult and time-consuming for hospitals to update their chargemasters, as well as train billing staff on all new coding procedures for Medicare claims. Because of this prolonged effort, often times hospitals incorrectly bill for certain procedures, which in turn affects decisions made by CMS for assignment of new technologies into appropriate APC clinical categories.

In addition, it takes some time for new technologies to diffuse through the healthcare system and for an accurate picture to emerge regarding the utilization and associated resources of the new technology. For these reasons, we think it is important for CMS to provide a sufficient grace period under the New Technology APC. This period helps to ensure development of a claims-based evidentiary record leading to the most appropriate long-term APC assignment decision.

Unfortunately, this has not always been the case for some new technologies that have received Category I or III CPT codes. Upon notice of assignment of a new code, CMS has assigned these technologies straight to clinical APCs. Prior to receiving a new Category I or III CPT code, procedures are coded with unlisted or miscellaneous codes. Per CMS criteria, claims including unlisted codes are dismissed from use for calibrating APC relative weights. It is not possible for CMS to have the complete information necessary (including claims reflecting this) to assign these procedures to an appropriate APC category. Based on this, it is not possible to obtain sufficient claims data for proper APC category placement.

NEMA urges CMS to reconsider movement of the following procedures into categories that will create economic disincentives for use and in turn limit patient access. In addition, we request that CMS consider a better specified process for ensuring the appropriate and consistent APC assignment of new technology services. We offer the following technology-specific comments.

b. Proposed Payment Rates for PET/CT Scans

The technologies of positron emission tomography (PET) and computed tomography (CT) have been combined in a single multimodality detection instrument. The PET/CT scanner provides, in a single patient sitting, both the data to be expected from a high-end advanced spiral CT scanner and information recorded by a top of the range PET scanner, capable of depicting the distribution of positron-labelled tracers such as fluorodeoxyglucose (FDG). Routine image fusion is obtained, CT data being merged with PET data to aid in the exact localization of the site of FDG uptake. CT information is also used for the purpose of attenuation correction, which is now almost instantaneous; as a consequence, whole-body PET/CT studies can be obtained in less than 15 min. This has led to an increase in patient acceptance and throughput (30 percent over that achieved with PET alone).[9]

For the past 5 years, combined positron emission tomography (PET) and computed tomography (CT), or PET/CT, has grown because the PET portion provides information that is very different from that

[9] "The contribution of PET/CT to improved patient management." P J Ell, FMedSci, FRCP, FRCR Institute of Nuclear Medicine, UCL, London, UK, British Journal of Radiology (2006) 79, 32-36

obtainable with other imaging modalities. However, the paucity of anatomic landmarks on PET images makes a consistent "hardware fusion" to anatomic cross-sectional data extremely useful. Clinical experience indicates a single direction: Addition of CT to PET improves specificity foremost, but also sensitivity, and the addition of PET to CT adds sensitivity and specificity in tumor imaging. Thus, PET/CT is a more accurate test than either of its individual components and is probably also better than side-by-side viewing of images from both modalities.[10] Fluorodeoxyglucose (FDG) PET/CT appears to provide relevant information in the staging and therapy monitoring of many tumors, including lung carcinoma, mesothelioma, colorectal cancer, lymphoma, melanoma, and many others, with the notable exception of prostatic cancer. The published literature on the applications of FDG PET/CT in oncology is still limited, but several well-designed studies have demonstrated the benefits of PET/CT.[11]

PET/CT scans has emerged as one of the most important technologies used for the management of patients with cancer. Because of the enhanced images received, physicians are able to pinpoint tumor position and detect cancer cells often well before they are visible. Patients benefit from PET/CT scans through earlier diagnosis, more accurate staging, more precise treatment planning and improved monitoring of therapy. In 2004, PET/CT was a new technology with no established codes. This technology was granted three separate CPT codes by the American Medical Association (AMA) and in March 2005, CMS assigned these codes to New Technology APC 1514.

In the 2007 proposed rule, CMS states there is adequate claims data for CPT codes 78814, 78815, and 78816 to move from the New Technology APC 1514 (New Technology- Level XIV, $1,200-$1,300) to a "clinically appropriate" APC (proposed APC 0308, $865.30). This represents a 30 percent decrease in payment, far below the true costs of providing this service. NEMA strongly disagrees with this proposed decision. PET/CT is an enhanced technology that is not comparable to PET or CT scans alone. CMS is obligated to place CPT® codes in categories that are similar clinically, as well as on the basis of average resource use. CMS currently does not have accurately reported claims data to justify movement of these new technologies into an existing clinical APC.

IV. APC-Specific Policies

a. Proposed Payment Rates for CT and CTA

CT Angiography (CTA) displays the vasculature of a patient in a three-dimensional format enabling a wide variety of clinical uses and benefits. The procedure itself consists of a conventional CT scan, combined with sophisticated three-dimensional post processing to render images of arterial and venous vasculature. This ground-breaking procedure offers precise visualization of clogged arteries without use of invasive catheters.[12]

NEMA is concerned regarding the proposed payment levels for CTA procedures (APC 662, $302.85). CTA procedures continue to be reimbursed at a lower rate than conventional CT procedures, although the resource costs of CTA consistently exceed conventional CT.

Inaccurate CTA claims data coupled with CMS methodological issues involving application of cost-to-charge ratios for procedures introduced after 2001, have resulted in an APC payment rate for CTA procedures that is significantly below that for CT procedures alone. Emerging technology, such as CTA,

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[10] "Integrated PET/CT: Current Applications and Future Directions." Gustav K. von Schulthess, MD, PhD, Department of Nuclear Medicine, University Hospital of Zurich, Radiology. 2006; 238(2):405-22

[11] Please see Addendum A for a list of peer-reviewed literature and showcasing the importance of PET/CT.

[12] "Roles of Nuclear Cardiology, Cardiac Computed Tomography, and Cardiac Magnetic Resonance: Assessment of Patients with Suspected Coronary Artery Disease," Berman, DS, et. al., *Journal of Nuclear Medicine*, V 47, No 1, January 2006, pp. 74-82. Also see "How New Heart-Scanning Technology Could Save Your Life," by Christine Gorman and Alice Park, *Time*, Sept 5, 2005, pp. 58-71.

needs time to become integrated into the healthcare system and in all sites of service that it is available. To accurately understand the implications of emerging technology, a "waiting period" should be put in place to fully comprehend the cost-effectiveness of these technologies as they replace more costly older technology and promote health outcomes leading to better quality of life for Medicare beneficiaries.

We continue to urge CMS to set reimbursement for CTA procedures at a level at least on parity with the sum of that of the CT APC payment, plus the post processing APC payment. This may be accomplished by adjusting upward the payment rate for APC 662, or alternatively assigning CTA procedures to an existing APC that more closely reflects the resource costs of performing this service.

b. Proposed Payment Rates for Myocardial PET Scans

NEMA believes that CMS's proposal to assign multiple myocardial PET scans to the same APC as single myocardial PET scans will significantly underpay providers for multiple scanning procedures. Multiple scans require greater hospital resources, as well as longer scan times, than single scans. CMS currently divides these PET scans (single and multiple) into two separate APCs paid at $800.55 and $2,484.88, respectively. The placement of both single and multiple PET scans into one APC (APC 0307, $721.26) will cause an onset of dramatic declines in payment for these facilities. In addition, this provision of combining single and multiple scans is inconsistent with other APC classifications for nuclear medicine procedures, which often group such procedures into different classification levels based on the same criteria.

CMS also indicated in the proposed rule that the 2005 claims data show a reduction in costs for multiple PET scans. Over the past years, reimbursement for myocardial PET scans has been in a state of fluctuation. In 2005, the APC rate for these procedures was approximately $735; in 2006 CMS created two separate APC classifications as noted above. In light of the wavering of payment for this procedure, and its APC classification status, this illustrates the need for sound long-term data to confirm true costs. NEMA recommends that CMS should retain the current APC assignment and relative payment weights for single and multiple studies in CY 2007. This approach would provide for the capture of more accurate claims data for these procedures in order to establish more appropriate APC assignment in CY 2008.

V. Radiology Procedures

a. Multiple Imaging Payment Reduction Policy

NEMA agrees with the APC Panel[13] to postpone implementation of the multiple procedure reduction policy for imaging services to allow CMS to gather more data on the efficiencies associated with multiple imaging procedures that may already be reflected in OPPS payment rates for imaging services. We commend CMS for following the APC panel's recommendation to continue collecting data regarding this issue.

VI. Radiopharmaceuticals

CMS is proposing to increase the threshold for separate payment for radiopharmaceuticals and other drugs from $50 to $55 and to use mean hospital cost data to establish payment allowances for radiopharmaceuticals. It is important to mention these policies are inconsistent with the recommendations provided by the APC Advisory Panel.[14] NEMA asks CMS maintain the threshold for separate payment at $50. On a separate note, we do agree with CMS to continue to pay for fluorodeoxyglucose (FDG) separately as this would significantly impact the reimbursement for the APCs which it is associated.

[13] APC Advisory Panel Recommendation (March, 2006)

[14] APC Advisory Panel Recommendation #19 (August, 2006)

VII. Ancillary Outpatient Services

a. Addition of Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)

NEMA takes pride in the fact that we represent manufacturers that produce products which provide high-quality, cost-effective, and clinically-proven screening machines, providing physicians with superior tools for early disease detection. In the past, abdominal aortic aneurysms were rarely identified until they ruptured and patients died. Today, physicians are able to utilize ultrasound scans to detect these life-threatening aneurysms reducing the risk of death by more than 40 percent.[15] We thank CMS for its proposals offering appropriate and reasonable coverage and payment for a preventive service that will save beneficiaries' lives. We also appreciate the proposal to evaluate future coverage considerations through the NCD process.

VIII. Conclusion

NEMA respects the importance and necessity of implementing sound fiscal healthcare policies. With healthcare budgets under continuous pressure, effective treatments are paramount to payers, providers and patients. Our goal is to ensure that Medicare beneficiaries retain access to the significant clinical benefits of high-quality imaging products and services.

We ask CMS to develop policy decisions intended to recognize that much of the growth within the imaging environment emerges from the off-setting savings created by these innovative procedures-through less-invasive care, quicker recovery and fewer complications and are often overlooked in assessments of growth in imaging spending. A better approach to managing this heightened utilization is to rely upon sound evidence and practice guidelines developed by physician groups so proper standards are in place. Imaging advocacy groups, such as NEMA, also feel it is necessary to instill guidelines to promote proper equipment maintenance and utilization. NEMA looks forward to sharing its ideas with CMS in the upcoming months. Finally, we urge CMS to look to the future, as developments in molecular, cellular, functional and genetic imaging promise a new era of prediction and prevention of disease, not just diagnosis and treatment.[16]

We strive to continue working with CMS on these matters under the hospital outpatient prospective payment system. If you have any questions or would like to discuss these matters further, please contact me at 703-841-3279.

Respectfully Submitted,

Andrew Whitman
Vice President, Medical Products

CC: Carol Bazell, MD

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[15] "Screening for Abdominal Aortic Aneurysm: A Best-Evidence Systematic Review for the U.S. Preventive Services Task Force," Fleming C, Whitlock EP, Beil TL, Lederle FA; *Annals of Internal Medicine*, Feb 2005, Vol 142, No 3; 203-211. Also, "Screening for Abdominal Aortic Aneurysm: Recommendation Statement, U.S. Preventive Services Task Force, *Annals of Internal Medicine,* Feb 2005, Vol 142, No 3; 198-202.

[16] "Advances in Biomedical Imaging," Tempany MC, McNeil BJ, *Journal of the American Medical Association,* 2001, Vol. 285: 562-567

Addendum A

Clinical Value of PET/CT over Dedicated PET

Piotr Maniawski MS, Senior Manager,
PET/CT Clinical Science, Philips Medical Systems

Clinical Value of PET/CT over Dedicated PET

Piotr Maniawski MS, Senior Manager, PET/CT Clinical Science, Philips Medical Systems

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The technologies of positron emission tomography (PET) and computed tomography (CT) have been combined in a single multimodality detection instrument. The PET/CT scanner provides, in a single patient sitting, both the data to be expected from a high-end advanced spiral CT scanner and information recorded by a top of the range PET scanner, capable of depicting the distribution of positron-labelled tracers such as fluorodeoxyglucose (FDG). Routine image fusion is obtained, CT data being merged with PET data to aid in the exact localization of the site of FDG uptake. CT information is also used for the purpose of attenuation correction, which is now almost instantaneous; as a consequence, **whole-body PET/CT studies can be obtained in less than 15 min. This has led to an increase in patient acceptance and throughput (30% over that achieved with PET alone)** (Ref. 1).

For the past 5 years, combined positron emission tomography (PET) and computed tomography (CT), or PET/CT, has grown because the PET portion provides information that is very different from that obtainable with other imaging modalities. However, the paucity of anatomic landmarks on PET images makes a consistent "hardware fusion" to anatomic cross-sectional data extremely useful. Clinical experience indicates a single direction: **Addition of CT to PET improves specificity foremost, but also sensitivity, and the addition of PET to CT adds sensitivity and specificity in tumor imaging. Thus, PET/CT is a more accurate test than either of its individual components** and is probably also better than side-by-side viewing of images from both modalities (Ref 2.). Fluorodeoxyglucose (FDG) PET/CT appears to provide relevant information in the staging and therapy monitoring of many tumors, including lung carcinoma, mesothelioma, colorectal cancer, lymphoma, melanoma, and many others, with the notable exception of prostatic cancer. For prostatic cancer, choline derivatives may become useful radiopharmaceuticals. The published literature on the applications of FDG PET/CT in oncology is still limited, but several well-designed studies have demonstrated the benefits of PET/CT. The following is a short list of some of the key papers:

When comparing the accuracy of tumor staging in solid tumors, **PET/CT proved significantly more accurate in assessing tumor-node-metastasis system stage compared with CT alone, PET alone, and side-by-side PET + CT** ($P < .0001$). Of 260 patients, 218 (84%; 95% CI, 79% to 88%) were correctly staged with PET/CT, 197 (76%; 95% CI, 70% to 81%) with side-by-side PET + CT, 163 (63%; 95% CI, 57% to 69%) with CT alone, and 166 (64%; 95% CI, 58% to 70%) with PET alone. Combined PET/CT had an impact on the treatment plan in 16, 39, and 43 patients when compared with PET + CT, CT alone, and PET alone, respectively (Ref 3.)

PET/CT imaging also increases the accuracy and certainty of locating lesions in **colorectal cancer. More definitely normal and definitely abnormal lesions (and fewer probable and equivocal lesions) were identified with PET/CT than with PET alone.** Staging and restaging accuracy improved from 78% to 89% in a study conducted by researchers at the Johns Hopkins Hospital (Ref 4.)

In staging of non–small-cell lung cancer, integrated PET–CT provided additional information in 20 of 49 patients (41 percent), beyond that provided by conventional visual correlation of PET and CT (Ref 5). Integrated PET–CT had better diagnostic accuracy than the other imaging methods. Tumor staging was significantly more accurate with integrated PET–CT than with CT alone (P=0.001), PET alone (P<0.001), or visual correlation of PET and CT (P=0.013); node staging was also significantly more accurate with integrated PET–CT than with PET alone (P=0.013). In metastasis staging, integrated PET–CT increased the diagnostic certainty in two of eight patients.

