Submitter : Mrs. Susan McNamee

Date: 09/08/2006

Organization : National PET Scan Management, LLC

Category : Other Health Care Provider

Issue Areas/Comments

Medicare Contracting Reform Impact

Medicare Contracting Reform Impact

see attachment

CMS-1506-P-38-Attach-1.DOC

Attach #
38

September 8, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of National PET Scan, LLC to address an issue of great importance to Medicare beneficiaries with cancer. National PET Scan, LLC is a leading diagnostic imaging center, and diagnoses and monitors approximately 6000 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth on the proposed hospital outpatient rule will seriously underpay hospitals and IDTF's, and could compromise beneficiary access to this vital technology.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

CMS proposes to reduce the Medicare payment rate for PET/CT to \$865—the same rate proposed for conventional PET—from its current rate of \$1,250. Based on my experience, I believe that \$865 is far below the true cost to our imaging centers providing PET/CT services, and that such a reduction would significantly underpay National PET Scan, LLC. The proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to National PET Scan, LLC of acquiring, maintaining, and operating a PET/CT scanner are substantially

higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Further, CMS bases the proposed rate reduction on only nine months of hospital claims data from 2005 and to my knowledge did not even consider the data from IDTF's that use the same or better equipment. This is inconsistent with the fact that hospitals typically do not update their charge masters frequently enough to account for new CPT codes that are first implemented mid-way through a calendar year. Claims data from 2005 therefore does not reflect the current cost to any hospital's outpatient department or any IDTF's centers of providing PET/CT.

The proposed payment rate reduction for PET/CT would seriously underpay hospitals and IDTF's that will be paid under the hospital rates according to the DRA, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current PET/CT payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Susan McNamee
Director, Billing and Collections
National PET Scan Management, LLC
One Independent Drive
Suite 2201
Jacksonville, FL 32202
904-861-0042
smcnamee@nationalpetscan.com

Submitter : **Mrs. Sharon Grusemeyer** **Date: 09/08/2006**

Organization : **South Jersey Healthcare**

Category : **Nurse**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

The goal of the HCAHPS survey is to assess aspects of the patient s hospital experience, including communication with doctors & nurses, responsiveness of the staff, pain management and discharge information. Basically all discharged patients will receive a survey, regardless of their ability to understand/complete the survey. It is stated that the patient should complete the survey; proxies are not allowed to respond on behalf of the patient. However, someone other than the person who received care can read the questions to the patient and record response.
How is the integrity of the HCAHPS survey protected especially when sending to a prisoner in a state that does not exclude them, or a center that cares for mentally incompetent or incapacitated clients? There is no way to validate the survey was completed by the actual client that receives the care.

Submitter : **David Cohen** **Date: 09/08/2006**

Organization : **Southwest PET/CT Institute**

Category : **Other Health Care Provider**

Issue Areas/Comments

Radiology Procedures

Radiology Procedures

PET/CT Imaging

CMS-1506-P-40-Attach-1.DOC

Attach #
40

Southwest PET Institute, LLC

3503 N Campbell Avenue, Suite 155
Tucson, AZ 85719
(818) 224-6617
Fax (818) 224-6671

September 8, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Southwest PET/CT Institute in Tucson to address an issue of great importance to Medicare beneficiaries with cancer. Southwest PET/CT Institute is a leading oncologic treatment center, and treats approximately 2,000 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth on the proposed hospital outpatient rule will seriously underpay this facility, and could compromise beneficiary access to this vital technology.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

CMS proposes to reduce the Medicare payment rate for PET/CT to $865—the same rate proposed for conventional PET—from its current rate of $1,250. Based on my experience, I believe that $865 is far below the true cost to our hospital outpatient department of providing PET/CT services, and that such a reduction would significantly underpay Southwest PET/CT Institute. The proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to Southwest PET/CT Institute of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Further, CMS bases the proposed rate reduction on only nine months of hospital claims data from 2005. This is inconsistent with the fact that hospitals typically do not update their charge masters frequently enough to account for new CPT codes that are first implemented mid-way through a calendar year. At Southwest PET/CT Institute, for example, we typically update our charge masters quarterly. Claims data from 2005 therefore does not reflect the current cost to our center of providing PET/CT.

The proposed payment rate reduction for PET/CT would seriously underpay us, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current PET/CT payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

David Cohen
President

Submitter : **David Cohen** **Date: 09/08/2006**

Organization : **Indian Wells PET/CT Center**

Category : **Other Health Care Provider**

Issue Areas/Comments

Radiology Procedures

Radiology Procedures

PET/CT Imaging

CMS-1506-P-41-Attach-1.DOC

Attach #
41

Desert Positron Imaging Center, LLC

INDIAN WELLS PET/CT CENTER

74-785 Highway 111, Suite 101
Indian Wells, CA 92210
(818) 224-6617
Fax (818) 224-6671

September 8, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Indian Wells PET/CT Center to address an issue of great importance to Medicare beneficiaries with cancer. Indian Wells PET/CT Center is a leading oncologic treatment center, and treats approximately 1,100 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth on the proposed hospital outpatient rule will seriously underpay this facility, and could compromise beneficiary access to this vital technology.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

CMS proposes to reduce the Medicare payment rate for PET/CT to $865—the same rate proposed for conventional PET—from its current rate of $1,250. Based on my experience, I believe that $865 is far below the true cost to our hospital outpatient department of providing PET/CT services, and that such a reduction would significantly underpay Indian Wells PET/CT Center. The proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to Indian Wells PET/CT Center of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Further, CMS bases the proposed rate reduction on only nine months of hospital claims data from 2005. This is inconsistent with the fact that hospitals typically do not update their charge masters frequently enough to account for new CPT codes that are first implemented mid-way through a calendar year. At Indian Wells PET/CT Center, for example, we typically update our charge masters

quarterly. Claims data from 2005 therefore does not reflect the current cost to our center of providing PET/CT.

The proposed payment rate reduction for PET/CT would seriously underpay us, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current PET/CT payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

David Cohen
President

Submitter : **Ms. Sandra Oprsal** **Date: 09/11/2006**

Organization : **Ingham Regional Medical Center**

Category : **Individual**

Issue Areas/Comments

Visits

Visits

In the discussion of the merits and faults of various proposed coding and payment systems for emergency room and clinic visits, there was a brief consideration of assignment of levels of service based on ICD-9-CM diagnosis codes. This was dismissed as being extremely complex, demanding significant interpretive work on the part of the coder (who may not have clinical experience), and subject to variability across hospitals .

I strongly urge you to reconsider developing a model of assignment of levels of service based on diagnosis codes. At Ingham Regional Medical Center, we very successfully used a simple grid of about 175 diagnosis codes to assign E & M levels to emergency room visits from the time that APCs were implemented through early 2003. I was the Supervisor of the Coding department at that time, and found that this was system was not at all complex, and required very little interpretive work on the part of the coder, who by the way, certainly does have sufficient training to understand clinical disease process and ability to translate documented diagnoses to codes. We found, in fact, that the system was so easy to follow that even the nurses in the ED could consistently and accurately assign facility E & M levels, based on the grid. Nurses were able to mark the appropriate E & M level on the charge ticket. The Coding department performed spot checks and random sample audits to assure that the grid was being followed. We were very pleased with the lack of variability among different coders as well as nurses. The diagnosis grid was developed by one of our area HMOs, Physician s Health Plan. We found it necessary to slightly refine their grid by eliminating some duplication, and we added approximately ten or so diagnoses. Changes to the grid were made with collaboration between the Coding Supervisor and the ED Nurse Manager.

I felt that the diagnosis grid that we used complied with the intent of the OPPS rules. Separately paid services such as intravenous infusions, x-rays, EKGs, lab tests, etc, had no bearing on the level of service assignment. The use of the diagnosis grid consistently resulted in a normal bell-shaped curve distribution of level of service assignments. The grid was simple to use, and could be applied consistently and accurately by both Coders and Nurses. An understanding of the rules for diagnosis code assignment is already part of every Coder s training, and did not require additional training or capture of additional documentation. The level of service assignments correlated well with resource consumption that was not otherwise captured in payments for other separately payable services.

Submitter : **Mrs. Anne Jundt** **Date: 09/11/2006**

Organization : **Mrs. Anne Jundt**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

There are only three months of trial abstraction that hospitals will have before their results have a chance of affecting their APU. We are already working on but this does not seem fair that we only have three months of trial abstraction. Thanks

Submitter : **Ms. Nichole Braccino** **Date: 09/12/2006**

Organization : **University of Missouri Health Care**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Ancillary Outpatient Services

Ancillary Outpatient Services

CMS should delay implementation of the new facility E/M codes until the National Guidelines for facility E/M have been approved and finalized. Facilites have differing guidelines now, and for CMS to map the existing E/M codes with the new G codes as proposed would cause confusion for both CMS and facilities. This change has the potential for months of clean up due to billing and reimbursement errors.
In regards to the Critical Care proposed codes, it seems that since these new codes are time-based, it is going against CMS's statement in the final rule on April 7, 200 pg. 18450: "We believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore, we will pay for critical care as the most resource intensive visit possible..."
Critical Care codes should be considered by most as resource intense rather than time based, especially since there are no guidelines for time based Critical Care codes.

OPPS: Drug Administration

OPPS: Drug Administration

CMS should stay with the drug administration guidelines that were provided for 2006. To change to the CPT codes would cause much confusion, and CMS does not have codes or guidelines for 'concurrent' and/or 'subsequest' injections and/or infusion therapy. Changes such as these are time consuming and costly for all providers, and only adds to the overall price of health care for our nation as a whole.

Submitter : **Mrs. Valerie Rinkle** **Date: 09/12/2006**

Organization : **Asante on Behalf of the Provider Round Table**

Category : **Hospital**

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

Please see the attached comments regarding packaged revenue codes.

CMS-1506-P-45-Attach-1.DOC

Attach #
45

Asante Health System, OR
Avera Health, SD
Baptist Healthcare System, KY
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Forrest General Hospital, MS
Health First, Inc., FL
Mercy Medical Center, IA
Our Lady of Lourdes Regional Medical Center, LA
Saint Joseph's Hospital, WI
Saint Mary's Hospital, MN
Sisters of Mercy Health System, MO
Southwestern Vermont Medical Center, VT
University of Colorado Hospital, CO
University Health System, TX
White River Medical Center, AR

September 12, 2006

Submitted electronically and in hard copy: http://www.cms.hhs.gov/regulations/ecomments
Centers for Medicare & 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: File Code CMS-1506-P

Dear CMS:

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers from around the country who gathered to provide comments on the 2007 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on August 23, 2006. The providers listed above appreciate the opportunity to submit these comments for consideration by CMS. A full list of the current PRT members is provided in **Appendix A**.

Introduction

The Provider Roundtable (PRT) is a group of 17 different hospitals and health systems representing over 50 hospitals from around the country. Like many others, our hospitals, and the departments within our institutions, continue to struggle with OPPS and its many coding and billing complexities. Providers are often too busy, or unaware of the overall process, to submit comments to CMS on their own. Therefore, the members of the PRT collaborated to provide substantive comments with an operational focus which CMS' staff should consider during the OPPS policymaking and recalibration process each year.

We appreciate the opportunity to provide CMS with our comments, and recognize that providers must become involved in the comment process if OPPS is to improve with time.

Packaged Revenue Codes

The PRT reviewed the list of packaged revenue codes and became concerned when non-OPPS service revenue codes were listed. We compared the 2006 list of packaged revenue codes to the list of revenue codes from the OCE that allow charges with no HCPCS code present. We then compared to the list of packaged revenue codes from the 2007 proposed rule.

We believe some changes need to be made in the list of packaged revenue codes that are more consistent with OPPS payment policy and also with appropriate billing of OPPS services. Continuing to package costs from some claims with suspect revenue codes may result in poor median cost calculations.

The following table provides these comparisons and our comments.

Comparison of Packaged Revenue Code Lists

2007 proposed rule	Description	2006 final rule	Oct 2006 OCE list blank HCPCS OK-meaning allow as a packaged revenue code	PRT Comments
250	PHARMACY	250	250	
251	GENERIC	251	251	
252	NONGENERIC	252	252	
254	PHARMACY INCIDENT TO OTHER DIAGNOSTIC	254	254	
255	PHARMACY INCIDENT TO RADIOLOGY	255	255	
257	NONPRESCRIPTION DRUGS	257	257	
258	IV SOLUTIONS	258	258	
259	OTHER PHARMACY	259	259	
260	IV THERAPY, GENERAL CLASS	260	260	
262	IV THERAPY/PHARMACY SERVICES	262	262	
263	SUPPLY/DELIVERY	263	263	
264	IV THERAPY/SUPPLIES	264	264	
269	OTHER IV THERAPY	269	269	
270	M&S SUPPLIES	270	270	
271	NONSTERILE SUPPLIES	271	271	
272	STERILE SUPPLIES	272	272	
			273	These are non-covered charges.

