Submitter : **Mr. Tim Gould** **Date: 10/06/2006**

Organization : **DAPA**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

I am requesting the proposed 15% cut for Partial Hospitalization Services be stopped. Coupled with last years 12.5% reduction, the proposed rate will make it impossible to cover the costs needed to provide intensive programs. I strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations.

Submitter : **Mrs. Tamar Thompson** **Date: 10/06/2006**

Organization : **Bracco Diagnostics Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment concerning policies and payments for drugs and radiopharmaceuticals.

Policy and Payment Recommendations

Policy and Payment Recommendations

Please see attached letter

CMS-1506-P-286-Attach-1.DOC

October 6, 2006

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

VIA: Electronic Submission

Re: Comments on Proposed 2007 HOPPS Rule – CMS-1506-P

Dear Administrator McClellan:

Thank you for providing Bracco Diagnostics Inc. with this opportunity to submit comments on the 2007 proposed hospital outpatient prospective payment system (HOPPS) rule published in the August 23, 2006 Federal Register. Bracco Diagnostics Inc. is a global manufacturer of contrast imaging agents and radiopharmaceuticals used in medical imaging procedures. The products that we offer are used in outpatient hospital procedures performed in radiology departments, cardiac catheterization laboratories, and nuclear medicine departments across the United States. Please accept this letter as an adjunct to our September 1, 2006 submission (***temporary comment number 91284***) concerning myocardial Positron Emission Tomography (PET) payment rates and Ambulatory Payment Classification (APC).

In this letter we are specifically commenting on the HOPPS non pass through payment rates for drugs, biologicals and radiopharmaceuticals *with* Healthcare Common Procedural Coding System (HCPCS) codes but no claims data, drug packaging thresholds, and radiopharmaceutical payment policies.

<u>HOPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals</u>

Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals.

107 College Road East Princeton NJ 08540 Telephone (609) 514-2200 Fax (609) 514-2429

We understand that the Centers for Medicare and Medicaid Services (CMS) believes that the packaging of drugs is consistent with the concept of the prospective payment system. However, we do not believe that the single claim methodology that CMS uses for recalibrating APCs considers hospital full costs, (in the charges reduced to cost methodology) associated with packaged drugs and radiopharmaceuticals. In most instances, drugs and radiopharmaceuticals are appropriately reported on multiple procedure claims and most likely not factored into the rate of the APC. Eliminating the packaging threshold lends homogeneity to the APC groupings. **For these reasons, Bracco supports the August 2006 APC Advisory Panel recommendations (#19 and #28) to eliminate the packaging threshold and allow separate payment for all drugs, biologicals and radiopharmaceuticals with HCPCS codes and to provide hospitals with a claims analysis that identifies the contributions of packaged costs to the median cost of each drug administration service.**

Proposed Payment Policy for Radiopharmaceuticals

Respectfully, we disagree with CMS' recommendation to implement prospective payment system (PPS) rates for radiopharmaceuticals in 2007 based on 2005 claims data. In the November 10, 2005 HOPPS final rule, CMS stated it was using hospital specific overall cost to charge (CCR) to derive the cost of radiopharmaceuticals and related handling and overhead cost from the hospitals' reported charges. CMS also stated that CCR was the best available proxy for the average acquisition cost of the radiopharmaceuticals along with their handling cost[1]. By recommending a PPS payment system for 2007, we believe that CMS is communicating an inconsistent message to hospitals. **Bracco supports the August 2006 APC Advisory Panel recommendation (#20) to continue using CCR as the payment methodology for radiopharmaceuticals for one year.** Continuing to allow hospitals to use CCR for one more year provides an opportunity for industry to work with CMS to develop a long term radiopharmaceutical payment policy. Perhaps the most appropriate payment methodology for radiopharmaceuticals is one that allows manufacturers to assist CMS in the development of payment rates through manufacturer or central pharmacy sales reporting, much like the Average Sales Price (ASP) payment model used for drugs.

Many manufacturers do not have the capability to report the data needed to set the payment levels for radiopharmaceutical overhead and handling cost. However, hospitals and pharmacy operations could most likely report this information to CMS. Developing a payment formula based on sales price, handling cost, and overhead utilizing HCPCS codes instead of national drug codes (NDC) would surely provide equitable payment rates for hospitals.

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[1] November 10, 2005 Hospital Outpatient Prospective Payment System Final Rules and Regulations, Federal Register Vol. 70, No. 217, page 68653-68654.

Bracco recommends that CMS work with industry to develop a payment methodology *similar* to that of the ASP model based on HCPCS codes that are calculated on a scale that combines manufacturer sales reporting with hospital and central pharmacy reported data including transportation costs to arrive at an appropriate payment rate for radiopharmaceuticals.

Proposed Payment Policy for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes, But Without HOPPS Claims Data

We disagree with CMS' recommendation to package payment for drugs, biologicals, and radiopharmaceuticals that have HCPCS codes but do not have claims data. When drugs are packaged into the procedural component hospitals often do not separately report the HCPCS code that describes the use of the drug. We are specifically expressing concern with CMS' recommendation to package HCPCS code J2805, Sincalide injection (brand name Kinevac®).

In 2005, CMS created J code J2805 to describe Sincalide injection with an effective date of January 1, 2006. Because this newly created code was not available for reporting in 2005 claims data does not exist to determine hospital per administration cost. CMS should not use the Average Sales Price (ASP) data as an "estimate" of the per administration cost for Kinevac. Sincalide injection is often sold to hospital customers through wholesalers or pharmacy distributors. Consequently, the ASP data that Bracco provides to CMS for this product does not reflect the mark up (often up to10%) that the pharmacy or wholesalers may have charged to hospitals to acquire Sincalide

We realize that Sincalide injection is not currently on pass through status however, we are asking CMS to consider using the ***premise*** of the pass through status payment policy as an alternative solution to reimbursing drugs and radiopharmaceuticals that do not have 2005 claims data rather than applying packaging status indicators to these products.

Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs, biologicals, and radiopharmaceutical agents. Under the recently amended statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years under the ASP methodology[2]. We believe the intent of this policy is to allow a period of time for CMS to collect claims data for these products. This data would identify true clinical and economic resources and determine utilization for these products which could then be used to determine the appropriate payment thresholds for these drugs and radiopharmaceuticals. Following the ***premise*** of the pass through payment policy for drugs and

[2] November 15, 2004 Hospital Outpatient Prospective Payment System Final Rules and Regulations, Federal Register Vol. 69, No. 219, page 65776.

radiopharmaceuticals that do not have 2005 claims data promotes payment policy consistency for outpatient hospitals.

Bracco respectfully requests that CMS continue to allow separate payment at ASP+ 6% for Sincalide injections by pairing the "J" code J 2805 with status indicator K until adequate claims data is available to determine the true per administration cost for this product.

Bracco recognizes the challenges that CMS faces in revising payment methodologies and would welcome the opportunity to meet with CMS to expand upon our recommendations in greater detail.

Thank you for the opportunity to comment on this important rule. Should you have any questions, please do not hesitate to contact me via telephone at 609-514-2274 or email tamar.thompson@diag.bracco.com.

Respectfully,

Tamar Thompson, RMA, CCS, CCS-P
Manager, Reimbursement Services
Nuclear Medicine

Attachments:

November 10, 2005 Federal Register Medicare Program Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Final Rule: http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=696079215601+0+1+0&WAISaction=retrieve

November 15, 2004 Federal Register Medicare Program Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; Final Rule:http://frwebgate3.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=97859021593+0+0+0&WAISaction=retrieve

Submitter : Mrs. Nancy Payne **Date:** 10/06/2006

Organization : Allina Hospitals and Clinics

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1506-P-287-Attach-1.DOC

Allina Hospitals & Clinics
Regulatory Affairs
PO Box 43 Mail Route 10105
Minneapolis, MN 55440-0043

ALLINA.
Hospitals & Clinics

October 6, 2006

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS – 1506-P and CMS 4125-P, Medicare: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule, August 23, 2006 Federal Register.

Dear Ms. Norwalk:

On behalf of Allina Hospitals & Clinics, I appreciate the opportunity to comment on the proposed rule concerning the hospital outpatient prospective payment system. Allina Hospitals & Clinics (Allina) is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. We provide a continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, medical transportation, retail pharmacy, home health and hospice services, as well as home oxygen and medical equipment. Allina serves communities throughout Minnesota and western Wisconsin.

The complexity of the OPPS program continues to challenge us. We encourage CMS's efforts to ease regulatory complexity, with continued attention to our goal of providing high quality patient care and long-term financial viability for our communities. We appreciate the options CMS presented in this rule and your openness to listen and understand real world application of the proposals. Please review and consider our comments as you write the final rule.

Partial Hospitalization (PHP)

We are very concerned about the continued reduction in partial hospitalization payments. The 15% reduction proposed for 2007 on top of the reductions taken in the last two years will force organizations to make decisions about continuing their PHP programs. These programs are very important in meeting the needs of an underserved population. Reduced access to outpatient mental health services will lead to increased utilization of inpatient psychiatric services for these patients. We ask that CMS, at a minimum, hold the current rate of reimbursement for partial hospitalization services so that the continuation of PHP programs is not at risk and the current level of access is maintained.

Outlier Payments

Outlier payments are important to our hospitals as a means of mitigating losses when treating high end cases. We urge CMS to continue with this payment structure. As we have communicated in our annual comments to CMS, we do not support the continual increase in the threshold to qualify for outlier payments. For 2007, the outlier threshold is proposed to increase from $1,250 to $1,825. We do not support this persistent attack on our ability to capture some level of reimbursement of those cases that legitimately qualify as outliers.

The size of the outlier set-aside pool has historically been greater than the actual need. We recommend that CMS either reduce the set-aside amount and retain those dollars in the OPPS rate setting structure or reduce the threshold for qualification so that the outlier pool is actually at a zero balance at the end of each year.

New Tech APCs

We oppose the movement of the PET codes out of new tech APC's and into clinically appropriate APCs. This change creates dramatic reductions in PET payments. We do not agree with CMS that these procedures have been "overpaid in the past" and feel strongly that there are data integrity issues that must be addressed before any payment reduction is finalized.

We have significant concern about the reimbursement reduction proposed for MEG APC values. We do not feel that the reduction is warranted. The low number of Medicare procedures and the wide variation in average cost for these procedures leads us to believe that CMS should continue to build a solid data foundation before making deep reductions in payments. This reduction will create significant impact on payments received from non-Medicare payers who follow the Medicare payment methodology and policies.

We appreciated CMS's approach to manage new technology with the new tech payment bands established in the past; however, when CMS makes the decision to move new technology out of the payment bands we ask that you should be looking for APCs that are high enough to actually recognize the cost of the new technology.

Radiology Procedures

CMS seeks comments on how to support more uniform and consistent reporting of charges and costs and UB revenue codes related to all cost centers, not just radiology. With the many functional areas involved in the revenue process, we would appreciate if CMS could be more explicit on which part of the payment process a regulation may be addressing such as pricing, charging, coding, billing, cost reporting, etc. It can be very challenging in interpreting regulations to figure out which process is being considered as the primary driver in a particular regulation.

Device Dependent APCs

Please review the edits that require a C-device code with a particular HCPCS code. We have issues with trying to submit claims with HCPCs for procedures that do not **always** require a C-device code such as an EP study.

Pass Through Drugs

If a drug is noted with a pass-through status, the drug should qualify for pass-through payment regardless of the reason it is being used so long as it is medically necessary. We experience administrative complexities trying to manage processes to ensure accurate billing for pass-through drugs for a specific diagnosis—such as the use of sodium hyaluronate in orthopedic circumstances but no pass-through for the same drug used appropriately for ophthalmic procedures.

OPPS: Non-Pass-Through Drugs

We do not support the use of ASP+5% for the separately payable drugs. If CMS is looking to build greater parity between physician offices and OPPS sites of service, we wonder why the physician offices would be reimbursed at ASP+6% versus the OPPS rate at ASP+5%. We would suggest that CMS pay both sites of service at the ASP+6% rate.
We appreciate the continued separate payment for antiemetics used in conjunction with chemotherapy.

We do not agree with the CMS approach to use either ASP+5%, WAC, or 95% of AWP when determining the payment rate for non-pass-through drugs with HCPCS but no data. We recommend that CMS use the 95% of AWP for all of these drugs or biologicals until the data exists to determine the appropriate payment calculation. We do not feel that CMS should have the option to reimburse based upon which one of the three different methods brings the lowest payment.

OPPS Brachytherapy

We do not see that CMS has factored into the cost of brachytherapy, the need for special handling required of the nuclear physicist to manage the sources safely outside of an installation. We seek payment consideration for these costs that are not currently factored into the rate setting methodology for the brachytherapy sources.

OPPS Drug Administration

After working for a full year to effectively implement the C-codes for drug administration, we support the proposal to continue the use of these codes for 2007. The majority of our non-government payers accept the C-codes. A change to straight CPT codes for drug administration would require significant systems changes and education that we would not be able to accomplish given the short timeframe between the publication of the final rule and implementation on January 1, 2007. We support the proposed separate payment for the first hour of infusion and for each additional hour of infusion as reported with the add-on codes for both chemotherapy and non-chemotherapy services.

We are very disappointed in the proposed elimination of the pre-administration charge for IVIG. Since 2003, hospitals have experienced dramatic reductions in payments for IVIG. The addition of the pre-administration charge last year was viewed as a way to acknowledge the financial hits we have taken over the years and recognized the resources required to assure a steady supply of this high demand drug. We disagree with CMS that supply is no longer an issue. We continue

to be challenged in securing enough of the drug to meet our patient needs. While we appreciate the ability to charge for an additional hour of IV administration, this amount does not adequately address the overall payment reduction we face with IVIG. We oppose any reduction in the payment for IVIG.

Visits

We appreciate CMS's efforts to make progress toward the development and implementation of national E&M coding guidelines. We support the implementation of the new G-codes and will map them to our current E&M guidelines. The differentiation between Type A and Type B emergency departments is helpful. We support the five-level structure for emergency and clinical visits.

In relation to the critical care description, we would like to see the 30-minute minimum removed. With our efforts around fast track for acute MI patients we find that we are moving these critical patients through in less than 30 minutes and we are not able to capture the intense resource utilization that occurs in that short timeframe. We request that CMS redefine the critical care code to note "up to 74 minutes" and drop the 30-minute minimum.

The exclusion of separately payable procedures from the acuity checklist has created more complexity in the acuity system. We support the recognition of resources used to perform these procedures (especially labs and EKGs). More and more staff time is involved in completing these procedures and we would like to recover those costs. However, we do not support a structure that would create greater risk of double billing. We ask that CMS continue to support a structure in which minor procedures charges can continue to be included in the assignment of the level.

Inpatient Procedures

While we appreciate that CMS proposes to remove eight procedures from the Inpatient Only List, we continue to support the Advisory Panel's recommendation to eliminate the entire Inpatient Only Procedure List. Physicians make decisions regarding the appropriateness of inpatient or outpatient status for procedures based upon numerous patient variables. Regulations should not supersede the physician's level of knowledge, expertise and assessment of these patient variables in determining whether or not a procedure can be done safely as an inpatient or an outpatient.

Hospital Quality Data

We vehemently oppose the application of IPPS quality reporting requirements to OPPS reimbursement. Inpatient quality indicators are focused on **inpatient** care and should not be viewed as a "proxy" for outpatient care. While we feel it is important to measure the quality of ambulatory care, we feel strongly that OPPS payments should not be impacted. We challenge CMS to look outside the boundaries of the hospital and look at measuring the effectiveness of chronic disease management provided in a variety of ambulatory settings. This focus should start in the physician office, not the hospital, where a specific procedure is many times the impetus for outpatient care.

ASC Comments

We have major concerns associated with the 30% reduction in endoscopy procedures. These procedures should be paid at the full OPPS rate. There are no differences in anesthesia or overhead resources used. We do not support any action that would lead to reduced access to these procedures for the Medicare population. We anticipate that the proposed reimbursement reductions would prompt closure of endoscopy facilities and limit overall access and choice for Medicare beneficiaries.

NTIOLs

We have no comments specific to the criteria for new technology intraocular lenses; however, we are concerned about the low rates of reimbursement for IOLs in general. The rates do not adequately factor in true practice expense.

ASC Packaging

We do not support the elimination of the separate payments for implanted devices. Implant costs are the same or greater in the ASC and must be reconciled and accounted for in the payment formula if the separate payment is not retained.

ASC Office Based Procedures

We ask that CMS continue to exclude office-based procedures from the ASC list. These procedures are currently safely done in the physician office where it is convenient for both the patient and the physician. It would not be cost effective to shift this work to an ASC, as these are typically low-cost procedures and better done in the lower-cost physician office.

In summary, Allina appreciates the opportunity to provide comments on the Proposed OPPS Rule for Calendar Year 2007. We hope that CMS will consider our recommendations. If you have any questions, please feel free to contact me at 612-262-4912. We look forward to seeing the final rule.

Sincerely,

Nancy B. Payne

Nancy Payne, RN, MA
Director of Regulatory Affairs
Allina Hospitals & Clinics

Submitter : **Mr. Christian Downs** **Date: 10/06/2006**

Organization : **Association of Community Cancer Centers**

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

OPPS

OPPS

See Attachment

CMS-1506-P-288-Attach-1.PDF

The premier education and advocacy organization for the oncology team

ACCC
Association of Community Cancer Centers

October 6, 2006

BY ELECTRONIC FILING

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

Re: CMS-1506-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates)

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers (ACCC), I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on August 23, 2006 (the "Proposed Rule").[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

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

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies in the most appropriate settings. Hospital outpatient departments are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. Because advanced cancer treatments often are associated with considerable risk, several are available only through hospital-based oncologists, nurses and pharmacists. Patients receiving these treatments must have substantial on-site clinical support in case of adverse reactions. ACCC members often serve patients who have numerous complications or histories of infusion reactions. In addition, some treatments, such as those involving radiopharmaceuticals, are available only in hospitals because they require specialized equipment and handling that is only available in that setting. Finally, hospital outpatient departments play an important role in the early adoption of new technologies and frequently serve patients who have recently completed participation in clinical trials.