Diagnostic accuracy and impact on patient management with integrated PET/CT in differentiated thyroid cancer was studied in 40 patients (Ref 6). Diagnostic accuracy was 93% and 78% for PET/CT and PET,

respectively (P = 0.049, per-patient analysis). In 17 (74%) of 23 patients with suspicious (18)F-FDG foci, integrated PET/CT added relevant information to the side-by-side interpretation of PET and CT images by precisely localizing the lesion(s). In tumor-positive PET patients, PET/CT fusion by co-registration led to a change of therapy in 10 (48%) patients. Futile surgery was prevented in an additional 3 patients. Integrated PET/CT is able to improve diagnostic accuracy in a therapeutically relevant way in patients with iodine-negative DTC. The authors concluded that by precisely localizing tumor tissue, image fusion by integrated PET/CT is clearly superior to side-by-side interpretation of PET and CT images.

The additional value of PET/CT over PET in FDG imaging of **oesophageal cancer** has been also demonstrated (Ref 7). PET/CT provided better specificity and accuracy than PET for detecting sites of oesophageal cancer (81% and 90% vs 59% and 83% respectively, $p < 0.01$). Fusion was of special value for interpretation of cervical and abdomino-pelvic sites, for disease assessment in loco-regional lymph nodes before surgery and in regions of postoperative anatomical distortion. PET/CT had an impact on the further management of four patients (10%), by detecting nodal metastases that warranted disease upstaging (n = 2) and by excluding disease in sites of benign uptake after surgery (n = 2). Authors concluded that **PET/CT improves the accuracy of FDG imaging in oesophageal cancer and provides data of diagnostic and therapeutic significance for further patient management.**

Combined PET/CT has been shown to be more accurate than PET or CT alone for the depiction of malignancy in the head and neck (Ref 8.). ROC analyses demonstrated that PET/CT is significantly superior to PET or CT alone for depiction of malignancy in the head and neck ($P < .05$). In this study, PET/CT had a sensitivity of 98%, a specificity of 92%, and an accuracy of 94%. Radiologist confidence was substantially higher with the combined modality.

References:

1. The contribution of PET/CT to improved patient management. P J Ell, FMedSci, FRCP, FRCR Institute of Nuclear Medicine, UCL, London, UK, British Journal of Radiology (2006) 79, 32-36
2. Integrated PET/CT: Current Applications and Future Directions. Gustav K. von Schulthess, MD, PhD, Department of Nuclear Medicine, University Hospital of Zurich, Radiology. 2006; 238(2):405-22
3. Accuracy of Whole-Body Dual-Modality Fluorine-18–2-Fluoro-2-Deoxy-D-Glucose Positron Emission Tomography and Computed Tomography (FDG-PET/CT) for Tumor Staging in Solid Tumors: Comparison With CT and PET. Gerald Antoch, Department of Diagnostic and Interventional Radiology, and Department of Nuclear Medicine, University Hospital Essen, Essen, Germany. J Clin Oncol. 2004; 22(21):4357-68
4. Direct Comparison of 18F-FDG PET and PET/CT in Patients with Colorectal Carcinoma Christian Cohade, MD, Medhat Osman, MD, PhD, Jeffrey Leal, BA and Richard L. Wahl, MD Division of Nuclear Medicine, Russell H. Morgan Department of Radiology and Radiological Sciences, Johns Hopkins Hospital, Baltimore, Maryland. Journal of Nuclear Medicine 2003 Vol. 44 No. 11 1797-1803
5. Staging of Non–Small-Cell Lung Cancer with Integrated Positron-Emission Tomography and Computed Tomography. Didier Lardinois, M.D. N Engl J Med. 2003; 348(25):2500-7
6. Integrated PET/CT in differentiated thyroid cancer: diagnostic accuracy and impact on patient management. Palmedo H, Department of Nuclear Medicine, University Hospital of Bonn. J Nucl Med. 2006; 47(4):616-24
7. The additional value of PET/CT over PET in FDG imaging of oesophageal cancer. Bar-Shalom R; Department of Nuclear Medicine, Rambam Medical Center, Haifa, Israel. Eur J Nucl Med Mol Imaging. 2005; 32(8):918-24
8. Head and neck malignancy: is PET/CT more accurate than PET or CT alone? Branstetter BF Departments of Radiology, University of Pittsburgh School of Medicine, Pittsburgh, USA. Radiology. 2005; 235(2):580-6

Submitter : Mr. Travis Gay **Date: 10/09/2006**

Organization : Mills Biopharmaceuticals

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

October 3, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

Mills Biopharmaceuticals, Inc. is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

Located in Oklahoma City, Oklahoma, Mills Biopharmaceuticals manufactures brachytherapy seeds used to treat patients diagnosed with cancer. The company is dedicated to providing innovative delivery technologies to the health care community. Mills Biopharmaceuticals appreciates the opportunity to submit comments to CMS regarding the proposed payment for Brachytherapy sources.

Payment Methodology for Brachytherapy Sources
We believe that it would be inappropriate to implement a new payment system for 2007 that would establish set payment rates for brachytherapy sources based upon median costs. The variations in cost of each source require a unique payment methodology for radioactive sources.

The CMS claims data shows large variations in per unit cost reported (see table below) on claims across hospitals, which further validates the concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2007.

HCPCS and Description Variation of Cost per Unit (2005 Hospital Claims)
C1716 Gold-198 $3 - 943
C1717 HDR Iridium-192 $0 4,746
C1718 Iodine-125 $0 - 14,632
C1719 Non-HDR Iridium-192 $3 1,761
C1720 Palladium-103 $0 - 20,825
C2616 Yttrium-90 $1,676 - 62,071
C2632 Iodine-125 solution $0 7,253
C2633 Cesium-131 $28 - 15,797
C2634 High Activity Iodine-125 $2 4,526
C2635 High Activity Pd-103 $3 5,212
C2636 Linear Palladium-103 $0 -1,690

The recommended payment methodology will not appropriately capture the variation of brachytherapy source configurations. We urge CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device.

Mills Biopharmaceuticals recommends that CMS continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices. This recommendation also was made by the APC panel at the August 24, 2006 meeting and the PPAC on August 26, 2006.

High Activity Brachytherapy Sources
The data used by CMS to establish proposed payment rates for high activity iodine and palladium sources for 2007 (see table below) shows a huge variation in per unit cost reported on claims by hospitals across the county. This variation validates our concern regarding the data that CMS is using to establish payment rates for fiscal year 2007.

HCPCS and Descriptor Variation of Cost per Unit
(2005 Hospital Claims)
C2634 High Activity Iodine-125 $2 - $4,526
C2635 High Activity Palladium-103 $3 - $5,212

In addition to the variations in cost reported by the data, high activity source proposed payment rates have been established based upon claims data from a small

number of hospitals. A combination of data from the manufacturers that supply high activity iodine sources indicates that approximately 112 hospitals across the country ordered high activity sources in 2005. The data reflects information based upon less than 50% of these hospitals.

HCPCS and Descriptor Hospitals Reporting
(2005 Hospital Claims)
C2635 High Activity Palladium-103 20
C2634 High Activity Iodine-125 50

CMS data outlined in the table below indicates rank order anomalies in proposed payments for high activity brachytherapy devices. High Activity Iodine-125 sources (C2634) always cost more than low activity sources (C1718). T

Submitter : **Mr. Nick Poulios** **Date: 10/09/2006**

Organization : **Elan Pharmaceuticals, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-385-Attach-1.DOC

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October 10, 2006

Honorable Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: OPPS-1506-P, "Pass Through Drugs" and "OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"

Dear Dr. McClellan:

On behalf of Elan Corporation, plc ("Elan"), I want to thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Notice of Proposed Rulemaking (NPRM) regarding changes to the Hospital Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2007 (the "Proposed Rule"). Elan is mindful of the considerable resources that the Agency has dedicated to developing the Proposed Rule and appreciates the opportunity to comment.

We urge CMS to consider our recommendations to clarify Section V.A. "Proposed Transitional Pass-Through Payment for Additional Costs of Drugs and Biologicals" as summarized below:

- CMS should update its pricing file for TYSABRI® (natalizumab injection), Q4079, to include the current Wholesale Acquisition Cost (WAC) plus 6 percent payment rate of $7.72 per mg.
- CMS should reimburse separately paid, unbundled drugs and biologicals equally in 2007 and beyond, irregardless of the drug or biological's pass-through status

BACKGROUND

Elan is a neuroscience-based biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies to treat neurologic disorders, autoimmune diseases (including monoclonal antibodies) and severe pain.

On June 5, 2006, the US Food and Drug Administration (FDA) approved a Supplemental Biologicals License Application (sBLA) for the reintroduction of TYSABRI (natalizumab) as monotherapy treatment for relapsing forms of multiple sclerosis (MS).

We are pleased to be able to once again offer TYSABRI for appropriate MS patients, who must meet and comply with the requirements of our special distribution and risk management program called the TOUCH™ Prescribing Program. TYSABRI is one of the nine drugs and biologicals granted Pass-Through status for CY 2007.

COMMENTS TO THE PROPOSED RULE

Pass-Through Drugs

Update Current Payment Rate for TYSABRI

The Proposed Rule states that the Final Rule will include the **most recent pricing information,** including appropriate WAC based payment for new drugs. Addenda A and B of the Proposed Rule contain the OPPS proposed payments by HCPCS codes for CY 2007. In this list the payment rate for TYSABRI Q4079 (natalizumab injection) is listed as $6.39 per mg. This value is not reflective of the current October 2006 WAC plus 6 percent value that was recently published in the October OPPS and ASP pricing files. **The price that is currently listed for TYSABRI in the October OPPS Pricing file is $7.72[1] per mg.**

We urge CMS to update this value in publication of the Final Rule to reflect the policy of paying for Pass-Through drugs at WAC plus 6 percent[2]. Publication of the accurate reimbursement rate for TYSABRI should eliminate payment variations and create uniform payments across carriers.

OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals

Consistent Payment for High Cost Drugs and Biologicals

In the absence of an expedited HCPCS coding process that would accommodate assignment of a permanent and product specific HCPCS code prior to the first day of each calendar year, Elan supports the assignment of temporary HCPCS "pass-through" codes for drugs that meet the current criteria for pass-through payment. We support this process to facilitate billing and timely payment in the hospital outpatient setting. However, when it comes to setting payment rates for certain drugs and biologicals that are not bundled, CMS should not establish different payment methodologies based on whether or not the drug retains pass-through status. Elan, therefore, urges CMS not to adopt the current proposal of reducing the payment rate for drugs that lose pass-through status from ASP plus 6 percent to ASP plus 5 percent in 2007 and in future years.

CONCLUSION

We are pleased to offer a novel product like TYSABRI to individuals suffering from a debilitating disease such as MS. We urge CMS to take our recommendations into consideration in order to provide appropriate access to Medicare beneficiaries. By providing consistent and stable payment methodologies between settings of care, CMS will help ensure beneficiary access and prevent shifts in site of service.

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[1] Updated WAC for TYSABRI, effective June 10, 2006 is $7.28 per mg.

[2] Payment for drugs that do not have a full quarter's worth of ASP data will be paid at WAC+6% until the Average Sales Price has been established.

We appreciate the opportunity to comment on this Proposed Rule and hope our recommendations help you structure the Final Rule. If you have any questions, please feel free to contact me at 858-320-7681.

Sincerely,

Nick Poulios, PhD
Vice President, Reimbursement
Elan Pharmaceuticals

Submitter : Dr. John J. Munro III **Date:** 10/09/2006

Organization : Source Production & Equipment Co., Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-386-Attach-1.PDF

#356

spec

October 6, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

Source Production & Equipment Co., Inc. is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

This comment letter specifically addresses the proposed payment methodology for Ytterbium-169 brachytherapy sources in 2007 and the rationale for recommending the current payment methodology of hospital charges reduced to costs be continued.

Source Production & Equipment Co., Inc. was incorporated in 1974 and develops and manufactures technology for industrial nondestructive testing and medical device industries. The Company also develops, manufactures and sells radioactive products for the treatment of cancer, including high dose rate Iridium-192 sources for the treatment of a variety of cancers and is a contract manufacturer for a new, FDA approved radioactive source, Ytterbium-169.

Ytterbium-169 (C2637)

Ytterbium-169 is a High Dose Rate (HDR) brachytherapy source and has been approved by the FDA in 2005. As required by the MMA, CMS assigned a HCPCS code for Ytterbium so hospitals could appropriately report the cost of the source to CMS. This source will be available in 2007 and we understand that CMS does not have hospital claims data to determine an appropriate cost for Ytterbium-169.

CMS considered four (4) options in establishing payment for Ytterbium-169. CMS proposes to assign Ytterbium-169 (C2637) to its own APC with a payment rate set at or near the lowest proposed payment rate for any brachytherapy source paid on a per source basis (Option 2).

Ytterbium-169 is a HDR source with unique characteristics and differences in application than other sources. As a high dose rate source used for temporary brachytherapy, this source would be used for a number of patients, similar to the use of Iridium-192 HDR sources. Ytterbium-169 (C2637) has a shorter half-life than HDR Iridium-192 (C1717) and requires source replacement every 32 days vs. 90 days for HDR Iridium-192. In addition, Ytterbium-169 requires different shielding and has a unique target activity compared to HDR Iridium-192. Most importantly, the physical characteristics of Ytterbium-169 are expected to provide certain specific clinical advantages over the currently-used Iridium-192.

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Since there are no other sources that are comparable to this new brachytherapy source, the most appropriate payment methodology for Ytterbium-169, and any new brachytherapy source, would be to establish a charge reduced to cost (CCR) methodology in order to collect cost data from hospitals. This option would be similar to the CMS policy for New Technology APCs.

Source Production & Equipment Co., Inc. recommends that CMS adopt Option 1 proposed by CMS and reimburse Ytterbium-169 (C2637) at charges adjusted to cost, consistent with the payment methodology that should be used for all brachytherapy sources.

Conclusion

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care. Payment as proposed by CMS in the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule would effectively eliminate the use of Ytterbium-169 from the arsenal available to physicians.

Thank you for your consideration of these important issues.

Sincerely,

John J. Munro III, Ph.D.
Vice President

Submitter : **Ms. Irene Plenefisch** **Date: 10/09/2006**

Organization : **SonoSite, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

SonoSite, Inc. comments on Packaged Services and APC Relative Weights. "See Attachment."

CMS-1506-P-387-Attach-1.DOC

CMS-1506-P-387-Attach-2.DOC

#381

SonoSite

October 12, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
ATTN: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates.

Dear Dr. McClellan:

SonoSite, Inc., appreciates the opportunity to comment on the Proposed Rule for the 2007 Hospital Outpatient Prospective Payment System (HOPPS) (CMS-1506-P). SonoSite is a manufacturer of high quality portable ultrasound systems located in Bothell, Washington. SonoSite manufactures and markets ultrasound systems that provide full diagnostic ultrasound studies and are optimized for use at the point of care. SonoSite's products are used throughout the hospital outpatient setting to provide a wide variety of diagnostic and guidance ultrasound imaging services.