274	PROSTHETIC/ORTHOTIC DEVICES	274		This Revenue Code is for non-implanted prosthetic/orthotic devices which require a HCPCS code and are paid under the MPFS and have a SI "A" under OPPS. Costs under this revenue code should not be packaged under OPPS. Furthermore, the OCE will not allow charges under this revenue code to be reported without a HCPCS code. Therefore, the PRT requests CMS remove revenue code 274 from the packaged revenue code list.
275	PACEMAKER DRUG	275	275	
276	INTRAOCULAR LENS SOURCE DRUG	276	276	
278	OTHER IMPLANTS	278	278	
279	OTHER M&S SUPPLIES	279	279	
280	ONCOLOGY	280	280	The PRT is unable to identify any oncology service that would not be characterized by a CPT/HCPCS code. Therefore, the OCE should require CPT/HCPCS codes for line items billed with revenue code 28X and should not consider these services packaged. Hospitals billing charges under revenue code 28X without a CPT/HCPCS would be suspect and should not be included as packaged costs.
289	OTHER ONCOLOGY	289	289	See above comments for revenue code 280.
290	DURABLE MEDICAL EQUIPMENT	290		By definition, DME is for use in the home, not in the outpatient hospital setting. Furthermore, the OCE requires a HCPCS code when this revenue code is billed and DME is not billable by hospitals to Intermediaries. The hospital must obtain a DMERC provider number and separately bill DME to the DMERC. Therefore, packaged costs billed by hospitals for outpatients under this revenue code are suspect and should not be used in the rate setting process.
343	DIAGNOSTIC RADIOPHARMS	343	343	Radiopharmaceuticals are required to be billed with HCPCS codes. While CMS may ultimately determine that radiopharmaceuticals are packaged HCPCS, this determination is made individually for each radiopharmaceutical HCPCS code, therefore, charges billed under 343 or 344 without the appropriate HCPCS codes should be suspect. The PRT recommends the OCE edit for HCPCS codes on these revenue codes and that these revenue codes be removed from the list of packaged revenue codes.
344	THERAPEUTIC RADIOPHARMS	344	344	See the above comment for revenue code 343.
370	ANESTHESIA	370	370	
371	ANESTHESIA INCIDENT TO RADIOLOGY	371	371	
372	ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC	372	372	
379	OTHER ANESTHESIA	379	379	
390	BLOOD STORAGE AND PROCESSING	390	390	

399	OTHER BLOOD STORAGE AND PROCESSING	399	399	
560	MEDICAL SOCIAL SERVICES	560	560	Services characterized by revenue codes in the 56X series are separately billabled only by Home Health Agencies. Hospitals billing charges under the 56X revenue code series are billing for suspect services and therefore, the revenue codes in the 56X series should not be on the packaged revenue code list and charges submitted with these revenue codes should not be used in the rate setting process.
569	OTHER MEDICAL SOCIAL SERVICES	569	569	See the above comments for revenue code 560.
621	SUPPLIES INCIDENT TO RADIOLOGY	621	621	
622	SUPPLIES INCIDENT TO OTHER DIAGNOSTIC	622	622	
624	INVESTIGATIONAL DEVICE (IDE)	624	624	
630	DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS	630	630	
631	SINGLE SOURCE	631	631	
632	MULTIPLE	632	632	
633	RESTRICTIVE PRESCRIPTION	633	633	
			637	These are non-covered charges.
681	TRAUMA RESPONSE, LEVEL I	681	681	
682	TRAUMA RESPONSE, LEVEL II	682	682	
683	TRAUMA RESPONSE, LEVEL III	683	683	
684	TRAUMA RESPONSE, LEVEL IV	684	684	
689	TRAUMA RESPONSE, OTHER	689	689	
700	CAST ROOM	700	700	
709	OTHER CAST ROOM	709	709	
710	RECOVERY ROOM	710	710	
719	OTHER RECOVERY ROOM	719	719	
720	LABOR ROOM	720	720	
721	LABOR	721	721	
			732	
762	OBSERVATION ROOM	762	762	
			801	
			802	
			803	
			804	
			809	
810	ORGAN ACQUISITION	810	810	
819	OTHER ORGAN ACQUISITION	819	819	
			821	
			822	

		823
		824
		825
		829
942 EDUCATION/TRAINING	942	942

Conclusion

The Provider Roundtable would sincerely like to thank CMS and its staff for reviewing and considering our comments. Although we are still a relatively new group, the PRT members are very encouraged by the policy-making process and appreciate how our input can have an impact on future year's rules and policies. We are very grateful to CMS for considering our comments in past years as well as again this year. We hope the operational issues we have outlined will be helpful to CMS in considering future system changes. If you have any questions or require additional information, please contact our spokesperson Valerie Rinkle, listed below.

Comments were submitted electronically by Valerie Rinkle, MPA, Asante Health System. A full list of the provider roundtable members is included below in **Appendix A**.

Sincerely yours,

Members of the Provider Roundtable

Appendix A: Current Members of the Provider Roundtable

Jennifer L. Artigue, RHIT, CCS
Dir. Revenue Mmgt, CDM & Medical Records
Our Lady of Lourdes Regional Medical Center
Lafayette, LA

Kathi L Austin, CPC, CPC-H, CCP
Corporate Director Revenue Integrity
Sisters of Mercy Health System
St. Louis, MO

Barbara Bunge, RHIA, CCS, CCS-P
Coding Quality Specialist, HIM
Mercy Medical Center
Cedar Rapids, IA

Kathy Dorale, RHIA, CCS, CCS-P
Director of Health Information Management
Avera Health
Sioux Falls, SD

Janet V. Gallaspy, BS, RN, CPUR, CPC-H
Medical Auditor, Corporate Compliance
Forrest General Hospital
Hattiesburg, MS

Jerry Hill, MA
Charge Management Coordinator
University Health System
San Antonio, TX

Marion G. Kruse, BSN, RN, MBA
Columbus, OH

Carol Leffeler, RN, BA
CDM Coordinator
White River Medical Center
Batesville, AR

Monica Lenahan, CCS
Coding Manager
University of Colorado Hospital
Denver, CO

Bonnie Malterer, RHIT, BA
APC Coordinator, Outpatient Coding Supervisor

St. Mary's Hospital
Duluth, MN

Yvette Marcan, RN, MA, RHIA, CCS
APC Coordinator
Health First, Inc.
Melbourne, FL

Terri Rinker, MT(ASCP), DLM, MHA
Reimbursement Manager
Community Hospital Anderson
Anderson, IN

Valerie A. Rinkle, MPA
Revenue Cycle Director
Asante Health System
Medford, OR

Julie Rodda, RHIT
Coding Specialist
St. Joseph's Hospital
Marshfield, WI

John Settlemyer, MBA/MHA
Director, Financial Services/CDM
Carolinas Healthcare System
Charlotte, NC

Marianne Seymour, RHIT, CCS
Medical Necessity Coordinator
Southwestern Vermont Medical Center
Bennington, VT

Denise Williams, RN, CPC-H
Charge Management Coordinator
Baptist Healthcare System
Louisville, KY

Submitter : **Ms. Denise Majeski** **Date: 09/12/2006**

Organization : **Lake Forest Hospital**

Category : **Nurse**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

I speak for the team at Lake Forest Hospital to support the need for reimbursement for the use of CPT-90761 with modifications to the AMA definition of CPT's for unit based variables. This will provide consistancy among all payer sources.
We support the need for the use of CPT codes and eliminate the use of G-codes.We would have fewer problems in terms of back-end edits and resource utilization for manual reviews.
We support the the use of g0332 to receive reimbursement for the preadministration services for IVIG administration.
CMS should provide separate APC payments for multiple injections of the same drug/substance as we do not expend fewer resources such as nursing time,room time and preparation time. These are the same as when different drugs are injected.
We need to see the modifier 59 eliminated as it is confusing to use and should not be needed when providing other services.

OPPS: New HCPCS and CPT Codes

OPPS: New HCPCS and CPT Codes

The team at Lake Forest Hospital supports the use of the distinction made between ED and dedicated emergency departments and the use of 5 new G codes for DED.Recognition is needed that treatment of outpatient visits have been for the treatment of emergency medical conditions on an urgent basis without reqiring a previously scheduled appointment. This will help to eliminate overcrowding in our emergency rooms.
We ask you to consider removing the timing from the new critical care codes and consider 2 levels instead-one for critically ill/injured without trauma activation and another for trauma activation.

Submitter : **Dr. Mark Gittleman** **Date: 09/12/2006**

Organization : **Breast Care Specialists, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1506-P-47-Attach-1.DOC

Attach # 47

September 12, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of both codes from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial for my patient population. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Mark Gittleman, MD, FACS

Mark A. Gittleman, MD, FACS
Breast Care Specialists, PC
Allentown, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Daleela Dodge** **Date: 09/13/2006**

Organization : **Lancaster Surgical Group, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-48-Attach-1.DOC

Attach # 48

September 12, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial for my patient population. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Daleela G. Dodge, MD

Daleela G. Dodge, MD
Lancaster Surgical Group, PC
Lancaster, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Jeffrey Falk** **Date: 09/13/2006**

Organization : **Magee-Womens Surgical Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-49-Attach-1.DOC

Attach #
49

Magee-Womens Hospital

of University of Pittsburgh Medical Center

Magee-Womens Surgical Associates

Suite 2601
300 Halket Street
Pittsburgh, PA 15213

September 12, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 from the New Technology to the Clinical payment rate.

With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. Partial breast irradiation (PBI) allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting treatment access for this deadly disease for Medicare patients.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Jeffrey Falk, MD, FACS
Pittsburgh, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Paul Newman** **Date: 09/13/2006**

Organization : **Lancaster Surgical Group, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-50-Attach-1.DOC

AHW. #
50

September 12, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial for my patient population. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Paul Newman, MD

Paul G. Newman, MD
Lancaster Surgical Group
Lancaster, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Thomas Bauer** **Date: 09/13/2006**

Organization : **Apple Hill Surgical Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-51-Attach-1.DOC

Attachment
57

September 13, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. I would like to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of both codes from the New Technology to the Clinical payment rate.

Access to partial breast irradiation (PBI) is crucial for my patient population, allowing the treatment process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital and I will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting treatment access for this deadly disease to Medicare beneficiaries.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Thomas L. Bauer, MD

Thomas L. Bauer, MD, FACS
Apple Hill Surgical Associates
York, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Dennis Johnson** **Date: 09/13/2006**

Organization : **Apple Hill Surgical Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-52-Attach-1.DOC

Attach # 52

September 13, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. I am sharing my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of both codes from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. Partial breast irradiation (PBI) allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, my hospital and I may no longer be able to cover the cost of the procedure; therefore limiting access to Medicare patients.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Dennis Johnson, MD

Dennis E. Johnson, MD
Apple Hill Surgical Associates
York, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Susan Greenwood** **Date: 09/14/2006**

Organization : **St. Bernards Medical Center**

Category : **Hospital**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

Before 30 day mortality for AMI, HF, and Pneumonia is added to the publicly reported data set and RHQDAPU, we would want the mortality rate to be adequately risk adjusted, preferably using the APRDRG methodolgy. A raw mortality rate from administrative data would not be an acceptable indicator to publicly report if it were not risk adjusted.

Submitter : **Dr. David Hartzell** **Date: 09/14/2006**

Organization : **St. Rita's Medical Center**

Category : **Pharmacist**

Issue Areas/Comments

Medication Therapy Management Services

Medication Therapy Management Services

AMA categorizes MTM services as category III because the provision of MTMS is not common. While CMS is correct in asserting that MTM are not new services, the provision of these services is not the standard of care and are logistically difficult to provide when pharmacist staffing is largely determined by dispensing activities. Until revenue sources are available for pharmacists to be able to provide MTM services, institutions will not be able to absorb the overhead associated with their time away from the distributive function. There is widespread cost data to support the increased involvement of pharmacists with medication therapy management. CMS can use this data for support of new APCs and their associated payment rates.

Submitter : Dr. Thomas Frazier

Date: 09/14/2006

Organization : Thomas G. Frazier, MD, FACS

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-55-Attach-1.DOC

Attach ff
55

September 14, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of CPT 19296 from the New Technology to the Clinical payment rate.

Roughly 170,000 women are diagnosed annually with early stage breast cancer. These patients move on to lumpectomy followed by radiation therapy; however, the statistics show many of these women do not complete 6-8 weeks of radiation. Therefore I recommend Partial Breast Irradiation (PBI) for carefully selected breast cancer patients. The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Access to PBI is crucial for my patient population. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital and I will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

Thomas G. Frazier, MD

Thomas Frazier, MD
Main Line Health System
Bryn Mawr, PA

cc. Senator Arlen Specter, Chairman, Appropriations Labor-HHS Subcommittee
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Date: 09/15/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

Attention: CMS-1506-P - Rule: Hospital Outpatient Prospective Payment System (OPPS)

Dear Administrator,

Thank you for allowing me the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have some serious concerns regarding your proposed changes.

Roughly 170,000 women are diagnosed annually with early stage breast cancer. These patients move on to lumpectomy followed by Radiation Therapy. However, statistics show many of these women do not complete their 6-8 weeks of Radiation Therapy. Therefore I recommend Partial Breast Irradiation Therapy for carefully selected Breast Cancer patients. With Partial Breast Irradiation Therapy, a woman can complete her Radiation treatments in five days. The women are more compliant and can return to their normal work and family duties in a timely fashion.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for heeding these recommendations. We would like to continue servicing our Medicare patients.