Our members also play an important role in the health care safety net. In some cases, hospital outpatient departments are the only sites available for Medicare and uninsured patients who need cancer care. Hospital outpatient departments also are becoming the only option for Medicare beneficiaries who lack supplemental insurance. In 2004, the Medicare Payment Advisory Commission (MedPAC) found that oncologists in some markets sent Medicare beneficiaries without supplemental insurance to hospitals to receive chemotherapy, rather than face the financial burden of unpaid coinsurance if they treated these patients in physicians' offices.[2] MedPAC recently testified to the House Ways and Means Subcommittee on Health that, in 2005, these practices increased the number of patients they sent to hospitals for care, and hospitals in those markets reported that they were treating more patients without supplemental insurance who required innovative therapies.[3] As hospitals face growing numbers of patients who need care for cancer and other serious illnesses, but have nowhere else to turn, their ability to continue to provide care will depend on Medicare's payment rates.

Adequate OPPS payment rates for cancer drugs[4] and the services required to prepare and administer them are critical to ensuring patient access to care. Since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Medicare payments for cancer drugs

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[2] Statement of Mark Miller, Executive Director, MedPAC, to the House Ways and Means Subcommittee on Health, July 13, 2006.

[3] Id.

[4] We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.

have been reduced significantly. When CMS introduced reimbursement based on average sales price (ASP) in the physician office setting, it also implemented new, revalued codes for drug administration services, the Improved Quality of Care for Cancer Patients Undergoing Chemotherapy Demonstration Project, and transition payment of 32 percent in 2004 and three percent in 2005. These adjustments helped to protect Medicare beneficiaries' continued access to cancer care in physician offices. Although the MMA's reforms are likely to produce similar reductions in OPPS reimbursement for cancer drugs, CMS has not made comparable adjustments in the hospital outpatient setting. As a result of these changes, many of our members are finding it difficult to continue to provide quality, multi-disciplinary cancer care. Several members were forced to close their infusion units and others have expressed concerns that they will not be able to offer outpatient cancer care if Medicare continues to reduce its payment rates.

We are disturbed that CMS proposes again to reduce payment for many separately paid drugs, to average sales price (ASP) plus five percent, in 2007. We strongly disagree with CMS' conclusion that these rates will be adequate to reimburse hospitals for both the costs of acquiring and preparing drugs for administration, and we urge the agency to address serious flaws in its calculations.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2007 and beyond adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Recalculate its payment rates for separately paid drugs by including charges for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes and setting rates at no less than ASP plus six percent;
- Continue to study mechanisms to reimburse hospitals for their pharmacy service costs;
- Pay separately for all drugs with HCPCS codes;
- Continue to pay separately for anti-emetics;
- Continue to reimburse separately paid radiopharmaceuticals based on the hospital's charge adjusted to cost using hospital-specific cost to charge ratios;
- Implement the proposed new APCs for drug administration services and the changes recommended by the Advisory Panel on APC Groups to allow hospitals to be reimbursed appropriately for drug administration services.
- Continue to make payment for the preadministration services associated with providing intravenous immune globulin (IVIG).

- Implement the proposed new APCs and codes for evaluation and management services provided during clinic visits and continue to work to refine the draft guidelines for the use of those codes;
- Adopt codes, with appropriate reimbursement, to reflect coordinated care services provided by several professionals.
- Postpone the adoption of a policy to reduce payment for second and subsequent imaging procedures within the same family when performed in the same session;
- Implement the proposed payment rates for brachytherapy APCs;
- Delay the movement of positron emission tomography/computed tomography (PET/CT) scans to a clinical APC; and
- Reevaluate its proposal to assign nonmyocardial PET scans to a clinical APC.

These issues and others are described in depth below.

I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals – NonPass-Throughs

A. Payment for Drugs and Biologicals

1. CMS' proposed rates are not adequate to reimburse hospitals for their pharmacy acquisition and service costs

ACCC is disturbed by CMS' proposal to reimburse separately paid drugs without pass-through status at 105 percent of ASP.[5] CMS claims that these rates will be sufficient to cover hospitals' acquisition costs as well as pharmacy handling costs. A survey of our members indicates that this may not be true. Over half of the respondents to our survey said that the proposed rates would not be adequate reimbursement for the costs of providing five commonly used oncology and supportive care drugs. One member hospital reports that Medicare's current payments at ASP plus six percent are less than acquisition cost for 93 out of 157 separately payable drugs on its formulary. In other words, Medicare payment is insufficient to cover the cost of purchasing the drug, much less the costs of preparing it for administration, for 59 percent of the separately payable drugs on that hospital's formulary. This situation will only worsen if reimbursement is lowered to ASP plus five percent.

We especially are concerned that CMS again proposes to make no additional payments for pharmacy handling costs. As we explained in our comments on the OPPS proposed rule for 2006, the advanced drugs we use to

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[5] 71 Fed. Reg. at 49585.

help our patients fight cancer require careful handling by specially trained personnel. These costs include the services needed to ensure that each patient receives the correct dosage of each drug, in the correct sequence, and through the safest administration method. Hospitals employ complex medication use processes in which physicians, nurses, and pharmacists review drug choices at each step of their prescribing, dispensing, and administration. Pharmacists make essential contributions to these processes by using a sequence of activities commonly referred to as "safety through redundancy." Registered pharmacists consult with physicians to determine drug interactions and contraindications, toxicity management and verification of therapy appropriateness, and dosing before and during administration of chemotherapy to a patient. Pharmacists also perform critical quality assurance tasks during the preparation of drug, such as labelling, recording, and tracking mixed drugs for safety purposes, sampling drugs at random to verify quality, and developing and reviewing protocols to flag potential interactions. These costs also include supplies, equipment, and facilities used in preparing drugs. In recent years, these costs have increased substantially as many hospitals renovate their facilities to comply with the new sterile compounding standards of the United States Pharmacopeia Chapter 797. The remaining pharmacy service costs include contract negotiations, building and information systems maintenance and upgrades, transportation of drugs within the hospital, and disposal of unused products (that typically involve the housekeeping department) to comply with Environmental Protection Agency (EPA) and National Institute for Occupational Safety and Health (NIOSH) regulations.

When it enacted the MMA, Congress recognized that an acquisition cost-based reimbursement methodology might not account for these pharmacy service costs. The MMA allows the Secretary to adjust OPPS rates to reflect these costs, based on the results of a MedPAC study of pharmacy service and handling costs. MedPAC's report, released in June 2005, concluded that these costs are significant and that an adjustment is warranted. MedPAC cited studies that found pharmacy service overhead costs to make up 26 to 33 percent of pharmacy departments' direct costs, with the rest of the costs attributed to the acquisition cost of drugs.[6] Most of the overhead costs reflect ancillary supplies (gowns, booties, masks) and salaries and benefits of pharmacists and technicians. MedPAC also noted that hospitals do not have precise information about the magnitude of their pharmacy expenses,[7] and therefore are not likely to have included all of these costs into their charges for drugs. If CMS used the MedPAC report's lower estimate of overhead costs – 26 percent of direct costs –

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[6] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

[7] Id. at 140.

to adjust payments for drugs, it would result in a payment rate of ASP plus 39 percent, assuming that ASP is equal to acquisition cost for all hospitals.

Other studies have reported similarly large estimates of hospital's pharmacy service costs. A study commissioned by the National Patient Advocate Foundation found that the average cost per dose of chemotherapy administration, including all of the costs listed above, is $36.03, in addition to the acquisition cost of the drug.[8] Our own calculations indicate that the cost of pharmacist interventions is not captured by CMS' reimbursement for the drug. One of our members reported an average of 3.1 pharmacist interventions per hour over a 15 month period. Most interventions lasted 15 to 30 minutes, and the average pharmacist salary and benefits at that hospital was $56 per hour, producing a per-intervention cost of $14 to $28. These costs are in addition to the time needed to prepare a drug when no intervention is necessary.

2. CMS' methodology for calculating the proposed rates is deeply flawed.

In spite of the evidence demonstrating the significant costs of safely preparing drugs in hospital outpatient departments and indicating that these costs are not reflected in hospitals' charges, CMS continues to assert that hospitals set charges for drugs high enough to include these costs. Working on the assumption that hospitals' charges in 2005 included charges for pharmacy service costs, CMS attempted to calculate the mean unit cost for separately payable drugs by applying a constant cost-to-charge ratio (CCR) to these charges.[9] It then compared the aggregate expenditures calculated from claims data to aggregate expenditures calculated based on ASPs.[10] CMS concludes that the mean unit costs for separately payable drugs are equal, on average, to ASP plus five percent.[11]

We believe that CMS' methodology for determining payment rates for separately payable drugs and their handling costs is deeply flawed. Not only does the methodology fail to recognize that hospitals' charges might not include their substantial pharmacy handling costs, but, to the extent that those costs are

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8 Gary Oderda, Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices, http://www.npaf.org/pdf/gap/utah.pdf.

9 71 Fed. Reg. at 49584-85.

10 Id.

11 Id. at 49585.

included in hospitals' charges,[12] it also fails to capture them accurately. This result is due to two errors in CMS' methodology. First, CMS applies a constant CCR to pharmacy charges, although hospitals do not apply a constant markup to their charges. Contrary to CMS' expectations, hospitals tend to apply larger markups to charges for lower cost items than to higher cost items. A hospital might charge $10 for a drug with an acquisition cost of $2, a mark up of 400 percent, while it would charge $2200 for a drug that costs $2000, a mark up of 10 percent. If CMS applies a single CCR to both drugs, it would overestimate the cost of the $2 drug and underestimate the cost of the $2000 drug. This effect is known as "charge compression." The payment rates based on these estimates could exceed the cost of the lower cost drug but would be below the cost of the higher cost drug.[13] The Government Accountability Office (GAO) found that this methodology "does not recognize hospitals' variability in setting charges, and, therefore, the costs of services used to set payment rates may be under or overestimated."[14] CMS itself has recognized that charge compression could create inaccurate payment rates and has commissioned a study to determine how to address it in the inpatient prospective payment system.[15]

Analysis of CMS' claims data shows that applying a constant CCR to charges for drugs produces widely varying estimates of drugs' mean unit costs. As a percentage of ASP, these costs ranged from ASP minus 100 percent to ASP plus 2395 percent. We believe that a methodology that produces such disparate estimates of costs cannot be relied upon to set accurate payment rates.

Second, in addition to failing to recognize the effects of charge compression, CMS uses claims data for only separately paid drugs to in its comparison of the estimated total costs for drugs to ASP. CMS assumes that comparing the estimated costs, calculated from claims data, to ASP will capture the overhead costs associated with separately payable drugs. Because hospitals do not markup charges for drugs uniformly, however, a disproportionate share of overhead tends to be associated with the charges for lower cost drugs. Many of

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[12] We note that, although hospitals' aggregate charges for all drugs, including inpatient drugs and drugs that are packaged under the OPPS, may include handling costs, a hospital's charge for an individual drug is not likely to include the overhead attributable to that particular drug.

[13] M.J. Braid, K.F. Forbes, and D.W. Moran, Pharmaceutical Charge Compression under the Medicare Outpatient Prospective Payment System, Journal of Health Care Finance, Spring 2004, p. 21-33.

[14] GAO, Medicare: Information Needed to Assess Adequacy of Rate-Setting Methdology for Payments for Hospital Outpatient Services, GAO-04-772, September 2004, at 16.

[15] 71 Fed. Reg. 47870, 47897 (August 18, 2006).

these lower cost drugs have HCPCS codes and ASPs, but are packaged into payment for other services under the OPPS, and others do not have codes or ASPs but are included in hospitals' pharmacy charges. Leaving the lower cost drugs out of the analysis means that a large portion of hospitals' handling costs are not reflected in the estimated costs. If the packaged drugs with HCPCS codes are included in CMS' calculations, the mean unit cost for all drugs with ASPs, on average, would be equal to ASP plus eleven percent. If the lower cost drugs without codes and ASPs were included, the mean unit cost likely would be even higher.

3. CMS should recalculate its payment rates for separately payable drugs and should set payment rates for these drugs at no less than ASP plus six percent.

To set appropriate payments for drugs in 2007, CMS should include all drugs with HCPCS codes, not just the drugs that currently are paid separately, in its calculations of total pharmacy costs. The study of charge compression in the inpatient PPS may provide useful insights for the OPPS, as well. Until CMS receives this report and develops a method to adjust for charge compression, CMS should include all of these drugs in the calculations to help ensure that all pharmacy costs, including acquisition and handling services, are reflected in its data. We urge CMS to recalculate payment rates and set payment in 2007 at no less than ASP plus six percent, the rate applicable in physicians' offices, as recommended by the Advisory Panel on APC Groups (the APC Panel) at its August meeting.[16]

4. CMS should continue to study and work with stakeholders to develop appropriate payments for pharmacy service costs.

For future years, CMS should continue to study mechanisms to reimburse hospitals appropriately for their pharmacy service costs. ACCC will continue to work with our members to help CMS learn more about the challenges hospitals face in measuring and reporting charges for these services. As MedPAC noted in its report, many hospitals are unaware of the magnitude of their pharmacy service costs and thus cannot set charges to include all of these costs. CMS should help hospitals set charges that could be used to calculate future payments by providing clear guidance on how to report costs and set charges for these services. We also recommend that CMS consider other options for making payment for pharmacy services, such as the use of codes similar to

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[16] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

those proposed by the agency last year[17] or payment for medication therapy management codes.

5. CMS should pay separately for all drugs with HCPCS codes.

CMS proposes to increase the packaging threshold to $55 per day.[18] ACCC is concerned that increasing the packaging threshold could reduce the number of drugs that are separately paid and could harm beneficiary access to appropriate care. We support the APC Panel's recommendation to pay separately for all drugs with HCPCS codes. This policy is consistent with CMS' payment policies for physician offices and would help eliminate financial incentives to choose one therapy or site of service over another. As discussed above, it also is consistent with our recommended method of calculating mean unit costs for 2007. Additionally, unpackaging these drugs would help to improve the overall accuracy of the OPPS. An analysis of the claims data found that only four percent of claims for packaged drugs are submitted with a drug administration claim and are used to set rates for these services. Over 40 percent of the claims for packaged drugs were submitted with claims for other services, and more than half of the claims for packaged drugs are not used in CMS' analysis. This indicates that the costs of packaged drugs are not actually included in payment for drug administration services, although they are included in the OPPS. Paying separately for these drugs would help CMS to calculate more accurate payments for all of the services in which drugs are used.

Paying separately for all drugs with HCPCS also would eliminate disparities between the hospital outpatient and physician office settings and would not provide financial incentives to use more costly separately paid drugs even when a bundled drug may be more clinically appropriate. Most of our hospitals currently code for bundled drugs, so billing for them separately would not create a substantial additional administrative burden.

ACCC commends CMS' proposal to pay separately for anti-emetics.[19] We agree that separate payment for anti-emetics will help ensure that Medicare's payment rules "do not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."[20]

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17 70 Fed. Reg. 42674, 42730 (July 25, 2005).
18 71 Fed. Reg. at 49582.
19 Id. at 49583.
20 Id.

We also support CMS' decision not to apply an "equitable adjustment" to any drugs in 2007. As CMS noted last year, this decision will "permit market forces to determine the appropriate payment" for drugs.[21]

B. Payment for Radiopharmaceuticals

ACCC also is concerned that CMS' proposed prospective payment rates for radiopharmaceuticals will be inadequate to protect beneficiary access to important cancer therapies. Radiopharmaceuticals are extremely complex therapies to prepare and administer. Preparation and administration of each drug requires a unique bundle of services, such as compounding, dosimetic and therapeutic infusions, and scanning of the patient to assess biodistribution of the therapy. The costs of these services vary for each therapy, and many of these costs are not reimbursed under the OPPS.

Instead of paying for these therapies based on each hospital's charge reduced to cost as it did in 2006, CMS proposes to establish payment for these therapies in 2007 using mean costs derived from calendar year 2005 claims data through the use of hospital-specific departmental CCRs.[22] Similar to CMS' calculations of unit costs for drugs, its proposed methodology for setting payments for radiopharmaceuticals is flawed because it fails to adjust for charge compression and relies on incomplete data. As we explained above, application of a constant CCR to hospital charges produces inaccurate estimates of cost because hospitals do not apply constant markups to the therapies they provide. Additionally, CMS plans to use 2005 claims data to set these rates, even though CMS issued guidance only last year for hospitals to set charges to include "all costs associated with the acquisition, preparation, and handling of these products."[23] CMS issued those instructions in the OPPS final rule for 2006 to ensure that "payments under the OPPS can accurately reflect all of the actual costs associated with providing these therapies to hospital outpatients."[24] We are disappointed that CMS is not waiting for hospitals to adjust their charges so it will have more accurate data on which to base payments. CMS' proposed rate setting methodology cannot produce accurate rates until it has accurate data on costs and charges.

ACCC is concerned that if the OPPS does not appropriately reimburse for all of the costs of providing radiopharmaceuticals, hospitals will not be able to continue to provide these advanced treatments. We are

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21 Id. at 42727.
22 Id. at 49587.
23 Id. at 68653.
24 Id.

particularly concerned about ensuring access to therapeutic radiopharmaceuticals, such as BEXXAR® and Zevalin®. The rates calculated through the proposed methodology will be substantially reduced from 2005 levels, possibly below hospitals' acquisition costs. The proposed rate for Y-90 Zevalin® is 42 percent less than the 2005 rate and 38 percent less than the average purchase price reported by the GAO in 2005.[25] Payment for BEXXAR® would fall by 39 percent from the 2005 levels. CMS also proposes to move the codes for administration of these therapies from new technology APCs to clinical APCs, producing significant reductions in reimbursement. Faced with reduced payment for both the radiotherapies and their administration, many hospitals may not be able to offer these therapies in 2007.