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Packaged Services

I. Issue – Continued Packaged Status of Ultrasound Guidance for Vascular Access

In the proposed HOPPS rule, the Centers for Medicare and Medicaid Services (CMS) states that for 2007, CPT code *76937 -- Ultrasonic guidance for vascular access* shall continue to be assigned a status-indicator of N, thus bundling the payment for this separate ultrasound study. Again, this proposal is in direct conflict with a decision made by CMS in the 2003 Final HOPPS rule. In the 2003 Final Rule, CMS proposed to accept the recommendations of the APC Panel and provide separate payment in 2003 for all radiology guidance codes designated as "N" in 2002. CMS' deviation from its current policy on separate payment for radiology guidance codes by assigning a status indicator of "N" to CPT code +76937 creates a provider incentive not to perform this service when

it is medically indicated.[1] Thus, the adoption of this important patient safety practice is curtailed by CMS' existing payment policy.

II. Recommendation

To ensure that Medicare beneficiaries have access to safe, high quality care, SonoSite recommends that the Status Indicator assigned to CPT code +76937 be changed to an "S" allowing for separate payment of this service when provided in the hospital outpatient setting and that CPT code +76937 be assigned to APC 0268 - Ultrasound Guidance Procedures.

III. Supporting Information

Analysis of 2004 OPPS Data Reveals Low Level of Utilization

In response to questions asked by the APC Advisory Panel as well as CMS, SonoSite, Inc. commissioned Direct Research, LLC to analyze the claims file that CMS released with the 2006 OPPS Proposed Rule to determine the level of utilization of +76937 in the hospital outpatient setting in 2004.

The results of this data analysis showed for those vascular access procedures that +76937 can be used with, CPT codes 36555 to 36585, CPT code +76937 was reported an average of 14 percent of the time with the greatest utilization rate no more than 25 percent. The data confirms that it is currently not the typical practice to use ultrasound to guide vascular access procedures.

HCPCS	Label	APC for this HCPCS	Count of claims lines for this HCPCS	Percent of vasc. access claims with +76937	Number of claims with +76937	
36555	Insert non-tunnel cv cath	0621	234	**6%**	14	
36556	Insert non-tunnel cv cath	0621	19,589	**15%**	2,954	
36557	Insert tunneled cv cath	0622	216	**18%**	39	
36558	Insert tunneled cv cath	0622	26,230	**23%**	6,111	
36560	Insert tunneled cv cath	0623	93	**17%**	16	
36561	Insert tunneled cv cath	0623	48,814	**10%**	4,747	
36563	Insert tunneled cv cath	0623	558	**4%**	24	
36565	Insert tunneled cv cath	0623	3,205	**6%**	190	
36566	Insert tunneled cv cath	1564	606	**7%**	40	
36568	Insert tunneled cv cath	0621	246	**18%**	44	
36569	Insert tunneled cv cath	0621	30,561	**25%**	7,516	
36570	Insert tunneled cv cath	0622	37	**8%**	3	
36571	Insert tunneled cv cath	0622	14,395	**6%**	836	

[1] Federal Register, Vol. 67, No. 212, Friday, November 1, 2002, pg. 66724

36575	Repair tunneled cv cath	0621	1,218	**0%**	3	
36576	Repair tunneled cv cath	0621	563	**0%**	2	
36578	Replace tunneled cv cath	0622	924	**1%**	9	
36580	Replace tunneled cv cath	0621	2,265	**2%**	49	
36581	Replace tunneled cv cath	0622	9,075	**2%**	200	
36582	Replace tunneled cv cath	0623	1,265	**2%**	27	
36583	Replace tunneled cv cath	0623	122	**1%**	1	
36584	Replace tunneled cv cath	0621	2,065	**4%**	80	
36585	Replace tunneled cv cath	0622	341	**2%**	8	
		Total	**162,622**		**22,913**	**14%**

In light of this information, in order to help encourage the use of this important safety practice, SonoSite requests that CMS assign a status indicator of "S" to CPT code +76937 and crosswalk to APC 0268 - Ultrasound Guidance Procedures.

AHRQ Recommends Ultrasound Guidance of Central Venous Catheter Placement

AHRQ's June 2001 report entitled "Making Health Care Safer: A Critical Analysis of Patient Safety Practices"[2] cites the use of real-time ultrasound guidance of central venous catheter insertion to be one of the top 11 practices needed to improve patient safety.

AHRQ indicates in its report that "The majority of CVC insertions are placed using the landmark method" – meaning that no ultrasound guidance is used—resulting in unsuccessful insertion in up to 20% of cases. So-called "blind insertions" have significantly higher rates of serious complications such as arterial puncture, hematoma, pneumothorax, and brachial plexus injury.

AHRQ concluded that when ultrasound is used to guide CVC insertions there is a reduction in the relative risk of 78%.

Assigning a status indicator of "S" to CPT code +76937 and crosswalking it to APC 0268 would ensure that Medicare beneficiaries who need CVC placements would have access to ultrasound guidance and thus suffer fewer multiple insertion attempts and complications.

Inappropriate Packaging

CMS' rationale for packaging services is that the performance of one service necessitates performance of the second service, i.e., the services are "directly related and integral."[3]

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[2] Shojania KG, Duncan BW, McDonald KM, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43. (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

[3] Federal Register, Vol. 69, No. 157, Monday, 8/16/04, pg. 50453.

Yet when CPT code +76937 was created it was for the purpose of billing ultrasound guidance "in conjunction with another procedure for which ultrasound is not inherent."[4]

Previously CMS has acknowledged that payment affects provider behavior and that therefore, medically important, yet discretionary services must be afforded "separate payment so as not to discourage their use where appropriate."[5] We applaud the reasoning expressed in that earlier judgment and contend that the same logic applies in this instance.

APC Relative Weights

I. Issue – Selection of Codes for Bypass List

For CY 2007, CMS is proposing to continue to use single procedure claims to determine the medians upon which the APC prices are set. In order to maximize the number of single claims CMS is expanding the number of codes on the bypass list to a total of 454 codes. These codes are thought to not have significant packaged costs, such that the removal of those packaged costs from the APC to which the bypassed codes are assigned, will not result in depressed valuation of that APC. However, we have found that this line of reasoning may not be the case for CPT code 76942 – ultrasound guidance of needle placement.

II. Recommendation – Remove CPT Code 76942 from Bypass List or Calculate the Median Cost for APC 0268 excluding the Bypassed Lines; Evaluate Impact of Placement on List for other Ultrasound Procedures

In order to maintain an appropriate payment for APC 0268 – Level 1 Ultrasound Guidance Procedures, SonoSite requests that CMS remove CPT code 76942 from the bypass list.

III. Supporting Information

SonoSite appreciates the Agency's efforts to increase the accuracy of the APC relative payment weights by including multiple procedure claims data. However, we are concerned that disregarding as much as $50 in packaged costs will result in inaccurately low median cost calculations of the APC's to which those codes are assigned.

CMS states that one of its criteria for determining suitability for the bypass list is whether the median cost of packaging observed in the single claim is equal to or less than $50. This suggests that packaging costs as great as $50 are removed from the data used to calculate the median for the APC's to which those bypassed claims are assigned. We believe that a threshold even significantly lower than that could depress the payment rate on an APC that only carries a payment of approximately $75.

An analysis by Direct Research, LLC, indicates that placement on the bypass list of CPT Code 76942 has the potential to depress the value of APC 0268. According to the

[4] CPT Changes 2004, An Insider's View, American Medical Association, 2003.
[5] Federal Register, Vol. 67, No. 212, Friday, November 1, 2002, page 66768.

Direct Research analysis, for CPT code 76942, the natural singles have a higher median than the bypassed codes. Further, when all packaged costs are removed from the natural singles, the median is close to the median for the bypassed codes. These two pieces of evidence strongly suggest that the use of bypassed lines to calculate the median reduces the median by ignoring significant packaged costs associated with this procedure.

Thus removing CPT code 76942 would allow for a more accurate accounting of the hospitals' costs of providing ultrasound guidance for needle procedures in an outpatient setting. If this unacceptably reduces the number of pseudo single claims available for setting APC payment rates, then we would ask that CMS calculate the median cost for APC 0268 using natural single claims only.

***

SonoSite, Inc. appreciates the opportunity to provide comments on this proposed rule. If SonoSite can provide CMS with additional information regarding this matter, please do not hesitate to contact me at 425-951-1205 or Irene.Plenefisch@sonosite.com.

Sincerely,

Irene Plenefisch
Director, Payer and External Relations

Submitter : **Date: 10/09/2006**

Organization : **American Therapeutic Corporation**

Category : **Congressional**

Issue Areas/Comments

Medicare Contracting Reform
Impact

Medicare Contracting Reform Impact

Dear Members of Congress,
I currently work at a Community Mental Health Center as a program therapist. I work mostly with outpatient clients, however, also help out when needed with the partial hospitalization program. I grew up in the Health Care field. My grandfather opened the first nursing home in South Florida, my father has operated nursing homes for years and he also served as the President of Florida Health Care Association for 2 years. Taking care of the community has been a priority in my family's lives. I became a social worker because I saw the need of mental health professionals in nursing homes, assisted living facilities, and other supportive housing environments. My work is very rewarding in that when a client of ours completes one of our programs, their improvement and ability to care for themselves has greatly improved. I feel that the reason our clients benefit so much from our services is because we are able to offer them the hightest quality of care. All of our staff are trained in the field and licensed with the state, we maintain a safe and clean environment, and the objective of each and every employe in our facilities is to provide the best patient care possible. In order to uphold such a high level of excellence we MUST be supported by our chosen representatives and Medicare. I know I am not alone when I say that I am sure there are other area's where budget cuts can be made. It surely does not seem appropriate to make cuts where people's lives may be in jeopardy if not receiving proper care. The fact of the matter is that mental illness affects ALL OF US. Hopefully when the time comes that one of my family members or yours needs help, Medicare cuts have not been implemented, ensuring the highest level of care for them. Thank you.

Submitter : **Date: 10/09/2006**

Organization : **Immune Deficiency Foundation**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-389-Attach-1.DOC

#384

IMMUNE DEFICIENCY FOUNDATION

October 9, 2006

Mark McClellan, M.D., Ph. D
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Washington, D.C. 20201

Re: CMS-1506-P; Comments on "OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals" and "OPPS: Drug Administration"

Dear Dr. McClellan:

The Immune Deficiency Foundation (IDF), founded in 1980, is the national patient organization dedicated to improving the diagnosis and treatment of patients with primary immune deficiency diseases through research, education, and advocacy. Thousands of individuals and their families who live with primary immune deficiency diseases count on IDF for (1) education programs and materials that focus on the recognition and diagnosis o f p rimary im mune de ficiency dis eases, im portant l ife m anagement, p atient care resources, and support for patients and family members, (2) research and medical education programs that improve diagnosis and treatment of primary immune deficiency diseases, and (3) advocacy to promote policies that positively affect the primary immune deficiency community.

We are providing our comments on the August 23, 2006, Federal Register proposed rule regarding changes in (1) Medicare's hospital outpatient payment policy for nonpass-through drugs and biologicals, and specifically the proposed rule's payment policy for IVIG, and (2) Medicare's payment policy for IVIG drug administration in the hospital outpatient setting. Our comments below supplement others submitted by a group of IVIG stakeholders of which IDF is a part for purposes of responding to the August 23 proposed rule.

Comments on Proposed Reduction in Medicare Payments for IVIG and Other Nonpass-Through Drugs and Biologicals Furnished in Hospital Outpatient Settings from ASP+6 to ASP+5

IDF is concerned that the proposed reduction in payments for IVIG in the hospital outpatient setting to ASP+5 will compromise access of patients with primary immune deficiency disease (PI) to this life-saving product. Access to IVIG is critical to patients

with PI. At least 7 of every 10 PI patients have diagnoses for which IVIG is the only effective treatment. About 20% of these patients are on Medicare. This translates into at least 10,000 persons, nationwide, who are being treated with IVIG under Medicare. Since January 2005 when Medicare reimbursement for IVIG changed for physicians providing IVIG infusion in their offices, IDF has received thousands of phone calls and emails from patients and physicians who have had serious issues of access to IVIG.

In order to provide current information on the impact of Medicare reimbursement's changes on treatment with IVIG in the PI community, IDF has undertaken three national surveys in partnership with the American Academy of Asthma, Allergy, and Immunology (AAAAI): a survey of patients with PI, a survey of physicians treating patients with PI, and a survey of hospital pharmacists dispensing IVIG. Only the patient survey is sufficiently advanced at this time to present preliminary findings of the impact of the 2005 change in reimbursement on Medicare patients with PI. These findings show that access to IVIG has been affected by the changes in reimbursement and these findings point to a possible exacerbation of access problems for PI patients receiving IVIG in hospital outpatient settings.

Methodology of Patient Survey. IDF drew the sample for the national patient survey from the Foundation's database of PI patients. Although it is impossible to draw a strictly random sample of this very low-incidence population, no other organization maintains a list of PI patients as large as IDF's, so that the data should be as accurate as can be practically obtained. The survey was mailed to a random sample of 3,000 households from IDF's list, which we believe represents a cross-section of patients nationwide, as well as a supplemental sample of 135 households whom we believe to include PI patients on Medicare. IDF included the supplemental sample of Medicare patients in order to have a sufficient number of responses from Medicare patients to be able to analyze that key segment separately, in order to evaluate what impact the change in reimbursement policy has had on that group.

To date, IDF has received nearly 800 completed questionnaires from the first mailing of the survey. After deducting bad addresses and deceased responses, we have a response rate of approximately 25% to the first mailing. A second mailing has just been done. IDF's objective is to have a completed sample of approximately 1,000 patients with PI. Our preliminary findings presented in these comments on the August 23 Federal Register proposed rule are from the first 763 completed surveys from adult patients or parents of children with PI. This includes a national sample of 268 Medicare patients with PI.

Findings. Approximately 70% of respondents are currently being treated with IVIG. Specifically, 532 patients of the 763 total respondents are currently being treated with IVIG, 206 of which are Medicare patients. Another 41 stopped being treated since the beginning of 2005. Of these who stopped receiving treatment, 11 cited inadequate insurance coverage or higher expenses and 3 mentioned difficulty in obtaining IVIG.

One of the impacts of Medicare reimbursement has been to force patients from their usual site of service for infusions to other sites of service where payment rates were higher

and/or Medicare patients were still accepted. More than a third of Medicare patients (34%) reported that they are now being treated at a different site since December 2004, compared to about one-fifth (21%) of non-Medicare patients. Moreover, when asked the reason for the change in site of infusion, 38% of Medicare patients said that the change was due to insurance reimbursement reductions/inadequate insurance, as compared to 9% of non-Medicare patients. More than a quarter of Medicare patients (27%) who had changed site of infusion said it was because IVIG was no longer available at the previous site, compared to 6% of non-Medicare patients.