Respectfully,

Christina L. Dial, D.O.

cc: Senator Mike Enzi, Chair, Senate Health, Education, Labor and Pensions Committee

Senator Dianne Feinstein, Co-Chair, Senate Cancer Committee

Senator Sam Brownback, Co-Chair, Senate Cancer Committee

Senator Thad Cochran, Chairman, Senate Appropriations Committee

Carolyn Mullen, Deputy Director, Division of Practitioner Services

Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : **Dr. George Webber** **Date: 09/15/2006**

Organization : **Knoxville Comprehensive Breast Center**

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

See Attachment

CMS-1506-P-57-Attach-1.DOC

Attach # 57

September 12, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Access to partial breast irradiation (PBI) is crucial for my patient population. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, I may no longer be able to provide PBI to my Medicare patients, as my hospital will not be able to cover the cost of the procedure. The procedure requires a device with a cost of $2750, more than the proposed Clincal APC is reimbursing. As a result, we will be limiting Medicare patients' access to treatments for this deadly disease.

As a practitioner focusing on breast cancer treatment, I urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact the proposal outlines.

Sincerely,

George Webber, MD

George R. Webber
Knoxville Comprehensive Breast Center
6307 Lonas Drive
Knoxville, TN

cc. Senator Bill Frist, Majority Leader Bill Frist
Carol Bazell, MD, MPH, Director, Division Outpatient Services
Helen Pass, MD, FACS, President, American Society of Breast Surgeons
Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Dr. Albert Varner** **Date: 09/15/2006**

Organization : **Endoscopy Center of Marin**

Category : **Physician**

Issue Areas/Comments

Medicare Contracting Reform Impact

Medicare Contracting Reform Impact

If Medicare reimbursement for out patient colonoscopies is reduced to 62% of what hospital out patient depts. are paid, it would make them money losers for free standing GI centers like ours. This would require us to limit the number done, or to stop doing them, at our center. In this case, doing them at the local hospital might or might not be feasible and access to this service would certainly be jeopardized. Please do not reduce further the technical fees paid to GI centers like ours for Medicare endoscopy procedures. Thank you. Al Varner, MD

Submitter : **Dr. Stanley Pollack** **Date: 09/15/2006**

Organization : **Surgical Breast Care Specialist**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-59-Attach-1.DOC

Attach A
59

September 15, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing our facility the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

Our facility opposes this proposal and requests CMS reconsider maintaining assignment of the New Technology APC for an additional year. The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Partial breast irradiation (PBI) allows the radiation process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, our facility may not be able to cover the cost of the procedure, which requires a device with a cost of $2750. Our procedure costs are more than the proposed Clincal APC is reimbursing.

We urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. Thank you for your careful consideration and review in this important matter.

Sincerely,

Staneley B. Pollack MD

Surgical Breast Care Specialist
200 North Village Ave Suite 210
Rockville Center, NY 11570

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

Submitter : **Dr. Karen Karsif** **Date: 09/15/2006**

Organization : **NY Hospital Queens**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-60-Attach-1.DOC

Attach# 60

September 15, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator:

Thank you for allowing our facility the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 23, 2006. This letter is written to share concern regarding the proposed RVU reduction for CPT19296 and CPT 19297, when performed in the hospital, and the reassignment of these codes from the New Technology to the Clinical payment rate.

Our facility opposes this proposal and requests CMS reconsider maintaining assignment of the New Technology APC for an additional year. The proposed reduction and reassignment will have a detrimental impact for Medicare patients with a breast cancer diagnosis. Partial breast irradiation (PBI) allows the radiation process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction and reassignment takes place, our facility may not be able to cover the cost of the procedure, which requires a device with a cost of $2750. Our procedure costs are more than the proposed Clincal APC is reimbursing.

We urge CMS to reconsider the proposed RVU reduction and the reassignment to the Clinical payment rate. Please leave CPT 19296 and CPT 19297 in the New Technology rate for another year so that CMS can collect the correct supporting cost documentation. Thank you for your careful consideration and review in this important matter.

Sincerely,

Karen Karsif MD FACS
New York Hospital Queens
56-45 Main St
Flushing NY 11355

CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee
Helen Pass, MD, FACS, President, American Society of Breast Surgeons

Submitter : **Dr. David Beatty** **Date: 09/15/2006**

Organization : **Dr. David Beatty**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-61-Attach-1.DOC

Attach # 61

Office of The Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates

Dear Administrator,

I appreciate the opportunity to share my comments on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I would like to share my concerns regarding the proposed reduction of the RVUs by 4 units when CPT code 19296 is performed by the Surgeon in the Hospital as well as the proposed reduction of the conversion factor by 5.1%. Further the proposed APC reassignment for the hospital for CPT codes 19296 and 19297 from New Technology APC (1524 & 1523) to Clinical APCs (030 & 029) will impact services due to the cost of the device (catheter) not being adequately captured in the clinical APC payment rate.

A reduction of the RVUs will not allow me to place the catheter in the hospital and will negatively affect my ability as a Physician to treat Medicare patients with this important procedure in the hospital. The hospital will be forced to not provide the catheter for Medicare beneficiaries as the catheter will be priced higher than the Clinical APC rate. Partial breast irradiation is a very important therapy for Medicare patients with breast cancer and unfortunately with these proposed changes it will negatively affect their opportunity to receive this standard of care technology. Please understand the value of this procedure and need for Medicare patients to have ease of access and availability to partial breast irradiation therapy which first begins with placement of the catheter. I will not be able to perform this procedure in the hospital for Medicare patients if CMS upholds this current proposal.

I must offer a firm recommendation that CMS freeze the current RVUs and with only a slight reduction in the conversion factor. I also maintain that you must delay your reassignment of the CPT codes 19296 and 19297 from New Technology APC to Clinical APC for at least another year as it is investigated more.

Thank you for allowing me to address this issue and provide you with feedback on the proposal. I appreciate your time and efforts on this issue.

Sincerely,

David Beatty, MD

David Beatty, M.D.
Surgeon
Swedish Cancer Center
1221 Madison Street, Ste. 400
Seattle, WA 98104

cc: Senator Maria Cantwell WA (D)
Senator Patty Murray WA (D)

cc: Carol Bazell, MD, MPH, Director, Division Outpatient Services

cc: American College of Surgeons
Mark A. Malangoni, MD, Chair, American College of Surgeons

Submitter : **Date: 09/17/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 11, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P

Rule: Hospital Outpatient Prospective Payment System (OPPS)

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

Dear CMS Administrator,

Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). This letter is written to show my deep concern regarding the pending changes.

Forsyth Hospital provides Partial Breast Irradiation (PBI) Therapy treatment to your Medicare beneficiaries. PBI uses a surgically implanted catheter to deliver the radiation directly to the tumor bed and uses high dose radiation to treat the tumor bed. Partial Breast Irradiation Therapy is a very important treatment modality for Medicare age women since it provides women the option to shorten their course of radiation from 6-7 weeks to five days.

I am quite concerned about the proposed changes to 19296 and 19297 and respectfully request that CMS keep APC #1524 assigned to this new technology for an additional year until better data can be collected. The proposed reassignment to APC #0030 is not sufficient payment for the catheter which is priced at $2,750.

Again, I appreciate the opportunity to comment on file #CMS-1506-P. Medicare patients should have availability and access to all breast cancer treatment options. I strongly urge CMS to reconsider the assignment of breast brachytherapy to APC #0030 and keep breast brachytherapy assigned to the old APC #1524.

I really appreciate you time and attention to this very important issue,

Judy D. Sears, M.D.
Piedmont Radiation Oncology, PA
Forsyth Regional Cancer Center

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

Carol Bazell, MD, MPH, Director, Division Outpatient Services

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

CMS-1506-P-62-Attach-1.DOC

Attachmt
62

September 11, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P

Rule: Hospital Outpatient Prospective Payment System (OPPS)

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

Dear CMS Administrator,

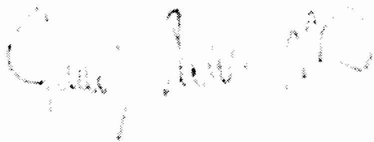
Thank you for the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). This letter is written to show my deep concern regarding the pending changes.

Forsyth Hospital provides Partial Breast Irradiation (PBI) Therapy treatment to your Medicare beneficiaries. PBI uses a surgically implanted catheter to deliver the radiation directly to the tumor bed and uses high dose radiation to treat the tumor bed. Partial Breast Irradiation Therapy is a very important treatment modality for Medicare age women since it provides women the option to shorten their course of radiation from 6-7 weeks to five days.

I am quite concerned about the proposed changes to 19296 and 19297 and respectfully request that CMS keep APC #1524 assigned to this new technology for an additional year until better data can be collected. The proposed reassignment to APC #0030 is not sufficient payment for the catheter which is priced at $2,750.

Again, I appreciate the opportunity to comment on file #CMS-1506-P. Medicare patients should have availability and access to all breast cancer treatment options. I strongly urge CMS to reconsider the assignment of breast brachytherapy to APC #0030 and keep breast brachytherapy assigned to the old APC #1524.

I really appreciate you time and attention to this very important issue,



Judy D. Sears, M.D.
Piedmont Radiation Oncology, PA
Forsyth Regional Cancer Center

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

Carol Bazell, MD, MPH, Director, Division Outpatient Services

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Mr. Steven Vaughan** **Date: 09/17/2006**

Organization : **Jackson County Memorial Hospital**

Category : **Pharmacist**

Issue Areas/Comments

Medication Therapy Management Services

Medication Therapy Management Services

The benefits of pharmacist provided diabetes and anticoagulation services are far greater than the political issues that surround the withholding of medication management APC codes.
Please review the diabetes and stroke data for the state of Oklahoma and the need of education for our people. Diabetes is a critical health issue in our state.
Restricting highly trained doctors of pharmacy from utilizing their training and recognizing the documented impact that medication management provides, when healthcare shortages abound is incomprehensible.
Please reconsider medication therapy management APC as recommended by the APC Panel. The impact of one APC on diabetes and anticoagulation therapy would be tremendous.

Submitter :

Date: 09/17/2006

Organization :

Category : Physician

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

September 11, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P - Rule: Hospital Outpatient Prospective Payment System (OPPS)

Dear Administrator,

Thank you for allowing me the opportunity to provide comments on file #CMS-1506-P for the CY 2007 / 2008 CMS proposed Hospital Outpatient Prospective Payment System (OPPS). I have some serious concerns regarding your proposed changes.

At Forsyth Hospital, we take pride in the services offered to Medicare beneficiaries. We are extremely professional and pay a lot of attention to detail. We are very adept in administering brachytherapy services.

The reassignment of CPT codes 19296 & 19297 to APC #0030 is not sufficient payment for the catheter which is priced at $2,750. Our recommendation is for CPT codes 19296 & 19297 to remain under APC #1524 for at least one more year so additional data can be collected on this service.

Thank you for heeding these recommendations. We would like to continue servicing our Medicare patients.

Respectfully,

Lisa S. Evans, MD
Piedmont Radiation Oncology, PA
Forsyth Regional Cancer Center

cc: Representative Sue Myrick, Energy and Commerce Health Subcommittee, Co-Chair, House Cancer Caucus

Senator Richard Burr, Senate Health, Education, Labor and Pensions Committee

Carol Bazell, MD, MPH, Director, Division Outpatient Services

Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology (ASTRO)

James Rubenstein, MD, Chairman, American College of Radiation Oncology (ACRO)

W. Robert Lee, MD, President, American Brachytherapy Society (ABS)

Submitter : **Mr. Shashank Soni** **Date: 09/17/2006**

Organization : **Virginia Oncology Associates**

Category : **Other Health Care Professional**

Issue Areas/Comments

OPPS: National Unadjusted Medicare Payment

OPPS: National Unadjusted Medicare Payment

I am writing on behalf of Virginia Oncology Associates to address an issue of great importance to Medicare beneficiaries with cancer. Virginia Oncology Associates is a leading oncologic treatment center, and treats approximately 800 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth on the proposed hospital outpatient rule will seriously underpay hospitals, and could compromise beneficiary access to this vital technology.
Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures such as biopsies required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

CMS proposes to reduce the Medicare payment rate for PET/CT to $865 the same rate proposed for conventional PET from its current rate of $1,250. Based on my experience, I believe that $865 is far below the true cost to our hospital outpatient department of providing PET/CT services, and that such a reduction would significantly underpay Sentara. The proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to Sentara of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Further, CMS bases the proposed rate reduction on only nine months of hospital claims data from 2005. This is inconsistent with the fact that hospitals typically do not update their charge masters frequently enough to account for new CPT codes that are first implemented mid-way through a calendar year. At Sentara, for example, we typically update our charge masters annually. Claims data from 2005 therefore does not reflect the current cost to our outpatient department of providing PET/CT.

The proposed payment rate reduction for PET/CT would seriously underpay hospitals, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current PET/CT payment rate of $1,250.

Thank you for your attention to this important matter.