We urge CMS to continue to use the 2006 payment methodology for radiopharmaceuticals for at least one more year. As CMS noted last year, this methodology protects against rapid reductions that could harm beneficiary access to these therapies.[26] In the Proposed Rule, CMS also acknowledges that this methodology is an acceptable proxy for average acquisition costs.[27] Additionally, the APC Panel recommends that CMS continue to use this methodology in 2007.[28] ACCC recommends that CMS use this methodology for 2007 and evaluate the data at the end of that year to determine how to set rates in the future.

II. Drug Administration

ACCC strongly supports the agency's decision to create six new drug administration APCs and to make separate payment for additional hours of drug administration services.[29] ACCC has long advocated for separate payment for these drug administration services under the OPPS. Under the current APCs, payment for second and subsequent hours of drug administration services is packaged into payment for the first hour. These rates do not reflect the true cost of providing drug therapies, particularly for the 40 percent of our patients who receive infusions of chemotherapy and other drugs that usually take two hours or more to administer. In 2006, hospital outpatient departments are paid significantly less than physicians' offices for administering chemotherapy infusions – 22 percent less than a physician's office for administering a 2-hour

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25 GAO, Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting, GAO-05-733R, July 14, 2005, at 6.

26 70 Fed. Reg. 68515, 68653 (November 10, 2005).

27 71 Fed. Reg. at 49587.

28 Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

29 71 Fed. Reg. at 49600.

chemotherapy infusion, 24.6 percent less for a 3-hour infusion, and 34.7 percent less for a four-hour infusion. By making separate payment for additional hours of drug administration services, CMS would close this payment gap and protect beneficiary access to care. This is particularly important for patients who require infusions administered over periods of eight hours, seven days a week, or in other situations that are outside normal physician office hours. Although we understand that other stakeholders have recommended that CMS use Current Procedural Terminology (CPT)[30] codes instead of C-codes for drug administration services, until hospital-specific CPT codes are developed, we believe that continued use of the C-codes is the most appropriate way to ensure that hospitals are adequately paid for these services. We urge CMS to finalize this proposal.

Although we support CMS' proposal to make separate payment for additional hours of infusion services, we are concerned by the significant decrease in payment for the first hour codes. We ask CMS to verify that its calculations are correct and that those rates are appropriate. We also recommend that the agency consider that only four percent of claims for packaged drugs are made with a claim for a drug administration service. If CMS does not make separate payment for all drugs with HCPCS codes – as the APC Panel recommends and we urge the agency to do – it must be aware that most of its claims data for drug administration services do not include the cost of packaged drugs.

To further improve equity between hospital outpatient departments and physicians' offices, we support the APC Panel's recommendation to allow hospitals to separately bill and receive payment for therapeutic infusions and hydration infusions provided in the same encounter.[31] Because these services share codes under the OPPS, a hospital that administers both a one-hour hydration infusion and a one-hour therapeutic infusion would be paid for the first hour of one infusion under APC 440 and a reduced rate for subsequent hour for the other infusion under APC 437. In contrast, under CMS' current guidance, hospitals can report a first hour code for each of other types of infusions, such as chemotherapy or therapeutic infusion, if both infusions meet the requirements for billing a first hour of each type of infusion.[32] We

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[30] Current Procedural Terminology or CPT is a trademark of the American Medical Association.

[31] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

[32] January 2006 Updated of Hospital Outpatient Prospective Payment System Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785,

recommend that CMS adopt a similar policy for hospital outpatient departments and allow hospitals to be paid using the initial infusion code for both the hydration infusion and the therapeutic infusion.

We also continue to be concerned that the current drug administration codes do not allow additional payment for a second IV push of the same drug. If the drug is packaged, hospitals do not receive any payment for the second drug or its administration service. ACCC supports the APC Panel's recommendation to make payment for a second or subsequent intravenous push of the same drug by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology.[33] Paying separately for all drugs with HCPCS codes also would help to establish appropriate payment for all drugs and their administration services.

Additionally, we ask CMS to clarify its guidance on the use of the chemotherapy drug administration codes under the OPPS. CMS' guidance on these codes instructs hospitals to "report chemotherapy drug administration HCPCS codes when providing non-radionuclide anti-neoplastic drugs to treat cancer and when administering non-radionuclide anti-neoplastic drugs, anti-neoplastic agents, monoclonal antibody agents, and biologic response modifiers for treatment of noncancer diagnoses."[34] This guidance is consistent with the CPT's guidance for physician offices, but it does not state clearly that these codes should be used for administration of standard and specialty IVIG. Because IVIG is a biologic response modifier, its administration should be billed using the code for chemotherapy administrations, C8954, not C8950, the code for non-chemotherapy intravenous infusion for therapy or diagnosis. We also ask CMS to clarify that DNA or RNA based therapies are biologic response modifiers that should be billed under chemotherapy administration codes as well.

Finally, we recommend that CMS continue to make payment for preadministration-related services for standard and specialty IVIG. IVIG is an important component of treatment regimens for certain types of cancers. In recent years, changes in Medicare's payment for IVIG may have affected beneficiary access to this therapy. Hospitals have faced challenges in obtaining

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Change Request 4258, Dec. 16, 2005 (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

[33] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

[34] January 2006 Updated of Hospital Outpatient Prospective Payment System Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, Dec. 16, 2005 (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2.2).

IVIG, and in particular, it has been difficult for hospitals to acquire the exact brand best suited for each patient's needs. For 2006, CMS implemented a $75 payment for preadministration-related services for IVIG. We are disappointed that CMS proposes to eliminate this payment for 2007.[35] This proposal, combined with the proposed reduction in reimbursement, will make it even more difficult for hospitals to provide each patient with the appropriate brand IVIG for his or her treatment. We urge CMS to recognize that hospitals continue to bear extra costs in obtaining IVIG and to continue to make the payment for pre-administration services.

III. Evaluation and Management Services (Visits)

We also are pleased that CMS has made progress on new codes and APC assignments for evaluation and management services.[36] As we have explained in the past, improving payment rates and providing appropriate coding guidelines for evaluation and management services can help ensure appropriate payment for cancer therapy support services. The proposed new HCPCS codes for clinic visits and their APC assignments are an important step toward providing appropriate payment for cancer therapy support services, such as management of courses of treatment, nutritional counseling, counseling, patient and family education, and risk assessments.

We also ask CMS to adopt codes, with appropriate reimbursement, that describe clinic visits in which patients receive cancer care from several professionals. For example, in addition to an oncologist and nursing staff, a patient might meet with a nutritionist to discuss changes to the patient's diet, a social worker to plan for home care, and a counselor to address the psychological and emotional aspects of cancer treatment. In 2000, CMS created a code, G0175 (scheduled interdisciplinary team conference (minimum of three exclusive of patient care nursing staff) with patient present), to describe visits in which numerous physicians meet with the patient concurrently. When it created this code, CMS recognized that patients with complex conditions, such as cancer, require carefully coordinated care. Unfortunately, in practice it often is nearly impossible and an inefficient use of resources to have a patient's caregivers meet with the patient as a group. Currently, a facility can report only one evaluation and management code if the patient has sequential visits with several professionals in the same clinic setting, regardless of the amount of time the patient spends with each caregiver. Alternatively, the hospital could bill for each visit if it required the patient to visit separate clinics within the hospital, although the patient would experience greater inconvenience. Hospitals need to

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[35] 71 Fed. Reg. at 49604.

[36] 71 Fed. Reg. at 49607-12.

be reimbursed appropriately for providing coordinated cancer care services in a way that is efficient for the patient, the professionals, and the hospital.

We recommend that CMS revise the definition of G0175 to describe multidisciplinary care as it is actually provided in clinics for cancer and other serious illnesses, such as AIDS and diabetes – through the coordinated efforts of multiple professionals who meet with the patient individually. We also recommend that CMS assign the revised code to a new APC that would represent a sixth level of care. This level would be analogous to proposed APC 617 for critical care. Like critical care in an emergency room, multidisciplinary specialty care in a clinic setting requires more resources than the current highest level clinic visit, involves the work of numerous staff, and requires the patient to remain in the clinic for many hours. Setting payment for this APC at a level equal to the critical care APC would help hospitals continue to provide these important services in a manner that is most convenient and effective for patients and staff. It also would encourage the provision of high quality, coordinated patient care.

We also thank CMS for its efforts to refine the draft guidelines for use of these codes. We believe the guidelines identify helpful criteria for distinguishing each level of service. We believe that the guidelines will need additional examples to describe services provided by non-nursing professionals, such as nutritionists and social workers, who are essential providers of cancer therapy support services. Although these professionals provide valuable services that help patients achieve the full benefits of their cancer therapies and avoid adverse events, saving Medicare program expenditures, it currently is not clear how hospitals can bill for these services in a manner that reimburses them appropriately for their costs. Hospitals need up-to-date guidelines on the use of the new evaluation and management codes that address these important and potentially cost-saving services.

IV. Multiple Diagnostic Imaging Procedures (Radiology Procedures)

ACCC supports CMS' proposal to postpone the adoption of a policy to reduce payment for second and subsequent imaging procedures within the same family when performed in the same session.[37] We commend CMS for deciding to conduct additional studies in order to determine the actual savings yielded from the performance of multiple imaging services in a single session before adopting payment reductions for those services. We remain extremely concerned, however, that CMS will implement an inappropriate payment reduction in the future. As we have indicated previously to CMS, diagnostic

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[37] Id. at 49567.

imaging procedures are vital to the treatment of cancer. These services are essential both to diagnosing the disease and evaluating its treatment. A payment reduction for second and subsequent imaging procedures may impede beneficiary access to these essential imaging services. Furthermore, payment cuts could encourage greater use of invasive diagnostic procedures, unnecessarily exposing patients to potential complications resulting in additional costs to the beneficiary and to Medicare. A decrease in payment for multiple imaging procedures also may cause hospitals to perform each imaging procedure in a different session over an extended period of time, both inconveniencing the patient and delaying beneficiary access to important services. Finally, ACCC believes such a reduction may discourage investment by hospitals in essential new technologies.

As we have stated previously, there is no standard economy of scale when multiple procedures are performed. Technologist time and contrast material administered are not necessarily reduced by the performance of multiple procedures in one session. Rather, the requirements related to patient preparation for some imaging procedures may be different such that substantial time between each procedure may be necessary even if multiple procedures are performed in a single session. In addition, equipment costs, including depreciation and maintenance, are tied to the number of images produced and not the number of sessions in which those images are created.

In the event CMS adopts a payment reduction policy for multiple imaging services performed in a single session in the future, we encourage CMS to base that reduction upon the actual savings realized when more than one imaging procedure is conducted in a single visit and to apply a payment reduction only to those procedures for which the costs currently do not reflect efficiencies resulting from performance of multiple procedures in a single session.

V. Brachytherapy

ACCC strongly supports CMS' proposed payment rates for brachytherapy APCs, specifically the proposed rate for APC 0651 of $1025.37 (applicable to CPT code 77778) and the proposed rate for APC 0163 of $2160.59 (applicable to CPT code 55859).[38] Brachytherapy is an innovative and important cancer treatment that hospitals should be able provide to those patients who could benefit from it. Therefore, we are pleased that CMS followed the March 2006 APC Panel recommendation to reevaluate the proposed payment rates for brachytherapy APCs. We commend CMS for its recognition that the historical instability in the

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[38] Id. at 49563.

payment rates for this vital service has caused difficulty for hospitals in planning and budgeting. Continued instability and unsuitable payment rates could jeopardize hospitals' ability to offer this life-saving therapy to patients. We believe the new rates proposed by CMS are more appropriate for this service and will help enable hospitals to offer brachytherapy to beneficiaries in need of the treatment. Moreover, greater stability in the payment rates will facilitate necessary planning and budgeting by hospitals.

VI. New Technology APCs

A. PET/CT Scans

ACCC is troubled by the agency's proposal to move concurrent PET/CT scans (specifically, CPT codes 78814, 78815, and 78816) from New Technology APC 1514, with a payment rate of $1250, to APC 0308, Nonmyocardial PET Imaging, with a proposed payment rate of $862.29.[39] We agree with the APC Panel's August 2006 recommendation that CMS maintain concurrent PET/CT scans in New Technology APC 1514 at the payment rate of $1250.[40] The innovative technology provided by concurrent PET/CT scans is dramatically improving diagnosis and treatment of cancer patients by offering diagnostic capability superior to PET scans alone. Concurrent PET/CTs can reduce diagnostic errors and the need for certain invasive procedures and can assist in assessing the effectiveness of cancer treatments. In addition, the service allows for more accurate localization of abnormalities, tumors and nodes and more precise prescription of radiation fields.[41] PET/CT scans therefore can decrease the incurrence by Medicare and beneficiaries of additional costs that may stem from diagnostic errors and less appropriate treatment. ACCC is greatly concerned that premature assignment of PET/CT scans to a clinical APC, resulting in a significant reduction in the reimbursement for such services, will hinder patient access to this life-saving technology. The reduction in payment for PET/CT scans may discourage hospitals from investing in this important new technology. Finally, the assignment could create an incentive for hospitals to perform PET and CT scans separately in order to receive payment for each, that not only would inconvenience cancer beneficiaries but also would prevent such patients from realizing the benefits associated with the concurrent scans.

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39 Id. at 49553 and Addendum B.

40 Advisory Panel on APC Groups, Meeting Report for August 23-24, 2006, available at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp

41 See PET/CT's High Accuracy Fuels Rapid Adoption, Community PET a Supplement to Diagnostic Imaging, available at http://www.diagnosticimaging.com/communitypet/4.jhtml.

We believe that CMS should make no changes to payment for this service until it has received more accurate claims data so that cancer patients may continue to receive those services most applicable to their condition. We strongly encourage CMS to delay the movement of PET/CT scans to a clinical APC, as recommended by the APC Panel, in order to provide hospitals additional time to adopt accurate coding and to modify their chargemasters to reflect the appropriate cost and charges for this exciting new procedure.

B. Nonmyocardial PET Scans

ACCC also is concerned by the agency's proposal to assign Nonmyocardial PET scans (in particular, CPT codes 78608, 78811, 78812, and 78813) to clinical APC 0308, Nonmyocardial PET Imaging, with a proposed payment rate of $862.29.[42] PET scans currently receive payment based on a 50/50 blend of the median cost of PET scans and the New Technology APC 1516 payment rate, resulting in a payment rate of $1150. The PET scan is a vital tool in the diagnosis of cancer and to evaluation of the effectiveness of treatment for cancer patients. We believe that lowered reimbursement for PET scans may deter hospital investment in this important technology and could diminish its availability to cancer beneficiaries. We recommend that CMS either reevaluate its proposal to assign Nonmyocardial PET scans to a clinical APC or reconsider the rate for APC 0308 in order to ensure continued access by Medicare beneficiaries.

VI. Conclusion

ACCC urges CMS to protect cancer patients' access to quality care in the most appropriate setting by providing appropriate reimbursement for cancer treatments under the OPPS. Toward this end, we believe it is imperative that CMS recalculate payments for separately paid drugs without pass-through status to ensure that all of the pharmacy service costs associated with those drugs are included in their reimbursement. At a minimum, payment for these drugs should be set at no less than ASP plus six percent. We recommend that CMS continue to study mechanisms to reimburse hospitals for their pharmacy service costs and pay separately for all drugs with HCPCS codes, including anti-emetics. CMS should continue to reimburse separately paid radiopharmaceuticals based on the hospital's charge adjusted to cost using hospital-specific cost to charge ratios, as well.

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[42] 71 Fed. Reg. at 49552.

We support implementation of the proposed new APCs for drug administration services and the changes recommended by the Advisory Panel on APC Groups to allow hospitals to be reimbursed appropriately for drug administration services. We also recommend that CMS implement the proposed new APCs and codes for evaluation and management services provided during clinic visits and continue to work to refine the draft guidelines for the use of those codes. In addition, CMS should adopt codes, with appropriate reimbursement, that describe clinic visits in which patients receive cancer care from several different professionals. We agree that CMS should postpone the adoption of a policy to reduce payment for second and subsequent imaging procedures within the same family when performed in the same session. We also agree with CMS' proposed payment rates for brachytherapy APCs. Finally, we recommend that CMS delay the movement of PET/CT scans to a clinical APC and reevaluate its proposal to assign Nonmyocardial PET scans to a clinical APC.

ACCC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at (301) 984-9496, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

Christian G. Downs

Christian G. Downs
Executive Director

CMS-1506-P-289 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : Dr. Henry Blair **Date & Time:** 10/06/2006

Organization : Dr. Henry Blair

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-289-Attach-1.DOC

October 3, 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 this opportunity to offer comment on the proposed changes to the 2007 Payment rates and to specifically comment on the impact these proposed rates will have on breast conservation therapy in patients with breast cancer.

There are two areas of concern in the HOPPS proposed rule. First is the proposed assignment of 19296 and 19297 to new APCs and then the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from -22.8% to -37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. This is an important option for women electing breast conservation surgery followed by radiation therapy. Traditional whole breast radiation is a 5 day a week treatment, for 6-7 weeks. Breast brachytherapy offers the option of treating the lumpectomy cavity in a much shorter 5 days (twice daily) of treatment.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate date.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ration payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data.
Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Henry Blair, MD
6780 Mayfield Road
Mayfield Heights, OH 44124
440-312-4700

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Dr. John Feldmeier** **Date: 10/06/2006**

Organization : **Dr. John Feldmeier**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-290-Attach-1.DOC

October 3, 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 this opportunity to offer comment on the proposed changes to the 2007 Payment rates and to specifically comment on the impact these proposed rates will have on breast conservation therapy in patients with breast cancer.

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CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in considerable decreases in 2007 payment. The table below illustrates the reductions, ranging from -22.8% to -37.0%.