Among Medicare patients who are currently infusing IVIG, the proportion infusing in physician private offices has dropped from 21.1% prior to 2005 to 9.1% today. The shift away from the doctor's office has moved many Medicare infusers to hospital outpatient or ho spital inf usion c linics. P rior t o 20 05 o nly 47. 5% o f M edicare p atients r eported usually getting their infusions in hospital outpatient or hospital infusion clinics, and currently, 55.6% of Medicare patients are receiving their infusions in hospital outpatient or infusion clinics. For non-Medicare patients, there was no corresponding shift away from the doctor's office. Proportions remained at 13.3 % both before and after 2005. The proportions using hospital outpatient or infusion clinics actually declined for non-Medicare patients from 36.3 % to 31.5%, with more non-Medicare patients shifting to home health care for their infusions. Since these dramatic shifts in site of infusion occur only for Medicare patients, Medicare reimbursement is the likely cause. The consequence is that Medicare patients are being shifted into hospitals where they are at greater risk for disease transmission, and this is transforming the patient mix in hospitals.

IDF believes that it does not make sense to move a PI patient out of a physician's office to a hospital where an immune-compromised patient can be exposed to an opportunistic infection. Nevertheless, some PI patients transitioned to the new setting, at least, had access to IVIG. However, with the new proposed reduction in Medicare payment for IVIG in hospital outpatient settings, IDF is concerned that these patients will experience new dislocations in service and even serious problems in access to IVIG. Even before this reduction would take effect, we have heard from many p atients c urrently having problems with continued access to IVIG in hospital outpatient settings. After January 1, 2006, when hospitals moved from AWP to ASP+6%, IDF heard that some hospital outpatient clinics had stopped providing IVIG to patient's altogether, because reimbursement was inadequate. Patients in some states have been particularly hit hard, especially those in Texas, Nebraska, and Florida, where few hospitals remain that treat with IVIG. As noted above, IVIG is the only effective treatment for 70% of PI patients.

What are the consequences for Medicare as well as non-Medicare PI patients who experience access problems for IVIG? Our 2006 patient survey shows that Medicare (31%) and non-Medicare patients (29%) were a bout as likely to say that they had to switch to another brand of IVIG since the beginning of 2005. This is problematic because patients with immune problems require brand-specific IVIG, since each product is dif ferent. P atients t reated with b rands t heir bodies do no t t olerate c an s uffer l ife-threatening anaphylactic reactions. In fact, in a 2005 survey, IDF documented that many Medicare PI patients moving to hospital outpatient sites suffered serious reactions to the

brands of IVIG that were used by hospitals and that were different from the ones they had been using in their physicians' offices. Some were hospitalized and many had increased infections. Product choice is critical for PI patients.

In addition, Medicare (17%) and non-Medicare (18%) were about equally likely to say that they had to pay more for IVIG since the beginning of 2005. These two findings together suggest that a tight market has affected product availability, product choice, and product price over the past 2 years for IVIG users regardless of type of insurance coverage.

Furthermore, Medicare patients (25%) were twice as likely as non-Medicare patients (13%) to report that their treatments had to be postponed since the beginning of 2005. Medicare patients (13%) were also twice as likely as non-Medicare patients (6%) to report that the time intervals between infusions had been increased since the beginning of 2005. Finally, Medicare patients (8%) were seven times as likely as non-Medicare (1%) patients to report that their dosage had been reduced since 2005. These differences between Medicare and non-Medicare users of IVIG are statistically significant. Since the main difference between the two populations is their type of insurance coverage, the survey findings demonstrate a serious reimbursement impact on the treatment of Medicare patients needing IVIG.

IDF's patient survey also asked users of IVIG if they had experienced any negative health effects as a result of problems in getting or paying for IVIG since the beginning of 2005. Once, again, Medicare patients (27%) were nearly three times as likely as non-Medicare patients (10%) to report having negative health effects as a result of problems in getting or paying for IVIG. Those experiencing problems reported more infections, bronchitis, pneumonia, and increased use of antibiotics. For more than one in 9 (11%) of Medicare patients reporting negative health effects (about 3% of all Medicare patients using IVIG), the health consequences were severe enough to require hospitalization.

Conclusion. IDF's survey of PI patients suggests a substantial minority of patients is experiencing limited product choice and increased product cost regardless of insurance status. However, serious problems of dislocations that have come with many PI patients having to leave the physician's office for infusion, as well as postponed infusions, increased intervals between infusions and reduced dosage have fallen disproportionately on Medicare patients. The significant difference in these treatment experiences and changes in site of care, by Medicare status, along with higher rates of negative health outcomes, is clearly a reimbursement problem that began in January, 2005, with the change to ASP+6 methodology. IDF is concerned that these problems are likely to continue, without a change in reimbursement for care in physicians' offices, and will likely be magnified with a reduction in reimbursement for IVIG in the hospital outpatient setting as proposed in the August 23 rule, creating even more dislocations for PI patients requiring IVIG. As noted above, we have already heard in 2006 a significant number of reports of problems with access for PI patients dependent on hospital outpatient departments for infusion.

Comments on Proposed Payment Policy for IVIG Administration and Elimination of IVIG Preadministration Payment

IDF applauds the proposed rule's recognition that IVIG administration requires considerable hospital resources throughout the infusion period. We would add that IVIG administration requires significant resources regardless of site of treatment. This is one of the reasons physicians have not been able to continue infusion services in their offices, since the change to the ASP+6 reimbursement methodology for IVIG.

IDF is concerned that hospital outpatient departments under the new policy will not be able to cover their costs for IVIG patients, especially for those, who require shorter periods of time for infusion. The average amount of time PI patients spend infusing IVIG is 3 hours. The proposed new policy would provide hospitals with a separate payment for the first hour of infusion, along with payments for each of the additional hours required for IVIG infusion. Critically for IVIG users, it would also eliminate the preadministration-related services add-on provided by CMS for 2006 for both hospital outpatient and physician offices in recognition of the extra costs and resources needed by these sites for IVIG infusion.

IDF is concerned that as a result of these changes, Medicare's payment for IVIG administration will be less than it is now, especially for patients requiring shorter periods of time for infusion. CMS should continue the preadministration-related services add-on indefinitely until it has sufficient data to demonstrate that the change in drug administration payments to an hourly basis for hospital outpatient departments does not jeopardize PI patients' access to care in those settings. IDF is concerned that when combined with the reduction in payment for IVIG itself in these settings to ASP+5, changes in payment for administration—both in terms of an hourly payment and elimination of the preadministration add-on--may further compromise access to IVIG for PI patients—already a serious problem for Medicare PI patients, as discussed above.

Thank you for your consideration of these issues of tremendous importance to the access of primary immune deficient patients to their life-saving therapy of IVIG. We look forward to sharing the final findings of the IDF patient survey with you shortly.

Sincerely yours,

Marcia Boyle
President

Submitter : Mr. Evan Morris **Date:** 10/09/2006

Organization : Hoffmann-La Roche

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Hoffmann-La Roche is pleased to present submit the following comments to CMS. Please see attachment.

CMS-1506-P-390-Attach-1.PDF

October 9, 2006

BY HAND DELIVERY AND EMAIL
www.cms.hhs.gov/regulations/eRulemaking

Mark McClellan, MD, PhD.
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; Comments Regarding The Hospital Prospective Payment System and CY 2007 Payment Rates

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche") appreciates this opportunity to submit comments regarding proposed rule *Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates.*[1] As a company dedicated to bringing innovative, effective, high quality therapies to patients, Roche supports updating payment policies under the outpatient prospective payment system (the "OPPS") to reimburse the provision of important services in a fair and equitable manner. Roche also supports updating payment policies under the OPPS to provide Medicare beneficiaries with access to the most appropriate therapies. While we generally endorse the changes presented in the proposed rule, we have some recommendations that we request that you consider in developing the final 2007 rule. Specifically:

- Roche disagrees with the Agency's[2] proposal to pay for the acquisition and overhead costs of separately paid drugs[3] at a combined rate of the average sales price ("ASP"), plus 5 percent. We believe that the reduction of payments that is proposed for separately payable drugs and biologicals will unfairly burden hospitals.

- Roche asks CMS to closely monitor the impact of policy changes, in particular the application of reimbursement from the competitive acquisition program ("CAP") to the OPPS setting, and not make modifications contrary to the original intent of the pass-through program. Transitional pass-through payment status is a critical reimbursement incentive that encourages appropriate use of new innovative drugs.

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[1] 71 Fed. Reg. 49506 (August 23, 2006)

[2] The term Agency refers to the Centers for Medicare and Medicaid Services or CMS.

[3] The term "drugs" refers to drugs and biologicals.

Hoffmann-La Roche Inc. 1425 K Street, N.W. Suite 650 Washington, D.C. 20005 Federal Government Affairs Tel. 202-408-0090 Fax 202-408-1750

- We ask CMS to expand its guidance on codes with Comment Indicator "NI". Roche understands the need to "flag" new HCPCS codes with indicators that have been assigned to new technology. We would like CMS to clarify the length of time allowed for public comment for HCPCS codes with Comment Indicator "NI", and at what point the indicator will be removed.

A more detailed explanation of these comments and concerns is set forth below.

I. Proposed Payment for Specified Covered Outpatient Drugs (SCOD)

The Social Security Act (SSA) requires that payment for SCODs, or drugs for which a separate Ambulatory Payment Classification (APC) has been established and that is either a radiopharmaceutical agent or is a drug or biological for which pass-through payment was made on or before December 31, 2002 (subject to certain exceptions), in CY 2006 and subsequent years, be equal to the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to any adjustment for overhead costs and taking into account the GAO hospital acquisition cost surveys for CYs 2004 and 2005. If hospital acquisition cost data are not available, payment must equal "the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."

Although last year CMS paid for SCODs at ASP+6 percent, this year CMS proposes paying for them at ASP+5 percent. To arrive at this figure, CMS compared two sources of data - - ASP data from the fourth quarter of CY 2005 and mean "costs [of drugs] derived from the CY 2005 hospital claims data." CMS maintains that its data analysis demonstrates that using mean costs to set SCOD payment rates for drugs would be "equivalent to basing their payment rates, on average, at ASP+5 percent." CMS then asserts that hospitals set charges for drugs high enough to reflect their pharmacy handling costs as well as their acquisition costs. CMS further states that, therefore, payment for drugs and pharmacy overhead at a combined ASP +5 percent rate would serve as the best proxy for the combined acquisition and overhead costs of each of these products.

We are concerned that there are flaws in this analysis. First, the analysis does not distinguish costs from charges. CMS assumes that hospitals set charges at a level that is high enough to "reflect" handling and acquisition costs, but does not cite any reliable data to support this premise. In this regard, CMS' assumption is based on a MedPAC analysis[4] that did not clearly distinguish charges and costs. Second, CMS does not adequately explain how it determined its average reimbursement of ASP+5 percent from charges reduced to costs. For instance, CMS suggests that ASP+5 percent for the fourth quarter 2005 was equal to the mean "costs [of drugs] derived from the CY 2005 hospital claims data," but does not specify whether all CY 2005 or only fourth quarter 2005 claims data were considered. CMS also does not discuss the degree to which ASP+5 percent matches costs determined from charges across a range of drugs.

[4] The Medicare Payment Advisory Committee Report, "Report to the Congress" March 2006.

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Given these analytical flaws, we are concerned that this proposed shift to payment of ASP+5 percent may not adequately compensate for acquisition and handling costs and will impede beneficiary access to important drug therapies. Implementing the proposed ASP+5 percent change introduces complexities in the CMS drug payment provisions with no clear benefit in terms of accuracy of payment. For these reasons, we suggest that CMS maintain the current rate-setting methodology for most separately paid OPPS drugs and biologicals, and maintain payment at ASP+6 percent.

II. Pass-Through Drugs

CMS proposes to continue to reimburse pass-through drugs and biological products at ASP+6 percent, except for drugs that also are included in the Competitive Acquisition Program (CAP), which will be reimbursed at the CAP rate. We support CMS's decision to continue reimbursement for non-CAP covered drugs and biologicals that are eligible for pass-through payment at ASP+6 percent. This enforces CMS's intentions of proper billing code adoption and appropriate reimbursement for drugs entering the market.

However, although we appreciate CMS's commitment to consistent payment practices; we are concerned in regard to the proposed rate-setting for these drugs that may also be included under the CAP list. CMS states that drugs and biologicals with pass-through status which are covered under the CAP will be reimbursed at the "amounts determined under the competitive acquisition program."[5] We ask CMS to clarify that, as required by the statute, it will base payment for these drugs and biologicals on the amount by which "the average price for the drug or biological for all competitive acquisition areas and year established under [Section 1847B] as calculated and adjusted by the Secretary for purposes of this paragraph" exceeds the portion of the applicable Medicare OPD fee schedule associated with the drug or biological.[6] Importantly, the statute directs the Secretary to adjust the average CAP prices to account for the purposes of the pass-through program, which is to provide appropriate incentives for the development of innovative therapies for Medicare beneficiaries. The statute also requires the Secretary to consider pass-through payments on an individual drug-by-drug basis, not an aggregate basis as the Proposed Rule suggests. We believe that setting the payment amount for pass-through drugs and biologicals at the CAP negotiated amount would be inconsistent with the statutory language and with the purpose of the pass-through program. It also could have unintended consequences for the prices proposed and negotiated in the CAP program.

We also encourage CMS to set the payment amount for pass-through drugs and biologicals at WAC+6 percent until an ASP payment rate or an individual payment rate under the CAP is set. This payment metric will ensure that these drugs are paid adequately and will thus be accessible to Medicare beneficiaries who need these therapies in the hospital outpatient setting.

On a separate note, we would like CMS to confirm in the Final Rule that once a permanent J-code or temporary Q-code is assigned to a pass-through drug and its corresponding temporary C-

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[5] Fed. Reg. at 49581

[6] 42 U.S.C. § 1395l(t)(6)(D)(i).

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code is deleted, that the J-code or temporary Q-code remains on the pass-through status list until its expiration date after a minimum of two years, up to three years.

III. Estimated Transitional Pass-Through Spending

As noted in the proposed rule, the applicable percentage of total payments under OPPS which results in the pass-through payment for drugs, biologicals, radiopharmaceuticals and categories of devices has decreased each year since CY 2003, from 2.5 percent to the now proposed 1.87 percent. We are concerned about this downward trend in support for innovative therapies. The pass-through system provides essential compensation to hospitals for costs not covered in the APC payments, and reductions in the payment inevitably cause a slower uptake of new drugs and devices, which may lead to suboptimal care for Medicare beneficiaries. We urge CMS to reconsider the proposed 1.87 percent and maintain a more appropriate payment level.

IV. Comment Indicator "NI"

As has been done in the past, CMS proposes to continue to assign Comment Indicator "NI" to HCPCS codes indicating to the public an interim payment amount has been assigned. Roche understands the need to "flag" new HCPCS codes with indicators that have been assigned to new technologies, but we ask CMS to clarify the length of time allowed for public comment for HCPCS codes with Comment Indicator "NI", and at exactly what point the "NI" designation will be removed.

V. Conclusion

We appreciate the opportunity to provide comments and recommendations. We hope that our suggestions will assist CMS in its mission to provide Medicare beneficiaries with access to high quality therapies. Thank you for your attention to this matter. Please feel free to contact me if you have any questions or need additional information.