Submitter : **Mr. Scott Lucas** **Date: 09/18/2006**

Organization : **Great Plains regional Medical Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Impact

Impact

The proposed reduction in reimbersement in PET and PET/CT Studies would mean that we would do these studies at an actual loss of 31%. We are a rural hospital and pay a mobile service to do our PET Scans once a week. we pay $1250 per scan which means that we currently break even on Medicare patients. The new rate would mean that we would pay 31% more than we can recover from medicare thus we will actually loose $388 per scan. I see no way that this is sustainable or fair to us or to the Medicare Patients that rely on us for care that saves lives and sometimes eases deaths. You may not care that we are out here in rural America but we matter as much as your city friends and our care is just as important. This is the quick way to shut down services in rural areas. Please reconsider these poorly thought out and clearly unfair plans for cuts in PET reimbersements. You will be killing services that you or a family member may someday need

Submitter : **Dr. Haywood Brown** **Date: 09/18/2006**

Organization : **Duke University Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1506-P-67-Attach-1.PDF

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

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

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

Submitter : **Dr. Millie Behera** **Date: 09/18/2006**

Organization : **Duke University Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-68-Attach-1.PDF

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 : **Mr. Luke Martindale** **Date: 09/18/2006**

Organization : **United Focused Ultrasound**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-69-Attach-1.PDF

Attach # 69

ULTRASOUND United Focused Ultrasound • 700 NW Gilman Blvd. #189 • Issaquah WA 98027-5335 • Phone 772.708.4586 • Fax 206.201.5165 • www.ufu.net

September 14, 2006

The Honorable Mark McClellan, MD
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 CY2007 Payment Rates

Dear Dr. McClellan:

After reviewing the proposed rule regarding changes to the Hospital Outpatient Prospective Payment System payment rates for calendar year 2007, we would like to take the opportunity to submit the following comments regarding the APC assignment of the Magnetic Resonance Guided Focused Ultrasound (MRgFUS) procedure.

Uterine fibroids (leiomyomas) are common noncancerous (benign) tumors of the uterus. Uterine fibroids may cause heavy bleeding, pelvic discomfort and pain and create pressure on other organs. In the United States, 30% of all women between the ages of 25 and 50 are diagnosed with symptomatic uterine fibroids. Thirty-five to fifty percent of women will seek treatment for their symptoms, and 400,000 will undergo a surgical procedure to relieve the symptoms of uterine fibroids.

Hysterectomy is currently the primary treatment option for uterine fibroids. Hysterectomy is an invasive surgical procedure and is a very expensive procedure for the hospital as well as the health care system. While the clinical results are highly efficacious, there are several drawbacks that cannot be overlooked. Invasive surgery carries with it the risks associated with anesthesia, a high degree of pain post-surgery; and a recovery period of six to eight weeks, during which patients are unable to complete normal activities. It is also an expensive procedure that incurs many direct and indirect costs.

The MRgFUS procedure (HCPCS 0071T and 0072T) offers patients a non-surgical treatment option that allows them to return to normal activities the following day. Patients who undergo the MRgFUS procedure have fewer disability days (decreased days of missed work or days in bed) and lower use of medical resources.

The MRgFUS procedure is reported by providers using CPT codes 0071T and 0072T. These two procedure codes are current assigned to inappropriate APCs. The current assignment to APCs 195 and 202 have a payment rate that does not cover the cost of the care provided by our organization. The proposed rule for 2007 maintains the assignment of the MRgFUS procedure to these two APC codes, with a recommended modest increase in the payment rate. It is our opinion that the payment rate for this

procedure has, and continues to be, far below the cost incurred by our hospital to provide this service. We anticipate our average charges at our out patient facility for the MRgFUS procedure in 2006-2007 to range from **$16,500 to $25,000.** The lack of adequate reimbursement under APC 195 and 202 is a true barrier to access in the MRgFUS market.

It is our understanding that APC classifications are intended to appropriately group services that are similar both clinically and in terms of the resources they require. The payment rate established for each APC is based upon claims data submitted by hospitals and is designed to cover hospitals' operating and capital costs.

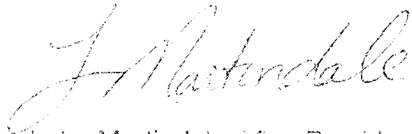
By definition: *Services in each APC are similar clinically and in terms of the resources they require.* Based upon this principle, we request that code 0071T and 0072T be reassigned to a more resource and clinically appropriate APC for FY2007.

While we realize the majority of patients who suffer from uterine fibroids are not Medicare eligible, the payment rates that CMS establishes for many services are used as benchmarks by commercial payers. Nationwide, between 170,000 and 300,000 women will undergo a hysterectomy to relieve the symptoms of uterine fibroids. The ability to provide a treatment alternative that provides both clinical and economic advantages is of tremendous value to hospitals and healthcare providers.

We respectfully urge CMS to reassign HCPCS codes 0071T and 0072T to a clinically and resource appropriate APC for 2007 so that participating centers and hospitals can provide this important treatment option to patients who suffer from uterine fibroids.

Again, we would like to thank you for considering our comments as they relate to reclassification of these procedures.

Respectfully,



Luke Martindale, Vice President
United Focused Ultrasound, Inc.

Submitter : **Mrs. Valerie Rinkle** **Date: 09/18/2006**

Organization : **Asante on behalf of the Provider Round Table**

Category : **Hospital**

Issue Areas/Comments

Visits

Visits

Please see the attached comments on visit payment levels and visit guidelines from the Provider Round Table.

CMS-1506-P-70-Attach-1.DOC

Attach #
#70

Asante Health System, OR
Avera Health, SD
Baptist Healthcare System, KY
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Forrest General Hospital, MS
Health First, Inc., FL
Mercy Medical Center, IA
Our Lady of Lourdes Regional Medical Center, LA
Saint Joseph's Hospital, WI
Saint Mary's Hospital, MN
Sisters of Mercy Health System, MO
Southwestern Vermont Medical Center, VT
University of Colorado Hospital, CO
University Health System, TX
White River Medical Center, AR

September 18, 2006

Submitted electronically and in hard copy: http://www.cms.hhs.gov/regulations/ecomments
Centers for Medicare & 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: File Code CMS-1506-P

Dear CMS:

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers from around the country who gathered to provide comments on the 2007 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on August 23, 2006. The providers listed above appreciate the opportunity to submit these comments for consideration by CMS. A full list of the current PRT members is provided in **Appendix A**.

Introduction

The Provider Roundtable (PRT) is a group of 17 different hospitals and health systems representing over 50 hospitals from around the country. Like many others, our hospitals, and the departments within our institutions, continue to struggle with OPPS and its many coding and billing complexities. Providers are often too busy, or unaware of the overall process, to submit comments to CMS on their own. Therefore, the members of the PRT collaborated to provide substantive comments with an operational focus which CMS' staff should consider during the OPPS policymaking and recalibration process each year.

We appreciate the opportunity to provide CMS with our comments, and recognize that providers must become involved in the comment process if OPPS is to improve with time.

Hospital Coding and Payment for Visits

New HCPCS G-codes

The PRT supports the creation of HCPCS G-codes specific to hospitals for reporting facility levels of care for the emergency room and clinic visits. Many of us have trouble with Medicaid and non-Medicare payers recognizing that hospital reporting of the physician CPT codes is acceptable to show the clinic level services we provide. Having specific codes just for hospital use should facilitate resolution of this issue with these payers. However, several PRT members are concerned that state Medicaid and other local payers may not recognize the new G-codes if made final for 2007, even though we believe they should under HIPAA. We urge CMS to stress the importance of this code set and its applicability to the hospital setting so we can avoid problems with state Medicaid programs and other local payers if these HCPCS G-codes are made final for 2007.

We also urge Medicare to make sure that Medicaid accepts these new G-codes if made final so that we do not have problems with claims that crossover to Medicaid. Medicaid programs owe legitimate co-payments when secondary to Medicare. CMS must make sure that these crossover claims, related to Beneficiaries that are eligible for Medicare and Medicaid, are reimbursed appropriately under Medicaid programs.

Finally, we urge CMS to work with the AMA to make a formal proposal to convert the G codes for hospital visits to full-fledged CPT codes for 2008. This will ensure that hospitals report one code set to Medicare, Medicaid and commercial payers which ensures consistent charging in the same manner for the same services to both Medicare and non-Medicare payers. Note that consistent code sets among all payers for the same services best supports the development of price transparency policies.

We also support the movement towards five levels of payment for these services. We are pleased to see that CMS elected to remove the distinction between new versus established versus consult patient types, as we believe any differences among these types of patients are best addressed by the actual visit levels assigned, assuming the level guidelines are constructed in a manner to capture escalating hospital resource intensity. Moreover, we support the concept of having separate HCPCS G-codes to distinguish between true emergency departments per the CPT definition and other clinic/emergency settings treating urgent care patients. Therefore, we support the concept of the Type A & B HCPCS G-codes, but urge CMS to provide additional guidance on the use of Type A versus Type B emergency department HCPCS G-codes so all providers are clear on what codes to report. For example, full-fledged hospital emergency departments that clearly qualify for Type A HCPCS G-codes often operate sub-units or locations within the emergency department that are open or closed based on morning, afternoon or evening fluctuations in patient loads and in the types of patients treated. Often such sub-units are called "Fast Track areas". It is clear to PRT members, that all visits within this full-fledged ED of the hospital should report the Type A ED visit G-codes since the hospital ED itself is open 24/7 even

though the sub-unit area may not be. We believe that urgent care clinics that are wholly physically separate departments of the hospital or that are hospital-based but off campus would report the Type B ED codes because these clinics are physically separate from the 24/7 emergency department and no portion of these clinics are open 24/7. We believe it is important for CMS to clarify when to report the Type A vs. Type B HCPCS G-codes, sooner rather than later so that providers are not confused in reporting these codes if made final for OPPS 2007 and so that different types of providers or non-Medicare payers do not challenge hospitals on the correct codes for reporting visits. This will ensure that CMS receives accurate and complete data from the outset to use for future years' APC rate setting calculations.

Finally, we are concerned with CMS' use of time in the description of the new HCPCS G-codes proposed for critical care. CMS issued coding and billing instructions concerning critical care at the outset of the OPPS. On page 17 of Chapter II for Claims Processing System Modification for OPPS (the FI training manual) there is no indication that a time threshold of 30 minutes or more was required before reporting CPT code 99291. In addition, on page 18452 of the April 7, 2000 rule CMS states, *"we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore, we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."* Given the above information, we cannot understand why CMS is now proposing a time threshold for reporting the newly proposed critical care codes. The 30-minute time threshold for CPT 99291 applies to physician billing for their professional services, but not to hospitals under OPPS. The APC payment covers the hospital staff and facility resources expended when critical care is reported -- these resources are expended immediately, not after 30 minutes. In addition, CMS should continue to recognize what it recognized previously - that it will be burdensome for hospitals to keep track of the number of minutes spent caring for a critical care patient in the Emergency Department.

If new HCPCS G-codes for critical care are finalized for OPPS 2007, CMS should eliminate the reference to time in the definition of HCPCS codes Gccc1 and Gccc2. The PRT believes the inclusion of this new time requirement in the description for the proposed G-codes as stated in the 2007 OPPS proposed rule is inadvertent. Therefore, the PRT urges CMS to eliminate the time requirement and to continue with its long-standing OPPS policy concerning billing for critical care services.

In addition, the PRT recommends CMS consider a different structure for the newly proposed critical care codes. First, we recommend using the CPT guideline to define a critical care patient as one with a critical illness or injury that acutely impairs one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition. Critical care involves high complexity decision making to assess, manipulate and support vital system function(s) to treat single or multiple vital organ system failure and/or to prevent further life threatening deterioration of the patient's condition. Second, we believe it is appropriate to distinguish between critical care with and without trauma activation.

Hospitals deploy extensive resources to care for a critically ill or injured patient in the hospital, yet there are two levels of critical care for a hospital. The first level involves a patient who is critically ill or injured and extensive staff and facility resources are expended to evaluate and treat the patient. The second level involves activation of a trauma response team. This level

entails even more staff and facility resources to be expended. Because there are specific packaged revenue codes for field-activated trauma response, we believe that it is appropriate to recognize these two levels of critical care with separate APCs. APC 0617 should encompass the first level and the second, higher level that includes the trauma response team should be assigned to a separate new APC 0xxx. Both of these critical care levels include services and resources that are radically different from a high level ED visit 99215 proposed to be reported with HCPCS G-code Gyyy5 in 2007. The PRT proposes the following definitions for critical care G-codes for use under OPPS 2007:

> Gccc1 – Hospital Critical Care without Trauma Activation – APC 0617. (The patient must meet the CPT definition of a critically ill or injured patient, but there is neither a time threshold nor trauma response team activation.)
>
> Gccc2 – Hospital Critical Care with Trauma Activation – new APC. (The patient must meet the CPT definition of a critically ill or injured patient and there is a trauma activation called and billed on this account. Revenue codes in the 68x series have been established for reporting trauma response/activation. For this new APC, Critical Care with Trauma Activation, CMS could also consider an edit requiring the presence of the 68x revenue codes and the new Gccc2 code be reported on the claim.

The PRT believes the primary outcome of changing the current policy will result in providers more accurately reporting the actual service(s) provided – in this case critical care. Furthermore, by packaging trauma activation charges with the specific critical care visits for which they occur, the acuity and resource use of these visits will be better quantified. In addition, CMS will be able to collect data on the type of critical care visits with and without trauma activation and make future payment policy decisions based on more accurate data. The consequence of making no change is that providers will have to implement burdensome documentation requirements to track critical care visits and time. It is unclear what time is to be counted for a hospital critical care visit. Restructuring new critical care APCs will align OPPS payment with actual practice and resource utilization.

Payment Levels and Payment Rates

As expressed in our comments above, the PRT supports the use of proposed HCPCS G codes for hospital ED and clinic visits and the proposed 5 APC payment levels for each respective group of visits. We understand that the payment rates for these levels result from 2005 claims data reflecting hospitals use of their own facility guidelines for ED and clinic visit reporting.