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19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate. This is an important option for women electing breast conservation surgery followed by radiation therapy. Traditional whole breast radiation is a 5 day a week treatment, for 6-7 weeks. Breast brachytherapy offers the option of treating the lumpectomy cavity in a much shorter 5 days (twice daily) of treatment.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate date.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with cost to charge ration payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

I recommend that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data.
Additionally, I recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

John Feldmeier, DO, FACRO

John Feldmeier, DO, FACRO
Professor and Chair
Department of Radiation Oncology
University Medical Center
3065 Arlington Avenue
Toledo, OH 43614
419-383-5114

cc. Carolyn Mullen, Deputy Director, Division of Practitioner Services
W. Robert Lee, MD, President, American Brachytherapy Society
James Rubenstein, MD, Chairman, American College of Radiation Oncology
Prabhakar Tripuraneni, MD, Chair, American Society of Therapeutic Radiation and Oncology

Submitter : **Dr. Roger Macklis** **Date: 10/06/2006**

Organization : **Cleveland Clinic**

Category : **Physician**

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

October 6, 2006

To Whom It May Concern:

I am writing to register my strong concerns about the proposed 2007 rates for CMS reimbursement of radioimmunotherapy (RIT) treatment for malignant lymphoma. As you may know, radioimmunotherapy is a novel combination of antibody treatment and molecular targeted radiotherapy. There are currently two approved compounds used for RIT, both of which are indicated in the treatment of B-cell malignant lymphoma and related conditions. The treatment regimen for these two compounds (I-131 tositumomab or Bexxar and Y-90 ibritumomab tiuxetan, or Zevalin) is complex and, at a large institution like the Cleveland Clinic, requires the direct involvement of practitioners from three different departments: Medical Oncology, Radiation Oncology, and Nuclear Medicine. In addition, the complexity of the treatment process requires numerous hospital services from the pharmacy and radiation safety groups if it is to be done safely.

Unlike many other components of unsealed source radiopharmaceutical therapy, the use of these two RIT agents produce dramatic objective responses with 60 to 80 percent response rates published in many clinical trials related to the management of indolent B-cell lymphoma. The currently utilized 2006 rates cover the extensive acquisition and preparation processes involved in the handling of the radioactive products and I would agree with our radiation oncology professional society (ASTRO) in recommending that CMS extend the current 2006 cost-based policy for the administration of these two biologically targeted radiopharmaceuticals. I would also concur with ASTRO that the agency consider basing future payment rates on the average sales price (ASP) data. In contrast, the currently proposed 2007 rates do not cover any of the preparation and handling costs necessary for the safe use of these radioactive products and credible estimates suggest that hospitals will be reimbursed only about half of their actual costs in acquiring the product and preparing it for safe patient administration.

The Cleveland Clinic has been a leader in the use of these compounds and has conducted multiple training and scientific sessions related to their safe and effective use. We have spent a great deal to time and effort developing the team approach and the safety infrastructure required to deliver both of the currently approved compounds to our patient groups. We have talked with patient advocates from the Leukemia and Lymphoma Society and other private foundations about the importance of these compounds in malignant lymphoma care. I think that it is highly unlikely that the Cleveland Clinic will be able to continue to continually offer these products if they are reimbursed at only half of their actual costs to deliver. I thus strongly urge you to continue the current 2006 rates while the strategy for the use of these compounds is being reviewed and I would suggest that you work with ASTRO and other professional organizations to discuss the process of care involved in the safe use of these biologically targeted radiopharmaceutical medications.

Please contact me if you require any additional information.

Sincerely yours,

Roger Macklis, M.D.
Professor of Medicine (Radiation Oncology)
Cleveland Clinic Lerner College of Medicine and
Dept of Rad Oncology
Taussig Cancer Center
9500 Euclid Ave
Cleveland OH 44195

CMS-1506-P-292 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : Ms. Terry Kelly **Date & Time:** 10/06/2006

Organization : Meridian Health

Category : Hospital

Issue Areas/Comments

Visits

Visits

Since one of the intents of HIPAA was to have uniform coding, I do not understand the logic of the development of "G" codes for use with visit coding. Many insurance companies do not accept HCPCS codes, leading to a 2 code system in hospital Charge description masters, and the potential for confusion among coders. The fact that CMS cannot agree upon E & M evaulation assigment guidelines should not be a determining factor in creating new codes that will add to more confusion and increased management functions of a 2 code system for hospitals.
The lack of guidelines on E & M level coding is allowing local FI's to "interpret" the vague CMS guidelines to the advantage of the FI, and when the hospitals tries to dispute an audit decision to disallow a level assignment, it basically comes down to a matter of interpretation by a nurse reviewer, which can vary by person, of what our coding grids reflect.
"G" codes are not going to solve the assignement of a E & M level issue, only confuse it. If you are willing to allow another year to go by without specific level assignment guidelines, why institute a "G" code coding system, that will inevitably change when someone acutally can come up with a coding assignment system that we can all agree upon?

Submitter : **James Matons** **Date: 10/06/2006**

Organization : **BrachySciences**

Category : **Device Industry**

Issue Areas/Comments

OPPS: Brachytherapy

OPPS: Brachytherapy

See Attached Letter

CMS-1506-P-293-Attach-1.PDF

BRACHYSCIENCES

October 6, 2006

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

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

Dear Dr. McClellan:

BrachySciences is an organization that is dedicated solely to brachytherapy and products that improve and expand the use of brachytherapy for the treatment of cancer. BrachySciences develops markets, sells and distributes brachytherapy sources and delivery systems used in brachytherapy implants.

Because of the dedication that BrachySciences has to brachytherapy, we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule related to cancer treatment with brachytherapy sources and technology.

Payment Methodology for Brachytherapy Sources

We believe that it would be inappropriate to implement a new payment system for 2007 that would establish set payment rates for brachytherapy sources based upon median costs. The variations in cost of each source require a unique payment methodology for radioactive sources. The cost variation of one source may be greater than tenfold based upon the intensity of the source.

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

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

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

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

Payment for NEW Brachytherapy Sources

In the proposed rule, CMS solicited comments regarding establishing payment amounts for new brachytherapy sources eligible for separate payment when no hospital claims-based cost data is available. The only effective way for CMS to capture cost data regarding new brachytherapy sources is for CMS to establish payment to hospitals for new brachytherapy sources at hospital charges reduced to cost when no hospital claims-based cost data is available.

BrachySciences recommends that CMS implement a three year payment policy for new brachytherapy sources at hospitals' charges adjusted to cost.

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

Thank you for your consideration of these important issues.

Sincerely,

James Matons
President
jmatons@brachysciences.com

Submitter : **Mrs. Anna Laliotis** **Date: 10/06/2006**

Organization : **Thomas Memorial Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P-294-Attach-1.TXT

Comments
for
The Centers for Medicare and Medicaid Services

File Code: CMS-1506-P

Regarding the August 23, 3006
42 CFR Parts 410, 414 et al. Medicare: Hospital Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

The following comments are provided regarding the proposed regulations published in the Federal Register (FR) on August 23, 2006 to update the hospital outpatient prospective payment system for CY 2007.

1) The proposed payment rate of $208.80 for Partial Hospitalization (PHP) services is low and inadequate considering the scope of services and costs required to render PHP services. The large payment fluctuations ranging from $206.82 to $286.82 and now proposed to $208.80 for PHP services from 2001 to this proposed rate for 2007 indicates that CMS' data and analysis regarding median per diem costs for PHP services have been and remain fundamentally flawed. It is recommended that CMS further research and conduct detailed provider-level research to better understand the costs necessary to deliver PHP services in hospital and CMHC settings.

   Psychiatric partial hospitalization is a distinct and organized intensive outpatient treatment of less than 24 hours of daily care, designed to provide patients with profound or disabling mental health conditions an individualized, coordinated, intensive, comprehensive, and multidisciplinary treatment program not provided in a regular outpatient setting. Often PHP treatment must offer a minimum of 20 hours a week of structured program provided over at least a five-day time period. The minimum patient participation is three (3) hours per day of care with a minimum of 12 hours per week. Active treatment consists of clinically recognized multi-model interventions including physician services, psychiatric

evaluation, history and physical, individual/group/family psychotherapy, education and training, and occupational therapy. PHP group sizes vary with acuity of illness of the participants, but the maximum size of therapeutic group should not exceed 10.

Based upon the above criteria, generally PHP programs average approximately 6.00 FTE staff members to include a program director, therapists, nursing, technicians and program assistants totaling approximately $270,000 annually in salaries and wages. Non-salary direct operating expenses include PRN staffing, education, supplies and other operating expenses averaging approximately $55,000 annually. Generally PHP program services are delivered in approximately 2,000 square feet and entail approximately $300,000 in capital related, employee benefits, administration, plant operations, maintenance, cafeteria, medical records, and other dwelling related costs. Given PHP guidelines to include those stated above generally limiting the maximum size of therapeutic groups to 10, a well operated PHP program averages 8.00 patients per day over a 250 day annual period generating 2,000 PHP days per year. Given the above description of typical PHP services at costs of approximately $625,000 annually to deliver 2,000 PHP patient days, the average PHP cost per PHP day is approximately **$314.24**, representing a cost 50.49% higher than that of the proposed PHP rate of $208.80. ***It is recommended that CMS further research and conduct provider-level research to more accurately understand the costs necessary to deliver PHP services in hospital and CMHC settings and establish a more accurate rate for PHP services accordingly. It is recommended the rate for PHP services be set at approximately $314.24 per patient day, and no less than the RY 2006 rate of $245.91.***

2) Please see the attached table concerning the historic rates of OPPS Psychotherapy Services and Medication Management.

Rate Year	APC 322	APC 323	APC 324	*APC 325*	APC 374
2001	$65.46	$91.75	$92.74	*$76.88*	$58.03
2002	$59.05	$88.57	$137.95	*$70.25*	$45.30
2003	$69.23	$96.91	$128.35	*$74.28*	$59.63
2004	$69.85	$101.97	$133.53	*$81.10*	$61.39
2005	$73.60	$100.23	$161.59	*$83.62*	$62.06
2006	$73.22	$97.59	$137.58	*$79.95*	$67.07
***2007**	$72.32	$105.68	$135.95	*$66.40*	$70.84
% Change	+.013%	+8.28%	<1.18%>	*<16.94%>*	+5.62%

As detailed within the table above all psychotherapy APC's encompassing CPT Codes 90801 through 90862 have been reasonably consistently valued since 2001. The proposed rates for RY 2007 also are valued consistently from RY 2006, with the major exception of Group Psychotherapy, CPT Codes 90853 and 90849 mapping to APC 325. The proposed rate of $66.40 represents a proposed decrease from RY 2006 of 16.94%.

The APC's listed above to include APC 325 are often utilized within Hospital Outpatient Psychiatric Treatment Services (OPTS) representing a range of services in a continuum of ambulatory psychiatric services. This range of services provides for the diagnosis and active treatment to individuals with mental disorders using a variety of modalities. Generally patients who need more than eleven (11) hours of psychiatric services per week are considered for PHP services rather than this OPTS level of care. ***In order for hospitals to maintain this important level of care, at a lesser cost when compared to inpatient psychiatry and partial hospitalization, it is recommended that CMS increase the rate for APC 325 Group Psychotherapy to $82.49 which represents the average (3.18%) increase from RY***

2006 to RY 2007 for the remaining psychotherapy APC's. The rate for APC 325 should be no less than the RY 2006 rate of $79.95.

Submitter : **Suzanne Klimberg** **Date: 10/06/2006**

Organization : **UAMS, Division of Breast Surgical Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-295-Attach-1.DOC

September 18, 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 (CMS-1506-P), published in the Federal Register on August 22, 2006.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether - the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Suzanne Klimberg, MD

Suzanne Klimberg, MD
Arkansas Cancer Research Center
Breast Surgical Oncology
4301 West Markham, #725
Little Rock, AR 72205-7199

Cc: Senator Blanche Lincoln, Senate Finance Committee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

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

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : Ronda Henry-Tillman **Date:** 10/06/2006

Organization : UAMS, Division of Breast Surgical Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-296-Attach-1.DOC

September 18, 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 (CMS-1506-P), published in the Federal Register on August 22, 2006.

By reassigning CPT 19296 & 19297 from a New Technology APC to a Clinical APC, CMS will cause unnecessary challenges in scheduling Medicare beneficiaries for surgery at the hospital because the facility may decline to offer the service altogether - the catheter is priced higher than the proposed Clinical APC payment rate. As a result, many Medicare beneficiaries diagnosed with breast cancer will be denied access to this safe and effective means of delivering radiation therapy.

In order for me to continue to provide access and availability of this hospital outpatient procedure for Medicare beneficiaries, I am requesting that CMS continue using the current New Technology APC for an additional year in order for CMS to consider actual supply and other cost data in establishing the 2007 APC assignment for the placement of breast brachytherapy catheters for interstitial radioelement application (CPT 19296 and 19297).

It is imperative this hospital outpatient procedure be available to those women who are clinically eligible to receive BCS and are being offered APBI as a treatment option by their physician.

Sincerely,

Ronda Henry-Tillman, MD

Ronda Henry-Tillman, MD
Arkansas Cancer Research Center
Breast Surgical Oncology
4301 West Markham, #725
Little Rock, AR 72205-7199

Cc: Senator Blanche Lincoln, Senate Finance Committee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

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

Mark A. Malangoni, MD, FACS, Chair, American College of Surgeons

Submitter : **Paul Ortiz** **Date: 10/06/2006**

Organization : **The Methodist Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-297-Attach-1.DOC

September 26, 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:

We appreciate the opportunity to provide comment on the CMS proposed rule (CMS-1506-P), published in the Federal Register on August 22, 2006. Two areas of concern in the HOPPS proposed rule, specifically, the proposed assignment of 19296 and 19297 to new APCs and the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from 22.8% to 37.0%.

HCPCS Code	**2006 APC**	**2006 Payment**	**2007 Proposed APC**	**2007 Proposed Payment**	**Payment Change 2006-2007**	**Percent Change 2006-2007**
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, this facility will not have the ability to continue to offer this breast cancer treatment option to Medicare eligible women, who are eligible for this course of treatment, since the cost of the device exceeds the proposed payment rate. Our current cost for these codes (supplies only) is $4,075.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned must cover the cost of the device. The cost of the brachytherapy device is the same whether it is implanted at the time of lumpectomy or at a separate time.

This facility also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with the current cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

In summary, The Radiation Oncology Department at The Methodist Hospital recommends that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, we recommend that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Paul Ortiz

Paul Ortiz
Director, Radiation Oncology
The Methodist Hospital
6565 Fannin, DB1-077
Houston, TX 77030
713-441-4809

Cc: Senator Kay Bailey Hutchison, Senate Appropriations Labor-HHS Subcommittee

Representative Joe Barton, Chairman, Energy and Commerce Committee

Representative Michael Burgess, Energy and Commerce Health Subcommittee

Representative Kay Granger, Appropriations Labor-HHS Subcommittee

Carol Bazell, MD, MPH, Director, Division of Outpatient Care

Submitter : **Date: 10/06/2006**

Organization :

Category : **Hospital**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

In order for our Accounting system to effectively and accurately report IV Push Drug administration of only one unit PER EACH DRUG administered, it would be necessary to have a separate HCPCS code for each additional drug administered OR a modifier for each additional drug administered.
For example:
C8952- IV push of initial substance
C89xx- IV push of 1st additional substance
C89xx- IV push of 2nd additional substance
C89xx- IV push of 3rd additional substance
etc...
OR... with modifier
C8952- IV push of initial substance
C8952xx- IV push of 1st additional substance
C8952xx- IV push of 2nd additional substance
C8952xx- IV push of 3rd additional substance
etc...

By having a separate HCPCS code for each drug, it is easier for both staff and systems to manage the reporting of only one unit per drug that is pushed over one encounter, especially for ED and or Observation patients that could be an "outpatient" for multiple hours and/or over one date of service.

Respectfully submitted and thank you for your consideration.

Submitter : Dr. Christopher Schultz **Date:** 10/06/2006

Organization : Medical College of Wisconsin

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-299-Attach-1.DOC

October 5, 2006

The 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

Subject: Calendar Year 2007 OPPS Proposed Rule // CMS-1506-P

Dear Administrator:

In accordance to the above referenced Proposed Rule, CMS is welcoming public comment regarding proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. With that, this letter is written to submit specific comment to the proposed payment method changes for radionuclide sources. I appreciate the chance to address with you my interest to this topic. I am requesting your attention to a liquid radioisotope, Iodine I-125 billed out by hospitals using HCPCS code C2632. This radioisotope is used to treat persons with brain tumors that originally develop in the brain and those that are spread to the brain from primary tumors that develop elsewhere.

As a Radiation Oncologist I am dedicated to providing the best care and treatment options available to my patients. With malignant brain tumor patients, one of a limited number of effective treatment options is internal radiation which involves the GliaSite Radiation Therapy System. In this system a balloon attached to a catheter is placed in surgical cavity after the bulk of the brain tumor is surgically removed. Post operatively the balloon is filled via the attached catheter that is located under the scalp with a liquid radiation source called Iotrex. The radiation treats the tumor cells remaining at the edge of the operative site. Iotrex comes in a 1 milliliter vial containing 150 millicuries. Typically a dose of 150 to 450 millicuries of Iotrex is necessary for each case. In the Proposed Rule the payment for Iotrex would be moved from being paid based on the hospital's charge adjusted to cost to a median unit cost ($19.32). This will be a hardship to the hospitals should the proposed method go into effect as the cost filed on the CMS websites lists a rate that does not sufficiently meet the cost of 1 millicurie much less the usual 150-450 millicuries of Iotrex required for a typical case. Hospitals would not be able to cover their costs for the Iotrex course much less the other infrastructure costs involved in performing this procedure. Should this change go into effect it simply will not be possible to offer this promising treatment to brain tumor patients who unfortunately have very limited treatment options. In my opinion it is vital that internal radiation using Iodine I-125 continue to be made available as a treatment option to the patients, including Medicare beneficiaries that suffer from these brain tumors. I have cared for patients that undergo this particular radiotherapy procedure and have seen first hand the benefit they have received in prolonged survival and quality of life.