Respectfully submitted,

Evan T Morris

Evan Morris
Executive Director, Federal Government Affairs

Hoffmann-La Roche Inc. 1425 K Street, N.W. Suite 650 Washington, D.C. 20005 Federal Government Affairs Tel. 202-408-0090 Fax 202-408-1750

Submitter : **Mrs. Elena Cooper** **Date: 10/09/2006**

Organization : **Bloomfield Surgi-Center, LLC**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-391-Attach-1.DOC

AMBULATORY CENTER OF EXCELLENCE IN SURGERY

1255 Broad Street Suite 200 Bloomfield, NJ 07003
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(Bloomfield Surgi-Center, LLC)

October 09, 2006

Mark B. McClellan, M.D., Ph.D., 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: CMS-1506-P - Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List

Dear Dr. McClellan:

I am the Administrator of Bloomfield Surgi-Center, LLC dba Ambulatory Center of Excellence in Surgery in Bloomfield, New Jersey. Each year, our surgery center provides 200 procedures to 150 Medicare beneficiaries. Medicare patients represent 35 percent of our business and ensuring appropriate payment for their services is vital to our ability to serve our community. Please accept the following comments regarding Section XVII of the proposed rule, which would make revisions to policies affecting ambulatory surgical centers for CY 2007. 71 Fed. Reg. 49505 (August 23, 2006).

I. Proposed ASC List Update Effective for Services Furnished On or After January 1, 2007

A. Criteria for Additions to or Deletions from the ASC List

We commend CMS for proposing to update the ASC list for CY 2007, but believe the update falls short by not making extensive revisions to the criteria used to determine which procedures may be reimbursed in the ASC setting. As a result, beneficiary access to ASC services will continue to be limited by arbitrary criteria in CY 2007.

1. The inclusionary ASC list should be abandoned.

The limited, inclusionary list of covered ASC procedures is no longer the best way to address the safety and appropriateness of ASC services. Within currently accepted standards of medical practice - in which vast numbers of procedures may performed in a variety of outpatient settings - use of the ASC list has undesired consequences for the most optimal delivery of outpatient procedural services.

First, and most importantly, the ASC list limits the ability of physicians to select the site of service they believe is most clinically appropriate for their patients. A physician's assessment of the medical needs of the patient and the capabilities of the facility should determine whether a patient receives care in the ASC setting.

Second, the list limits Medicare beneficiaries' access to procedures that many other patients routinely receive in ASCs. Private payers do not restrict the access of their insureds to ASC services. Decisions regarding the site of service are recognized to be the province of the insured's physician. As a result, several minimally invasive procedures not available to Medicare patients in the ASC setting, such as spinal disc decompression and laparoscopic cholecystectomy, are commonly performed for selected privately insured patients - at significant savings to the patient and to the insurer. As long as CMS continues to maintain an ASC list, Medicare beneficiaries' access to appropriate services will always lag behind that of the private sector.

The ASC list should be abandoned. In its place, CMS should adopt the recommendations of the Medicare Payment Advisory Commission (MedPAC) and develop a list of services specifically excluded from coverage. In fact, CMS already has such an exclusionary list; for purposes of hospital outpatient payment under the Outpatient Prospective Payment System, CMS has developed and uses an "inpatient only" list. Because Medicare-certified ASCs have proven over the past two decades that they are capable of safely performing the same scope of services provided in hospital outpatient departments, this list may also be used to identify procedures excluded from coverage in ASCs.

Alternatively, if CMS develops a separate exclusionary list for ASCs, then that list should be based on the criteria identified by MedPAC in their March 2004 report. Specifically, MedPAC recommended the current list of ASC approved procedures by replaced "with a list of procedures that are excluded from payment based on clinical safety standards and whether the service requires an overnight stay".

2. The criteria used to revise the Medicare list of procedures that may be performed in an ASC are outdated and do not serve the interest of the Medicare program or its beneficiaries.

Section 1833(i)(1) of the Social Security Act requires CMS to determine which surgical services are safely and appropriately offered in an ASC. CMS selects the services represented on the current list of approved procedures based on criteria outlined in the Code of Federal Regulations at §416.65. We believe CMS is inappropriately limiting beneficiary site-of-service choices by continuing to make procedure list determinations using obsolete and outdated criteria that CMS itself previously proposed to substantially revise (63 Fed. Reg. at 32298).

a. Requirement that procedures be commonly performed in an inpatient setting.

When the Medicare ASC benefit was originally implemented in the 1980s, most surgical procedures were performed in an inpatient setting. In the intervening decades, the outpatient setting has become the accepted setting for many types of surgical procedures. As new clinical approaches to surgery, anesthesia and pain management have been incorporated into standard medical practice, certain procedures have moved almost exclusively to the outpatient environment. New procedures have evolved that were never commonly performed in an inpatient setting. Examples include newer arthroscopic and endoscopic interventions, and surgical treatments using laser or radiofrequency instrumentation. These procedures were developed predominately in an outpatient setting and are performed safely and cost-effectively on thousands of commercial insurance and self-pay patients each year.

To continue to require that a procedure be commonly performed in the inpatient setting before it can be deemed appropriate for the ambulatory surgery setting is no longer consistent with current standards of practice. We recommend general standard (1) "Covered surgical procedures are those surgical and other medical procedures that are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC" be eliminated as obsolete. This recommendation is also supported by MedPAC's 2004 report which specifically states, "it no longer makes sense to consider inpatient volume when updating the ASC list."

c. Requirement that a procedure not be commonly performed in physicians' offices

Current CMS guidelines provide that a procedure performed 50 percent or more of the time in a physician's office cannot be reimbursed in an ASC. In effect, this limits a physician's options to an inpatient or HOPD setting for patients for whom an office setting would be inappropriate. The higher costs generally associated with inpatient and HOPD reimbursement as compared to ASC reimbursement rates have been well documented by the OIG and MedPAC. Eliminating ASCs as an option for procedures which can be safely performed in the outpatient setting imposes unnecessary costs on both the Medicare program and individual beneficiaries. Conversely, allowing ASCs to serve as a site-of-service option to HOPDs for care has allowed the Medicare program to achieve significant cost savings.

While physicians may safely perform many procedures on healthy Medicare beneficiaries in the office setting, sicker beneficiaries may require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition. Even when a procedure is frequently performed in an office there are circumstances when the office is an inappropriate or unavailable setting. A brief summary of these factors follows.

Patient Characteristics – Patient characteristics affect the selection of the appropriate site of service. Factors such as body habitus, comorbid conditions and even the patient's ability to lie in certain positions or hold still for long periods of time may affect whether a procedure can or should be performed in a physician office.

Another consideration is whether other procedures are being performed at the same time. If a patient is having a procedure performed in an ASC and another procedure that can be performed in an office is also needed, the patient and the Medicare program benefit from having both procedures performed at the same time.

Additionally, a procedure may be scheduled for a facility when the physician thinks it likely that a diagnostic procedure will result in the need for a therapeutic intervention. For example, a diagnostic cystoscopy (CPT code 52000) may be scheduled at an ASC because the physician thinks it likely that a cystoscopy with biopsy (CPT code 52204), requiring instruments and cautery not available in the office, will be necessary.

Procedure Differences –Procedures that are coded the same are not always identical. To some extent, the variations found in site of service may reflect the variation in procedures within the same CPT code. A prostate needle biopsy, 55700, provides a good example. The number of biopsies described by this code varies widely according to practice patterns. Some physicians routinely take 12-20 biopsies. Due to the more invasive nature of multiple biopsies, conscious sedation is used, making a facility the more appropriate setting unless the performing physician has specialized staff and equipment.

Office Differences – Physician offices vary greatly in terms of equipment and personnel. To a great extent, this varies based upon the volume in the office. A small office may simply not be able to afford certain equipment. Offices also have vastly different personnel. For example, some offices have certified registered nurse anesthetists or nurses trained in advanced cardiac life support and others do not. The procedures that can be performed in an office vary greatly based upon the staff available to assist the physician performing the procedure.

Medical Liability Policy Differences – In order to lower premiums for medical liability insurance, physicians may agree not to perform certain procedures in their office. For example, policies may vary in the types of surgery covered or the types of anesthesia covered.

State Laws and Regulations – State laws and regulations impose limitations on what can be done in offices. To be able to perform certain types of procedures, these state provisions may require specific equipment, staff or even accreditation. If the office does not meet these requirements, these procedures cannot be performed in the office. For example, Indiana prohibits physicians that do not have specified continuing medical education in anesthesia from performing surgery involving conscious sedation in an office setting. Also, some state regulations limit anesthesia in the office to patients in certain American Society of Anesthesiologists (ASA) physical status classifications, meaning that some patients can have procedures involving anesthesia in the office but others cannot.

As was noted in the preamble to the interim final rule of May 2005, the rate of performance in ASCs of the physician office procedures originally proposed for deletion has remained relatively stable over the past 10 years. In other words, the inclusion of these procedures on the ASC list has not induced substantial shifts in sites of service, which suggests site-of-service selection is being driven by clinical need. If CMS remains concerned about the potential for financial incentives to improperly influence site-of-service selection, then the

logical solution is to address any unjustified payment variations in the new payment system, rather than denying ASC coverage for procedures commonly performed in physician offices.

MedPAC has also recommended that CMS abandon the requirement that procedures be performed less than 50 percent of the time in physician offices to be added to the list. The Commission has specifically stated, "Physicians should have the discretion to decide which setting is most clinically appropriate for individual patients."

c. Operating and recovery time limits are unnecessary.

The ASC industry supported CMS's 1998 proposal (63 Fed. Reg. at 32298) to discontinue using the time limits on operating, anesthesia, and recovery time currently defined under 42 C.F.R. § 416.65(b), which are used as a basis for determining whether a procedure should be added to or deleted from the ASC List. The numeric threshold rules presently employed by CMS are obsolete and too often result in the exclusion of procedures that are entirely appropriate for the ASC setting. The current rule that the ASC List should be restricted to procedures that generally do not require more than 90 minutes operating time or 4 hours recovery time is outdated. This standard was developed in the early 1980s and predates numerous technological advances that are now standard in the ASC setting. Both thresholds are arbitrary and without clinical significance.

As MedPAC has observed, these time requirements are "unnecessarily rigid," particularly given the numerous technological advances that are now standard in the ASC setting. With the development of short-acting general anesthetics, the length of operating time is immaterial in determining whether a procedure is appropriately performed in an ASC. The key question is when is the patient ready to be discharged, not how long the surgery takes. Moreover, with respect to the four-hour limit on recovery time, a number of states have expanded the concept of "ambulatory" over the 20 years by permitting ASCs to perform procedures requiring stays of up to 24 hours.

B. Procedures Proposed for Addition to the ASC List

We commend CMS for updating the ASC list again for 2007. These regular updates help ensure Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients.

All of the proposed additions are clearly clinically appropriate. However, we are concerned the payment group assignments for certain of the procedures will result in reimbursement at a level insufficient to cover the cost of performing the procedure.

We are concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333.00). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339.00). Because this

particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs. Further, using the median cost information supplied in the HOPD, CMS has established the APC payment for this service at $1542.47. We believe the HOPD data is a more reliable proxy for the cost of providing this service.

We are also concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1339.00) and Group 1 ($333.00), respectively. The cost of the intravascular stent averages $1725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which exceeds the current maximum Group 9 reimbursement level. Therefore, no level of reimbursement currently available to ASCs would be sufficient to cover the device costs for these procedures. Unfortunately, there is no real opportunity for ASCs to receive separate reimbursement for the stent. Because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. In light of this, we believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, we still believe CMS should add the procedures to the list because they are clinically appropriate services and doing so will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

C. Suggested Additions Not Accepted

1. Procedures suggested for addition, but not accepted because they are commonly performed in physician offices

Many procedures that were suggested through public comment for addition were rejected on the basis that they are commonly performed in the physician offices. CMS has determined if a procedure is performed 50 percent or more of the time in the office setting, it is inappropriate for addition to the ASC list. CMS relies on Part B claims data when determining the frequency with which procedures are performed in various settings. However, it has been well established by the OIG that site of service reporting on physician claims can be a highly unreliable indicator of the actual site of service; significant error rates (80 % and higher) for selected services have been reported. Given the probability of significant flaws in the data CMS uses to make these decisions, we do not believe continued reliance on this data is appropriate.

As noted above, there is no evidence that including procedures on the ASC list that are frequently performed in the office setting leads to over-utilization of those procedures in the ASC setting. CMS itself has acknowledged that inclusion of certain services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs (70 Fed. Reg. at 23696).

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the

Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

For example, there are patients requiring endoscopic evaluation for reanastomosis following a partial colectomy with colostomy, in which both a colonoscopy via stoma (CPT code 44388) and flexible sigmoidoscopy (CPT code 45330) are needed for a complete evaluation. Non-Medicare patients can have both procedures performed at the same session in an ASC. This is not the case for Medicare beneficiaries. While the colonoscopy via stoma (CPT code 44388) is an ASC list procedure, the flexible sigmoidoscopy (CPT code 45330) is not. In order to have both procedures performed concurrently as an outpatient, the Medicare beneficiary must been seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also costs both the program and its beneficiaries significantly more. Having both these procedures performed in an HOPD costs the Medicare program $649.44, with a minimum beneficiary copayment of $129.89. If the Medicare program would allow the flexible sigmoidoscopy in the ASC setting, assuming a Group 1 payment assignment, the cost of the two procedures together would be $458.82, with a beneficiary copayment of $91.76.

As is the case with many procedures commonly performed in the physician office, there are certain patients whose medical condition requires a procedure be performed in a facility setting. In the case of flexible sigmoidoscopy, this would include patients with anal stenosis and anastomotic strictures, who require sedation for a humane examination. Current CMS policy does not allow these patients to access care in the more affordable ASC setting.

Though certain procedures are commonly performed in the office setting, the physician should not be restricted in the exercise of professional judgment when determining the most appropriate site of service. Hospital outpatient departments are not restricted in their ability to serve as the site of service when the physician determines the office setting will not meet the needs of the patient. When medically necessary, ASCs should also be an option for those Medicare beneficiaries requiring the services of a facility for appropriate and safe care. Therefore, we urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

2. Procedures suggested for addition, but not accepted because CMS states they do not meet current clinical criteria

a. Osteochondral arthroscopic grafting

Several commenters suggested the addition of CPT codes 29866 and 29867 describing arthroscopic knee procedures in which osteochondral autografts or allografts are placed. These procedures meet the current clinical criteria for addition to the ASC list. Surgery and anesthesia times are under 90 minutes, and recovery times generally average four hours. As with other arthroscopic knee procedures, blood loss is minimal.

b. Laparoscopic cholecystectomy

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. The first laparoscopic cholecystectomy performed in the United States was performed at an ambulatory surgical center in 1988. Now, these procedures are commonly performed for non-Medicare patients in the ASC setting. Although CMS has not included these procedures on the ASC list to date, CMS data shows these procedures are routinely performed on an outpatient basis in Medicare patients; Medicare volume data shows these procedures were being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, we believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. We recognize an ASC will not be the appropriate site for all Medicare beneficiaries. However, by not adding these procedures to the ASC list, CMS effectively denies all Medicare beneficiaries access to the ASC.

CMS has also rejected the procedures on the basis of "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." (70 Fed. Reg. at 23700). CMS stated that if an open procedure were required, the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. We are aware of just one recent study which exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of Surgery in September of 2002. In this retrospective analysis of 200 procedures, no patient required conversion to an open cholecystectomy. While conversion to an open cholecystectomy is possible, it is not common. In fact, based on available data, the risk appears to be slight rather than substantial.