With the introduction of new codes, five APC payment levels, and the upcoming release of national hospital ED and clinic visit level guidelines, the PRT is concerned with the resulting payments from application of the proposed guidelines and how the payments would not, on their face, reflect relative hospital resource utilization between the two major types of visits – type A ED visits versus hospital clinic visits. Furthermore, we are concerned that the application of the proposed guidelines with the 2007 payment rates also results in beneficiaries paying more in co-payment for the same service in a clinic versus an ED. This does not create appropriate

incentives for use of scarce healthcare resources. Beneficiaries should pay less in co-payments when having services rendered in organized clinics versus showing up in a hospital emergency department on an unscheduled basis. Furthermore, co-payments should be a factor to encourage beneficiaries to choose the most appropriate setting for health care services. Under the 2006 payment levels a Level I clinic visit co-payment was almost 50% less than a Level I ED clinic co-payment ($10.47 versus $18.71). With the 5 proposed APC visit payment levels for 2007, the Level I clinic visit co-payment is almost equivalent to a Level I ED visit co-payment ($9.95 versus $10.25).

)06 PC	2006 Pmt	2006 Co-Pmt	20 07 HCPCS	2007 HCPCS Description	2007 APC	APC Description	2007 Pmt	2007 Co-Pmt
300	52.37	10.47	Gxxx1	Level I Hospital Clinic Visit	0604	Level 1 Clinic Visits	49.75	9.95
300	52.37	10.47	Gxxx2	Level 2 Hospital Clinic Visit	0605	Level 2 Clinic Visits	61.90	12.38
301	60.25	12.05	Gxxx3	Level 3 Hospital Clinic Visit	0606	Level 3 Clinic Visits	83.38	16.68
302	87.67	17.53	Gxxx4	Level 4 Hospital Clinic Visit	0607	Level 4 Clinic Visits	105.13	21.03
302	87.67	17.53	Gxxx5	Level 5 Hospital Clinic Visit	0608	Level 5 Clinic Visits	130.65	26.13
310	73.79	18.71	Gyyy1	Level I Hospital Type A ED Visit	0609	Level 1 Type A Emergency Visits	51.23	10.25
310	73.79	18.71	Gyyy2	Level 2 Hospital Type A ED Visit	0613	Level 2 Type A Emergency Visits	84.50	16.90
311	129.18	34.26	Gyyy3	Level 3 Hospital Type A ED Visit	0614	Level 3 Type A Emergency Visits	133.52	26.70
312	224.78	51.89	Gyyy4	Level 4 Hospital Type A ED Visit	0615	Level 4 Type A Emergency Visits	214.14	42.83
312	224.78	51.89	Gyyy5	Level 5 Hospital Type A ED Visit	0616	Level 5 Type A Emergency Visits	330.98	66.20
320	477.73	131.61	Gccc1	Hospital Critical Care 30-74 Min	0617	Critical Care	493.44	98.69
kgd			Gccc2	Hospital Critical Care @ Addl 30 Min	Pkgd			

It is best to illustrate these concerns with examples. The draft visit guidelines released by CMS on its website essentially copy Level I ED interventions and define them as Level III Clinic interventions. This has the unfortunate result of paying a hospital less for the same service when performed on an unscheduled basis in the ED versus payment in a clinic setting where the service is likely scheduled and pre-planned with appropriate staff, supplies and equipment. Clinic settings should be more efficient and cost-effective, in general, than 24/7 hospital emergency departments. The 24/7 Type-A ED is the most resource intensive setting for health care services to be rendered and therefore should reflect appropriate payment and co-payment rates.

Under the draft guidelines released by CMS on its website, if the sole service rendered is a first aid procedure, this qualifies as a Level I ED intervention paying $49.75 of which $9.95 is the beneficiary co-payment whereas the same first aid procedure in a Clinic setting qualifies as a Level III Clinic intervention paying $83.38 of which $16.68 is the beneficiary co-payment. This means that performing the same service in the ED supposedly costs less than in a hospital clinic. On the surface this payment structure does not make sense to us. Furthermore, beneficiaries will be financially rewarded to come with minor healthcare problems to an ED setting rather to a more appropriate clinic setting.

As a whole, Type-A ED visit APC payments should be a significant order of magnitude greater than hospital Clinic visit APC payments as this reflects actual hospital expense. CMS should be able to evaluate this from the hospital cost report data, even if provider claims data

does not reflect this due to each hospital using its own internally developed guidelines. A reasonableness test should be applied to the APC visit payment levels as it is more expensive and resource intensive to operate hospital 24/7 emergency departments than hospital clinics. For example, the Level 1 through 5 ED visits may have higher payment rates by the same order of magnitude compared to Level 1 through 5 Clinic visits. The visit levels should reflect relative resource intensity of interventions and services provided in each setting. Often, it is not the specific intervention that is resource intensive in and of itself, but the setting and circumstances that make it resource intensive (unscheduled, urgent, multiple staff involved to deliver the service in an ED setting vs. the same intervention delivered as a scheduled service in a clinic setting).

Another example from the draft guidelines released by CMS on its website is when the sole service provided is hospital staff assisting the physician with a patient examination such as a pelvic or prostate exam. Under the draft guidelines, if the exam is the sole service, this qualifies as a Level 1 ED intervention paying $49.75 of which $9.95 is beneficiary co-payment whereas the same examination in a Clinic setting qualifies as a Level 3 Clinic intervention paying $83.38 of which $16.68 is the beneficiary co-payment. Again, this implies that performing the same service in the ED supposedly costs less than when the service is provided in a hospital clinic. The circumstances under which a physician would perform such examinations in the ED usually entail many more resources than in a clinic. The exam room usually has to be set up for the specific examination with staff going to various locations both within the ED and to other hospital departments to obtain the appropriate equipment and supplies for the examination. In the clinic setting however (excluding Type-B ED visits) the clinic is specifically set up for such examinations and the patient is typically scheduled. The result of applying the draft guidelines and the interventions/services listed and comparing APC payment rates across the ED and clinic setting does not make intuitive sense to us.

Therefore, we urge CMS to look at the ED and clinic payment levels and proposed guidelines as a whole and make reasonable policy decisions regarding APC payment rates for services and beneficiary co-payments across the ED and the clinic settings especially since consistent provider data is currently lacking due to each provider having developed and used its own guidelines. Once CMS implements national visit coding guidelines for facility use we believe provider claims data will be more consistent and reflect the higher resource use in an ED setting.

Commercial insurances have addressed this issue by developing flat patient co-payment amounts for ED versus clinic visits regardless of the level of visit. CMS should evaluate whether it makes sense for the beneficiary co-payment to be the same regardless of the level of visit, for example, a $15.00 co-payment for clinic visits and a $50.00 co-payment for ED visits are common amounts imposed by commercial insurances. It is important that beneficiary co-payments do not encourage inappropriate ED visits thereby straining hospitals limited resources even further. It is also just as important that the APC payment rates for visits in the two settings appropriately reflect relative resource use.

National Guidelines Development Process

The PRT offers its comments concerning the eight areas that CMS has requested input about, regarding the development of national hospital visit coding guidelines. In concert with establishing the national guidelines, the PRT requests that CMS publish a more specific definition of "separately identifiable" for the hospital outpatient setting. We expand on this request in the discussion below.

A. Three versus Five Levels of Codes

The PRT agrees with CMS' decision to have five levels of codes and agrees that it would be difficult to pay five levels using current guidelines, which assign to only three APCs. We believe that significant variation exists within the levels that would correspond to the five proposed G codes, and that five payment levels are justified for both clinic and Type A and B emergency visits.

B. Lack of Clarity for Some Interventions

The PRT believes that -- with well-defined guidelines for each intervention that include relevant clinical examples -- the majority of coders and staff assigning levels will be clear as to how to apply the guidelines. CMS has stated that it is committed to provide a minimum of 6-12 months notice to hospitals prior to implementation of national guidelines in order to give providers sufficient time to make the necessary system changes and educate their staff. We believe 6 – 12 months is a sufficient amount of time, and should not be problematic for the majority of the provider community. Once CMS revises and releases the guidelines, providers will become more proficient at "documenting for the guidelines" and in the assignment of levels based on the guidelines, which will result in more accurate visit claims data. It may be advantageous for CMS to communicate to providers the areas that were found to be unclear when the AHA/AHIMA model was tested, and use these areas as examples to train providers on the proper documentation and assignment of the levels.

C. Treatment of Separately Payable Services

The PRT agrees that separately payable interventions should be used as a proxy for increased resource utilization by allowing the inclusion of the interventions into the national visit guidelines. The PRT believes this should not be construed as double dipping. The guidelines should reflect "coordination of care" including getting patients ready for the procedures that need to be performed. We believe that the resource utilization of multiple separately payable services helps define the resource level of the separate visit itself.

We do not believe this would result in attributing the same hospital resources to both the visit and the separately payable services. Many of the separately payable services are interventions that occur in separate hospital departments and that require separate department resources to perform the service on the patient. The coordination of care leading up to the separately payable service in the performing department involves separate resource utilization within the clinic and ED. So, the number and type of separately payable services can help define the true hospital resources expended for the patient in the visit itself. By including the interventions in the level guidelines, the national visit guidelines will become a true

characterization of the hospital resources involved in a visit rather than an itemization or an all-inclusive list. The PRT agrees that -- if interventions become packaged or unpackaged -- the guidelines will be difficult to stabilize and it will, therefore, be difficult to obtain consistent data for future rate-setting purposes. The PRT urges CMS to use the American College of Emergency Room Physician (ACEP) model to identify examples of interventions that can serve as useful proxies.

The PRT further urges CMS to create guidelines that will be usable for clinical staff and have the potential to allow seamless conversion to an electronic medical record (whereby the level can be assigned based on standard documentation practices for interventions and nursing services). This means that the specific documentation requirements to support the guidelines should be widely recognized as common standard of practice that are likely to be built as discrete data elements/fields into electronic documentation systems. An example of resource utilization for separately payable services which require the coordination of care from the emergency room staff follows -- A patient who is going for an angiogram requires consent, education, and mental preparations in the emergency room prior to being transported to the department to have the angiogram. These resources are integral to the coordination of care for the patient, but not related to the actual resources involved in the performance of the angiogram procedure in the Radiology department. Another example is presented by a patient who requires an MRI and must be transported physically to the Radiology department by the emergency room staff. The transport requires resource consumption and coordination of care by ED personnel because the patient may have monitors and other medical conditions that require close observation prior, during and after the procedure.

The PRT reminds CMS to ensure that NCCI edits do not include the new G codes (or CPT codes if established) for hospital ED and outpatient visits.

D. Some Interventions Appear Overvalued

The PRT believes that the majority of the interventions are placed appropriately and do not appear to be overvalued. In the Proposed Rule, CMS noted that, "in field testing the AHA/AHIMA guidelines, a vast majority of the clinic and emergency visits reviewed were assigned to Level 1 during the review." Even with modifications to the guidelines, we do not believe interventions will be overvalued. Some interventions may be undervalued or not accounted for in the leveling system at all. For example, in the draft ED guidelines, if a nurse performs a complete body system assessment (above the triage), which may include a coma scale or neurological evaluation, but there are no other interventions listed under Level One, the visit would not even assign to a Level One ED visit. Yet, the nurse may have spent considerable time above the initial triage time interviewing the patient. It is noted that the Clinic Visit Guidelines has a Level 1 Intervention of "clinical staff assessment (excluding physician) or single specialized clinical measurement or assessment." This is not present in the ED guidelines. We believe that this intervention should be added to the ED guidelines. Every effort should be made to ensure that no disparities exist between the value of an intervention in the ED versus the Clinic.

"Oxygen administration – initiation and/or adjustment from baseline oxygen regimen" is listed on the proposed guidelines as a Level 1 intervention. The PRT disagrees with this low level assignment. The administration and adjustment of oxygen is a resource-intensive treatment that requires multiple assessments of the patient's respiratory rate, level of consciousness, skin color (including monitoring for the appearance of or the resolution of cyanosis), oxygenation of nail beds, pulse oximetry readings (which are not separately payable under APCs), chest auscultation for lung status, and communication with the physician. These factors, along with any other parts of the patient's treatment that may affect his/her respiratory status, must be constantly reassessed before and after any change in the oxygen administration level. This process is much more involved than just increasing or decreasing the oxygen flow.

Specimen collection requires varying degrees of resources, depending on the patient's level of comprehension of instructions and ability to follow those instructions. The examples cited in the guidelines are usually types of specimens that the patient can obtain after instruction from hospital staff. What appears superficially to be a "simple low resource" function is not so simply defined in an Emergency Department situation, however. By virtue of being in an Emergency Department setting, a patient's level of stress and anxiety can cause distraction and lack of concentration which may result in multiple explanations of what is needed. Depending on the situation, direct assistance from hospital staff may be required in order to collect the specimen. Specimen collection as a Level 1 intervention is appropriate in a clinic or other outpatient situation, but not in the Emergency Department.

E. Concerns of Specialty Clinics

The PRT believes that one set of guidelines can be used for all clinics and outpatient areas other than the Emergency Department. Outpatient clinics have many services in common, such as dressings, infusions, injections, etc. The biggest differences revolve around the intensity of resources involved in coordination of care and counseling, which vary depending on the patient's problem list, level of education/understanding, family resources, etc. These differences can best be addressed by a time factor. Time is the single biggest resource that varies between outpatient clinics. The guidelines should reference all resources provided by "qualified hospital staff" and not be limited to nursing. In most instances, multiple professional disciplines are involved in providing the best care for the beneficiary. Coordinating care for beneficiaries often involves a team effort within a single department and/or across multiple hospital departments with several staff working sequentially with the patient to achieve the best outcome possible.