I ask you to please reconsider this proposed payment methodology and reconsider the need to continue with paying for sources, including Iodine I-125, at cost. Respectfully, I urge CMS to continue providing beneficiaries access to proven cancer treatment options, including those within the field of radiation oncology therapy. I support the recommendation the APC Advisory Panel is submitting to CMS regarding radiation therapy sources.

Thank you for your time and willingness to take my comments and appeal under consideration.

Sincerely,

Christopher J. Schultz, MD

Christopher J. Schultz, MD
Professor
Radiation Oncology
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226
(414) 805-4480

cc: Senator Herb Kohl, Senate Appropriations Labor-HHS Subcommittee
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Dr. Wade M. Mueller **Date:** 10/06/2006

Organization : Medical College of Wisconsin

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-1506-P-300-Attach-1.DOC

October 4, 2006

The 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

Dear Administrator:

The CMS-1506-P Proposed Rule published in the Federal Register on August 23, 2006 has within its contents a payment methodology change for C2632, I-125 liquid radionuclide commonly referred by its brand name of Iotrex. This letter is written to provide comment specific to the potential payment change to Iotrex that could impact one of the important treatment options offered to brain cancer patients. I wish to first thank you though for allowing me the opportunity to share my comments with you and others at CMS. I respect CMS in the value and importance the agency places in receiving public comments, as well as the considerations taken upon review of such remarks and observations.

I have been made aware of a potential changes to various radiotherapy sources, but today I wish to specifically speak to the liquid radioisotope, Iotrex. It is reported with code C2632. Iotrex is used in radiation therapy following excision or debulking of a malignant brain tumor. Iotrex is used to therapeutically target the tissue closest to the resection tumor cavity. In my experience patients have typically responded well to this internal radiation treatment and results support increased survival and improvement to the quality of life. My concern results in learning the payment rate CMS is proposing of $19.32 per mCi does not sufficiently meet the cost per one mCi contained with the one mL vial of Iotrex. Generally speaking the I-125 vial contains up to 150-200 millicuries. If indeed the proposed payment for Iotrex goes into effect, this will create a barrier to Medicare beneficiaries diagnosed with brain cancer receiving an important option in the treatment of their malignancies. Please reconsider your proposal and continue paying for Iotrex at cost. Let's provide the means for beneficiaries with such a devastating disease to have this radiation treatment as an option to care.

Along with the APC Advisory Committee, I too support and recommend CMS continues to pay for radionuclides at hospitals charges reduced to cost.

Thank you for your consideration and evaluation in this important matter.

Regards,

Wade Muller, M.D.

Wade M. Mueller, M.D.
Medical College of Wisconsin
9200 West Wisconsin Avenue
Milwaukee, WI 53226
(414) 805-5402

WMM/sf

cc: Senator Herb Kohl, Senate Appropriations Labor-HHS Subcommittee
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Mr. Michael Rodgers **Date:** 10/06/2006

Organization : The Catholic Health Association of the US

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Dr. Steven Kalkanis **Date:** 10/06/2006

Organization : Neurosurgery Associates - Oakland

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

please find attachment

CMS-1506-P-302-Attach-1.DOC

October 4, 2006

The 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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, *Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P)*. This letter specifically addresses a concern relative to a proposed Medicare payment for Iotrex®, an Iodine I-125 liquid radioisotope source assigned to HCPCS code, C2632.

I am a neurosurgeon and routinely care for Medicare beneficiaries, some of whom are diagnosed with malignant brain tumors, known as, glioblastomas. Generally, treatment involves surgically removing the tumor and then delivering radiotherapy in these patients post-operatively using Iotrex (HCPCS code C2632), an Iodine I-125 radionuclide solution. The benefit of using Iotrex for treatment of brain cancer patients includes an increase in survival and preservation of quality of life.

My hospital has recently informed me that CMS is proposing a significant change in the payment methodology for Iotrex which will impact Medicare beneficiary access to this cancer therapy. Currently Iotrex is paid on charge adjusted to cost. CMS is proposing moving payment based on "median costs". The proposed payment rate of $19.32 per millicurie (mCi) does not meet the per mCi cost delivered in a 1-mL single use vial (150 mCI). If the rate CMS is proposing goes into effect, this will negatively impact the hospital's ability to provide Iotrex to the patients. Ultimately it is the beneficiary and his/her family that will suffer the consequences.

I am in support of the APC Advisory Panel's recommendation to continue cost payment, thereby request CMS continue payment for Iotrex under a cost payment method. If CMS moves ahead with an alternative payment approach then I recommend application of a "mean" unit cost as the basis for payment. The mean is a better representation of costs associated with Iotrex and consistent with the proposed payment method for other therapeutic radionuclides.

Again, I appreciate your consideration of this important matter and strongly urge CMS to reconsider the proposed payment methodology of median unit cost and instead continue paying charges reduced to cost.

Sincerely,

S. Kalkanis, MD

Steven N. Kalkanis, M.D.
Neurosurgery Associates – Oakland
44199 Dequindre, Suite 400
Troy, MI 48085
(248) 964-3800

cc: Senator Debbie Stabenow, Senate Cancer Coalition
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Dr. Jack Nettleton **Date:** 10/06/2006

Organization : Great Lakes Cancer Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

please find attached

CMS-1506-P-303-Attach-1.DOC

Great Lakes Cancer Institute
McLaren Regional Medical Center Campus
Department of Radiation Oncology
4100 Beecher Road • Flint, MI 48532
(810) 342-3800 • Fax (810) 342-3784

October 4, 2006

The 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

Dear Administrator:

Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule filed in the Federal Register on August 23, 2006. This letter addresses a concern of mine with respect to a proposed Medicare payment reduction for Iotrex, an Iodine I-125 liquid radioisotope source, which is reported using HCPCS code, C2632.

I specialize in Radiation Oncology and routinely care for Medicare beneficiaries, some of whom are diagnosed with glioblastomas, often referred to as malignant brain tumors. Once the neurosurgeon resects the tumor and implants a balloon catheter within the cavity for purposes of receiving internal radiation, the patient, once recovered will then be cleared to start outpatient radiation therapy. The delivery of internal radiotherapy includes use of Iotrex which targets the tissue nearest the cavity where the tumor was removed. Use of Iotrex is beneficial in the treatment of brain cancer patients because it increases their survival and preserves quality of life.

CMS is proposing a significant payment change of median cost for Iotrex, along with several other radiation therapy sources. The proposed payment method impacts Medicare beneficiary access to cancer therapy as hospitals will not be able to continue offering these radiation cancer treatment options due to payment reductions. For example, right now Iotrex is paid to the hospital based on charge reduced to cost. CMS has listed a proposed payment rate of $19.32 per millicurie (mCi). This rate does not meet the per mCi cost delivered in a 1-mL single use vial (150 mCI).

I am submitting this comment letter as an appeal to CMS that the Agency will continue paying Iotrex and other radiation sources at cost to ensure all radiation oncology treatment options are available to Medicare beneficiaries diagnosed with this deadly disease. Of further note, I've learned the APC Advisory Panel has also made this recommendation to CMS of which I stand in agreement to the Panel's recommendation.

Thank you again for allowing me to share my comments and I appreciate your consideration in this very important matter.

Sincerely,

J. Nettleton, MD

Jack Nettleton, M.D.

cc: Senator Debbie Stabenow, Senate Cancer Coalition
Carol M. Bazell, M.D., M.P.H., Director, Division of Outpatient Care
Kenneth McKusick, MD, Chair, Nuclear Medicine APC Task Force

Submitter : Michael Rodgers **Date:** 10/06/2006

Organization : The Catholic Health Association of the US

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-304-Attach-1.PDF

THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

October 10, 2006

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

REF: CMS-1506-P

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

Dear Dr. McClellan:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments, with two exceptions, on the above notice of proposed rulemaking (NPRM), which was published in the *Federal Register* (Vol. 71, No. 163, pages 49506-49977) on August 23, 2006. Today, through separate correspondence, we are also submitting our comments on the NPRM for the Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update (Section XXIII – File code CMS-4125-P). In addition, we will submit our comments on the NPRM for the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates in subsequent correspondence.

WASHINGTON OFFICE
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1. Volatility of APC Relative Weights

CHA continues to object to the year-to-year volatility of the ambulatory payment classification (APC) weights and urges the Centers for Medicare and Medicare Services (CMS) to take appropriate steps to ensure stability in APC weights.

Comparing CY 2006 (final rule) to the proposed CY 2007 rule (see below table) reveals that in most instances the APC weight volatility will likely significantly increase. This signal of increasing instability among APC weights creates unnecessary challenges to a hospital's ability to adequately plan and budget, even for the short term, let alone for the long term.

APC Weight Volatility	CY 2006 Final Rule	CY 2007 Proposed Rule	Percent Change
DECREASE:			
Total	219	277	+26.5%
10% or more	59	59	0.0%
20% or more	12	27	+125%
INCREASE:			
Total	148	360	+143.2%
10% or more	41	109	+165.6%
30% or more	17	26	+52.9%

CHA understands that changes in weights are inevitable. However, it believes that the magnitude of the changes (both positive and negative) should be moderated. One approach is to adjust medians derived from claims data to limit the amount of change that occurs from year-to-year. A stability policy should adjust the medians from claims data to ensure that no APC's median falls more than 5 percent compared to the medians used for payment in 2006.

2. Device-Dependent APCs.

CHA strongly recommends that CMS continue the CY 2006 policy of adjusting the median costs of device-dependent APCs' medians for which comparisons with prior years are valid to the higher of the CY 2007 unadjusted APC median or 90 percent of the adjusted median on which the payment was based for the CY 2006 OPPS.

CMS proposes to base the payment rates for device-dependent APCs in CY 2007 on median costs calculated using claims with appropriate device codes and which have no token charges for devices reported on the claim. The agency does not propose any adjustment of these median costs as in years past to moderate the decreases in medians from CY 2006 to CY 2007; thus, there will be no payment floors or use of external data in CY 2007.

A comparison of the final CY 2006 payment rate to the proposed CY 2007 payment for device-dependent APCs revealed that payment would:

- decrease for 11 APCs, including 6 which decreased by more than 10%; without any hold harmless floor, their reduction would range from 22 to 12.8 percent, and
- Increase for 30.

In CY 2005 CMS adopted a hold harmless policy to begin the transition to the use of pure claims data for all APC services in order to ensure the appropriate relativity of the median costs for all payable OPPS services. CHA understands and appreciates this goal, but believes such a transition must be

gradual. The policy must do a better job of balancing the desirability of the goal and the continued availability of critical and essential outpatient services for Medicare beneficiaries. Complete termination of the hold harmless policy could well tip the scale against the continuation of certain services.

3. Visits – Emergency Department Visit Guidelines

As CMS reported, the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) convened an independent expert panel for the purpose of developing hospital visit guidelines. The panel submitted its recommendations in June 2003 for reporting three levels of hospital clinic and emergency visits and a single level of critical care services to CMS. I response, CMS noted several areas of concern regarding the proposed guidelines. The following comments, based on evaluations by several of our member facilities, are offered in regard to the AHA/AHIMA Emergency Department Visit Guidelines.

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

B. Lack of clarity for some interventions: We agree with CMS that there is a lack of clarity in specific intervention descriptions. Several member facilities piloted the AHA/AHIMA guidelines using both nursing and coding staff to interpret the guidance. There observations are as follows:

- There is a lack of specificity in certain definitions. Additional descriptions and definitions would be beneficial in reducing incorrect interpretations by coders.
- It would be helpful to provide examples of patient acuity or symptoms as additional explanation for visit levels. For instance, an example might be a description of the typical patient for the respective visit levels.
- Based on existing guidelines, several ED encounters did not meet any criteria to be assigned a Level I ED visit. For example, patient presenting with chest pain, received an initial nursing assessment, vitals, and low pain scale assessment. Patient received blood chemistry (with separately billed venipuncture), EKG, x-ray, no oral or sublingual medications. Patient was discharged home with a diagnosis of costochondritis and instructions to take Ibuprofen. It would be inappropriate to disallow payment for a patient who presents to the ED with chest pain and requires clinical evaluation to rule out cardiac risk.

- Current guidelines do not take trauma level care into consideration for ED level.
- More clearly define ED visit level criteria. For example:
  - Are triage assessments for the Emergency Medical Treatment and Active Labor Act (EMTALA) requirements considered to be a Level I ED visit?
  - Does a primary assessment qualify for Level I ED Intervention "assisting physician with examination?"
  - Are scheduled follow-up visits appropriate to be assigned to an ED visit level when there are no other health provider options?
  - Need to clarify if the application of an off-the-shelf splint (not separately billable) is considered first aid?
  - Can interaction with home health, community services, housing authorities, or some other type of assistance be considered contributory factors or do they need to be specific to law enforcement or protective services personnel?

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

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

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

More specifically, the following interventions have not been identified as contributory factors to ED visit level determinations: ace/sling application, pre-fabricated splint application, different levels of dispositioning, seizure precautions, language barrier, drug and/or alcohol influence, triage/primary care assessment, assisting with activities of daily livings (ADLs), obtaining consents, prepping for surgery, preparing an ED patient for Observation/Inpatient status, oral suction, remaining with the patient during testing procedures, arranging transportation for a departing patient, discharge instructions, burn/abrasion care/wound care (more than simple first aid), working with a patient in restraints, behavioral health assessments, post mortem care, pediatric 1:1 (no adult), telephone calls to follow-up on potential drug seeker (numerous telephone calls are placed to local clinics and pharmacies to obtain information about the patients' prescription drug use).

4. Inpatient Only Procedures.

CHA continues to urge the elimination of the inpatient list primarily because the list is not binding on physicians.

The list was created to identify procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the Hospital outpatient prospective payment system (OPPS). There are numerous problems created by the inpatient list as have been documented in past comments. The biggest continuing problem is that such a list is not binding on physicians. Consequently, since the physician receives payment when a procedure on the inpatient list is performed on an outpatient basis, there is no incentive for the physician to perform the procedure on an inpatient basis. This is a particularly troubling issue in teaching hospitals. This fact underscores the reality that it is the physician, not the hospital, who determines whether a procedure will be performed in the outpatient or inpatient setting.

In the past, CMS has responded to such comments by saying that "[it] believes that appropriate education of physicians and other hospital staff by CMS, hospitals and organizations representing hospitals is the best way to minimize any existing confusion." From our perspective, it does no good for hospitals or their representative organizations to try to educate physicians as to this situation. Physicians, quite understandably, pay little attention to how hospitals are paid. Their behavior is affected only by how they personally are paid. And the CMS provider education staff does not appear to have made any headway on this matter as well.

5. Medicare Contracting Reform Mandate

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

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

A. **CHA strongly supports the right of a large health system comprised of individual providers to request the consolidation of its Medicare billing activities to the MAC with jurisdiction over the geographic locale in which the system's home office or billing office (if located in a different locale) is located.**

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

C. **This recognition should also be extended to a health care system which timely requested and was acknowledged as meeting the requirements for designation to one intermediary/MAC; but for which a final transition (to the one intermediary/MAC) had not taken place due to issues solely on the part of Medicare.**

In closing, thank you for the opportunity to review and comment on the proposed hospital outpatient PPS rule for CY 2007.

Sincerely,

Michael Rodgers
Senior Vice President, Public Policy and Advocacy

Submitter : **Dr. Engracio Samala** **Date: 10/06/2006**

Organization : **Northern Blvd Radiation Oncology LLP**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P-305-Attach-1.WPD

October 6, 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.

Two areas of concern in the HOPPS proposed rule. Specifically, the proposed assignment of 19296 and 19297 to new APCs and the proposed payment methodology for brachytherapy sources in 2007.

CMS implemented breast brachytherapy CPT codes 19296 and 19297 on January 1, 2005 and assigned these codes to New Technology APCs 1524 and 1523 respectively. CMS proposes to reassign these codes from New Technology APCs to clinical APCs in 2007. The CMS proposed APC assignment for CPT Codes 19296 and 19297 would result in significant decreases in 2007 payment. The table below illustrates the reductions, ranging from –22.8% to –37.0%.

HCPCS Code	2006 APC	2006 Payment	2007 Proposed APC	2007 Proposed Payment	Payment Change 2006-2007	Percent Change 2006-2007
19296 Breast interstitial radiation treatment, delayed	1524	$3,250	30	$2,508.17	($741.83)	**-22.8%**
19297 Breast interstitial radiation treatment, immediate	1523	$2,750	29	$1,732.69	($1,017.31)	**-37.0%**

Should CMS finalize the proposed APC assignments, it will limit our ability to offer this breast cancer treatment option to Medicare eligible women since the cost of the device surpasses the proposed payment rate.

CMS should maintain 19296 and 19297 in the New Tech APCs 1524 and 1523 respectively so that it may collect claims data through calendar year 2006 and reevaluate reassignment to a more appropriate APC for 2008. These CPT codes are device-dependent and the APC they are assigned, must cover the cost of the device. The cost of the brachytherapy device is the same when implanted at time of lumpectomy or at a separate say post-lumpectomy.

Our hospital also purchases the radiation source to be used in breast conservation treatment and bills C1717 for the HDR Iridium 192. It is necessary to continue with the current cost to charge ratio payment methodology in order to continue providing breast conservation treatment to our Medicare patients. Our hospital must be able to cover the costs of this radiation source so that we may continue to provide this less invasive, highly-effective cancer treatment to Medicare beneficiaries.

Our Lady of Mercy Hospital recommends that breast brachytherapy codes 19296 and 19297 remain in their current New Technology APCs (1524 and 1523 respectively) for 2007 to allow the opportunity to collect additional claims data. Additionally, we recommends that CMS continue current payment methodology for all brachytherapy sources at hospital charges adjusted to cost calendar years 2007 and 2008.