When determining the site of service for an ambulatory elective laparoscopic cholecystectomy, the surgeon may be rigorous in the application of patient selection criteria, thereby minimizing the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure

and postoperative stabilization. Again, the application of patient selection criteria would make such conversions a rare occurrence.

c. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery times can extend beyond four hours, these procedures can be performed without an overnight stay. As we noted above, we believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

In this notice of proposed rulemaking, CMS proposes to add CPT codes 13102, 13122 and 13133 to the ASC list effective January 1, 2007. CPT code 13153 is also included in this series of codes and describes complex repair of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. However, this code is not currently on the ASC list, nor has CMS proposed its addition. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Based its similarity to the other proposed additions, CPT code 13153 should also be added to the ASC list effective January 1, 2007.

CMS should also add G0289, which describes a knee arthroscopy for removal of a loose body, foreign body, or chondroplasty concurrent with another surgical knee arthroscopy in a different compartment of the same knee. CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. The use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to add G0289 to the ASC list effective January 1, 2007.

There are several procedures that are appropriate additions to the ASC list. **<<I/We>>** believe that CMS should add these procedures to the list with an effective date of January 1, 2007.

CPT Code	Descriptor
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid

43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower esophageal sphincter
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve
64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)

II. Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses

We are supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). **<<I/We>>** also agree it would be more efficient to incorporate this into the annual update of ASC rates for the following calendar year. Including a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published would be very helpful, but we do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, we believe a 60 day comment period would be more appropriate.

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Specifically, we suggest §416.195(a)(4) be modified

to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:"

We are also concerned about CMS's proposal to revise the language at §416.190 to require that the content of each request for an IOL review include information specified on the CMS web site. It is our belief that the items CMS finds necessary for review should be published in the Federal Register, as any change in regulation should be open to review and comment by the public before being implemented.

* * * * *

Thank you for considering our comments. If you have any questions or need additional information, please do not hesitate to call me at 973-842-2150.

Sincerely,

Elena R. Cooper, RN
Administrator and Director of Nursing
Bloomfield Surgi-Center, LLC
Dba: Ambulatory Center of Excellence in Surgery

Submitter : **Mr. Michael Ziskind** **Date: 10/09/2006**

Organization : **Centocor, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment letter.

CMS-1506-P-392-Attach-1.PDF

#273

centocor inc

October 10, 2006

By Electronic Delivery

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Washington, D.C. 20201

Re: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of Centocor, Inc., I am writing to comment on the Centers for Medicare & Medicaid Services' (CMS's) Proposed Rule entitled "Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates" published in the August 23, 2006 Federal Register.[1] Centocor appreciates this opportunity to comment on important aspects of the Proposed Rule, and looks forward to working with CMS to ensure that the Final Rule is implemented in a manner that reflects our concerns.

As a leading biopharmaceutical company that discovers, acquires and markets innovative medicines and treatments that improve the quality of life of people around the world, Centocor is deeply committed to ensuring equitable and fair access to all necessary medicines for all patients. Among other life-improving medicines,[2] Centocor manufactures Remicade®, a product used by patients who suffer from the debilitating effects of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis, enabling these individuals to enjoy longer, more productive lives. Rheumatoid arthritis is a chronic disease that attacks the body's joints, causing inflammation, tissue destruction, and joint erosion. It affects over two million Americans, many of whom are Medicare beneficiaries. Each year, an additional 50,000 Americans are diagnosed with rheumatoid arthritis. Crohn's disease is a relatively rare condition, causing inflammatory disease of the intestine with symptoms that include diarrhea, severe abdominal pain, fever, chills, nausea and fistulae.[3] Ankylosing spondylitis is a painful and progressive form of spinal arthritis that can also affect internal organs, peripheral joints, and vision. Psoriatic arthritis is characterized by the complex symptoms of joint inflammation and skin lesions. Plaque psoriasis is an inflammatory disorder characterized by raised and inflamed lesions, or plaques, which can cause physical pain and emotional distress. Without proper

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[1] 71 Fed. Reg. 49,506 (Aug. 23, 2006).

[2] Centocor also manufactures ReoPro®, for acute coronary care.

[3] Fistulae are painful, draining, abnormal passages between the bowel and surrounding skin.

treatment, the pain associated with these conditions can severely impact the quality of life of afflicted individuals.

Although rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis are chronic and debilitating conditions, Remicade® is a highly effective treatment that can slow the progression of these diseases and significantly enhance the quality of patients' lives by reducing their pain and other incapacitating conditions. Because Remicade® cannot be self-administered by patients, the Medicare Program provides Part B coverage for this infused therapy both in the hospital outpatient department and physician office settings. Thousands of Medicare beneficiaries afflicted with these illnesses rely on Remicade® and other medications to manage their conditions and improve the quality of their lives.

This letter provides comments on two sections of the rule: (1) proposed changes to OPPS drug administration coding and payment for CY 2007; and (2) proposed payment for drugs, biologicals, and radiopharmaceuticals without pass-through status. Our detailed comments are set forth below.

I. PROPOSED CHANGES TO OPPS DRUG ADMINISTRATION CODING AND PAYMENT FOR 2007

The current Medicare OPPS provides uniform Ambulatory Payment Classification (APC) reimbursement to hospitals for the administration of complex chemotherapy services regardless of the length of the infusion. For example, hospitals are paid the same rate for a very complex infusion that lasts as long as five hours as for one that lasts only one hour. Because the single chemotherapy infusion APC includes a wide variety of services, there is great potential for significant underpayment for drug administration services under the OPPS.

To improve the overall accuracy of the payment, CMS is proposing to create six new APCs for drug administration services in 2007.[4] This new structure would allow for separate payments for the initial hour of infusion and each additional hour of service. For example, the first hour of chemotherapy infusion is assigned to APC 0441 with a proposed payment rate of $154.31.[5] Subsequent hours are assigned to APC 0438 with a proposed payment rate of $48.58.[6]

Centocor strongly endorses the new structure and applauds CMS for proposing this approach for 2007. This refinement will improve the overall accuracy of the system by more appropriately recognizing the levels of effort for drug administration and the related resource consumption. We agree with CMS and the APC Advisory Panel that these policies should be implemented in the 2007 Final Rule.

II. PROPOSED PAYMENT FOR DRUGS AND BIOLOGICALS WITHOUT PASS-THROUGH STATUS

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[4] 71 Fed. Reg. at 49,600.

[5] Id. at Addendum B.

[6] Id.

CMS is proposing to reduce reimbursement for drugs and biologicals without pass-through status in 2007 to a rate of Average Sales Price (ASP) plus five percent from the current level of ASP plus six percent.[7] Not only does CMS propose to reduce the overall reimbursement for these medications, but the agency also states that this new, reduced rate is sufficient to account for both the acquisition costs and hospital overhead costs associated with the products. Overall, Centocor endorses the analysis and recommendations in comments submitted by the Biotechnology Industry Organization (BIO) on this proposal, and encourages CMS to review these comments carefully. We share BIO's concerns that this proposal could result in inadequate payment rates for hospitals and thus threaten patient access to Remicade® and other Part B products. Until CMS can do a more complete analysis of hospital overhead cost issues related to pharmacy services, we urge the agency to maintain a rate of at least ASP plus six percent in the Final Rule for these therapies. In addition to the concerns addressed by BIO, we would emphasize the following points:

A. CMS's Key Assumption that Pharmacy Overhead Costs Are Typically Built into the Hospital Charges for Drugs and Biologicals Is Not Supported By Survey Data

In the Proposed Rule, CMS evaluated the two sources of data in determining adequacy of the proposed ASP plus five percent rate: (1) ASP data from the 4th quarter of 2005; and (2) the estimated median cost data from the 2005 hospital claims file.[8] In comparing the overall 2005 ASP-based reimbursement rates to the estimated median costs derived from the claims data, the agency concluded that an ASP plus five percent rate would be adequate in 2007 to cover both the acquisition and overhead costs of these Part B drugs and biologicals. In drawing this conclusion, CMS makes a key assumption that the hospitals include pharmacy overhead costs in their charges for Part B drugs.

In response to this question, Centocor commissioned The Resource Group in 2004 and again in 2006 to test the validity of this assumption. In 2004, The Resource Group conducted a survey of 1,500 hospitals and found that 57% of hospitals reported they did not include non-product costs such as administrative and overhead costs as a portion of their drug charges.[9] This finding is contrary to the CMS assumption that pharmacy overhead costs are uniformly built into hospital charges for drugs and biologics.

Within The Resource Group's 2004 survey, 386 hospitals responded to the question "does the pharmacy charge include an amount for anything other than the drug?" Of the 386 responses, 220 hospitals, or 57%, replied that they did not include non-product costs within their drug charges, while 166, or 43%, replied in the affirmative. To further validate the applicability of the

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[7] Id. at 49,585.

[8] Id. at 49,584-585.

[9] Three hundred and eighty-six hospitals responded to this survey question. The Resource Group study surveyed a random sample of 1,500 hospitals selected from all hospitals (except psychiatric) present in the CMS Providers of Service database as adjusted for duplicate entries and terminated facilities. At a 95% confidence interval plus or minus 5% error, the number of desired responses, rounded upward, was 400, or a 28% response rate. This response rate was achieved.

2004 research finding, The Resource Group is presently conducting a follow-on survey. The preliminary findings indicate that, of approximately 100 valid responses recorded to date, approximately 50% have indicated they did not include non-product costs within their drug charges.

These findings by the Resource Group are corroborated by a 2004 report about a survey conducted by the Government Accountability Office (GAO), which found that 58% of hospitals reported they did not include non-product costs such as administrative and overhead costs as a portion of their drug charges. The survey report recommended that CMS analyze variation in hospital charge-setting to determine if the OPPS payment rates uniformly reflect hospitals' costs for providing outpatient services, and, if they do not, to make appropriate changes to the methodology.[10]

Thus, the three surveys highlighted above indicate that 57%, 58% and a preliminary finding of approximately 50% of respondents did not include expenses such as overhead in their drug charges. Conversely, 43%, 42% and a preliminary finding of 50% of respondents do include expenses such as overhead as a portion of their drug charges. These findings call into question one of the key assumptions in CMS' position that the proposed rate adequately covers both hospitals' acquisition and overhead costs. CMS derives mean and median drug costs from charges contained in hospital claims data. Furthermore, in the Proposed Rule, CMS contends that "pharmacy overhead costs are already built into the charges for drugs, biologics and radiopharmaceuticals . . . ." [11] This key assumption concerning overhead costs and drug charges is again refuted by survey data that shows the majority of hospitals in fact do not include non-product costs such as pharmacy overhead on their drug claims.

B. The MedPAC-Authorized Survey of Hospital Charge-Setting Practices Found That Charges Are Often Not Closely Tied To Costs

The 2005 Medicare Payment Advisory Commission (MedPAC) study performed by The Lewin Group found that:

> The fact that charges are often not closely tied to costs implies that the current Medicare payment systems may not be closely tied to resource utilization. The findings from this study suggest that in certain instances, relative charges may not accurately proxy relative costs. Therefore, the

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[10] After surveying 113 hospitals, the report stated that 24 of the 57 hospitals responding to this question, or 42%, reported that they include non-product costs as a portion of their drug charges. We may therefore conclude that the remaining 33 hospitals, or 58%, do not include non-product cost as a portion of their drug charges. See U.S. Government Accountability Office, Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, Appendix II (Sept. 17, 2004), available at http://www.gpoaccess.gov/gaoreports/index.html.

[11] See 71 Fed. Reg. at 49,586.

impact of using charges to set payment rates in Medicare should be investigated more closely.[12]

This conclusion is further strengthened by the Lewin report's observation that the sample was biased toward hospitals with sophisticated pharmacies that may be more likely to reflect overall costs than those used by the broader population of hospitals.[13]

C. CMS Should Establish Separate Payment for Drug Overhead Costs, As Previously Recommended By MedPAC

As discussed in the CY 2006 Proposed Rule, in the Medicare Modernization Act of 2003, Congress directed MedPAC to study the overhead costs associated with the administration of separately payable drugs in hospital outpatient departments.[14] In June 2005, MedPAC issued its report, finding that the handling costs associated with such drugs are "nontrivial," and recommending that Medicare make an adjustment to the outpatient payment rates to reflect these costs.[15] Specifically, MedPAC recommended that CMS classify separately payable drugs into seven categories, reflecting the relative handling costs for each drug, and then collect hospital charge data for each of the categories to establish a budget neutral payment adjustment for drug handling costs under the OPPS.[16]

D. At a minimum, CMS should implement the 2% add-on that it proposed in 2006

Under the CY 2006 Proposed Rule, CMS recommended the creation of three drug handling categories with corresponding C-codes and APCs. Under this proposal, hospitals would have charged for overhead costs and reported these charges using the appropriate C-code. CMS would have then collected the charge data for two years and developed payment rates for the APCs. In the interim, CMS proposed to provide an add-on payment for pharmacy overhead costs equal to two percent of a drug's ASP.[17]

Testimony presented at the APC Advisory Panel meeting in August 2005 clearly demonstrated that the proposed two percent add-on would not adequately reimburse hospitals for these costs. Hospital stakeholders believed that the proposed pharmacy overhead payment rate of two percent of a drug's ASP did not adequately reflect the actual overhead costs incurred by hospitals in administering separately payable drugs. Additionally, in its June 2005 report,

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[12] See The Lewin Group, "A Study of Hospital Charge Setting Practices," (Dec. 2005) at vi, available at www.medpac.gov/publications/contractor_reports/Dec05_Charge_setting.pdf.

13 See id. at Appendix A-Screener Protocol, Q3, 26-27.

14 See 71 Fed. Reg. at 49,585.

15 See Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program 149 (June 2005) (hereinafter, "MedPAC Report").

16 See 70 Fed. Reg. 42729-30.

17 See id. at 42,730.

MedPAC found that pharmacy overhead costs represented between 26 and 28 percent of hospital pharmacy department costs.[18]

In its report, MedPAC also referenced a 1999 study of cost report data prepared by Kathpal Technologies entitled "High Cost Drugs Under the Outpatient Prospective Payment System," which estimated that overhead costs represent 35.9% of hospital pharmacy department costs.[19] This conclusion was validated by a replication of this study. In 2005 Centocor and a sister corporation jointly engaged two consulting firms, The Moran Company and The Resource Group, to replicate and validate the original study. Using more recent data, The Moran Company and The Resource Group found that overhead costs account for 38.8% of hospital pharmacy costs. Based on these calculations, in order to provide adequate reimbursement for these costs, CMS would have to provide a payment adjustment reflecting a 50-60% markup of drug costs, which is significantly higher than the proposed two percent of ASP.

While CMS did not proceed to establish separate payment for drug overhead costs in the 2006 Final Rule, it did commit to "solicit input. . . to explore alternative methodologies for capturing meaningful and complete pharmacy overhead costs for potential use in providing appropriate payments to hospitals for such services in future updates of the OPPS."[20]

We encourage CMS to implement its original proposal to establish separate payment for drug overhead costs in CY 2006 as a placeholder while it continues to solicit input on pharmacy overhead alternative methodologies.

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18 See MedPAC Report, at 140-141.