The PRT believes it is CMS' intention to use the "clinic guidelines" section for any outpatient area that is not classified as an Emergency Department. Many hospitals have outpatient departments that perform the same services as a clinic, but are not classified as a true clinic. Therefore, the PRT recommends that this section of the guidelines be titled "Outpatient Visit Guidelines". The draft guidelines on the CMS website contain the wording "ED" in this section also and the guidelines appear to be an exact copy of the ED section. While many of the same procedures can be conducted in an outpatient department and an Emergency Department, there will be differences in resource levels.

The guidelines should reference all resources provided by "qualified hospital staff" rather than being limited to nursing staff. In most instances, multiple professional disciplines are involved to provide the best care for the beneficiary. For example, a patient may present with symptoms that may be related to the interactions between medications. The patient brings all of his/her medications to the visit. A nurse or hospital pharmacist reviews each medication with the patient. The interview provides insight into whether the patient understands what each medication is for, the dosage he/she is supposed to take, concerns about taking any of the medications, compliance with taking the medication as prescribed. There may be recommendations made by the pharmacist for alterations in the regime (such as not taking two medications at the same time but staggering them to prevent side effects) and/or education for the patient by the pharmacist and/or nurse concerning the importance of compliance with the medication regime based on the clinical picture and patient's symptoms.

A patient with multiple wounds that necessitate different methods of caring for the various wounds requires much more time for teaching and education on wound care between clinic visits, when compared to a patient with a superficial wound. A diabetic patient with limited eyesight requires more time resources to ensure that he/she can check glucose levels and administer the appropriate dosage of insulin than does a patient with good eyesight. A patient with a limited school education requires more time to ensure his/her understanding of a complex treatment plan. These are all valid use of resources for the best care of the beneficiary. Time is the biggest single factor in resource involvement for these areas. The guidelines must have a mechanism for including this factor in the determination of visit levels.

The PRT recommends that the outpatient visit guidelines include a mechanism for increasing the visit level if more than 50% of the visit is spent on counseling and coordination of care. It is important for CMS to recognize that patient-specific education is an important component in the patient's quality of care. The patient must understand the procedure to consent to treatment, understand what will happen during a procedure, and understand what the plan of care is upon discharge. Specialty clinics/outpatient areas must go a step further to ensure that a patient can follow his/her treatment plan between clinic visits. This may require much coordination of assisting resources. Each patient's situation is different and, while the medical treatment may not be complex, the time spent coordinating the care for these patients can be very resource-intensive. The PRT believes it is imperative that CMS recognize that, in the outpatient setting, this as a resource that must be recognized as separately "countable" in the outpatient visit/clinic setting. In other words, it is a contributory factor for outpatient visits. These types of resources are difficult to include in a traditional "E&M" structure or as an intervention, as it can be hard to quantify these resources other than by using the time expended. Therefore, the PRT encourages CMS to define these time periods within the level guidelines. Similar to the E&M codes in the physician setting, the Outpatient Visit Guidelines should define time levels such that a higher level can be chosen when more than 50% of the visit is counseling and coordination of care. For non-Emergency Department outpatient settings, the PRT believes it is appropriate for staff to document the services provided and the face-to-face time spent with the patient.

The following table illustrates how a time-based proposal for outpatient visits would be affected by the coordination of care and counseling time:

HCPCS code	Descriptor	Total documented visit time	Coordination of care and counseling
Gxxx1	Level 1 hosp outpatient visit	30 minutes	15 minutes or more increases level to level 2
Gxxx2	Level 2 hosp outpatient visit	45 minutes	23 minutes or more increases level to level 3
Gxxx3	Level 3 hosp outpatient visit	60 minutes	30 minutes or more increases level to level 4
Gxxx4	Level 4 hosp outpatient visit	75 minutes	37 minutes or more increases level to level 5
Gxxx5	Level 5 hosp outpatient visit		

Under this proposal, if the services provided to the patient meet the guidelines for a Level 2 hospital visit which took 40 minutes and, based on the hospital staff documentation, 22 minutes is documented as "coordination of care" (such as education), the hospital would bill for a Level 3 outpatient visit.

Coordinating care for beneficiaries often involves a team effort across multiple hospital departments to provide the best outcome possible. For example, a patient may have a scheduled appointment with several different staff disciplines during one "outpatient visit". The patient begins in the oncology area and receives lab work and a chemotherapy treatment. The lab results reveal that the patient's blood counts are too low for this chemotherapy treatment. This patient is also diabetic and the medications administered before the chemotherapy treatments are beginning to cause his/her blood sugar levels to fluctuate. The patient has a scheduled visit with the Diabetes Nurse to discuss dietary changes and insulin dosage adjustments possibly needed during this time frame. This visit includes an assessment of the patient's current dietary habits; alteration in taste due to the chemotherapy treatments; and nausea and decreased appetite due to the chemotherapy treatments. The patient has noticed a sore on his/her foot and also has an appointment with the wound care nurse. The wound care nurse performs an assessment and discusses the wound with the patient's physician and a treatment plan is formulated. The patient is educated on the care of the wound. Each of these evaluations (oncology, diabetes, and wound care) addresses a unique issue for this patient and represents a distinct and separate visit in a distinct and separate outpatient department of the hospital with three separate sets of resources utilized. As is currently the practice under OPPS, the PRT recommends that each of these visits continue to be reported separately under the new guidelines.

Hospitals have concerns regarding how these three distinct visits might be required to be reported as one visit under revised guidelines. The guidelines should be structured to allow a separate visit code for each of the physically separate departments that expended resources. Because the services cross department lines and are separately provided, it will be a difficult task to combine the services into one level.

Therefore, the guidelines should be very specific regarding how to bill these multiple visits on the same date of service. Under current CMS billing guidelines, modifier -27 and condition code G0 are reported to indicate physically separate visits that occur in different departments on the same date of service. The PRT proposes that this structure be utilized in the scenario described above.

The PRT also recommends that CMS publish a specific definition of "separately identifiable" visit for the hospital setting (i.e. visit code qualifying for modifier -25). Clinical staff will need more specific guidelines for when to report a level code on the same date of service as a procedure. For example, if a patient presents to the wound clinic for a scheduled visit for debridement and reports a new lesion to the nurse, a separate assessment of this new wound must be provided. In this case, it is easy to identify that the visit resources are related to a new problem, not related to the reason for the scheduled visit, and therefore can be reported separately.

Although some kind of evaluation/assessment is usually required for any visit to assess the patient's progress since the last visit, there are no clear guidelines for when this assessment/evaluation is considered to be "more than the usual." CMS should define whether a new problem must exist in order to qualify for "separately identifiable". CMS should clarify the appropriate action in situations where a particular reaction is expected, but the individual patient's reaction is worse than expected. For example, nausea and vomiting is expected with some chemotherapy regimes. Hospitals need guidance on the procedure for instances in which the patient's vomiting continues beyond the expected period of time, and/or is much more severe than expected, both of which require significant hospital staff resources be expended in monitoring, assessing, and coordinating further treatments with the physician. At times, a patient's non-compliance with the plan of treatment creates a new situation for managing the patient's care that takes significant resources. However, it is not easy for hospitals to determine whether CMS would consider this a valid circumstance for reporting a separate outpatient visit code along with the procedure code.

For any outpatient visit, hospitals receive physician's orders for the services needed for the individual patient. There are times when the physician may write an order for a service that is not "typical" and could be provided at the physician's office rather than by a hospital outpatient department. The CMS guidelines must be structured in a way that prevents limiting the reporting of legitimate hospital services and allows them to be applied to any and every visit. For example, a patient may present to a hospital outpatient area with orders from the physician for adjustment of the gastric band component. This is usually considered to be a component of the physician's post-op care but, in this instance, the physician sent his or her patient to the hospital for this service. The guidelines must allow this service to be reported by the hospital.

Another example is an instance in which a PICC line was inserted in the physician's office and the patient referred to the hospital outpatient area for removal of the PICC line. There is no separately reportable CPT code for this procedure, and it would usually be expected to be performed in the physician's office. However, the guidelines must allow reporting of this service by hospitals using a visit code.

Finally, the PRT offers some specific examples of the different types of services provided in specialty clinics below.

Clinical Examples from Specialty Clinics

To assist CMS in development of hospital visit guidelines that will function well for hospital specialty clinics, the PRT provides some examples of specialty clinic visits and notes where the current proposed CMS guidelines do not address important clinical services provided in these clinics.

Geriatric
Reason for Visit: Poor Circulation in ankles and feet
Nursing Documentation: Vitals, Height, Weight, Temperature
Pain Assessment 4/10; Location: toes; Severity: pin prick sensation
Fall Assessment performed by the RN as a result of the questions answered by the hospital internal monitoring tool (get up and go). Nurse documented a low score of 3 and contacted the physician with the results.
Allergies reviewed: NKA all drugs/herbs OTC's foods and environmentals reviewed
Ankle and Foot Assessment: Foot and ankle assessment notes that the foot and ankle were cold to the touch, feet and ankle not pink in color notified physician who ordered a manual Ankle Brachial Index. An Ankle Brachial Index (not separately billable since manual exam) was performed and result documented per physician's order.
Finger stick glucose is performed.
Time: 1.5 hours

- Under the purposed CMS guidelines: Low level visit
- Under current hospital guidelines: High level visit

Oncology
Reason for Visit: Follow-up post op mastectomy
Nursing Documentation: Vitals, Height, Weight, Temperature
Pain Assessment: 6/10; Location: Breast suture area; Severity: aching, pain is sharp intermittently
Wound Assessment: suture are intact, no redness no drainage noted. Patient following discharge guidelines
Review allergies: NKA
Physician examines the patient, decides to increase the size of the tissue expanders placed during surgery. 2 tissue expanders are filled with 20cc of saline.
Time: 1 hour

- Under the proposed CMS guidelines: Low level visit. Filling of tissue expanders (which does not have an assigned CPT code) is not addressed under the proposed CMS guidelines. The procedure requires hospital time and resources and should be considered in the hospital visit level assigned.

- Under current hospital guidelines: Mid level visit raised to a high level visit due to the procedure to fill the tissue expanders.

Chronic Pain

Reason for Visit. Back pain and to check pain pump
Nursing Documentation: Vitals, Height, Weight. Temperature
Pain Assessment: 4/10, Location: low back going down the legs; Severity: pin prick sensation in leg and sharp pain to the lower back
Pain Management: documented medication treatment and its results, coping strategies, effect of pain on quality of life.
Allergies reviewed: NKA all drugs/herbs OTC's foods and environmentals reviewed.
Documented RN site assessment: clean, dry, no redness or infection noted;
RN assessed the pain pump and provided 30 minutes of teaching for taking care of the pump at home per physician order. Teaching was documented on the hospital teaching sheet. Pump refill was not necessary. Documented that the pump was working properly.
Time: 1.5 hours

- Under the purposed CMS guidelines: Low level visit. The proposed CMS guidelines do not take in to consideration 2 factors: 1. Maintenance of a pain pump without refill. Under current guidelines, CPT code 95990 (Refilling and Maintenance of implantable pump) must included both components before using that CPT code. Patient did not require refilling of the pump for this visit but nursing staff did provide maintenance and assessment of the pump. 2. The 30 minutes of patient teaching provided by the RN and directly related to a current medical condition.
- Under current hospital guidelines: High level visit.

Infectious Disease

Reason for Visit: Ear pain and difficulty breathing
Nursing Documentation: Vitals, Height, Weight, Temperature
Pain Assessment: 7/10 Location: bilateral ear pain; Severity: sharp throbbing pain to both ears
Allergies reviewed: NKA all drugs/herbs OTC's foods and environmentals reviewed
Assessment of respiratory: SOB started 3 days ago, dry cough, auditory wheezing heard
Physician ordered a resting pulse ox and a walking 5 minute pulse ox. Staff documented the results of both
Physician ordered the RN to flush both ears as the assessment indicated the pain was caused by impacted cerumen.
Physician requested the RN to remove the PICC line as it is not longer needed. RN documented and removed the PICC line
Time: 1.[illegible] hours

- Under the purposed CMS guidelines: Mid level visit. The proposed CMS guidelines do not take into consideration several factors. 1. Ear irrigation is not is not addressed and does not have an assigned CPT code. 2. Removal of a PICC line does not have an established CPT code, again training and competency is require by our staff in order to provide this type of service.
- Under current hospital policy: High level visit

Cancer genetic counseling clinic

The client is referred to the clinic by MD order. Usually a family member has cancer and the patient's MD, RN or social worker recommends possible cancer genetic counseling for the family. The client presents to the clinic nurses for the following services (approximately 1 ½ hours of time):

Obtain familial history related to cancer,

Discuss hereditary and sporadic cancer risk

Client views a 25 min video related to the process

Available and appropriate genetic testing options are reviewed, including benefits and limitations of genetic testing as well as associated management and cancer surveillance;

health care coverage, privacy, and genetic non-discrimination.

Blood work is drawn if appropriate and submitted to outside testing facility.

Consult notes are documented

Follow up to discuss testing results or as needed.

Time: 1.5 hours

Coumadin Clinic visit procedures

The patients present to the Coumadin Clinic based on a physician order.