Sincerely,

Engracio C. Samala, MD

Northern Blvd Radiation Oncology,LLP
158-06 Nothern Blvd
Flushing, NY 11358

CMS-1506-P-306 **Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates**

Submitter : Dr. Harvey Neiman **Date & Time:** 10/06/2006

Organization : American College of Radiology

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Medicare Program;Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Submitter : Amy Seals **Date:** 10/06/2006

Organization : MedLabs Research

Category : Other Health Care Professional

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Our agency, DAPA Family Recovery Programs is a freestanding Community Mental Health Center near the Medical Center of Houston, TX. We serve approximately 944 general adults and 194 geriatric patients on an annual basis. We provide intensive Psychiatric prgrams, including partial hospitalization services that are greatly needed by the severe and persistently mentall ill in our community. We are requesting the proposed 15% cut for Partial Hospitalization Services be stopped. Coupled with last year's 12.5% reduction, the proposed rate will make it impossible to cover the costs needed to provide our intensive programs. We strongly support the position of the Association of Ambulatory Behavioral Healthcare in all areas of their proposed considerations. Please consider not cutting the Partial Hospital Rate so drastically when most medical costar are actually increasing 4-6% annually. These programs need to be supported by reasonable reimbursement rates that sufficiently cover the costs of providing services to such a needy population. Thank you for your consideration.

Amy Seals, MA, LPC

Submitter : **Suzanne Bliss** **Date: 10/06/2006**

Organization : **Lymphoma Research Foundation**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter.

CMS-1506-P-308-Attach-1.DOC

October 6, 2006

Filed Electronically

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Hubert H. Humphrey Building
Room 314-G
Washington, D.C. 20201

Re: CMS-1506-P; Comments Regarding the Hospital Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

The Lymphoma Research Foundation (LRF) appreciates the opportunity to submit comments regarding the proposed rule setting payment rates in the hospital outpatient prospective payment system (OPPS) for calendar year 2007. LRF is a national voluntary health agency that funds research on lymphoma and provides a range of educational services to lymphoma patients and their families, friends, and caregivers.

We are writing to express concerns about the potential impact on patient care of the proposed change in the method for reimbursement of radiopharmaceuticals in 2007. Although LRF does not object to the recommendation to move to a fixed rate of payment for radiopharmaceuticals, we do not believe that the 2005 data on which 2007 payments would be based are complete and accurate. Without some adjustments in payment rates to account for acquisition, overhead, and handling costs, the 2007 payments may not be adequate to cover the costs to institutions related to radiopharmaceuticals. If payments to institutions are inadequate, these therapies will not be readily available to lymphoma patients.

We recommend that the Centers for Medicare & Medicaid Services retain in 2007 the current system of paying for radiopharmaceuticals based on each hospital's charge for each radiopharmaceutical adjusted to cost using each hospital's overall cost-to-charge ratio. This would provide the agency the opportunity to make adjustments in its proposed payment system to ensure that radiopharmaceutical payments are adequate when implemented in 2008. We also recommend that special attention be given to high-cost radiopharmaceuticals, for which a special payment methodology may be necessary.

We appreciate the opportunity to comment.

Sincerely,

Suzanne Bliss
Executive Director
Lymphoma Research Foundation
111 Broadway
19th Floor
New York, NY 10006
Phone: (212) 349-2910
Fax: (212) 349-2886
E-mail: sbliss@lymphoma.org

Submitter : Mr. Mark Leahey **Date:** 10/06/2006

Organization : Medical Device Manufacturers Association

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment - thank you.

CMS-1506-P-309-Attach-1.PDF

MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today For Better Health Care Tomorrow™

October 6, 2006

VIA ELECTRONIC SUBMISSION

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. McClellan:

I am submitting these comments of behalf of the Medical Device Manufacturers Association (MDMA), a national trade association, representing over a hundred innovative medical device companies. Our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

MDMA recognizes that the Centers for Medicare and Medicaid Services (CMS) aims to refine the Outpatient Prospective Payment System (OPPS) to increase payment accuracy for outpatient procedures and technologies. Part of that process is to determine proper reimbursement for technological advances in health care devices and patient treatment. MDMA supports this process, and we believe it is particularly important that CMS' reimbursement policies must not discourage new scientific breakthroughs that allow procedures to be performed faster, more accurately, and with less invasive approaches that minimize risk and recovery times.

We appreciate the opportunity to comment on the Calendar Year (CY) 2007 Hospital Outpatient Prospective Payment System (OPPS) proposed rule published on August 23, 2006.[1] Specifically, we continue to have concern regarding the following issues:

- The proposed rate-setting methodology for device-dependent ambulatory payment classifications (APCs), the importance of the mandatory use of C-codes, and the continued volatility of device-dependent APC payment rates;
- The need for a payment floor to moderate for decreases in median costs from 2006 to 2007;

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

- The use of credible external data; and
- Greater predictability and transparency in the New Technology and Pass-Through Application process and transition of technologies to clinical APCs.

I. The rate-setting methodology for device-dependent APCs must require hospitals to use C-codes and must ensure stable payment rates by implementing a payment floor to prevent dramatic decreases in payment similar to that established in 2006. (Device-Dependent APCs)

MDMA appreciates the agency's efforts to use data that reflect the best estimated costs for device-dependent APCs. CMS proposes to base the CY 2007 OPPS device-dependent APC medians on CY 2005 claims and the median costs calculated from those claims with appropriate device codes that do not have token charges on the claim.[2] We agree that CMS should use only correctly coded claims containing C-codes to set median rates for these APCs in order to better reflect hospital costs for device-dependent procedures. **MDMA believes that using a subset of correctly coded claims is a preferred method for rate setting than simply using all claims, and we support CMS implementing this proposal in the final rule.**

Although we support the use of only correctly coded claims in setting APC payment rates, we also urge CMS to ensure it has a sufficient number of these claims to calculate rates appropriately. It often takes a few months for hospitals to correctly code the device Healthcare Common Procedure Coding System (HCPCS) C-codes, especially for hospitals that have not reliably used these codes in the past. As a result, Medicare data for the first year or two after a new C-code is issued for a device may not accurately reflect the use of the device. It is imperative that CMS ensure that it uses mature device-specific data that accurately captures the device component of the APC.

At the APC Advisory Panel Meeting in August 2006, CMS noted that payment fluctuations were a result of previously inflated APC rates. However, CMS has presented no data to support this assumption. Further, the panel meeting presentations continually demonstrated, using credible supporting data, that hospitals are not only failing to adequately code claims, but are also failing to update their chargemasters to incorporate new device charges into their claims data. Poor chargemaster management in addition to charge compression continue to negatively impact device dependent APCs.[3]

This volatility in Medicare payment rates has been devastating for many device companies. When there is a drastic cut in payment, beneficiary access to certain procedures is threatened. Several of our member companies' products currently are being adversely affected by significant reimbursement volatility. For example, the payment rate for APC 0384 (GI Procedures with Stents) is proposed to fall nearly 13 percent from the 2006 APC rate of $1,601 to $1,395 in 2007. MDMA believes there are no underlying changes in the APC, devices used, or hospital charging practices that would justify such a decrease in payment. MDMA also notes that the 2004 and 2005 median costs of this APC are remarkable consistent, which further suggests that a

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[2] Id. at 49570.
[3] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006.

payment rate decrease is not warranted. It seems to MDMA member companies, that while CMS used a device screen in its 2007 proposal for APC 0384, the median costs were artificially dampened because the three CPT codes (43219, 43268 and 43269) accounting for over 90 percent of the single procedures claims do not require c-code reporting. It is only because CMS applied the c-code screen to all procedures in APC 0384, including these three procedures shown above, that the 2006 rate for APC 0384 better reflected the device costs. **MDMA urges CMS to take the same step this year, and apply a c-code screen to all procedures in APC 0384 to ensure device costs are reflected in the payment rate.**

In addition, at the August 23-25, 2006 meeting of the APC Panel, the proper placement of HCPCS code 36566 was discussed. CPT 36566, *Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s)*, requires two catheters via two separate venous access sites. Two systems are typically used for each patient, costing $1,750 each or $3,500 per procedure. As previously mentioned, other vascular access procedures are per device. The American Medical Association created the 36566 code using the existing language because the procedure is always performed with two devices.

To summarize, the Panel recommended the following:

- **HCPCS code 36566 should require the use of C1881 in the future. This was not permissible in 2005 or 2006 because 36566 was assigned to a new technology APC.**
- **HCPCS code 36566 should be assigned to an appropriately paying APC with payment between $3,500 and $4,750 for 2007.**
- **CMS should use correctly coded claims to guide APC payment. The Panel recommended that CMS receive information on claims from Medical Technology Partners.**

MDMA asks that CMS implement the Panel recommendation in the final rule.

MDMA would like CMS to review the APC placement and payment for HCPCS code 52648. HCPCS 52648, *Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)*, is assigned to APC 0429, *Level V Cystourethroscopy and other Genitourinary Procedures*.

There were 11,530 claims containing code 52648; however, only 719 of those claims also contained C9713. These 719 are much more likely to include the costs for providing the fiber or fibers required for photo vaporization treatment. Of the 11,530 claims containing 52648, median total charges were $9,347.48 and median costs were $2,731.67. In contrast, figures for the 719 claims that contained both 52648 and C9713 demonstrated higher medians of $9,738.63 (total charges) and $3,153.76 (costs). This difference of $400 is not overwhelming but is important in assigning 52648 to the proper APC.

While many of the 52648 claims were classified as Single Major claims, all of the 719 claims containing 52648 and C9713 were classified as multi-major (data provided by Medical Technology Partners). It is possible that CMS' methodology ***may have excluded consideration of all correctly coded claims*** (if median cost calculation was based upon only single major claims). This is important for establishing the methodology in the future.

In the future, CMS should only use correctly coded claims, which should include both 52648 and C9713.

The assignment of 52648 to APC 0429 appears reasonable based upon the 2005 data that is available, even though the cost calculation methodology has some biases that lower the actual cost of the procedure. **In the future, this methodology should help establish a proper payment for the procedure.**

Further, MDMA urges CMS to move CPT code 57267 (Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site), to APC 0202 (Level X Female Reproductive Procedures), as this would better reflect the device-intensive nature of this gynecology procedure. CPT code 57267 is also a resource intensive gynecologic procedure requiring the use of a device, which supports its assignment to APC 0202, a device-dependent APC. CMS has assigned other device-intensive gynecology codes to APC 0202, such as endometrial cryoablation (CPT code 58356) and hysteroscopic tubal occlusion (CPT code 58565).

While CMS did analyze 57267 claims in its proposed rule to better ascertain costs of this add-on procedure, its analysis was flawed because it grouped 57267 claims with the c-code for hernia repair (C1781), not the c-codes used to report mesh devices used in pelvic floor reconstruction procedures (C1762 and C1763). When proper c-codes are used with claims that better reflect 57267 costs, the median costs increase to almost $1,300, which is very close to the APC 0202 payment rate when the 50% multiple procedure reduction is applied. (CPT 57267 is always performed as an add-on code, and so would always be subject to the multiple procedure reduction.)

Finally, MDMA would like to recommend that CMS continue the current payment methodology (hospital charges adjusted to cost) for brachytherapy devices in the hospital outpatient setting when no hospital claims-based data is available. Further, MDMA recommends that CMS maintain breast brachytherapy codes 19296 and 19297 in their current New Technology APCs (1524 and 1523 respectively for 2007. Alternatively, CMS could assign CPT codes 19296 and 19297 to clinical APC 648 Breast Reconstruction with Prosthesis. To appropriately capture all procedures in APC 648, it is also recommended that CMS revise the APC group title from "Breast Reconstruction with Prosthesis" to "Level IV Breast Surgery." Breast brachytherapy CPT codes 19296, 19297 and 19298 require the use of a high cost device that is bundled into the procedure payment thus classifying these procedures as device-dependent. CPT 19296 and 19297 are similar both clinically and with respect to resource costs to procedures included in APC 648 Breast Reconstruction with Prosthesis. All of the procedures in APC 648 involve the placement of an expensive device, as do breast brachytherapy codes 19296 and 19297.

As an alternative, CMS could assign CPT codes 19296 and 19297 to APC 648 Breast Reconstruction with Prosthesis. The identical medical device is required for both breast brachytherapy procedures (CPT 19296 and 19297) and the cost of the catheter is exactly the same. Further, the cost of the device required for APC 648 Breast Reconstruction with Prosthesis is similar to the breast catheter required for CPT 19296 and 19297.

Moreover, CMS should implement mandatory code edits for brachytherapy procedure APCs 312, 313, and 651. MDMA continues to support mandatory reporting of all medical device "C" codes and related incentives to encourage hospitals to be more vigilant in reporting the total costs of performing device-related services. MDMA supports expanding the 2007 policy to all device-related and "device-dependent" APCs to promote "correct coding" and to improve the quality of the claims data. In addition to using device "C" codes hospitals should be educated on how to report charges for brachytherapy source devices utilized in the outpatient department. Finally, MDMA believes that APC relative weights should be based on appropriate claims.

In addition to using correctly coded claims, CMS must exercise caution when making cuts to device-dependent APCs. In 2006, CMS tried to provide a stable transition from 2005 rates by adjusting median costs for device-dependent APCs to the greater of the median from claims data or 90 percent of the payment median that was used to set the CY 2005 payment rate.[4] For 2007, CMS does not propose to set a floor to moderate for any decreases in median costs from 2006 to 2007. Although CMS notes that the median costs of "only" 6 APCs would decline more than 10 percent,[5] MDMA is concerned that large decreases in any individual device-dependent APC payment rates continue to perpetuate unpredictability in reimbursement and will lead to limited patient access to these high-technology devices and procedures. Such dramatic fluctuations in reimbursement rates greatly affect a small manufacturer's ability to continue to offer innovative therapies.

Because most of MDMA member companies have a single product, these substantial and unpredictable fluctuations cannot be offset by other products, especially when the same products have suffered rate decreases in prior years. Our member companies do not have flexibility in their pricing based on increasing cost of goods, inflation, and the more limited buying power of smaller companies. The value of innovation brought by small medical device companies will be lost if such companies continue to be subjected to payment fluctuations, and ultimately patients will suffer the consequences. **MDMA urges CMS to establish a payment floor for CY 2007 similar to the methods it used to set the CY 2006 rates to prevent large decreases in payments next year and that payments should not decrease more than 10 percent.**

II. CMS should use external data to set rates for device-related APCs and should protect the confidentiality of those data. (Device-Dependent APCs)

MDMA believes it is essential that CMS use the best available data in setting rates, whether such data are generated internally by CMS or accepted from outside sources. We agree with the APC Panel's recommendation that CMS should use readily available external data to validate costs

[4] Id. at 49569.
[5] Id. at 49570.

determined by CMS' claims data.[6] In particular, external data can be used to identify and adjust payment for technologies that have been under-funded in the past under the OPPS, as well as for those products and procedures that received significant cuts in recent years. External data also can be used to rectify the effects of charge compression on reimbursement rates. A system based on flat cost-to-charge ratio calculations often results in significant payment inequities because it fails to recognize that hospitals tend to apply smaller markups to higher cost items than to lower cost items. Manufacturers who believe their products are disadvantaged due to differential or disproportionate markups that are not factored into cost-to-charge ratio calculations should be allowed to present confidential data to CMS in support of their case for more adequate payment. CMS should incorporate these supplemental data into the median cost calculations to set appropriate APC weights.

To date, CMS has not taken advantage of enough opportunities to improve payment adequacy based on external data. We understand that CMS believes that, in many cases, the agency is able to determine reasonable rates with its own internal data and that using external data is essentially an "exception methodology" that gives the agency more complete information to use in setting rates. Use of external data should not just be an "exception methodology," however, particularly when data external to the agency is the most credible data source. In situations where manufacturers and hospitals can prove with external data that Medicare's payment is inadequate for their products, CMS should make every effort to use this external data and make appropriate reimbursements to ensure patient access to these products and devices. Furthermore, accepting external data gives CMS important supplemental data sources without committing the agency to reliance on any particular data source when setting payment rates. Consequently, accepting external data only can benefit the agency. **Consistent with CMS' goal of basing payments on the most accurate data, we encourage the agency to expand its practice of considering external data.**

For example, APC 0222 (Implantation of a Neurological Device) covers the insertion or replacement of neurostimulator pulse generators or receivers and system components (i.e., external transmitters, patient programmers and extensions). These device systems alleviate intractable pain in chronic pain patients. The proposed 2007 reimbursement rate for APC 0222 is based on 2005 hospital charge data. In 2005, radio-frequency (RF) receiver and non-rechargeable pulse generator systems were implanted predominantly, since rechargeable pulse generator systems were just being introduced to the market. For 2006, rechargeable pulse generators qualified for, and presently receive, the new technology pass-through payment, which will continue through 2007. The 2007 proposed payment rate for APC 0222 is $10,964, of which 78.1 percent, or $8,563, is the device-relation portion. According to IMS Health[7], an independent third-party market data supplier, for the first three quarters of 2005, the median hospital acquisition cost for RF receivers and non-rechargeable pulse generators alone was $11,596. Thus, the total proposed payment of $10,964 does not cover the hospital acquisition cost of the receivers/pulse generators, let alone the system components or any procedure-related costs. **The inaccurate estimate of costs in this APC is a result of charge compression and MDMA recommends that CMS use external data to ensure this and other device-**

[6] Id.

[7] IMS Health, Health Supply Index of non-federal, short-term acute care hospital purchases from January 1 through September 30, 2005.

dependent APCs are adequately reimbursed. Unless such external data is used, some patients will be denied access in the outpatient setting to these necessary devices and procedures.

III. CMS should establish greater predictability and transparency in the New Technology and Pass-Through application processes and transition of technologies to clinical APCs. (Pass-Through Devices, New Technology APCs)

Finally, MDMA remains concerned that the Pass-Through Application and New Technology APC processes lack predictability and transparency in several ways:

- Unlike the New Technology Diagnosis-Related Group (DRG) process used in the Hospital Inpatient Prospective Payment System (IPPS), CMS does not provide information on its website regarding technologies that have applied for New Technology APCs or pass-through statue or the number of applications that were received.
- CMS does not provide information about the timeliness of decision-making once a complete application is received.
- CMS does not provide information regarding the rationale for accepting or denying an application nor is the decision open for public comment as part of the proposed rule.