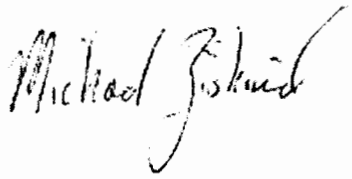
[19] See MedPAC Report, at 6.

[20] See 70 Fed. Reg. 68,515, 68,663 (Nov. 10, 2005).

III. CONCLUSION

We appreciate the opportunity to comment on the important issues raised by CMS's Proposed Rule. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,



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October 10, 2006

By Electronic Delivery

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200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of Centocor, Inc., I am writing to comment on the Centers for Medicare & Medicaid Services' (CMS's) Proposed Rule entitled "Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates" published in the August 23, 2006 Federal Register.[1] Centocor appreciates this opportunity to comment on important aspects of the Proposed Rule, and looks forward to working with CMS to ensure that the Final Rule is implemented in a manner that reflects our concerns.

As a leading biopharmaceutical company that discovers, acquires and markets innovative medicines and treatments that improve the quality of life of people around the world, Centocor is deeply committed to ensuring equitable and fair access to all necessary medicines for all patients. Among other life-improving medicines,[2] Centocor manufactures Remicade®, a product used by patients who suffer from the debilitating effects of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis, enabling these individuals to enjoy longer, more productive lives. Rheumatoid arthritis is a chronic disease that attacks the body's joints, causing inflammation, tissue destruction, and joint erosion. It affects over two million Americans, many of whom are Medicare beneficiaries. Each year, an additional 50,000 Americans are diagnosed with rheumatoid arthritis. Crohn's disease is a relatively rare condition, causing inflammatory disease of the intestine with symptoms that include diarrhea, severe abdominal pain, fever, chills, nausea and fistulae.[3] Ankylosing spondylitis is a painful and progressive form of spinal arthritis that can also affect internal organs, peripheral joints, and vision. Psoriatic arthritis is characterized by the complex symptoms of joint inflammation and skin lesions. Plaque psoriasis is an inflammatory disorder characterized by raised and inflamed lesions, or plaques, which can cause physical pain and emotional distress. Without proper

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[1] 71 Fed. Reg. 49,506 (Aug. 23, 2006).

[2] Centocor also manufactures ReoPro®, for acute coronary care.

[3] Fistulae are painful, draining, abnormal passages between the bowel and surrounding skin.

treatment, the pain associated with these conditions can severely impact the quality of life of afflicted individuals.

Although rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis are chronic and debilitating conditions, Remicade® is a highly effective treatment that can slow the progression of these diseases and significantly enhance the quality of patients' lives by reducing their pain and other incapacitating conditions. Because Remicade® cannot be self-administered by patients, the Medicare Program provides Part B coverage for this infused therapy both in the hospital outpatient department and physician office settings. Thousands of Medicare beneficiaries afflicted with these illnesses rely on Remicade® and other medications to manage their conditions and improve the quality of their lives.

This letter provides comments on two sections of the rule: (1) proposed changes to OPPS drug administration coding and payment for CY 2007; and (2) proposed payment for drugs, biologicals, and radiopharmaceuticals without pass-through status. Our detailed comments are set forth below.

I. PROPOSED CHANGES TO OPPS DRUG ADMINISTRATION CODING AND PAYMENT FOR 2007

The current Medicare OPPS provides uniform Ambulatory Payment Classification (APC) reimbursement to hospitals for the administration of complex chemotherapy services regardless of the length of the infusion. For example, hospitals are paid the same rate for a very complex infusion that lasts as long as five hours as for one that lasts only one hour. Because the single chemotherapy infusion APC includes a wide variety of services, there is great potential for significant underpayment for drug administration services under the OPPS.

To improve the overall accuracy of the payment, CMS is proposing to create six new APCs for drug administration services in 2007.[4] This new structure would allow for separate payments for the initial hour of infusion and each additional hour of service. For example, the first hour of chemotherapy infusion is assigned to APC 0441 with a proposed payment rate of $154.31.[5] Subsequent hours are assigned to APC 0438 with a proposed payment rate of $48.58.[6]

Centocor strongly endorses the new structure and applauds CMS for proposing this approach for 2007. This refinement will improve the overall accuracy of the system by more appropriately recognizing the levels of effort for drug administration and the related resource consumption. We agree with CMS and the APC Advisory Panel that these policies should be implemented in the 2007 Final Rule.

II. PROPOSED PAYMENT FOR DRUGS AND BIOLOGICALS WITHOUT PASS-THROUGH STATUS

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[4] 71 Fed. Reg. at 49,600.

[5] Id. at Addendum B.

[6] Id.

CMS is proposing to reduce reimbursement for drugs and biologicals without pass-through status in 2007 to a rate of Average Sales Price (ASP) plus five percent from the current level of ASP plus six percent.[7] Not only does CMS propose to reduce the overall reimbursement for these medications, but the agency also states that this new, reduced rate is sufficient to account for both the acquisition costs and hospital overhead costs associated with the products. Overall, Centocor endorses the analysis and recommendations in comments submitted by the Biotechnology Industry Organization (BIO) on this proposal, and encourages CMS to review these comments carefully. We share BIO's concerns that this proposal could result in inadequate payment rates for hospitals and thus threaten patient access to Remicade® and other Part B products. Until CMS can do a more complete analysis of hospital overhead cost issues related to pharmacy services, we urge the agency to maintain a rate of at least ASP plus six percent in the Final Rule for these therapies. In addition to the concerns addressed by BIO, we would emphasize the following points:

A. CMS's Key Assumption that Pharmacy Overhead Costs Are Typically Built into the Hospital Charges for Drugs and Biologicals Is Not Supported By Survey Data

In the Proposed Rule, CMS evaluated the two sources of data in determining adequacy of the proposed ASP plus five percent rate: (1) ASP data from the 4th quarter of 2005; and (2) the estimated median cost data from the 2005 hospital claims file.[8] In comparing the overall 2005 ASP-based reimbursement rates to the estimated median costs derived from the claims data, the agency concluded that an ASP plus five percent rate would be adequate in 2007 to cover both the acquisition and overhead costs of these Part B drugs and biologicals. In drawing this conclusion, CMS makes a key assumption that the hospitals include pharmacy overhead costs in their charges for Part B drugs.

In response to this question, Centocor commissioned The Resource Group in 2004 and again in 2006 to test the validity of this assumption. In 2004, The Resource Group conducted a survey of 1,500 hospitals and found that 57% of hospitals reported they did not include non-product costs such as administrative and overhead costs as a portion of their drug charges.[9] This finding is contrary to the CMS assumption that pharmacy overhead costs are uniformly built into hospital charges for drugs and biologics.

Within The Resource Group's 2004 survey, 386 hospitals responded to the question "does the pharmacy charge include an amount for anything other than the drug?" Of the 386 responses, 220 hospitals, or 57%, replied that they did not include non-product costs within their drug charges, while 166, or 43%, replied in the affirmative. To further validate the applicability of the

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[7] Id. at 49,585.

[8] Id. at 49,584-585.

[9] Three hundred and eighty-six hospitals responded to this survey question. The Resource Group study surveyed a random sample of 1,500 hospitals selected from all hospitals (except psychiatric) present in the CMS Providers of Service database as adjusted for duplicate entries and terminated facilities. At a 95% confidence interval plus or minus 5% error, the number of desired responses, rounded upward, was 400, or a 28% response rate. This response rate was achieved.

2004 research finding, The Resource Group is presently conducting a follow-on survey. The preliminary findings indicate that, of approximately 100 valid responses recorded to date, approximately 50% have indicated they did not include non-product costs within their drug charges.

These findings by the Resource Group are corroborated by a 2004 report about a survey conducted by the Government Accountability Office (GAO), which found that 58% of hospitals reported they did not include non-product costs such as administrative and overhead costs as a portion of their drug charges. The survey report recommended that CMS analyze variation in hospital charge-setting to determine if the OPPS payment rates uniformly reflect hospitals' costs for providing outpatient services, and, if they do not, to make appropriate changes to the methodology.[10]

Thus, the three surveys highlighted above indicate that 57%, 58% and a preliminary finding of approximately 50% of respondents did not include expenses such as overhead in their drug charges. Conversely, 43%, 42% and a preliminary finding of 50% of respondents do include expenses such as overhead as a portion of their drug charges. These findings call into question one of the key assumptions in CMS' position that the proposed rate adequately covers both hospitals' acquisition and overhead costs. CMS derives mean and median drug costs from charges contained in hospital claims data. Furthermore, in the Proposed Rule, CMS contends that "pharmacy overhead costs are already built into the charges for drugs, biologics and radiopharmaceuticals . . . ." [11] This key assumption concerning overhead costs and drug charges is again refuted by survey data that shows the majority of hospitals in fact do not include non-product costs such as pharmacy overhead on their drug claims.

B. The MedPAC-Authorized Survey of Hospital Charge-Setting Practices Found That Charges Are Often Not Closely Tied To Costs

The 2005 Medicare Payment Advisory Commission (MedPAC) study performed by The Lewin Group found that:

> The fact that charges are often not closely tied to costs implies that the current Medicare payment systems may not be closely tied to resource utilization. The findings from this study suggest that in certain instances, relative charges may not accurately proxy relative costs. Therefore, the

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[10] After surveying 113 hospitals, the report stated that 24 of the 57 hospitals responding to this question, or 42%, reported that they include non-product costs as a portion of their drug charges. We may therefore conclude that the remaining 33 hospitals, or 58%, do not include non-product cost as a portion of their drug charges. See U.S. Government Accountability Office, Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, Appendix II (Sept. 17, 2004), available at http://www.gpoaccess.gov/gaoreports/index.html.

[11] See 71 Fed. Reg. at 49,586.

impact of using charges to set payment rates in Medicare should be investigated more closely.[12]

This conclusion is further strengthened by the Lewin report's observation that the sample was biased toward hospitals with sophisticated pharmacies that may be more likely to reflect overall costs than those used by the broader population of hospitals.[13]

C. CMS Should Establish Separate Payment for Drug Overhead Costs, As Previously Recommended By MedPAC

As discussed in the CY 2006 Proposed Rule, in the Medicare Modernization Act of 2003, Congress directed MedPAC to study the overhead costs associated with the administration of separately payable drugs in hospital outpatient departments.[14] In June 2005, MedPAC issued its report, finding that the handling costs associated with such drugs are "nontrivial," and recommending that Medicare make an adjustment to the outpatient payment rates to reflect these costs.[15] Specifically, MedPAC recommended that CMS classify separately payable drugs into seven categories, reflecting the relative handling costs for each drug, and then collect hospital charge data for each of the categories to establish a budget neutral payment adjustment for drug handling costs under the OPPS.[16]

D. At a minimum, CMS should implement the 2% add-on that it proposed in 2006

Under the CY 2006 Proposed Rule, CMS recommended the creation of three drug handling categories with corresponding C-codes and APCs. Under this proposal, hospitals would have charged for overhead costs and reported these charges using the appropriate C-code. CMS would have then collected the charge data for two years and developed payment rates for the APCs. In the interim, CMS proposed to provide an add-on payment for pharmacy overhead costs equal to two percent of a drug's ASP.[17]

Testimony presented at the APC Advisory Panel meeting in August 2005 clearly demonstrated that the proposed two percent add-on would not adequately reimburse hospitals for these costs. Hospital stakeholders believed that the proposed pharmacy overhead payment rate of two percent of a drug's ASP did not adequately reflect the actual overhead costs incurred by hospitals in administering separately payable drugs. Additionally, in its June 2005 report,

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[12] See The Lewin Group, "A Study of Hospital Charge Setting Practices," (Dec. 2005) at vi, available at www.medpac.gov/publications/contractor_reports/Dec05_Charge_setting.pdf.

13 See id. at Appendix A-Screener Protocol, Q3, 26-27.

14 See 71 Fed. Reg. at 49,585.

15 See Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program 149 (June 2005) (hereinafter, "MedPAC Report").

16 See 70 Fed. Reg. 42729-30.

17 See id. at 42,730.

MedPAC found that pharmacy overhead costs represented between 26 and 28 percent of hospital pharmacy department costs.[18]

In its report, MedPAC also referenced a 1999 study of cost report data prepared by Kathpal Technologies entitled "High Cost Drugs Under the Outpatient Prospective Payment System," which estimated that overhead costs represent 35.9% of hospital pharmacy department costs.[19] This conclusion was validated by a replication of this study. In 2005 Centocor and a sister corporation jointly engaged two consulting firms, The Moran Company and The Resource Group, to replicate and validate the original study. Using more recent data, The Moran Company and The Resource Group found that overhead costs account for 38.8% of hospital pharmacy costs. Based on these calculations, in order to provide adequate reimbursement for these costs, CMS would have to provide a payment adjustment reflecting a 50-60% markup of drug costs, which is significantly higher than the proposed two percent of ASP.

While CMS did not proceed to establish separate payment for drug overhead costs in the 2006 Final Rule, it did commit to "solicit input. . . to explore alternative methodologies for capturing meaningful and complete pharmacy overhead costs for potential use in providing appropriate payments to hospitals for such services in future updates of the OPPS."[20]

We encourage CMS to implement its original proposal to establish separate payment for drug overhead costs in CY 2006 as a placeholder while it continues to solicit input on pharmacy overhead alternative methodologies.

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18 See MedPAC Report, at 140-141.

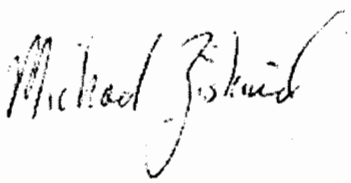
[19] See MedPAC Report, at 6.

[20] See 70 Fed. Reg. 68,515, 68,663 (Nov. 10, 2005).

III. CONCLUSION

We appreciate the opportunity to comment on the important issues raised by CMS's Proposed Rule. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,



Michael Ziskind,
Senior Director
Public Payor Policy, Strategy, and Marketing
Centocor, Inc.

Centocor, Inc.
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Horsham, PA 19044
phone 610.651.6000
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Submitter : **Mr. Michael Ziskind** **Date: 10/09/2006**

Organization : **Centocor, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Note: This is a second e-submission. Centocor, Inc. was accidentally misidentified as a "device" company instead of "drug" company.

CMS-1506-P-393-Attach-1.PDF

Submitter : Mr. Scott Davis **Date:** 10/09/2006

Organization : Memorial Healthcare System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Thank you for this opportunity to comment on these proposed changes. Scott Davis, Director of Revenue Cycle Management, Memorial Healthcare System, Hollywood, FL 33021

CMS-1506-P-394-Attach-1.DOC

#2914

October 9, 2006

Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W. Room 445-G
Washington, D.C. 20201

RE: **CMS-1506-P – Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (71 *Federal Register* 49505), August 23, 2006**

Dear Mr. McClellan:

Thank you for this opportunity to comment on the proposed rule revising Medicare outpatient hospital payments for federal fiscal year 2006.

Memorial Healthcare System is a governmental healthcare system in southern Florida. We are the "safety net" provider for our market area, accepting all patients regardless of ability to pay. We operate a Level I trauma center and three community hospitals, serving more than 13,000 Medicare inpatients annually. We offer comprehensive cancer services, including both chemotherapy and radiation therapy, as well as the only sickle cell program in the area.