Patients receive in-depth consultation, both verbal and written, concerning warfarin administration. Patients receive both verbal and written materials concerning clinic procedures, other drug information, diet interactions, drug interactions, frequency of lab tests, signs and symptoms of bleeding and the importance of compliance with medication and clinic procedures.

The Nurse obtains an in-depth history from the patient including current and past medical history. A complete list of current medications is also obtained from the patient.

Finger stick PT and INR is performed. Resulted are documented and adjustments made in the Coumadin dosage as needed.

Follow up visits are scheduled according to lab values, typically from 1 – 4 weeks.

A clinical summary note is faxed to the referring MD which details the changes in patient's dosage and lab values that were obtained during the visit as well as all other information regarding changes in vitamin K, diet, missed doses, upcoming medical/surgical procedures, etc.

Time (length of visit): varies between 10 and 30 minutes.

Ostomy Care
Reason for visit: Physician order to prepare patient for stoma.
Nurse assessment: Assess the patient's muscle parameters by having the patient sit, stand, and lie (if they can). Look for creases, old scars, umbilicus, and the general contour of the abdomen, and make sure the patient will be able to see the stoma. Methyl Blue dye is injected under the skin to mark the spot where the surgeon will create the stoma.
Education: Patient and family are educated about the stoma and what to expect. Patients often exhibit anxiety and nurses spend time to build rapport with patient and family. Fear and anxiety are particularly significant with cancer patients and the elderly..
Referral to Social Worker: Counsel patient on ostomy products, cost, vendor indigency programs
Time: 2 hours

F. Americans with Disability Act

The PRT is aware that there may be state case law that could result in visit guideline statements such as "Special needs requiring additional specialized facility resources" from the AHA/AHIMA model to a violation of the 'Americans with Disabilities Act". Regardless of the stated factor or criteria in the visit guidelines, patients with special needs often require more time and effort. The current E&M criteria for physician visits and most hospital guidelines today result in higher visit levels for patients with special needs/disabilities. This will be an issue for all settings including both hospitals and physicians' offices.

There are several types of cases that involve increased time and resource consumption for all types of medical conditions (i.e. emotional, physical, and mental) that could fall into this situation. Many examples could be listed here, which highlight the need to develop some type of standard for addressing the different types of needs for services that play a large part in resource consumption and intensity of service. Just as one example, culturally diverse locations require interpreters in the emergency care areas or outpatient departments/clinics for coordination of care.

For this reason, the PRT emphasizes the need for CMS to consider "time" as a factor to be included in the guideline interventions when "counseling and coordination of care" consume more than 50% of the patient visit. To alleviate CMS' concern about additional financial liability for the beneficiary who takes more time due to special needs or disabilities and therefore owes more in co-payment, the PRT encourages CMS to establish equal co-payment amounts across the five levels of hospital outpatient visit and five levels of Emergency Room APCs. The PRT encourages CMS to establish a co-payment for all hospital outpatient levels and a separate co-payment for all emergency room visit levels. The PRT believes that, if the co-payment is consistent within the visit guidelines across all levels, it will eliminate any potential violation of the law. This methodology would also eliminate any increased financial liability based on an individual's disability or other medical conditions.

G. Differentiation Between New and Established Patients, and Between Standard Visits and Consultations.

The PRT is pleased that CMS elected to remove the distinction between new versus established versus consult patient types, as we believe any differences among these types of patients are best addressed by the actual visit levels assigned, assuming those are constructed in a manner to capture hospital resource intensity rather than clinical acuity, as these are different things. We do believe that there is often additional expense for new patients, but we suggest that this can be listed as a contributory factor to visits rather than have distinct visit types for new and established patients.

H. Type A & B facilities

The PRT believes that CMS has already established the distinction between type A and B emergency facilities. Type A facilities are hospital emergency departments that are open 24 hours per day, 7 days per week. Type B facilities are NOT open 24/7, but rather have designated hours of operation (i.e., an off-site urgent care facility that is open Monday through Friday, 8am – 5pm).

Type A facilities have significantly higher resource costs than Type B facilities, mostly due to the staffing requirements associated with staying open 24-hours-a-day, 7-days-a-week, and being available to care for patients at any hour. Type B facilities expend fewer resources, since they are open fewer hours, treat fewer patients, and may not offer some of the critical services that hospital-based Emergency Departments offer.

CMS stated in the 2007 OPPS Proposed Rule (*Federal Register* page 49608, second column) that it has no way to distinguish the cost of visits provided in Type B (DED's) facilities verses Type A facilities from the hospital claims data. The PRT supports CMS' proposal to implement one set of five G-codes for use by a Type A facility and a second set of five G-codes for use by a Type B facility. Reporting separate code sets will improve data reporting and enable CMS to gather the appropriate claims data for establishing appropriate APC payments for both types of facilities.

The PRT also supports CMS' proposal that separate payment be established for Type B facilities due to the lower resource cost in comparison with Type A facilities.

Conclusion

The Provider Roundtable would sincerely like to thank CMS and its staff for reviewing and considering our comments. Although we are still a relatively new group, the PRT members are very interested in the policy-making process and appreciate how our input can have an impact on future year's rules and policies. We are very grateful to CMS for considering our comments in past years as well as again this year. We hope the operational issues we have outlined will be helpful to CMS in considering future system changes. If you have any questions or require additional information, please contact our spokesperson Valerie Rinkle, listed below.

Comments were submitted electronically by Valerie Rinkle, MPA, Asante Health System. A full list of the provider roundtable members is included below in **Appendix A**.

Sincerely yours,

Members of the Provider Roundtable

Appendix A: Current Members of the Provider Roundtable

Jennifer L. Artigue, RHIT, CCS
Dir. Revenue Mmgt, CDM & Medical Records
Our Lady of Lourdes Regional Medical Center
Lafayette, LA

Kathi L. Austin, CPC, CPC-H, CCP
Corporate Director Revenue Integrity
Sisters of Mercy Health System
St. Louis, MO

Barbara B[illegible], RHIA, CCS, CCS-P
Coding Quality Specialist, HIM
Mercy Medical Center
Cedar Rapids, IA

Kathy De[illegible], RHIA, CCS, CCS-P
Director of Health Information Management
Avera Health
Sioux Falls, SD

Janet V. [illegible], BS, [illegible], CPC, CPC-H
Medical Auditor, Corporate Compliance
Forrest General Hospital
Hattiesburg, MS

Jerry Hill, MA
Charge Management Coordinator
University Health System
San Antonio, TX

Marion G. [illegible], BSN, RN, MBA
Columbus, OH

Carol Le[illegible], RN, BA
CDM Coordinator
White River Medical Center
Batesville, AR

Monica L[illegible], CCS
Coding Manager
University of Colorado Hospital
Denver, CO

Bonnie M[illegible], RHIT, BA
APC Coordinator, Outpatient Coding Supervisor

St. Mary's Hospital
Duluth, MN

Yvette Marram, RN, MA, RHIA, CCS
APC Coordinator
Health First, Inc.
Melbourne, FL

Terri [illegible], MT(ASCP), DLM, MHA
Reimbursement Manager
Community Hospital Anderson
Anderson, IN

Valerie A. Rinkle, MPA
Revenue Cycle Director
Asante Health System
Medford, OR

Julie Rode[illegible], RHIT
Coding Specialist
St. Joseph's Hospital
Marshfield, WI

John [illegible], MBA, MHA
Director, [illegible] Services [illegible]
Carolinas HealthCare System
Charlotte, NC

Marianne Seymour, RHIT, CCS
Medical Necessity Coordinator
Southwestern Vermont Medical Center
Bennington, VT

Denise Williams, RN, CPC-H
Charge Management Coordinator
Baptist Healthcare System
Louisville, KY

Submitter : **Mrs. Valerie Rinkle** **Date: 09/18/2006**

Organization : **Asante on behalf of the Provider Round Table**

Category : **Hospital**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

Please see the attached comments on drug administration from the Provider Round Table.

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

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

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

Submitter : **Dr. Robert Young** **Date: 09/18/2006**

Organization : **Next Generation Radiology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-72-Attach-1.DOC

Attach #
72

September 21, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; New Technology APCs - Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Next Generation Radiology PET/CT to address an issue of great importance to Medicare beneficiaries with cancer. Next Generation Radiology PET/CT is a physician owned radiology practice, which provides PET/CT, among other imaging services. We serve approximately 1,100 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay our facility, and could compromise beneficiary access to this vital technology.

Medicare payment rates for PET/CT performed by free standing facilities traditionally have been determined by regional carriers. Under the Deficit Reduction Act Medicare payments for the technical component of PET/CT would be capped at the hospital outpatient rate. CMS proposes to reassign the PET/CT CPT codes from APC 1514- New Technology Level XIV with a current rate of $1,250 to a clinical APC 0308 – Non-myocardial PET imaging with a reduction in payment for PET/CT to $862—the same rate and APC assignment that is also proposed for the conventional PET CPT codes. For us this represents a cut up to 60% to 70% in one year from current carrier based payments.

Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

The hospital outpatient proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to Next Generation Radiology PET/CT of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

The proposed payment rate reduction for PET/CT would seriously underpay radiology facilities such as ours, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current APC assignment of the PET/CT CPT codes and corresponding payment rate of $1,250.

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,

Robert J. Young, MD

Submitter : **Mr. Geoff MacKay** **Date: 09/18/2006**

Organization : **Organogenesis, Inc.**

Category : **Private Industry**

Issue Areas/Comments

Skin Replacement Surgery and Skin Substitutes

Skin Replacement Surgery and Skin Substitutes

Please see attachment.

CMS-1506-P-73-Attach-1.PDF

Attach #
73

Organogenesis inc.

LIVING TECHNOLOGY

150 Dan Road, Canton MA 02021

September 13, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule; Skin Replacement Surgery and Skin Substitutes

Dear Administrator McClellan:

Organogenesis, Inc. appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year (CY) 2007. Our comment addresses the section of the proposed rule concerning Skin Replacement Surgery and Skin Substitutes. Organogenesis is a biotechnology company based in Canton, Massachusetts, that manufacturers and markets Apligraf® (J7340), a unique human skin substitute for diabetics and others who suffer from chronic ulcers. As set forth below, Organogenesis supports the Centers for Medicare and Medicare Services' (CMS) proposal to assign the new CPT codes for the application of Apligraf to APC 25, thus correcting the substantial reduction effected by the final hospital outpatient rule for CY 2006. This proposal reflects the work that is billed under the new skin substitute codes assigned by the American Medical Association (AMA) CPT Editorial Panel in 2005. Organogenesis will continue to work with the AMA CPT Editorial Panel and other professional societies on the new skin substitute CPT codes.

Background

Organogenesis filed a comment letter on January 3, 2006, addressing CMS's assignment of the new CPT codes in the final rule on November 1, 2005.

The publication of the final rule was the first time that Organogenesis learned either of the new CPT codes or their APC assignment. Organogenesis met with CMS on February 6, 2006 to discuss the assignment of the new CPT codes. Organogenesis also attended the March APC Advisory Panel discussion on skin substitutes, at which Dr. Robert Kirsner of the University of Miami presented on the application on Apligraf. Organogenesis again met with CMS on June 8, 2006 to discuss payment for application of skin substitutes, in anticipation of the proposed rule for CY 2007. We appreciate CMS' attention to this issue and willingness to meet over the past year.

Apligraf is a Medically Necessary Cost-Saving Product

Apligraf is a unique, bioengineered, cell-based human skin substitute for the treatment of chronic, hard-to-heal venous leg ulcers and diabetic foot ulcers. Like human skin, it is comprised of two layers, a dermis and an epidermis, consisting of living, functioning, responsive cells that stimulate the would to heal. The incidence of chronic wounds in the United States is approximately 5 to 7 million per year, with an annual management cost in excess of $20 billion.

Apligraf is the only active wound-healing product that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of venous leg ulcers, in addition to diabetic ulcers. Before Apligraf was available, physicians had few treatment options for hard-to-heal venous ulcers. Apligraf has preserved and improved the qualify of life of tens of thousands of diabetics and other elderly patients suffering from chronic leg and foot ulcers. Many of those patients would have had to undergo limb amputations without the benefit of Apligraf.

Apligraf and similar advanced bioactive products have been specified by leading clinicians in published algorithms as the standard of care for wounds that have not responded to conventional therapy. Apligraf is a proven cost-effective therapy for chronic foot ulcers, providing savings in wound care costs averaging $7,500 per patient.

New CPT Codes for the Application of Apligraf

Prior to November 2005, Apligraf was billed under CPT codes 15342 and 15343. When clinically appropriate, physicians could additionally bill code 15000 for wound bed creation and site preparation. CPT codes 15342 and 15343 were assigned to APC 24 (Level I Skin Repair). CPT code 15000 was assigned to APC 25 (Level II Skin Repair). In November, 2005, the AMA discontinued codes 15342 and 15343, and created two new CPT codes—15340 (*Tissue cultured allogeneic skin substitute, first 25 sq cm or less*) and 15341 (*Tissue cultured allogeneic skin substitute, each additional sq cm*)—to describe the work formerly billed under codes 15342 and 15343.