Pass-Through status and New Technology APCs are important vehicles for providing timely access to new technologies. Both assure that Medicare beneficiaries can receive treatment using new technologies and procedures in a timely manner and so that hospitals can integrate these technologies with assurance that there will be adequate payment. Equally important is the role these New Technology and Pass-Through assignments provide in allowing CMS to collect payment data to assure that the eventual clinical APC assignment best reflects the resources and the costs of those procedures and technologies and is clinically coherent. MDMA supports these goals, but we are concerned that CMS is transitioning products from New Technology APCs into clinical APCs more quickly in recent years than in the past. In some cases, CMS has bypassed the use of New Technology APCs in favor of immediate assignment of new CPT codes, especially Category III codes, to clinical APCs. Because CMS does not have a firm decision-making timeline to accept a complete Pass- Through or New Technology Application, it is impossible to determine if this application process is meeting its goal of providing early access to new procedures and treatments. Further, there is no forum for public discourse regarding the acceptance or denial of applications, preventing the public from understanding why some applications are approved or denied or to provide comments.

MDMA believes the New Technology and Pass-Through application processes require "sunshine" to ensure that they meet their goals and that new technologies eventually transition to appropriately paying and clinically coherent APCs. **MDMA encourages CMS to make public its timelines for decision-making and provide opportunity for public discourse, in a similar manner as the New Technology Add-On process in the IPPS, so that these processes continue to serve their intended roles and to assure that technologies and treatments are**

not "rushed" into a clinical APC before CMS has appropriate data to support such a transition.

MDMA also urges CMS to take care to base all assignments of new technologies to clinical APCs on accurate and complete data. **We urge CMS to implement the APC Panel's recommendation "that when CMS assigns a new service to a New Technology APC, the service should remain there for at least two years until sufficient claims data are collected."**[8] It takes hospitals several months to begin to accurately capture and reflect New Technology APCs and Pass-Through Categories in their billing processes and even longer for hospital chargemasters to accurately reflect new product costs. This was recurring concern recognized at the APC panel meeting in August 2006 following several data-driven presentations. CMS must recognize this delay and should continue to place new technologies in their temporary APC assignments so the data can mature. This would prevent dramatic reductions in payment from occurring due to APC assignments based on insufficient data. **Further, MDMA asks that CMS follow its earlier recommendations to use only correctly coded claims to determine the clinical APC assignment and to establish a payment reduction floor to provide stability in annual rate changes.**

IV. Conclusion

We look forward to working with CMS on these and other issues of concern regarding outpatient hospital reimbursement. If you have any questions or would like to discuss these ideas further, please contact me at 202-349-7174 or mleahey@medicaldevices.org.

Sincerely,

Mark B. Leahey
Executive Director
Medical Device Manufacturers Association

[8] Id.

Submitter : **Mr. Paul Altovilla** **Date: 10/06/2006**

Organization : **Diamond Healthcare**

Category : **Health Care Industry**

Issue Areas/Comments

OPPS

OPPS

2) Please see the attached table concerning the historic rates of OPPS Psychotherapy Services and Medication Management.

Rate Year	APC 322	APC 323	APC 324	APC 325	APC 374
2001	$65.46	$91.75	$92.74	$76.88	$58.03
2002	$59.05	$88.57	$137.95	$70.25	$45.30
2003	$69.23	$96.91	$128.35	$74.28	$59.63
2004	$69.85	$101.97	$133.53	$81.10	$61.39
2005	$73.60	$100.23	$161.59	$83.62	$62.06
2006	$73.22	$97.59	$137.58	$79.95	$67.07
*2007	$72.32	$105.68	$135.95	$66.40	$70.84
% Change	+.013%	+8.28%	<1.18%>	<16.94%>	+5.62%

As detailed within the table above all psychotherapy APC s encompassing CPT Codes 90801 through 90862 have been reasonably consistently valued since 2001. The proposed rates for RY 2007 also are valued consistently from RY 2006, with the major exception of Group Psychotherapy, CPT Codes 90853 and 90849 mapping to APC 325. The proposed rate of $66.40 represents a proposed decrease from RY 2006 of 16.94%.

The APC s listed above to include APC 325 are often utilized within Hospital Outpatient Psychiatric Treatment Services (OPTS) representing a range of services in a continuum of ambulatory psychiatric services. This range of services provides for the diagnosis and active treatment to individuals with mental disorders using a variety of modalities. Generally patients who need more than eleven (11) hours of psychiatric services per week are considered for PHP services rather than this OPTS level of care. In order for hospitals to maintain this important level of care, at a lesser cost when compared to inpatient psychiatry and partial hospitalization, it is recommended that CMS increase the rate for APC 325 Group Psychotherapy to $82.49 which represents the average (3.18%) increase from RY 2006 to RY 2007 for the remaining psychotherapy APC s. The rate for APC 325 should be no less than the RY 2006 rate of $79.95.

OPPS: National Unadjusted Medicare Payment

OPPS: National Unadjusted Medicare Payment

Comments
for
The Centers for Medicare and Medicaid Services

File Code: CMS-1506-P

Regarding the August 23, 3006
42 CFR Parts 410, 414 et al. Medicare: Hospital Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

The following comments are provided regarding the proposed regulations published in the Federal Register (FR) on August 23, 2006 to update the hospital outpatient prospective payment system for CY 2007.

1) The proposed payment rate of $208.80 for Partial Hospitalization (PHP) services is low and inadequate considering the scope of services and costs required to render PHP services. The large payment fluctuations ranging from $206.82 to $286.82 and now proposed to $208.80 for PHP services from 2001 to this proposed rate for 2007 indicates that CMS data and analysis regarding median per diem costs for PHP services have been and remain fundamentally flawed. It is recommended that CMS further research and conduct detailed provider-level research to better understand the costs necessary to deliver PHP services in hospital and CMHC settings.

Psychiatric partial hospitalization is a distinct and organized intensive outpatient treatment of less than 24 hours of daily care, designed to provide patients with profound or disabling mental health conditions an individualized, coordinated, intensive, comprehensive, and multidisciplinary treatment program not provided in a regular outpatient setting. Often PHP treatment must offer a minimum of 20 hours a week of structured program provided over at least a five-day time period. The minimum patient participation is three (3) hours per day of care with a minimum of 12 hours per week. Active treatment consists of clinically recognized multi-model interventions including physician services, psychiatric evaluation, history and physical, individual/group/family psychotherapy, education and training, and occupational therapy. PHP group sizes vary with acuity of illness of the participants, but the maximum size of therapeutic group should not exceed 10.

Based upon the above criteria, generally PHP programs average approximately 6.00 FTE staff members to include a program director, therapists, nursing, technicians and program assistants totaling approximately $270,000 annually in salaries and wages. Non-salary direct operating expenses include PRN staffing, education, supplies and other operating expenses averaging approximately $55,000 annually. Generally PHP program services are delivered in approximately 2,000 square feet and entail approximately $300,000 in capital related, employee benefits, administration, plant operations, maintenance, cafeteria, medical records, and other dwelling related costs. Given PHP guidelines to include those stated above generally limiting the maximum size of therapeutic groups to 10, a well operated PHP program averages 8.00 patients per day over a 250 day annual period generating 2,000 PHP days per year. Given the above description of typical PHP services at costs of approximately $625,000 annually to deliver 2,000 PHP patient days, the average PHP cost per PHP day is approximately $314.24, representing a cost

50.49% higher than that of the proposed PHP rate of $208.80. It is recommended that CMS further research and conduct provider-level research to more accurately understand the costs necessary to deliver PHP services in hospital and CMHC settings and establish a more accurate rate for PHP services accordingly. It is recommended the rate for PHP services be set at approximately $314.24 per patient day, and no less than the RY 2006 rate of $245.91.

Submitter : **Mr. Paul Altovilla** **Date: 10/06/2006**

Organization : **Diamond Healthcare**

Category : **Health Care Industry**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Comments
for
The Centers for Medicare and Medicaid Services

File Code: CMS-1506-P

Regarding the August 23, 3006
42 CFR Parts 410, 414 et al. Medicare: Hospital Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

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Submitter : **Ms. Wendy Trout** **Date: 10/06/2006**

Organization : **WellSpan Health**

Category : **Hospital**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

It continues to be challenging for facilities to use one set of rules for CPT based payers vs. Medicare. For instance, CPT only allows for one "initial" infusion service code (the primary service is selected from the variety of infusion services rendered), but Medicare allows for an intial code in each category of infusion services. This makes direct mapping from CPT codes to Medicare codes nearly impossible when Medicare doesn't follow CPT coding guidelines. We would recommend that Medicare once again consider their decision to only pay for one IV push code when multiple pushes are administered of the same drug. Providers do not expend fewer resources when the same drug is administered numerous times vs. different drugs being administered. The nursing time, room time, etc. are the same.

Visits

Visits

We are concerned about the time factor for the new proposed critical care codes. Most hospital systems are not geared to capture times of rendered services for hospital charges. Instead we would recommend a charge per critical episode.

Submitter : Ms. Tammy Thompson **Date:** 10/06/2006

Organization : Vidalia Medical Associates, PC

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Colorectal cancer is the leading cause of cancer-related deaths in our community for non-smoking men and women combined. Every year 56,000 people become the victims of the only preventable cancer -- colorectal cancer. Unlike breast cancer, skin cancer, or cervical cancer, where screening and exams are only an attempt to catch the disease in its early stages, colon cancer can be stopped long before any cancerous cells develop. Once one is diagnosed with colon cancer, there is less than a 40% chance of survival, and if one does survive, the picture is not pretty. After a combination of surgery and chemo, one may be missing part of the intestine and which part determines how bad things will be. If the patient is lucky enough, he may live with severe digestive problems for the rest of his life; if not, he may be living with a colostomy, which leaves a changeable bag attached to his side to catch the bowel movements. Colorectal cancer is a preventable disease and the best defense for preventing colorectal cancer is early detection and removal of pre-cancerous polyps.

5-Year Changes indicate that Mortality in Georgia from Colon & Rectum Cancer is rising. Annual Percentage Change (APC) over the five year period of 1998-2002 as calculated by SEER* Stat shows that Mortality Rates from Colon & Rectum Cancer in the State of Georgia is rising at annual rate of 1.8%. (Death data provided by the National Vital Statistics System public use data file. Over 90% of early colorectal cancers can be cured in asymptomatic (having no symptoms) patients if detected early and treated promptly, whereas there is less than a 40% survival rate in those who wait until symptoms develop.

I am an Administrator with Vidalia Medical Associates, PC, where I work closely with the physicians and staff of an Ambulatory Surgery Center (ASC). I am writing this because I see every single day the impact this center and its staff have on the lives of families as they go about their task of preventing colorectal cancer. The Center is located in Toombs County and is the FIRST Endoscopy center in rural America approved by the AAAHC and Medicare. The center s Endoscopy specialists have performed colon cancer screenings for over 25 years and have made these screenings their primary focus as physicians. They credit the center s efforts for Toombs County being in the lowest 10% statewide death rate from colon and rectum cancer. The success of the center shows in the stats.

I have tremendous concern over Medicare's proposed rule to change the payment system for ambulatory service centers (ASC), cutting the rates by more than 25% in 2008. The rates that are included in this proposed change will not even cover the costs of performing the procedures, including screening for cancer. The practice will lose money on every Medicare patient that comes to the ASC. The only alternative will be to treat those beneficiaries in the hospital at approximately nine times the out-of-pocket cost to the patient! This is a very sad suggestion, given that many of those beneficiaries already struggle to be able to afford food and healthcare at the same time. What a disservice to Medicare beneficiaries!

The ASC is a safe, economic site for these services and is very popular with elderly patients because of the convenience and the quality of care they receive. Congress needs to change its instructions on budget neutrality to avoid this result. I know that the ASC can continue to provide services to Medicare patients if the reimbursements make sense. This proposal, obviously, does not pass that test. If passed, you may be a part of the decision that restricts important healthcare to Medicare patients.

In conclusion, we want our patients to enjoy a longer and healthier life and our physicians see the colon cancer screenings as saving lives. It's that important.

Submitter : **Wendy Wifler** **Date: 10/06/2006**

Organization : **CyberKnife Coalition**

Category : **Health Care Provider/Association**

Issue Areas/Comments

New Technology APCs

New Technology APCs

SEE ATTACHED DOCUMENT . . .
On behalf of the CyberKnife? Coalition, a coalition of a number of the primary institutions in the United States that provide image-guided robotic stereotactic radiosurgery, we appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

CMS-1506-P-314-Attach-1.PDF

CYBERKNIFE®

CKC

COALITION

Georgetown University Medical Center, Washington, DC

Rocky Mountain CyberKnife Center, Boulder, CO

St. Joseph's Hospital, a member of HealthEast Care System, St. Paul, MN

CyberKnife Center of Palm Beach, West Palm Beach, FL

CyberKnife Center of Miami, FL

South Texas Stereotactic Radiosurgery, San Antonio, TX

San Diego CyberKnife Center, San Diego, CA

Riverview Medical Center, a member of Meridian Health, Red Bank, NJ

CyberKnife Radiosurgery Center of Iowa, Des Moines, IA

CyberKnife Center of New York, Johnson City, NY

Advocate Christ Medical Center, Oaklawn, IL

Naples Community Hospital, Naples, FL

Miller-Dwan Medical Center, Duluth, MN

CyberKnife Center of Central Florida, Sanford, FL

Winthrop University Hospital CyberKnife Center, Mineola, NY

CyberKnife Center of Treasure Coast, Stuart, FL

CyberKnife Centers of Jacksonville, FL

Tianjin Cancer Center, Tianjin, China

The CyberKnife Service of BroMenn Healthcare at The Community Cancer Center, Normal, IL

St. Joseph's Medical Center and Barrow Neurological Institute, Phoenix, AZ

Southwest Radiation Oncology, Oklahoma City, OK

Harris Methodist Fort Worth CyberKnife Center, Ft Worth, Texas

Aurora St. Luke's Medical Center, Milwaukee, WI

October 4, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

Re: New Technology APCs – Section c. Pages 49553 and 49554

On behalf of the CyberKnife® Coalition, a coalition of a number of the primary institutions in the United States that provide image-guided robotic stereotactic radiosurgery, we appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of ($1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of ($833.32). These proposed revisions would result in a reduction in payment averaging ($2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."[1] Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."[2]

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that ***"any SRS code changes would be premature without cost data to support a code restructuring"***. (CMS-1506-P, page 156).

[4] Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

We believe that the changes proposed by CMS for CY 2007 are based on flawed methodology. The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.***

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that ***CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.***

It is our understanding that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. We believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We believe this for the following reasons:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

   By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, our own analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

   The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. ***Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.***

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

In the next section, we present our analysis of the CY 2004 Identifiable Data Set Hospital OPPS file claims data for HCPCS Codes G0339 and G0340.

The analysis of the 2004 Identifiable Data Set Hospital OPPS file for CY 2004 for G0339 is illustrated in the following charts.

	2004 Identifiable Data Set Hospital OPPS File Summary			
	Charge Data All Reported Centers			
	G0339			
	Site	Average Charge	Units	Total
1	CyberKnife Service @ Community CC	$24,109.50	4	$96,438.00
2	Boulder Community Hospital	$16,983.92	60	$1,019,035.20
3	Advocate Lutheran General Hospital	$725.50	1	$725.50
4	Zale Lipshy University Hospital	$14,172.86	12	$170,074.32
5	Spectrum Health-Butterworth Campus	$6,285.93	2	$12,571.86
6	Wake Forest University Baptist MC	$6,375.66	13	$82,883.58
7	Clarian Health Partners	$12,370.69	32	$395,862.08
8	Wellmont Bristol Regional	$25,237.13	38	$959,010.94
9	Menorah Medical Center	$25,283.91	5	$126,419.55
10	UCLA	$14,689.69	1	$14,689.69
11	USC	$10,259.46	16	$164,151.36
12	St. Josephs St. Paul	$39,893.85	74	$2,952,144.90
13	NHC Healthcare Systems	$10,587.60	18	$190,576.80
14	Overlook	$14,153.49	9	$127,381.41
15	St. Anthony's Hospital	$33,334.39	43	$1,433,378.77
16	St. Josephs AZ	$17,401.59	24	$417,638.16
17	UPMC	$4,578.24	23	$105,299.52
18	St. Louis University Hospital	$31,188.27	10	$311,882.70
19	Methodist Cancer Center	$36,630.88	1	$36,630.88
20	UCSF	$6,629.72	17	$112,705.24
21	Stanford	$9,883.75	57	$563,373.75
22	University of Washington MC	$11,359.17	1	$11,359.17
23	Willis-Knighton MC	$6,199.92	13	$80,598.96
24	Sioux Valley Hospital	$9,087.41	5	$45,437.05
25	Yakima Valley Memorial Hospital	$6,175.59	7	$43,229.13
	Average Charge Total		486	$9,473,498.52
	Average Charge Per Unit			$19,492.80

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown - 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Charge Data CyberKnife Centers						
	G0339						
	Site		Average Charge		Units		Total
1	CyberKnife Service @ Community CC		$24,109.50		4		$96,438.00
2	Boulder Community Hospital		$16,983.92		60		$1,019,035.20
4	Zale Lipshy University Hospital		$14,172.86		12		$170,074.32
8	Wellmont Bristol Regional		$25,237.13		38		$959,010.94
9	Menorah Medical Center		$25,283.91		5		$126,419.55
11	USC		$10,259.46		16		$164,151.36
12	St. Josephs St. Paul		$39,893.85		74		$2,952,144.90
13	NHC Healthcare Systems		$10,587.60		18		$190,576.80
14	Overlook		$14,153.49		9		$127,381.41
15	St. Anthony's Hospital		$33,334.39		43		$1,433,378.77
16	St. Josephs AZ		$17,401.59		24		$417,638.16
17	UPMC		$4,578.24		23		$105,299.52
18	St. Louis University Hospital		$31,188.27		10		$311,882.70
19	Methodist Cancer Center		$36,630.88		1		$36,630.88
20	UCSF		$6,629.72		17		$112,705.24
21	Stanford		$9,883.75		57		$563,373.75
	Average Charge Total				411		$8,786,141.50
	Average Charge Per Unit						$21,377.47