Each year, the Centers for Medicare and Medicaid Services (CMS) updates the outpatient prospective payment systems to meet certain statutory requirements and to set forth changes in policy and regulations to reflect ongoing experience with these systems. A key objective of these updates and changes is ensuring that Medicare payments, on average, remain adequate to ensure effective patient care.

We are concerned that a number of the changes contained in this proposed rule run counter to this objective and risk jeopardizing Medicare beneficiaries' continued access to high-quality patient care services. We have stated our concerns in the attachment to this letter. Thank you for this opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please feel free to contact me.

Sincerely,

Scott J. Davis, CPA FHFMA
Director of Revenue Cycle Management
Memorial Healthcare System
3501 Johnson Street
Hollywood, FL 33021

(954) 987-2020 ext. 5105
SDavis@mhs.net

Detailed Comments to Changes to the Hospital Outpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

APC Relative Weights

We recognize the difference in calculations of the hospital-wide cost-to-charge ratios (CCR) between those done for payment purposes and those done for budgeting purposes, and we appreciate CMS's approach to achieving a single, consistent calculation. To facilitate such a calculation, **we would recommend a revision to the Medicare Cost Report Worksheet C to automate calculation of the CCRs excluding allied health costs.**

The hierarchy of CCRs is necessary to address the variations in billing practices across providers. Some of the assignments could be revised to more accurately reflect common cost report practices. Overall, **CMS should conduct a limited study of data providers are required to furnish to their fiscal intermediaries: the crosswalk from the Provider Statistical & Reimbursement (PS&R) report to the cost report cost centers.** Specific revisions to the hierarchy might include:

> Revenue code 0413, Hyperbaric Oxygen Therapy, should have only the hospital-wide CCR assigned, consistent with CMS's approach to determining the median cost for HCPCS code C1300.
>
> Revenue code 026X, IV Therapy, could have 5600 Drugs Charged to Patients as the secondary CCR before defaulting to the hospital-wide CCR.
>
> Revenue code 046X, Pulmonary Therapy, should have 4900 Respiratory Therapy as secondary and 3160 Cardiopulmonary Services as tertiary.
>
> Revenue code 074X, EEG, should have 5400 EEG as primary and 3280 EKG and EEG as secondary.

CMS has elected to eliminate from the claims used any that contain token charges for operating room services, while fiscal intermediaries have been instructed to follow a charge allocation process for making payment calculations, such as for outlier payments. In order to increase the number of usable claims in setting APC relative weights, it would appear reasonable to **follow the same process that the fiscal intermediaries use, allocating the charges from revenue code 0360 pro rata to all HCPCS codes bearing that revenue code, based on the currently existing relative weights, to create additional pseudo single claims.** This does assume that the actual relative costs remain proportional to the existing weights, and would dampen the degree of change in weights. Therefore, inclusion of such pseudo single claims might be done **only if the number of units of certain HCPCS codes on single-procedure claims is below a set threshold.**

With respect to conditional or independent bilateral services, we concur with CMS's decision to exclude those claims, since the total cost of a bilateral procedure (including packaged costs) is

generally less than 2 times the total cost of a unilateral procedure, and such cost savings are already reflected in each hospital's CCRs.

Packaged Services

The concept of "special" packaged services is a fair compromise to deal with some unique patient care scenarios, and we appreciate CMS's proposal.

We do ask for clarification of a statement made in that section of the proposed rule with respect to the billing of low level evaluation and management codes. We would like CMS to clarify that they are addressing only packaged services that could be billed with a recognized (albeit packaged) CPT or HCPCS code, and not changing policy with regard to billing for services that do not have a CPT or HCPCS assigned, such as a visit by a chemotherapy patient for purposes of a periodic port flush.

OPPS: New HCPCS and CPT Codes

Computer-aided detection for possible breast cancers is a significant advancement in the early detection and treatment of this disease. CMS has previously recognized and allowed separate payment for CAD associated with mammography. We believe that the additional work done with MRI of the breast for CAD should be recognized as having a similar clinical value. Therefore, **we request that HCPCS code 0159T be paid separately, if not via an APC rate, then by a separate payment under the physician fee schedule, like payments for other hospital-based mammography services**.

Other New Technology Services

The median cost and payment rate for interstitial radioelement application in the breast (CPT 19296 and 19297) does not make sense, since the cost of the catheter used for this service exceeds the median costs for the entire procedure and device combined. We cannot tell from the data whether this is due to how the additional pseudo single claims were created, but the end result is clearly problematic. **We request that CMS reconsider the calculation of the median cost of these procedures, taking into account that the cost of the device is a minimum of $2,750 each.**

Hyperbaric Oxygen Therapy

We agree with the CMS approach to determining median cost for HCPCS code C1300, to the extent that it helps eliminate from the calculation services that were obviously billed incorrectly. The use of the hospital-wide CCR appears to be the best option at this time. We would suggest that **allowing this HCPCS code to be billed with multiple revenue codes (not just a respiratory therapy revenue code) would allow hospitals to bill for the service sing a revenue code that more closely correlates to the cost center where the services are rendered**. Since the hospital-wide CCR is being used to compute the median cost for this service, we note that the table listing the hierarchy of revenue codes to cost centers should be revised to reflect this assignment.

Radiology Services

CMS has requested comments "on ways that hospitals can uniformly and consistently report charges and costs related to radiology services." We do have one suggestion in this area: permit billing of the surgical component of interventional procedures using the related radiology revenue codes, rather than limiting them to revenue codes such as 036X or 0761. This would permit CMS to assign a more appropriate CCR to those components, either as a packaged cost (e.g., injections for x-rays) or as separately paid APCs (e.g., image-guided breast biopsy).

Device-Dependent APCs

CMS has proposed redefining the modifier "FB" to include both devices that are replaced at no cost and those that are replaced at some discounted cost. CMS has further proposed to reduce the APC payment and the beneficiary coinsurance amount when one of 30 listed devices is so replaced.

We recognize and agree with the value placed on tracking information about the quality of devices used, and use of a modifier to identify replaced items is a relatively simple way to accomplish part of this goal. We also recognize and agree that the beneficiary should not incur a cost for an item where the provider incurs no cost. To that extent, the FB modifier is an appropriate identifier today, and the discount approach proposed by CMS appears to accomplish its intended purpose. However, where a device is replaced with a more expensive device, and the remaining balance of the cost is incurred by the provider, then some recognition of that cost is needed. Rather than revising the definition of modifier FB, **we recommend that CMS not require the use of modifier FB for devices replaced with a more expensive device, and rely instead on condition code 50 "Product Replacement for Known Recall of a Product" (or assign another condition code to describe replacements made without a known recall) to track replaced items, and that CMS not apply a discount to the payment for such replacements.**

OPPS: Nonpass-Through Drugs, Biologicals and Radiopharmaceuticals

CMS has proposed to increase the threshold for separate payment of drugs and biologicals to $55 per day cost. CMS has also proposed payment rates for nonpass-through drugs and biologicals at average sales price (ASP) plus 5 percent, reasoning that this approximates hospital acquisition cost plus overhead. We suggest that there may be a problem with the CMS calculation of cost based on hospital claims data, probably related to the issue of "charge compression."

The labor cost of pharmacy services is typically reported in the Medicare cost report on line 16, column 1. Additional departmental overhead costs would be reported in column 2, along with some costs of drugs charged to patients. After reclassifications and adjustments, the total costs of all pharmacy items would be the combined amounts from lines 16 and 56, column 7. A review of the cost report data from a sample of 302 hospitals indicates that pharmacy labor costs alone account for an average of 23.3% of total pharmacy costs for all hospitals, ranging from 0.03% to 81.1% (ST DEV = 11.7%). Even allowing that ASP may be above the actual cost paid

by some hospitals, the difference between 5 percent of ASP and 23% of total cost needs some explanation.

One possible explanation is charge compression, or a lower percentage markup between cost and selling price for higher-cost items. Application of a single CCR to tiered pharmacy prices would tend to over-allocate costs to low-cost drugs (drugs largely assigned no HCPCS code or a Status Indicator of "N"), and would result in median costs for high-cost drugs that are understated.

We recommend that CMS consider adjusting the markup formula used to estimate average hospital acquisition plus overhead cost, and, in the meantime, pay for nonpass-through drugs and biologicals at the same rate as in the physician office setting, that is, ASP plus 6 percent.

OPPS: Brachytherapy

CMS has proposed payment for brachytherapy sources based on APC rates not scaled for budget neutrality. We understand the reasoning and the methodology described, and concur that it appears to meet the intent of the law. We would appreciate one clarification, though: the definition of "source" leaves unclear whether multiple brachytherapy seeds would constitute multiple "sources" or (as they are implanted all at one time) a single "source." This would affect the number of units of the related code that are billed, as well as the charge per unit.

High-dose radiation therapy (HDR) employing a reusable iridium source is typically scheduled for two treatments per day. Thus, where the number of billed units in the claims file is suspect, a proxy of the number of dates of service billed times 2 could be used as the number of units for computing median cost.

Visits

CMS has proposed creation of new HCPCS codes and APCs for clinic visits and emergency room visits, while maintaining individual hospital protocols for establishing which level applies to any given patient. CMS has noted a range of effectiveness in setting visit levels from hospital to hospital, and we have also noted a range of effectiveness over time. Using any system that requires intervention by clinic or emergency room staff will necessarily consume more staff time and will, therefore, be subject to inaccuracies because of the time pressures to perform clinical (as opposed to administrative) duties. Even where all the information is clinical information that is already gathered in the normal course of treatment, the extra step of consolidating that information into the selection of a visit level amounts to a substantial portion of productive time. We would like to suggest that CMS consider an approach that assigns the visit level independently of the staff involved in the direct patient care. This would alleviate the administrative burden placed on patient care staff, and result in more objective assignment of visit levels. One option for such an approach would be to assign visit levels based on the diagnoses coded on the account, similar to the way diagnosis information is used to assign DRGs for inpatient services.

Another alternative would be to assign the same visit level as the physician, based on the rationale that if the same visit was furnished in a physician's office, the technical component of the physician payment would be based on the same visit level as the professional component.

One side note is important here: CMS states an expectation that the distribution of units of visits would result in a normal curve. However, that should be a normal curve nationally, not necessarily for an individual hospital. For example, a hospital designated as a Level I Trauma Center would be expected to have a higher percentage of more complex emergency room visits, which should skew the distribution above a "normal" curve.

Blood and Blood Products

CMS has proposed updated payment rates for blood and blood products without adjustment to the median costs derived from claims data. We understand that the median costs are derived from billed claims, and it is possible that some items are only furnished in low-cost providers, but we believe that the payment rates under APCs should also make some clinical sense. Review of the data in Table 39 indicates some items that should be reviewed further by CMS:

> P9036 Platelet pheresis irradiated, each unit should not have a lower payment rate than P9034 Platelets, pheresis, each unit.
>
> P9054 Blood, leukoreduced, frozen/deglycerized/washed, per unit should not have a lower payment rate than P9010 Whole blood for transfusion, each unit.

We suggest that CMS consider establishing median costs for the basic parts of blood (whole, RBC, platelets, platelet pheresis, and plasma) and set the payment rates for the treated products by adding costs uniformly for the treatments (irradiation, leukoreduction, cmv testing, freezing/thawing/deglycerizing, pooling, etc.).

Ancillary Outpatient Services

CMS has proposed making a change to the payment rate for APC 375, and to continue making just the one payment for all services on a claim with that APC assigned. We would like CMS to consider making payment for each separate APC assignable from the claim and each fee schedule amount that applies to the claim, and setting the payment rate for APC 375 to cover only the C-status procedure that applies. It appears that the variation in costs for the small sample of claims with this APC could be attributable to the variation in other services being packaged into that APC.

Submitter : **Ms. June Taubman** **Date: 10/09/2006**

Organization : **Ms. June Taubman**

Category : **Individual**

Issue Areas/Comments

OPPS Impact

OPPS Impact

To Whom It May Concern:

My mother is 96 years old and diagnosed with Alzheimer's disease. She is a physically healthy woman but suffers from macular degeneration and loss of hearing. She recently spent several months in a nursing home in New York. While there she was over-medicated and given very little attention. I could see the degeneration in her condition each time I visited.

Her granddaughter insisted that she move to Miami and participate in a program at the Dade Family Counseling Community Center. I cannot tell you how improved she is since participating in this program. The professional staff at the Center are compassionate people who are treating her with incredibly wonderful care. Her medication is being monitored very carefully in an effort to find the right combination for her. Lourdes Rodriguez, the head of the center, referred her to a retina specialist who is using a new drug in an effort to improve her vision. The group sessions have stimulated her mind to a level that I did not think was possible anymore.

The entire staff has gone out of their way to put my mother at ease and make her comfortable. They are sparing no effort to restore the maximum quality of life that she is able to enjoy.

We should have more programs like this for the elderly. Rather than cut back on costs for this program, they should be increased.

Sincerely,
June Taubman
305 East 40th St.
New York, NY 10016

Submitter : Mr. Russ Ranallo **Date:** 10/09/2006

Organization : Owensboro Medical Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-396-Attach-1.DOC

#376

October 6, 2006

The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Ref: [CMS-1506-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Calendar Year 2007 Rates.

Dear Sir/Madam:

The Owensboro Medical Health System (OMHS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, which establishes new policies and payment rates for hospital outpatient services for calendar year 2007. We are pleased by CMS' openness in soliciting comments on the numerous changes it proposes to this remarkably complex and difficult payment system.

Attached are our detailed comments regarding CMS's proposed changes. We hope that CMS will consider our recommendations and make the appropriate adjustments. Please feel free to contact me at (270) 688-2855 if you have any questions or if you require additional information.

Sincerely,

Russ Ranallo
Vice President, Financial Services

X-STOP Interspinous Process Decompression System (XSTOP)

CMS has granted pass through status effective January 1, 2007, which provides reimbursement for the XSTOP device.

We are commenting on our recommendation for the appropriate payment level under OPPS for the procedure used to implant the XSTOP, which will be billed in 2007 using the following two new Category III Current Procedural Terminology ("CPT") codes:

1. **0171T** (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level); and
2. **0172T** (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level).

Owensboro Medical Health System has performed four XSTOP cases during the past year. All four had similar utilization patterns and outcomes. We have analyzed the costs of the procedure as outlined below:

We evaluated the time and resources necessary to complete the procedure and calculated cost (excluding the device and any other separately reimbursable costs) through our cost accounting system.

After interviewing physicians and operating room staff to determine like procedures. We examined laminectomies and diskectomies and found a high degree of variability that limited our ability to compare these procedures to the XSTOP procedure.

We went further and extracted single procedure costs (less implants and any separately reimbursable costs) for all cases in APCs 49 through 52 (Level I through Level IV musculoskeletal procedures). We eliminated the high and low outlier cases and determined that the costs for the four XSTOP cases were much higher than those in APC 50 (Level II) and slightly (less than 5%) lower than APC 51 (Level III).

Therefore, we are recommending that the XSTOP procedures 0171T and 0172T be assigned to APC 51. The subsequent code would be paid at 50% of the APC 51 Rate since 0171T and 0172T would be billed together. We believe this recommendation best fits our cost experience on this procedure. We believe this technology is worthwhile and will help those with degenerative spine disease quickly regain their mobility and should be available to Medicare beneficiaries in the outpatient hospital setting.