The new codes additionally included the work formerly billed under CPT 15000. The AMA CPT Editorial Panel thus stated in its coding manual, published *after* the release of the final hospital outpatient rule for CY 2006, that the new codes 15340 and 15341 could not be billed in conjunction with code 15000. Notwithstanding this expansion of the scope of work covered by the two new codes, the Final Rule for CY 2006 used the claims data for the old codes (15342 and 15343) to assign the new codes (15340 and 15341) to APC 0024. In other words, CMS inadvertently crosswalked the old CPT codes to the new CPT codes, without accounting for the fact that the work previously billed under CPT 15000 had been added to the new CPT codes. As a result, total hospital payment for the application of Apligraf decreased from approximately $370.73 in 2005, to $138.48 in 2006 as illustrated by the following chart.

[illegible]	[illegible]	[illegible]
2005	15000 15342 15343	APC 25 - $269.62 APC 24 - $101.10 /2 = $50.55 APC 24 - $101.10 /2 = $50.55 **Total: $370.72**
2006	15000 15340 15341	Not billable APC 24 - $92.32 APC 24 - $92.32 /2 = $46.16 **Total: $138.48**

APC Advisory Panel Recommendations

At the March, 2006 meeting of the APC Advisory Panel, the Panel heard testimony from skin replacement experts and hospital administrators on the assignment of CPT codes for skin replacement and skin substitute procedures. Multiple presenters argued to the Panel that the codes for the first increment of body surface area, including CPT 15340, should be assigned to APC 0027 (Level VI Skin Repair), on the ground that such codes are similar to CPT code 15300 (Allograft skin for temporary would closure, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children). Accordingly, the Advisory Panel recommended that CMS assign CPT 15340 to APC 0027, and CPT 15341 to APC 0025.

In the proposed rule, however, CMS disagrees with Advisory Panel presenters that the clinical and hospital resource characteristics of CPT code 15300 were appropriately placed in APC 0027. On that basis, the proposed rule rejects the APC Advisory Panel recommendation that CPT 15340 be assigned to APC 0027.

Skin Substitute Products in 2007

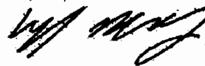
The proposed rule for CY 2007 would correct the substantial reduction in payment for Apligraf effected by the CY 2006 final rule, by assigning the CPT codes for "tissue cultured allogeneic skin substitute" to APC 0025. Organogenesis believes that this proposal represents a significant step toward ensuring that hospitals are appropriately reimbursed for Apligraf, and thus ensuring that Medicare beneficiaries suffering from chronic, hard-to-heal wounds have access to this vital treatment.

Moreover, external analysis of Medicare claims data strongly supports this adjustment. At the request of Organogenesis, the Moran Company compared charges for CPT code 15000 and the old CPT codes 15342 and 15343 to median charges for APCs 0024, 0025, and 0027. The Moran analysis demonstrated that the charges for the new codes would correspond to the upper end of the charges for APC 0025 and the lower end of charges for APC 0027. The full Moran analysis is included with this comment for your review. The below chart shows the median costs of Apligraf compared to the APC 24, 25 and 27.

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
24	$92.32	492,617	$167.24	$92.22
25	$315.74	30,696	$560.22	$315.37
27	$1,082.84	65,631	$1,187.19	$1081.66

Organogenesis is committed to working with professional societies and CMS to ensure proper coding and payment for all skin substitutes. Organogenesis thanks CMS for its close attention to this important issue, and looks forward to working closely with the agency to ensure that Medicare beneficiaries suffering from chronic, hard-to-heal wounds have access to the best therapy available.

Sincerely,



Geoff MacKay
President & CEO

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Memorandum April 27, 2006

TO: Antonio S. Montecalvo, Organogenesis Inc.

FROM: Mary Jo Braid-Forbes, The Moran Company

SUBJECT: Recalculating median costs of application codes

Two new skin substitute application CPT® codes (15340 for the first 25 sq cm and 15341 for each additional 25 sq cm) replaced 15342 and 15343 effective January 2006. Unlike their predecessor codes these new codes include preparation of the site and do not allow the concurrent billing of CPT® code 15000 for preparation of the wound site. The final 2006 Hospital Outpatient Prospective Payment System (OPPS) payment rates for the new skin substitute application codes do not fully account for this change in code definition. This memorandum describes the payment rate changes from 2005 to 2006 and presents the results of an analysis of an alternative methodology for calculating the median costs of the codes for CPT® code 15340, application of bilaminate skin substitute/neodermis, 25 sq cm, formerly 15342. We also describe the median costs of the three relevant APCs (0024, 0025, and 0027).

Findings:

- We calculated the median cost of 15342 in a manner consistent with the CMS methodology that also takes into consideration the change in the code definition which incorporates 15000. We found a median cost of ***$439.68***, 123 percent greater than the median cost we calculated without incorporating 15000. Incorporating 15000 as a packaged item on these claims also resulted in 30 percent more 'single' claims being used. If we restrict these claims further to only claims that always have both 15342 and 15000 the median cost is ***$555.31***.
- CMS used less than half of the occurrences of 15342 to calculate the median cost. Our calculations under the revised methodology (claims with 15342 which may or may not have 15000) use 60 percent.
- The median cost we calculated under the revised methodology is higher than the median cost CMS reports for APC 0024 and 0025, but lower than the median cost reported for APC 0027.

Background

The following codes are discussed below:

- 15000 Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues); first 100 sq cm or once percent of body area of infants and children
- 15342 Application of bilaminate skin substitute/neodermis; 25 sq cm
- 15343 each additional 25 sq cm

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Two new application codes (15340 and 15341) replaced 15342 and 15343 effective January 2006. Unlike their predecessor codes these new codes do not allow the concurrent billing of 15000 (APC 0025). CMS in the final 2006 rule kept these new codes in APC 0024 with payment rates of $ 92.32. These payment rates are slightly below the prior year payment rates of $101.10 (APC 0024) for 15342 and 15343. However, the new codes include the preparation of the wound site which formerly could be billed under 15000. So the payment for the procedure as a whole was cut due to the change in the meaning of the CPT codes that was not taken into consideration by CMS in setting the payment rate. In 2006 15000 is paid at $315.71. All of these codes have a status indicator of 'T' so a 50% multiple procedure reduction applies. Table 1 below summarizes the payment for the procedure in 2005 and 2006.

Table 1: Summary of payment changes in 2006

	2005	2006	% change
15000	$269.62	NA	
15342/15340	$101.10/2=$50.55	$92.32	
15343/15341	$101.10/2=$50.55	$92.32/2=$46.16	
Total procedure 25cm or less	$320.17	$92.32	-71%
Total procedure greater than 25 cm	$370.72	$138.48	-63%

Replicate the CMS "single bill" methodology to identify the claims that were used to set the payment rates.

CMS uses a methodology to identify "single bill" claims that they use in rate-setting. The median cost of these single bill claims (including packaged items) is used to calculate a relative weight. We can replicate the CMS median cost to with 5 percent. Table 2 below shows the results of our replication of the CMS single bill and median cost methodology.

Table 2: Replication of CMS single and median cost calculations, 2006 final rule (2004 data)

	TMC Single Count	CMS Single Count	Percent Difference	TMC Median	CMS Median	Percent Difference
15000	5,262	4,797	9.7%	$ 316.85	$ 334.10	-5.2%
15342	7,749	7,480	3.6%	$ 196.91	$ 188.39	4.5%
15343	674	679	-0.7%	$ 137.14	$ 133.34	2.8%

Determine what percentage of the total claims available is used by CMS for rates-setting.

CMS uses only claims that are determined to be 'single procedure' claims. Single procedure claims under this definition include both claims that have only one payable procedure on the claim and 'psuedo singles' that CMS creates by breaking apart claims that have multiple procedures. Even after the creation of 'pseudo singles' there are claims that remain that CMS does not use for the median cost and weight calculations. CMS used only about a quarter of all

the occurrences of 15000 for the median cost calculation and less than half of the occurrences of 15342. See Table 3.

Table 3: CMS singles as a percent of total, 2006 final rule (2004 data)

	Total	CMS Single Count	Singles % of Total
15000	17,896	4,797	26.8%
15342	16,655	7,480	44.9%
15343	2,410	679	28.2%

Calculate a new median cost for 15342 simulating both the new definition of the code (including 15000) and using the CMS methodology.

We simulated a new median cost for 15342 in two ways. First, we applied CMS's single/multiple claim logic to the 15342 claims but changed the definition of 15000 on these claims to be a packaged service rather than a separately payable service. This resulted in 30 percent more single claims. We then calculated the median cost of these claims including the costs associated with 15000. We calculated a median cost of $439.68, which is 123 percent greater than the median cost we calculated in our replication of the CMS medians without packaging 15000. Second, we created a subset of these single claims including only those with both 15342 and 15000. The subset included 58 percent of the claims in the first simulation and these claims had a median cost of $555.31.

Table 4: Simulation of median cost using new definition of the code using 2004 data used for the 2006 final rule

	Simulation Single Count	Percent Difference	Simulation Median	Percent Difference
15342 and 15000 packaged	10,053	29.7%	$ 439.68	123%
15342 AND 15000 on claim and 15000 packaged	5,890	-24.9%	$ 555.31	182%

Investigate APC medians that correspond to the median cost calculated under the revised methodology

In the 2006 final rule the 15340 and 15341 were kept in the same APC as their predecessor codes (APC 0024). The "true" median cost for APC 0024 as reported by CMS is $92.22. The median costs we calculated for 15340 code incorporating the revision to the code definition is at least $439.68 and as high as $555.31, depending on whether 15000 is required to be on the claims used in the median calculation. These revised median costs are much higher than the median cost of APC 0024 and even higher than the $315.37 median cost of APC 0025. However, it is

much lower than CMS's reported median cost of $1,081.66 for APC 0027. Table 5 below shows the CMS reported final rule median costs for these APCs.

Table 5: CMS 2006 final rule APC medians for APC 0024, 0025 and 0027

APC	Payment	"Single Frequency"	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CMS Adjusted Median of Total Cost	CV
0024	92.32	492617	2.24	7241.45	167.24	92.22	.	180.984
0025	315.71	30696	10.89	8035.92	560.22	315.37	.	160.384
0027	1082.84	65531	21.60	9779.11	1187.19	1081.66	.	64.15

Submitter : **Mr. Jason DeSalvo** **Date: 09/18/2006**

Organization : **Strategic Outpatient Services, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

Attached please find a letter containing my comments. Thank you.

Jason DeSalvo

CMS-1506-P-74-Attach-1.PDF

Attach # 74

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September 18, 2006

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

ATTN: FILE CODE CMS-1506-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT

Dear Administrator McClellan:

I am writing on behalf of Strategic Outpatient Services, Inc. (SOS) to address an issue of great importance to Medicare beneficiaries with cancer. SOS operates six (6) outpatient diagnostic imaging centers, which provide PET/CT imaging services to over 10,000 cancer patients annually. I appreciate the thoughtful attention that the Centers for Medicare and Medicaid Services (CMS) has devoted to cancer care in recent years. I am deeply concerned, however, that the substantial cuts in the payment rate for positron emission tomography with computed tomography (PET/CT) set forth both in the proposed physician fee schedule and the proposed hospital outpatient rule will seriously underpay outpatient imaging centers, and will compromise beneficiary access to this vital technology.

Medicare payment rates for PET/CT performed by doctors offices traditionally have been determined by regional carriers. Under the Deficit Reduction Act Medicare payments for the technical component of PET/CT would be capped at the hospital outpatient rate. CMS has proposed to reduce the hospital outpatient rate for PET/CT to $865—the same rate proposed for conventional PET—from its current rate of $1,250. For outpatient imaging centers that represents a cut of up to 60% to 70% in one year from current carrier based prices. More shocking however, is that the proposed combined reimbursement for PET/CT's technical component, professional component and allowable reimbursement for FDG will be almost 20% below SOS's cost of providing these services *excluding* an allowance for a return on invested capital. How can this

possibly be? Especially given that in today's managed care environment, what CMS does, Aetna, United Healthcare, Blue Cross Blue Shield, Cigna, etc. are all sure to follow.

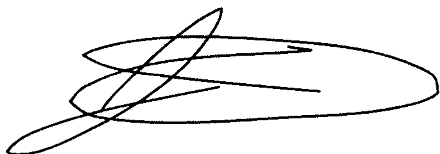
Over the past several years, PET/CT has replaced conventional PET as the standard of care for cancer patients. The fusion of PET and CT into a single imaging modality has enabled earlier diagnosis, more accurate staging, more precise treatment planning, and better therapeutic monitoring. These benefits ultimately reduce the number of invasive procedures—such as biopsies—required during cancer care, thus sparing patients pain and discomfort and saving hospitals valuable resources.

The hospital outpatient proposal does not recognize the important clinical and technological distinctions between PET/CT and conventional PET. In fact, the costs to SOS of acquiring, maintaining, and operating a PET/CT scanner are substantially higher than those for a conventional PET scanner. The payment rate for PET/CT should reflect this difference.

Many cancer patients live far from hospitals, and rely on outpatient imaging centers for oncologic imaging. The proposed payment rate reduction for PET/CT would seriously underpay outpatient diagnostic imaging centers, and risk limiting beneficiary access to this vital technology. I respectfully request that CMS maintain the current hospital outpatient PET/CT payment rate of $1,250. Furthermore, since the vast majority of PET/CT scans are presently performed in outpatient imaging centers, CMS should rapidly work to develop a payment methodology that takes the costs of operating in this very different environment into account and factor that into its "hospital" outpatient rates. <u>It makes no sense to have a cost-based reimbursement methodology based on the costs of less than half of the entities providing a given service.</u>

Thank you for your attention to this important matter. Please feel free to contact me for additional information.

Sincerely,



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