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Charge Data Non-CyberKnife Centers						
	G0339						
	Site		Average Charge		Units		Total
3	Advocate Lutheran General Hospital		$725.50		1		$725.50
5	Spectrum Health-Butterworth Campus		$6,285.93		2		$12,571.86
6	Wake Forest University Baptist MC		$6,375.66		13		$82,883.58
7	Clarian Health Partners		$12,370.69		32		$395,862.08
10	UCLA		$14,689.69		1		$14,689.69
22	University of Washington MC		$11,359.17		1		$11,359.17
23	Willis-Knighton MC		$6,199.92		13		$80,598.96
24	Sioux Valley Hospital		$9,087.41		5		$45,437.05
25	Yakima Valley Memorial Hospital		$6,175.59		7		$43,229.13
	Average Charge Total				75		$687,357.02
	Average Charge Per Unit						$9,164.76

* Non-CK Centers Represent 15% of all Units Reported
* Non-CK Centers Average Charge was 42% of the CK Centers Per Unit
* Non-CK Centers Represent 7% of all Average Charges

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown – 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Cost Data All Reported Centers						
	G0339						
	Site		Average Cost		Units		Total
1	CyberKnife Service @ Community CC		$8,098.38		4		$32,393.52
2	Boulder Community Hospital		$1,459.57		60		$87,574.20
3	Advocate Lutheran General Hospital		$330.39		1		$330.39
4	Zale Lipshy University Hospital		$4,910.89		12		$58,930.68
5	Spectrum Health-Butterworth Campus		$3,179.42		2		$6,358.84
6	Wake Forest University Baptist MC		$2,948.10		13		$38,325.30
7	Clarian Health Partners		$4,361.90		32		$139,580.80
8	Wellmont Bristol Regional		$4,734.48		38		$179,910.24
9	Menorah Medical Center		$6,242.60		5		$31,213.00
10	UCLA		$5,329.42		1		$5,329.42
11	USC		$5,079.46		16		$81,271.36
12	St. Josephs St. Paul		$11,437.57		74		$846,380.18
13	NHC Healthcare Systems		$8,489.14		18		$152,804.52
14	Overlook		$3,538.37		9		$31,845.33
15	St. Anthony's Hospital		$10,130.32		43		$435,603.76
16	St. Josephs AZ		$3,445.51		24		$82,692.24
17	UPMC		$1,156.54		23		$26,600.42
18	St. Louis University Hospital		$6,852.06		10		$68,520.60
19	Methodist Cancer Center		$7,597.24		1		$7,597.24
20	UCSF		$932.80		17		$15,857.60
21	Stanford		$2,590.53		57		$147,660.21
22	University of Washington MC		$6,471.32		1		$6,471.32
23	Willis-Knighton MC		$1,466.27		13		$19,061.51
24	Sioux Valley Hospital		$2,528.12		5		$12,640.60
25	Yakima Valley Memorial Hospital		$4,696.53		7		$32,875.71
	Average Cost Total				486		$2,547,828.99
	Average Cost Per Unit						$5,242.45

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown – 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Cost Data CyberKnife Centers						
	G0339						
	Site		Average Cost		Units		Total
1	CyberKnife Service @ Community CC		$8,098.38		4		$32,393.52
2	Boulder Community Hospital		$5,964.27		60		$357,856.20
4	Zale Lipshy University Hospital		$4,910.89		12		$58,930.68
8	Wellmont Bristol Regional		$4,734.48		38		$179,910.24
9	Menorah Medical Center		$6,242.60		5		$31,213.00
11	USC		$5,079.46		16		$81,271.36
12	St. Josephs St. Paul		$11,437.57		74		$846,380.18
13	NHC Healthcare Systems		$8,489.14		18		$152,804.52
14	Overlook		$3,538.37		9		$31,845.33
15	St. Anthony's Hospital		$10,130.32		43		$435,603.76
16	St. Josephs AZ		$3,445.51		24		$82,692.24
17	UPMC		$826.37		23		$19,006.51
18	St. Louis University Hospital		$6,852.06		10		$68,520.60
19	Methodist Cancer Center		$7,597.24		1		$7,597.24
20	UCSF		$932.80		17		$15,857.60
21	Stanford		$2,590.53		57		$147,660.21
	Average Cost Total				411		$2,549,543.19
	Average Cost Per Unit						$6,203.27

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Cost Data Non-CyberKnife Centers						
	G0339						
	Site		Average Cost		Units		Total
3	Advocate Lutheran General Hospital		$330.39		1		$330.39
5	Spectrum Health-Butterworth Campus		$3,179.42		2		$6,358.84
6	Wake Forest University Baptist MC		$2,948.10		13		$38,325.30
7	Clarian Health Partners		$4,361.90		32		$139,580.80
10	UCLA		$5,329.42		1		$5,329.42
22	University of Washington MC		$6,471.32		1		$6,471.32
23	Willis-Knighton MC		$1,466.27		13		$19,061.51
24	Sioux Valley Hospital		$2,528.12		5		$12,640.60
25	Yakima Valley Memorial Hospital		$4,696.53		7		$32,875.71
	Average Cost Total				75		$260,973.89
	Average Cost Per Unit						$3,479.65

*Non-CK Centers costs were 45% less than that of the CK Centers Per Unit

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown – 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

G0339 Image-guided Robotic Stereotactic Radiosurgery, Completed in one session (or the first of multiple sessions)

As illustrated, 15% of the claims came from nine (9) centers that did not have image-guided robotic systems for providing stereotactic radiosurgery but submitted claims under these codes. **The combination of a large percentage of newly operating centers beginning to bill for these services in CY 2004 and CY 2005 and the fact that 15% of the centers submitting claims were not eligible to bill the G0339 code has created an incomplete and inconsistent use of these codes. In addition, because the centers billing these codes erroneously provided treatment utilizing less expensive equipment, their inclusion affects the median cost of these codes.** For these reasons, it would be inappropriate to determine a permanent APC for image-guided robotic radiosurgery procedures based on claims submitted for CY 2004 and CY 2005.

In the next section, we present our analysis of the CY 2004 Identifiable Data Set Hospital OPPS file claims data for HCPCS Code G0340.

The analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for G0340 is illustrated in the following charts.

	2004 Identifiable Data Set Hospital OPPS File Summary							
	Charge Data All Reported Centers							
	G0340							
	Site		Average Charge		Units		Total	
1	CyberKnife Service @ Community CC		$ 7,861.79		8		$62,894.32	
2	Boulder Community Hospital		$ 8,450.59		80		$676,047.20	
3	Advocate Lutheran General Hospital		$ -		0		$0.00	
4	Zale Lipshy University Hospital		$ 9,145.00		7		$64,015.00	
5	Spectrum Health-Butterworth Campus		$ -		0		$0.00	
6	Wake Forest University Baptist MC		$ 4,228.96		16		$67,663.36	
7	Clarian Health Partners		$ 4,340.36		42		$182,295.12	
8	Wellmont Bristol Regional		$ 18,026.68		60		$1,081,600.80	
9	Menorah Medical Center		$ 18,204.42		8		$145,635.36	
10	UCLA		$ -		0		$0.00	
11	USC		$ 7,654.83		95		$727,208.85	
12	ST. Josephs St. Paul		$ 21,809.60		167		$3,642,203.20	
13	NHC Healthcare Systems		$ 7,562.57		15		$113,438.55	
14	Overlook		$ 8,869.52		15		$133,042.80	
15	St. Anthony's Hospital		$ 8,463.81		64		$541,683.84	
16	St. Josephs AZ		$ 9,142.21		56		$511,963.76	
17	UPMC		$ 4,578.24		23		$105,299.52	
18	St. Louis University Hospital		$ 11,695.60		17		$198,825.20	
19	Methodist Cancer Center		$ 26,164.91		2		$52,329.82	
20	UCSF		$ 6,801.88		56		$380,905.28	
21	Stanford		$ 9,950.64		152		$1,512,497.28	
22	University of Washington MC		$ 8,113.90		4		$32,455.60	
23	Willis-Knighton MC		$ 4,455.58		40		$178,223.20	
24	Sioux Valley Hospital		$ 4,317.55		8		$34,540.40	
25	Yakima Valley Memorial Hospital		$ 3,878.21		5		$19,391.05	
	Average Charge Total				940		$10,464,159.51	
			Average Charge Per Unit				$11,132.08	

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown – 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Charge Data CyberKnife Centers						
	G0340						
	Site		Average Charge		Units		Total
1	CyberKnife Service @ Community CC		$ 7,861.79		8		$62,894.32
2	Boulder Community Hospital		$ 8,450.59		80		$676,047.20
4	Zale Lipshy University Hospital		$ 9,145.00		7		$64,015.00
8	Wellmont Bristol Regional		$ 18,026.68		60		$1,081,600.80
9	Menorah Medical Center		$ 18,204.42		8		$145,635.36
11	USC		$ 7,654.83		95		$727,208.85
12	ST. Josephs St. Paul		$ 21,809.60		167		$3,642,203.20
13	NHC Healthcare Systems		$ 7,562.57		15		$113,438.55
14	Overlook		$ 8,869.52		15		$133,042.80
15	St. Anthony's Hospital		$ 8,463.81		64		$541,683.84
16	St. Josephs AZ		$ 9,142.21		56		$511,963.76
17	UPMC		$ 4,578.24		23		$105,299.52
18	St. Louis University Hospital		$ 11,695.60		17		$198,825.20
19	Methodist Cancer Center		$ 26,164.91		2		$52,329.82
20	UCSF		$ 6,801.88		56		$380,905.28
21	Stanford		$ 9,950.64		152		$1,512,497.28
	Average Charge Total				825		$9,949,590.78
	Average Charge Per Unit						$12,060.11

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Charge Data Non-CyberKnife Centers						
	G0340						
	Site		Average Charge		Units		Total
3	Advocate Lutheran General Hospital		$0.00		0		$0.00
5	Spectrum Health-Butterworth Campus	#	$0.00		0		$0.00
6	Wake Forest University Baptist MC		$4,228.96		16		$67,663.36
7	Clarian Health Partners		$4,340.36		42		$182,295.12
10	UCLA		$0.00		0		$0.00
22	University of Washington MC		$8,113.90		4		$32,455.60
23	Willis-Knighton MC		$4,455.58		40		$178,223.20
24	Sioux Valley Hospital		$4,317.55		8		$34,540.40
25	Yakima Valley Memorial Hospital		$3,878.21		5		$19,391.05
	Average Charge Total				115		$514,568.73
	Average Charge Per Unit						$4,474.51

* Non-CK Centers Represent 12% of all Units Reported
* Non-CK Centers Average Charge was 37% of the CK Centers Per Unit
* Non-CK Centers Represent 5% of all Average Charges

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown – 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Cost Data All Reported Centers						
	G0340						
	Site		Average Cost		Units		Total
1	CyberKnife Service @ Community CC		$ 2,586.70		8		$20,693.60
2	Boulder Community Hospital		$ 2,967.84		80		$237,427.20
3	Advocate Lutheran General Hospital		$ -		0		$0.00
4	Zale Lipshy University Hospital		$ 3,168.77		7		$22,181.39
5	Spectrum Health-Butterworth Campus		$ -		0		$0.00
6	Wake Forest University Baptist MC		$ 1,955.47		16		$31,287.52
7	Clarian Health Partners		$ 1,530.41		42		$64,277.22
8	Wellmont Bristol Regional		$ 3,381.80		60		$202,908.00
9	Menorah Medical Center		$ 4,494.67		8		$35,957.36
10	UCLA		$ -		0		$0.00
11	USC		$ 3,770.62		95		$361,979.52
12	ST. Josephs St. Paul		$ 6,252.81		167		$1,044,219.27
13	NHC Healthcare Systems		$ 6,063.67		15		$90,955.05
14	Overlook		$ 2,217.38		15		$33,260.70
15	St. Anthony's Hospital		$ 2,572.15		64		$164,617.60
16	St. Josephs AZ		$ 1,810.15		56		$101,368.40
17	UPMC		$ 826.37		23		$19,006.51
18	St. Louis University Hospital		$ 2,569.52		17		$43,681.84
19	Methodist Cancer Center		$ 5,426.60		2		$10,853.20
20	UCSF		$ 957.02		56		$53,593.12
21	Stanford		$ 2,608.06		152		$396,425.12
22	University of Washington MC		$ 4,622.48		4		$18,489.92
23	Willis-Knighton MC		$ 1,053.73		40		$42,149.20
24	Sioux Valley Hospital		$ 1,201.14		8		$9,609.12
25	Yakima Valley Memorial Hospital		$ 2,949.37		5		$14,746.85
	Average Cost Total				940		$3,019,687.71
	Average Cost Per Unit						$3,212.43

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown – 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Cost Data CyberKnife Centers						
	G0340						
	Site		Average Cost		Units		Total
1	CyberKnife Service @ Community CC		$ 2,586.70		8		$20,693.60
2	Boulder Community Hospital		$ 2,967.84		80		$237,427.20
4	Zale Lipshy University Hospital		$ 3,168.77		7		$22,181.39
8	Wellmont Bristol Regional		$ 3,381.80		60		$202,908.00
9	Menorah Medical Center		$ 4,494.67		8		$35,957.36
11	USC		$ 3,770.62		95		$361,979.52
12	ST. Josephs St. Paul		$ 6,252.81		167		$1,044,219.27
13	NHC Healthcare Systems		$ 6,063.67		15		$90,955.05
14	Overlook		$ 2,217.38		15		$33,260.70
15	St. Anthony's Hospital		$ 2,572.15		64		$164,617.60
16	St. Josephs AZ		$ 1,810.15		56		$101,368.40
17	UPMC		$ 826.37		23		$19,006.51
18	St. Louis University Hospital		$ 2,569.52		17		$43,681.84
19	Methodist Cancer Center		$ 5,426.60		2		$10,853.20
20	UCSF		$ 957.02		56		$53,593.12
21	Stanford		$ 2,608.06		152		$396,425.12
	Average Cost Total				825		$2,839,127.88
	Average Cost Per Unit						$3,441.37

	2004 Identifiable Data Set Hospital OPPS File Summary						
	Cost Data Non-CyberKnife Centers						
	G0340						
	Site		Average Cost		Units		Total
3	Advocate Lutheran General Hospital		$0.00		0		$0.00
5	Spectrum Health-Butterworth Campus		$0.00		0		$0.00
6	Wake Forest University Baptist MC		$ 1,955.47		16		$31,287.52
7	Clarian Health Partners		$ 1,530.41		42		$64,277.22
10	UCLA		$0.00		0		$0.00
22	University of Washington MC		$ 4,622.48		4		$18,489.92
23	Willis-Knighton MC		$ 1,053.73		40		$42,149.20
24	Sioux Valley Hospital		$ 1,201.14		8		$9,609.12
25	Yakima Valley Memorial Hospital		$ 2,949.37		5		$14,746.85
	Average Cost Total				115		$180,559.83
	Average Cost Per Unit						$1,570.09

*Non-CK Centers Costs were 31% Less than that of the CK Centers Per Unit

Not included in the CY 2004 Identifiable Data Set Hospital OPPS file: Georgetown – 2nd highest procedure volume center; Baltimore, Maryland (regulated state) - 6th highest procedure volume center; and Miami, 7th highest procedure volume center, and other smaller, less urban centers.

Green Shading = non-robotic SRS centers
Yellow Shading = image-guided r-SRS centers

G0340 Image-guided Robotic Stereotactic Radiosurgery Fractionated – Treatments 2 through 5

The CY 2004 Identifiable Data Set Hospital OPPS file contained 940 claims. Twelve percent (12%) of the claims came from centers using the G0340 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data for the purpose of calculating the appropriate APC results in a lower median cost.

The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for 2004 for true image-guided robotic stereotactic radiosurgery centers (CyberKnife) is reported at $3,229.63 per unit. For non-CyberKnife centers, the average cost is $2,218.77. In addition, the CY 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital has the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States; Miami CyberKnife Center with the 7th highest procedure volume in the United States; and other smaller, less urban centers.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that ***it is a "mature technology [with] stable median costs"*** (CMS-1506-P, p 157). This would be an accurate reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

G0339 and G0340 Code Descriptors

Given the confusion of some centers in determining which code to use, a further refinement of the code language might distinguish the technologies. If non-robotic stereotactic radiosurgery centers continue to use the r-SRS codes in the future, it will be impossible for CMS to determine whether and to what extent the median costs for this service exceed the median cost of radiosurgery performed using modified LINACs, as we believe they do. We suggest that a more precise and accurate descriptor of ***image-guided robotic*** stereotactic radiosurgery is:

Delivering radiobiologically ablative doses to stationary or moving planning target volume, in 1-5 fractions, with non-ablative radiation dose to non-target tissue, regardless of proximity to planning target volume. Identifying and correcting translational and rotational planning target volume targeting inaccuracy in real-time, through automated continuous feedback loop with <=0.5mm radial targeting error for stationary targets and <=1.5 mm radial targeting error for moving targets.

If the r-SRS code descriptors are not further refined it will be virtually impossible to determine appropriate APC rates in the future.

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

	# centers operating Jan 1st	New centers treating during year	% of centers in first year
2004 CY 2004	12	8	67%
2005 CY 2005	20	15	43%

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

Further, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from $3,479.65 (non-robotic SRS centers) to $6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to provide a similar analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated, however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge***. We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

▶No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

▶The code descriptor as proposed on page 16 for image-guided robotic stereotactic radiosurgery (r-SRS) could be used in a way that would promote more accurate capture of resources for all types of SRS procedures.

▶CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

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